Training Manual for

"GLIFWC Ceded Territory Traditional Food Regulatory System Project"

September 2020

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GREAT LAKES INDIAN FISH & WILDLIFE COMMISSION
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• MEMBER TRIBES •

MICHIGAN
Bay Mills Community
Keweenaw Bay Community
Lac Vieux Desert Band

WISCONSIN
Bad River Band
Lac Courte Oreilles Band
Lac du Flambeau Band
Red Cliff Band
St. Croix Chippewa
Sokaogon Chippewa

MINNESOTA
Fond du Lac Band
Mille Lacs Band

Boozhoo! (Welcome!)

In response to community interest and tribal leadership directives, GLIFWC obtained a federal Administration for Native Americans Social & Economic Development Strategies (ANA SEDS) grant to develop a model food code addressing the processing of traditional Ojibwe foods harvested in the off-reservation ceded territories. The project "GLIFWC Chippewa Ceded Territory Traditional Food Regulatory System Project" was funded by ANA and was implemented from 2017-2020. The purpose of this project is to provide a regulatory framework for tribal communities regarding the processing, distribution, labeling, and sale of treaty harvested to provide opportunities for the commercial sale of value-added products. Federal courts have ruled that the Tribes are entitled to regulate their members' off-reservation, treaty-reserved activities so long as they can demonstrate that the tribal conservation system effectively safeguards conservation and public health and safety. Similarly, tribal food codes must also be based upon sound science to adequately protect human health. In particular, food safety regulations need to identify and account for biological, chemical, and physical food safety risks that are "reasonably likely" to occur.

This manual was created as a part this project to assist tribal harvesters, food handlers, food processors, food managers, regulatory staff, leadership, and community members in making decisions around building a food system that includes traditional foods and provides for the sale of those food within and beyond reservation borders. In addition, it includes technical documents such as reports, model food safety documents, training material from trainings held in late 2020, and template records to support the successful implementation of a traditional food regulatory system.

Please note that the rules and standards contained herein consist of a model regulation and will not be considered enforceable unless ratified by a tribal governing body. Additionally, upon ratification, tribal governing bodies may amend, delete or change the regulation in order to account for the specific needs of their communities. The information provided is current as of publishing date listed on the document. Items without dates are current as of September 10th, 2020. This is a dynamic area of law, policy and science; accordingly, many of these documents will be updated from time to time. Please check our website www.GLIFWC.org for the most current versions of the documents.

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2018 TRADITIONAL FOOD CONTAMINANT AND FOOD SAFETY REPORT

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Background

Great Lakes Indian Fish & Wildlife Commission (GLIFWC) is an organization consisting of 11 sovereign tribal governments in Minnesota, Wisconsin, and Upper Michigan. The 11 Ojibwe[1] (Anishinaabe) member tribes include: Fond du Lac, Mille Lacs, St. Croix, Lac Courte Oreilles, Red Cliff, Bad River, Lac du Flambeau, Sokaogon-Mole Lake, Lac Vieux Desert, Keweenaw Bay, and Bay Mills reservations.

Figure 1: GLIFWC Member Tribe Locations and Ceded Territory Map.

All 11 tribal governments are signatories to treaties retaining off-reservation treaty rights to hunt, fish, and gather. GLIFWC assists its member tribes in implementing off-reservation treaty seasons and in the protection of treaty rights and natural resources. GLIFWC provides natural resource management expertise, conservation enforcement, legal and policy analysis, and public information services. GLIFWC exercises powers delegated by its member tribes.

[1] There are multiple terms used to refer to Ojibwe people. The Ojibwe people often call themselves Anishinaabe, which in Anishinaabemowin (the language of the Ojibwe people) meaning original people. An anglicized term for Ojibwe commonly used interchangeably is Chippewa. (GLIFWC 2016).

Incorporating Traditional Ecological Knowledge (TEK) into natural resource management plans, projects, and rules and regulations, upholds GLIFWC's Strategic Plan to infuse Anishinaabe culture and values into all of its endeavors. Although TEK has many definitions, GLIFWC recognizes it as a subset of wealth of Anishinaabe *gikendaasowin*, or traditional knowledge, based on a deep, enduring connection to the environment through observations shared throughout generations.

For Anishinaabe people, there are inseparable spiritual connections to animals, fish, and plants that carry on traditional lifeways centered on the land, air, and water that sustain treaty resources. Culturally, treaty resources embody both physical resources and spiritual resources. Accessing, utilizing, and sharing treaty resources helps tribal members to connect, practice, and sustain spiritual beliefs and lifeways from generation to generation.

Federal courts reaffirmed treaty rights for GLIFWC member tribes, which includes the right to the utilization and retail sale of treaty harvested materials, according to various stipulations beginning in 1987[2]. Tribal leaders expressed community members' desire and challenges to integrating traditional foods into tribally-operated, federal nutrition programs and to provide these foods for retail sale within their communities. On April 8th, 2015, tribal leaders and delegates, along with federal and state agency representatives, began a series of meetings with the Wisconsin Department of Agriculture, Trade and Consumer Protection (WI DATCP) to discuss these issues along with regulatory concerns.

In response to these meetings, on March 28, 2017, GLIFWC's Board of Commissioners directed GLIFWC to apply for grant funding to facilitate integration of traditional foods into tribally operated federal nutrition programs and to provide these foods for retail sale. The following September, GLIFWC successfully received grant funds from the Administration for Native Americans[3] for a 3-year "GLIFWC Chippewa Ceded Territory Traditional Food Regulatory System Project".

This project will provide the necessary scientific and legal foundation for GLIFWC member tribal communities to establish a Traditional Food Regulatory System capable of expanding the utilization of traditional foods in their communities. Project staff will provide trainings which will enable tribal communities to implement a food regulatory system with trained tribal members.

[2] Lac Courte Oreilles Band of Indians v. Wisconsin (1987) and Mille Lacs v. Minnesota (1999)
[3] Within the Administration for Children & Families, underneath the U.S. Department of Health & Human Services.

Introduction

This Traditional Food Contaminant and Food Safety Report is provided as part of the "GLIFWC Chippewa Ceded Territories Traditional Food Regulatory System Project" and provides a scientific foundation for policy development.

This report is a culmination of a thorough review of relevant scientific literature involving contamination of a biological, chemical, or physical nature in 14 traditional foods of the Anishinaabe people of the Great Lakes region (See Figure 1 on page 1).

Ten of the traditional foods were selected by tribal members via a Traditional Food Interest Survey administered during the winter of 2017-2018 (an excerpt of the survey can be seen in Appendix 1). The survey was made available for tribal leadership, tribal members of GLIFWC member tribes, tribally operated nutrition programs, and tribal food service employees and management. The survey was made available online, through tribal newsletters, over the phone, and by postal mail. The survey divided traditional foods into classifications, as seen in Table 1 on page 4, and asked which food and how frequently respondents would like to have access to these foods. Additionally, within each of these questions, respondents had the opportunity to write in answers or additional comments. A total of 326 surveys were completed, with seventy-seven percent of respondents being tribal members from GLIFWC member tribes. An additional 11% work as a food handler or administratively at a food establishment that serves tribal members (e.g. school on or near reservations, Head Start, casino, etc.).

Survey results were tabulated and analyzed to create an initial "Interest List" to include the food from each section with the highest interest rating. Once generated, the list was then presented to GLIFWC's Board of Commissioners, Voigt Intertribal Task Force, Lakes Committee, and GLIFWC's Advisory and Guidance Input Group of Elders (GAAGIGE) for additional input from tribal leadership, and elders from participating member tribes. Four recommendations were suggested by GAAGIGE: wild leeks/ramps, wild beach pea, hazelnuts, and morel mushrooms. Recommendations were added to the list to complete a list of 14 Identified Traditional Foods (as seen below).

Table 1: Categorization of Identified Traditional foods

IDENTIFIED TRADITIONAL FOODS LIST

Food	***Classification***
White-Tailed Deer	Large Game
Rabbit/Hare	Small Game
Duck	Migratory Birds
Turkey	Upland Game Birds
Whitefish	Great Lakes Fish
Walleye	Inland Fish
Fresh Berries	Fruit
Wild Leeks/Ramps	Bulb Vegetable
Wild Beach Pea	Legume
Hazelnut	Tree nut
Morel Mushroom	Fungi
Wild Rice	Grain
Berry Jams/Jellies	Value-Added
Maple Syrup	Value-Added
Animal Fat	Value-Added
Venison Jerky	Value-Added

This report outlines current scientific literature with the unknown risks outlined in the companion document. In addition to the scientific literature, relevant TEK has been incorporated, when available, to better understand the what risks are known and what remains unknown.

TABLE 2: THIS MATRIX OUTLINES BIOLOGICAL, CHEMICAL, AND PHYSICAL HAZARDS ASSOCIATED WITH IDENTIFIED TRADITIONAL FOODS.

		HAZARDS				
		BIOLOGICAL				
Common Name	**Scientific Name**	**Pathogen**	**Disease / Virus**	**Parasite**	**Prion (CWD)**	**Allergen**
Large/Small Game						
White-tailed Deer	*Odocoileus virginiatus*	X	X	X	X	
Snowshoe Hare	*Lepus americanus*	X	X	X		
Cottontail Rabbit	*Sylvilagus floridanus*	X	X	X		
Birds						
Ducks/divers						
Scaup/Bluebill	*Aythya affinis; A. marila*	X	X	X		
Ring-necked Duck	*Aythya collaris*	X	X	X		
Duck/dabblers						
Blue-winged Teal	*Anas carolinensis*	X	X	X		
Green-winged Teal	*Anas discors*	X	X	X		
Mallard	*Anas platyrhynchos*	X	X	X		
Wood Duck	*Aix sponsa*	X	X	X		
Upland						
Wild Turkey	*Meleagris gallopavo*	X	X			
Fish						
Walleye	*Sander vitreus*	X		X		X
Whitefish	*Coregonus clupeaformis*	X		X		X
Plants/ Fungi						
Wild Strawberry	*Fragaria vesca*	X				
Wild Raspberry	*Rubus idaeus*	X				
Wild Blueberry	*Vaccinium angustifolium*	X				
Wild Blackberry	*Rubus allegheniensis*	X				
Highbush Cranberry	*Viburnum opulus*	X				
Wintergreen	*Gaultheria procumbens*	X				
Elderberry	*Sambucus canadensis*	X				
Wild Ramps/Leeks	*Allium tricoccum*	X				
Hazelnuts	*Corylus americana*	X				X
Beach Pea	*Lathyrus japonicus*	X				
Wild Rice	*Zizania palustris*	X				
Morel Mushroom	*Morchella esculenta*	X				
Value Added						
Maple Syrup	*Acer saccharum*	X				
Jams/Jellies	Various species	X				
Venison Jerky	*Odocoileus virginiatus*	X	X	X	X	X
Animal Fat (duck)	*Anas spp.*	X				
		Pathogen	**Disease / Virus**	**Parasite**	**Prion (CWD)**	**Allergen**

TABLE 2: THIS MATRIX OUTLINES BIOLOGICAL, CHEMICAL, AND PHYSICAL HAZARDS ASSOCIATED WITH IDENTIFIED TRADITIONAL FOODS. (CONTINUED FROM PREVIOUS PAGE)

		HAZARDS				
		CHEMICAL			PHYSICAL	
Common Name	**Scientific Name**	**Heavy Metal**	**Chemical / Pesticide**	**Natural Toxin**	**Bullet Fragment**	**Shot Pellet**
Large/Small Game						
White-tailed Deer	*Odocoileus virginiatus*	X	X		X	
Snowshoe Hare	*Lepus americanus*	X	X		X	X
Cottontail Rabbit	*Sylvilagus floridanus*	X	X		X	X
Birds						
Ducks/divers						
Scaup/Bluebill	*Aythya affinis; A. marila*	X	X			X
Ring-necked Duck	*Aythya collaris*	X	X			X
Duck/dabblers						
Blue-winged Teal	*Anas carolinensis*		X			X
Green-winged Teal	*Anas discors*		X			X
Mallard	*Anas platyrhynchos*		X			X
Wood Duck	*Aix sponsa*		X			X
Upland						
Wild Turkey	*Meleagris gallopavo*	X				X
Fish						
Walleye	*Sander vitreus*		X			
Whitefish	*Coregonus clupeaformis*		X			
Plants						
Wild Strawberry	*Fragaria vesca*		X			
Wild Raspberry	*Rubus idaeus*	X				
Wild Blueberry	*Vaccinium angustifolium*	X	X			
Wild Blackberry	*Rubus allegheniensis*	X				
Highbush Cranberry	*Viburnum opulus*					
Wintergreen	*Gaultheria procumbens*					
Elderberry	*Sambucus canadensis*			X		
Wild Ramps/Leeks	*Allium tricoccum*					
Hazelnuts	*Corylus americana*					
Beach Pea	*Lathyrus japonicus*	X		X		
Wild Rice	*Zizania palustris*	X				
Morel Mushroom	*Morchella esculentoides*	X				
Value Added						
Maple Syrup	*Acer saccharum*	X				
Jams/Jellies	Various species					
Venison Jerky	*Odocoileus virginiatus*	X			X	
Animal Fat (duck)	*Anas spp.*	X	X	X		
		Heavy Metals	**Chemical / Pesticide**	**Natural Toxin**	**Bullet Fragment**	**Shot Pellet**

1. Biological Hazards

Biological hazards are biological substances, including bacteria, viruses, parasites, and prions, that cause harm or illness. These are more commonly referred to as pathogens. This report focuses on pathogens that cause disease or illness in humans. Pathogens can be found in a wide variety of environments and sources. The following sections outlines both environmental and food pathogens, and zoonotic pathogens.

TABLE 3: AN OVERVIEW OF BIOLOGICAL HAZARDS IN IDENTIFIED ANISHINAABE TRADITIONAL FOODS.

Biological Hazard Overview	Deer	Rabbit/ Hare	Duck	Turkey	Whitefish	Walleye	Berries	Wild Ramps	Beach Pea	Hazelnut	Morel Mushroom	Wild Rice	Maple Syrup	Berry Jam/Jelly	Animal Fats	Venison Jerky
Bacteria																
E. coli	X	X	X	X	X	X	X	X			X					
Salmonella	X	X	X	X	X	X	X	X								X
Listeria	X	X	X	X	X	X										
Shigella			X		X	X	X	X								
C. jejuni			X	X	X	X	X	X								
Y. enterocolitica	X	X	X		X	X	X	X								
F. tularensis		X	X	X	X	X	X	X								
C. botulism	Foods stored without oxygen (canned, vacuum packed, etc.)															
	X	X	X	X	X	X		X			X				X	
C. perfringens	Foods cooked and held at between 41°- 139°F for extended periods of time.															
	X	X	X	X	X	X										
B. ceruse	Cooked foods which are improperly cooled and/or improperly reheated.															
				X	X	X						X				
S. aureus	Smoked foods and dehydrated foods.															
	X	X			X	X										X
Parasite																
T. gondii	X															
Cryptosporidium			X	X	X	X	X	X								
Giardia			X	X	X	X	X	X								
Nematodes					X	X										
Diphyllobothrium			X	X	X	X										
E. multilocularis							X	X								
Trematodes	X				X	X										
Virus																
West Nile Virus				X												
Norovirus Hepatitis A	Human source. Harvesters in contact with contaminated water and ready-to-eat foods which come into contact with an infected food handler are at risk.															
Prion	X															

Environmental, Zoonotic[4], and Food Pathogens

In aquatic environments, pathogens can live in the water, sediment, on and within aquatic animals. In terrestrial[5] environments, pathogens can live in soils, on plants, on and within terrestrial animals. These pathogens can cause illness to humans but may not cause illness in the animal carrying the pathogen. The following are bacterial, viral, and parasitic pathogens that may potentially be present in the traditional foods that are the subject of this study at the time of harvest (see Table 3 on page 7).

Table 4: Habitats Associated with biological hazards in identified traditional foods. (*RTE = Ready-to-eat foods are foods which do not need an additional processing step before consumption. Examples include: deli meat, venison jerky, and jam.)

SOURCE HABITATS OF BIOLOGICAL HAZARDS			
	AQUATIC	**TERRESTRIAL**	**OTHER**
BACTERIA			
Escherichia coli	X	X	–
Salmonella spp.	X	X	–
Listeria monocytogenes	X	X	–
Shigella spp.	X	–	HUMANS
Campylobacter jejuni	X	X	–
Yersinia enterocolitica	X	X	–
Francisella tularensis	–	X	–
Clostridium botulinum	–	X	RTE* FOOD
Clostridium perfringens	–	X	RTE* FOOD
Bacillus cereus	–	X	RTE* FOOD
Staphylococcus aureus	–	–	HUMANS
PARASITE			
Toxoplasmosis gondii	X	X	–
Cryptosporidium spp.	X	–	–
Giardia lamblia	X	–	–
Nematodes	X	X	–
Diphyllobothrium latum	X	–	–
Echinococcus multilocularis	–	X	–
Trematodes	X	X	–
VIRUS			
West Nile Virus	–	X	–
Norovirus	X	–	HUMANS
Hepatitis A	X	–	HUMANS
PRION			
Chronic Wasting Disease	–	X	–

[4] Zoonotic refers to pathogens which can transfer to humans.
[5] Terrestrial refers to land-based.

Special Note About Water Events

Many pathogens in aquatic habitats are due to contaminated matter from animals and humans. Water can be contaminated by fecal matter when animals or humans desiccate in or near water sources, or when agricultural run-off or sewage overflows are carried into water sources. Events that can cause increase pathogen contamination in water:

- Large snowmelts
- Heavy rains
- Flooding

During these times, water runs off the landscape into lakes, ponds, and streams carrying with it fecal matter, chemical pollutants, and debris. A study conducted near the coast of North Carolina, from 1996 to 2000, found that the bacterial count after hurricanes, which often cause flooding, always increased. The average bacterial count prior to storms were less than 100 colony- forming units (CFU) per 100 ml whereas after storms, the bacterial count ranged from 131 to 16,900 cfu/ 100 ml (Mallin 2002).

Runoff from heavy rains also causes bacteria to rise. According to the Wisconsin Stormwater Manual, fecal bacteria counts are 20 to 40 times higher in urban areas then the health standard for recreational water. These high levels of bacteria are considered typical for runoff from both small and large cities in Wisconsin (Prey n.d., 6).

Additionally, runoff from agricultural areas using manure or housing animals can flow into streams which lead to rivers and into lakes. Water bodies with pathogenic contamination do not always show signs such as algae blooms or odors. Often information about bacterial or other pathogen counts can be found at a local natural resource office or health agency.

A. Bacterial Pathogens

E. coli Brief		
Habitat: Aquatic and Terrestrial		
Sources:		
• Animal Feces (including intestines) • Animal Hides	• Fecal Contaminated Water • Cross-contamination	
Primary Carriers:	*At Risk from Contaminated Water/Soil:*	
• Deer/Venison	• Fish • Duck • Berries	• Wild Ramps • Morel Mushrooms • Beach Peas

Escherichia coli is a large group of bacteria which is naturally found in the environment and animal intestines, including humans. Many strains, or types, of *E. coli* are harmless to humans, however, some strains are pathogenic, causing illness in humans. The pathogenic stains related to food are a type of *E. coli* that are capable of forming toxins within human intestines. In the United States food supply, the strain of *E. coli* that is of greatest concern is shiga toxin- producing *E. coli* (STEC), the most commonly identified being the O157:H7 subclass (CDC 2018).

The main source of pathogenic *E. coli* in terrestrial habitats are ruminant[6] animals, including deer, and their feces, however, it can be found in bird and human feces (CDC 2018c). *E. coli* often enters aquatic habitats through fecal contaminated flood water or storm run-off, agricultural run-off, or sewage overflow (CDC 2015). Fresh produce can be contaminated by untreated water or fecal matter from animals. Common food sources of STEC are undercooked ground beef and contaminated produce (NRAEF 2012). The typical route of exposure is through consuming food or water that has been contaminated with the bacteria, and through cross-contamination[7] and contact with animal or people (CDC 2018).

After consumption of the bacteria, STEC produces toxins in the intestines which cause illness. The Center for Disease Control and Prevention (CDC) estimates each year STEC causes 265,000 illness, 3,600 hospitalizations, and 30 deaths in the United States (CDC 2016) . Consuming only a small amount of STEC can make someone sick.

[6] Ruminant animals that can be found in North America include deer, cows, sheep, and goats.
[7] Cross contamination, or cross contact, occurs when a food comes into contact with a surface (e.g. cutting boards, utensils, food handler gloves, etc.) or other food which has pathogenic microorganisms or other contaminants on it. The contaminants from the surface can transfer on to the food and contaminate the food. This is likely to happen when raw foods come in contact with foods that are ready-to-eat or share the same food contact surface such as a cutting board or knife (NRAEF 2012).

Anyone can become ill from STEC, however, children under the age of five, people with weakened immune systems, and the elderly are at an elevated risk of developing STEC related complications. For all populations, the onset of symptoms can occur within eight hours or up to 10 days after exposure, however, symptoms most often appear three to four days after exposure, which can last for six hours or up to 10 days. These symptoms include: severe abdominal cramps, diarrhea, and vomiting (CDC 2018; DHHS 2011). Approximately about 5-10% of individuals with a STEC infection will develop a complication known as hemolytic uremic syndrome, which can lead to kidney failure. With timely medical treatment most patients will recover within a few weeks, however, some patients may suffer permanent damage or death (CDC 2018).

E. coli can survive with or without oxygen, relatively acidic or basic environments, and at wide temperature ranges (DHHS 2011). *E. coli* can also be found on the hide, fur, or feathers of animals (CDC 2018). Harvesters interested in white-tailed deer, plants eaten raw, and waterfowl or fish that may be in fecal contaminated water are at a higher risk of exposure to *E. coli* bacteria.

***Salmonella* Brief**	
Habitat: Aquatic and Terrestrial	
Sources:	
• Animal Feces (including intestines) • Animal Hides • Bird Feces	• Fecal Contaminated Water • Cross-contamination
Primary Carriers:	*At Risk from Contaminated Water/Soil:*
• Deer/Venison (including jerky) • Rabbit/Hare • Duck • Turkey	• Fish • Berries • Wild Ramps

Salmonella spp. is group of bacteria that is responsible for a food related illness known as nontyphoidal salmonellosis or salmonellosis. *Salmonella* is widely dispersed in nature, living in the intestines of animals, especially birds and reptiles, in terrestrial habitats. *Salmonella* is often found in aquatic habitats that have been contaminated by sewage from flood water or storm run-off, agricultural run-off, and/or sewage overflows (Bibi et al. 2015). Exposure to *salmonella* can occur through: contact with animals carrying the bacteria, fecal contaminated water, person-to-person contact, and cross-contamination. *Salmonella* enters the body through consumption of a contaminated substance (Abraham 2012). In the United States, outbreaks salmonellosis are more often associated with consumption of the bacteria with meat and poultry

products, however, outbreaks related to produce have increased, which are often due to contaminated water or fecal contamination (Hanning 2009).

According to the CDC, about 1.2 million people become ill from salmonellosis, a type of infection *salmonella*, which causes approximately 450 deaths annually in the United States. Of the 1.2 million cases of salmonellosis, approximately one million cases are believed to come from food sources (CDC 2018).

Salmonella is very infectious bacteria, needing only a small amount to infect a person. Anyone can become infected however, infants, persons with weakened immune systems, and the elderly, are at risk for severe illness and death. Typical onset of symptoms is six to 72 hours after exposure and lasts for four to seven days. Symptoms include: diarrhea, abdominal cramps, and fever (Abraham 2012).

Salmonella can survive in acidic conditions, does not need access to oxygen, and can survive dehydration. Harvesters interested in fowl, plants eaten raw, and fish from fecal contaminated water are at the most risk of exposure to S*almonella* bacteria.

***Listeria* Brief**	
Habitat: Aquatic and Terrestrial	
Sources:	
• Animal Feces (including intestines) • Bird Feces • Contaminated Soil	• Fecal Contaminated Water • Cross-contamination
Primary Carriers:	*At Risk from Contaminated Water/Soil:*

• Deer/Venison
• Rabbit/Hare
• Duck
• Turkey
	• Fish
	• Foods typically eaten raw:
	  o Berries
	  o Wild Leeks/Ramps

Listeria monocytogenes, more commonly referred to as listeria, is a bacteria found in contaminated water, soil, poultry, and cattle. *L. monocytoneges* is especially suited to survive in soil, without oxygen, is salt tolerant salt, and continues to grow[8] robustly in refrigerator temperatures (38°F-40°F) unlike most foodborne bacteria. Additionally, *L. monocytoneges* is known to easily spread from contaminated processing equipment that is not properly cleaned and sanitized, such as meat slicers. In aquatic habitats, *L. monocytoneges* can be found in contaminated water and fish intestines. In terrestrial habitats, *L. monocytoneges* can be found in soil, poultry or ruminant intestines, and on

[8] Bacterial growth refers to population size of the bacteria. In suitable growing conditions, bacteria can multiply or produce millions of bacterial cells within hours. The size of the bacterial cell does not change, only the number of that specific bacteria changes.

plants in contact with fecal contaminated water or feces (Food Safety Working Group n.d.; DHHS 2011) .

Consuming *L. monocytoneges* can cause two different infections that affect different populations. The most dangerous infection is listeriosis, which typically infects pregnant women, young children, elderly populations, and persons with weakened or suppressed immune systems (CDC 2018). While the number of listeriosis cases are typically low, approximately 1,600 cases reported annually, the mortality rate is higher than other foodborne illnesses (FDA 2017).

Listeriosis symptoms include headache, stiff neck, confusion, loss of balance, and convulsions, fever, and muscle aches. It can cause meningitis[9] and septicemia. [10] For pregnant women, listeriosis can lead to miscarriage, stillbirth, premature delivery, or life threatening infections (CDC 2018). The onset of symptoms can occur within three to 70 days of ingesting contaminated foods, and can last several days to several weeks. (Food Safety Working Group n.d.).

Healthy populations do not typically become ill with listeriosis, however, may become ill with listerial gastroenteritis, a relatively rare but mild illness characterized by fever and diarrhea. Typically the onset of symptoms takes 24 hours and lasts for about two days (Ooi and Lorber 2005).

L. monocytoneges can be found on wild birds, wild game, and on food growing in contaminated environments. Harvesters interested in fowl, game animals, plants eaten raw, or fish that may be in fecal contaminated water are at the most risk of exposure to *L. monocytoneges* bacteria.

[9] Meningitis is the swelling or inflammation of the protective tissue covering the brain and spinal cord. Many agents can cause meningitis including bacteria, viruses, fungi, parasites, head injury, chronic illnesses, and more. Medical attention is required immediately (Centers for Disease Control and Prevention 2017b).

[10] Septicemia is also known as blood poisoning and occurs when pathogenic bacteria from other parts of the body enter the bloodstream. This is a very serious illness requiring immediate medical attention (Encyclopaedia Britannica 2018).

Shigella Brief	
Habitat: Aquatic	
Sources:	
• Human feces	• Fecal Contaminated Water • Cross-contamination
Primary Carriers:	*At Risk from Contaminated Water:*

Humans are the primary carrier of *Shigella spp*. Therefore, the risk is contact with human feces or fecal contaminated water.	• Fish
	• Duck
	• Foods typically eaten raw:
	  o Berries
	  o Wild Leeks/Ramps

Shigella spp. is a group of pathogenic bacteria which travels in the fecal matter of people. Contaminated lakes and rivers are a source of exposure (CDC 2017). These bacteria are a concern in aquatic habitats however, they are not a concern in terrestrial habitats. Ingesting only a small amount of this bacteria can make a person ill. Route of exposure is through consuming contaminated substances including food and water. Another known route of exposure is food contaminated by flies which seek out human feces and human food.

According to the CDC, shigella causes about 500,000 cases of diarrhea annually in the United States. Consuming a substance contaminated with *shigella* can cause shigellosis. The onset of symptoms occurs between eight hours and two days after exposure and is characterized by moderate to severe diarrhea, stomach pain, and fever which can last for five to seven days. Anyone can become ill from *shigella* and all patients excrete the bacterial cells for several weeks after onset (CDC 2017). Harvesters interested in plants eaten raw, waterfowl, or fish that may be in fecal contaminated water are at the most risk of exposure to *shigella* bacteria.

C. jejuni Brief	
Habitat: Aquatic and Terrestrial	
Sources:	
• Bird Feces • Contaminated Soil	• Fecal Contaminated Water • Cross-contamination
Primary Carriers:	*At Risk from Contaminated Water/Soil:*

• Duck
• Turkey
	• Fish
	• Foods typically eaten raw:
	  o Berries
	  o Wild Leeks/Ramps

Campylobacter jejuni (*C. jejuni)* are bacteria found in the intestines of animals and birds. *C. jejuni* is most often associated with raw or under cooked poultry. In aquatic habitats, water becomes contaminated from feces through sewage overflow, after a storm or flood, and/or animal related agricultural runoff (Abraham 2012). In terrestrial habitats, it can be found in the intestinal tract and feces of cats, dogs, poultry, rodents, cattle, pigs, wild birds, and humans (FSIS 2013).

Consuming *C. jejuni* causes an illness known as campylobacteriosis, which infects approximately 1.3 million people annually. This illness is characterized by diarrhea (which may be bloody), fever, abdominal cramps, and nausea. Symptoms onset within two to five days after exposure and last about one week. Populations with weakened immune systems are at risk of the bacteria entering the bloodstream leading to life threatening conditions (CDC 2017).

Harvesters interested in plants eaten raw, waterfowl, or fish that may be in fecal contaminated water are at the most risk of exposure to *C. jejuni* bacteria.

***Y. enterocolitica* Brief**	
Habitat: Aquatic and Terrestrial	
Sources:	
• Animal Feces (including intestines) • Contaminated Soil • Vacuumed sealed foods	• Fecal Contaminated Water • Cross-contamination
Primary Carriers:	*At Risk from Contaminated Water/Soil:*

• Deer/Venison
• Rabbit/Hare
	• Fish
	• Duck
	• Foods typically eaten raw:
	  o Berries
	  o Wild Leeks/Ramps

Yersinia enterocolitica (*Y. enterocolitica*) are pathogenic bacteria that are associated with rabbit, hare, pig, and cattle intestines. In aquatic habitats, fecal matter can contaminate water through contact with contaminated feces or soil entering the water. For example, sewage overflow, after a storm or flood, and animal related agricultural runoff**.** In terrestrial habitats, *Y. enterocolitica* can be found in soils and feces from infected animals including: pigs, rodents, rabbits, hare, sheep, cattle, horses, dogs, and cats (CDC 2016).

People become infected with *Y. enterocolitica* when they consume contaminated foods or water, while person-to-person infection is rare. *Y. enterocolitica* causes a disease known

as enteric (intestinal) yersiniosis, which causes approximately 117,000 illnesses, 640 hospitalizations, and 35 deaths in the United States annually (CDC 2016a).

Onset of symptoms is usually 24 hours to 11 days after exposure, but can occur later, with symptoms persisting from a few days to a few weeks. In children, symptoms can include fever, abdominal pain, and vomiting. In healthy adults, symptoms are typically nonspecific, but includes diarrhea. In rare cases, immunologic diseases can occur, but this accounts for approximately two to three percent of all *Y. enterocolitica* infections. (Abraham 2012). Harvesters interested in game animals, plants eaten raw, waterfowl, or fish that may be in fecal contaminated water are at the most risk of exposure to *Y. enterocolitica* bacteria.

***F. tularensis* Brief**	
Habitat: Aquatic and Terrestrial	
Sources:	
• Rabbit meat	• Fecal Contaminated Water • Cross-contamination
Primary Carriers:	*At Risk from Contaminated Water/Soil:*
• Rabbit/Hare	• Fish • Foods typically eaten raw: o Berries o Wild Leeks/Ramps

Francisella tularensis are the bacteria which cause a disease termed tularemia or "rabbit fever".[11] There are several different ways to be exposed to tularemia, but 90 percent of people contract this disease through the cleaning and processing of rabbits (MI DNR 2018). Rabbit, hare, grouse, beaver, and muskrat[12] are all carriers of tularemia. As a result, people that harvest or trap these animals have a greater risk of contracting tularemia than the general public. Harvesters may be exposed to tularemia even without contact from visible open cuts or sores.

Individuals eating undercooked meat of infected cottontail rabbits, snowshoe hares,[13] or grouse are also at increased risk for exposure to tularemia. Tularemia cannot be killed

[11] There are two varieties of tularemia: Type A and Type B. Type A is the more serious version, however, Type B is more common. Certain subspecies of bacteria cause the different ailments (Conover and Vail 2015, 57).
[12] Ruffed grouse (*Bonasa umbellus*) and sharp-tailed grouse (*Tympanuchus phasianellus*) are both present in the ceded territories. However, ruffed grouse are more common.
[13] The scientific name of Eastern cottontail rabbit is *Sylvilagus floridanus*. The scientific name of snowshoe hare is *Lepus americanus*.

by freezing meat. Bites from ticks, deer flies, horse flies, midges, and mosquitoes are another mode of transmission of tularemia to humans (CDC 2018).[14]

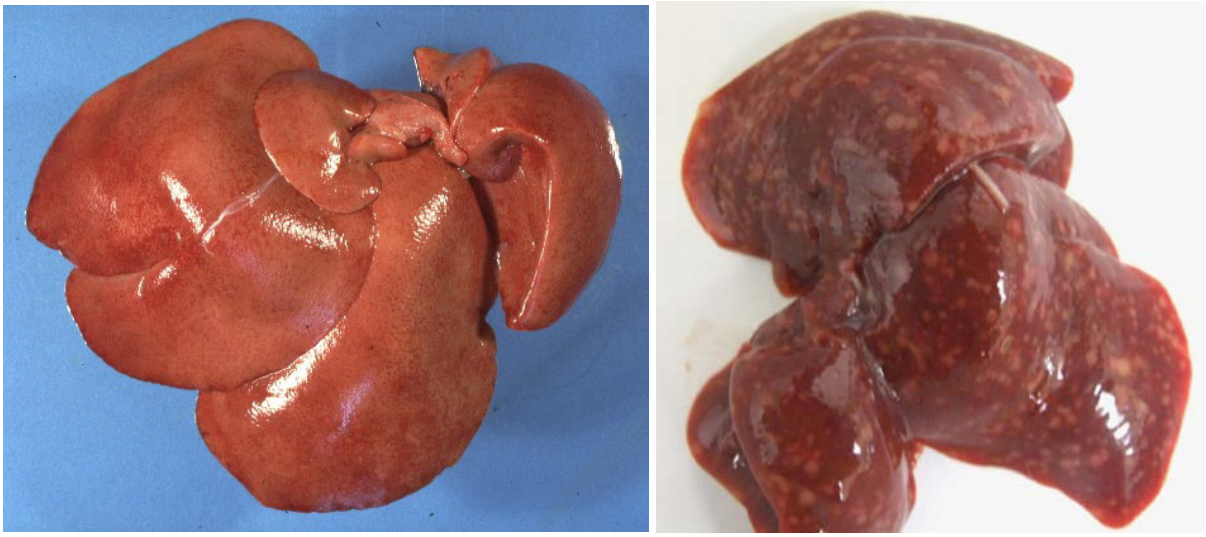


FIGURE 2: HEALTHY RABBIT LIVER (LEFT PHOTO) AND RABBIT LIVER INFECTED WITH TULAREMIA (RIGHT PHOTO). PHOTOS COURTESY OF IDAHO DEPARTMENT OF FISH AND GAME AND IOWA STATE UNIVERSITY

Two less common ways to contract tularemia include inhaling contaminated dust and drinking water containing the bacteria.[15] Although humans are not believed to transmit the disease to other humans, people can become infected with tularemia through infected pets, including cats and hamsters (Conover and Vail 2015; CDC 2018).

Symptoms of tularemia mimic other common sicknesses, therefore, it can be hard to diagnose at first. Symptoms usually appear anywhere from three to five days after exposure, which generally include: swollen lymph nodes, loss of appetite, fever, chills, muscle aches, headache, and fatigue. Some people also experience sore throat, chest pain, and a dry cough. However, symptoms vary depending on how a person was first exposed (Conover and Vail 2015). If the pathogen enters the eye, the eye often becomes watery, accompanied by a mucous discharge. If tularemia enters via skin, a solid, inflamed swelling often forms where the bacteria entered.

[14] Ticks in the United States that transmit tularemia to humans include the wood tick (*Dermacentor andersoni*), the dog tick (*Dermacentor variabilis*), and the lone star tick (*Amblyomma americanum*).
[15] Contaminated dust could get into the air by running over an infected animal or carcass with a lawnmower or tractor. Water could become contaminated by infected animals drinking from a particular area (CDC 2018x).

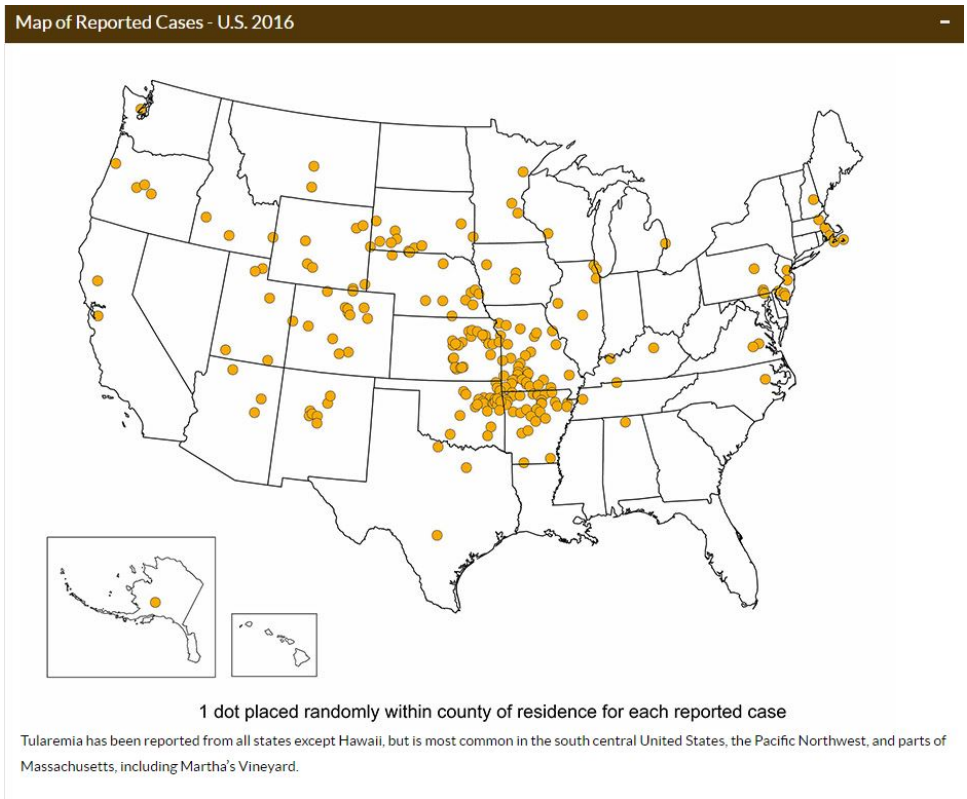


FIGURE 3: TULAREMIA CASES IN THE U.S. SINCE 2016 (CDC 2017).

Tularemia is not common in the ceded territories, with 13 cases being reported since 2016.[16] However, if left untreated[17], tularemia can become serious or life-threatening. Death from this disease is relatively rare, but typically occurs from secondary complications, such as pneumonia (Conover and Vail 2015). Harvesters interested in rabbits or hare are at an increased risk of exposure to tularemia.

Bacterial Pathogens Not Reasonably Likely to Occur

Highly-pathogenic avian influenza (bird flu), bovine tuberculosis, brucellosis, and Eastern Equine Encephalitis are diseases that have been documented in the ceded territories, but do not pose a reasonable human health hazard based upon their rarity of illness to humans in the area. For more information on these diseases, please see Appendix 2.

[16] Since 2016, five cases have been reported in Minnesota, four cases in Michigan, and three cases in Wisconsin (CDC 2018; Conover and Vail 2015, 59).
[17] Tularemia is treated with antibiotics (Conover and Vail 2015).

B. Food Pathogens

C. botulinum Brief	
Habitat: N/A - Becomes a Hazard After Processing	
Condition for Growth: Reduced oxygen-packaged Foods (Canned, Vacuum Packed, Oil Immersed)	
Sources:	
• Soil	• Fecal Contaminated Water
Processes of Concern:	*Examples:*
• Low Acid Canned Foods • Improperly Canned Foods • Vacuumed Packed Foods • Untreated Bulb-in-Oil Mixtures	• Home Canned Meat • Home Canned Vegetables • Fermented Meats • Fermented Fish • Vacuumed Packed Fish/Meat • Vacuumed Packed Vegetables • Untreated Infused Wild leek/Ramp oil

Clostridium botulinum *(C. botulinum)* is a bacteria found naturally in mammal intestines, fish intestines, and in soil (Center for Food Security and Public Health 2017). It is rare for the bacteria to cause illness, however, under the right conditions, it produces spores which create a powerful neurotoxin which can cause serious illness or death. Conditions that encourage the toxin formation are low or no oxygen, low sugar, low salt, low acid, and specific temperature ranges (CDC 2017a). These conditions are typically associated with improperly canned foods (especially home canned vegetables or meats), improperly prepared sausage, improperly fermented meats and fish, garlic in oil, foil wrapped baked potatoes, and improperly thawed vacuum packed foods (Center for Food Security and Public Health 2017; CDC 2017a). The *C. botulinum* bacteria can be killed through cooking but the spores are resistant to normal cooking temperatures. Toxins that are ingested must be treated with anti-toxin medication under medical supervision, as untreated botulism can be deadly. Commercially or home canned foods or vacuumed sealed foods which are bulging may be contaminated, however, foods often show no sign of contamination (Center for Food Security and Public Health 2017).

From 2009 to 2016, the CDC National Botulism Surveillance reported a total of 134 confirmed and probable cases of foodborne botulism, with 8 deaths. The onset of symptoms occurs within 4 hours or up to 8 days after exposure. Botulism symptoms include drooping eyelids, double or blurred vision, slurred speech, dry mouth, swallowing problems, muscle weakens, constipation, and swollen abdomen (Abraham 2012). To treat botulism, medical assistance is quickly needed (CDC 2017a). Recovery may include temporary paralysis or require the use of a ventilator and may take many weeks or months to fully recover (Abraham 2012). Individuals interested in consuming

vacuum packed, canned, or other reduced-oxygen packaged game, fish, or plants may be at an increased risk of exposure to the botulism toxin. Additionally, individuals interested in infusing oil with wild leeks/ramps or fermenting foods in oxygen free environments may be at an elevated risk.

***C. perfringens* Brief**	
Habitat: N/A - Becomes a hazard after processing	
Condition for Growth: Foods kept at temperatures between 41°-139°F for extended periods of time, includes cooked foods.	
Sources:	
• Soil	• Contaminated Water
Processes of Concern:	*Examples:*
• Dishes made with meat and poultry held at temperatures between 41°-139°F for extended periods of time.	• Venison Hot Dish • Smoked Fish/Game • Turkey Gravy

Clostridium perfringens (*C. perfringens*) are foodborne bacteria naturally found in the intestines of humans and animals, which survives only in the absence of air and produces heat resistant spores and toxins. Food sources of *C. perfringens* include meat and poultry, but is also found in soil and can easily contaminate foods through cross-contamination from humans and food contact surfaces. *C. perfringens* spores can survive normal cooking temperatures, and once the food temperature drops into the danger zone (41-139°F), the spores open, releasing bacteria that begin to multiply. *C. perfringens* multiplication occurs rapidly in temperature ranges of 60°-125°F (Division of Public Health 2004). *C. perfringens* is most often associated with large batches of food which are either improperly cooled, reheated, or held for service (CDC 2017a).

On average, one million cases are reported annually in the United States, making it a common foodborne illness. After consumption the bacteria can produce a toxin in the intestines. The onset of symptoms occurs six to 24 hours after exposure and typically begins suddenly lasting less than 24 hours. Symptoms include abdominal cramps and diarrhea, however, fever and vomiting are not a common symptoms (CDC 2017a). Individuals interested in consuming game, birds, or fish from dishes made in large batches may be at an elevated risk of exposure to *C. perfringens* bacteria.

B. cereus Brief	
Habitat: N/A - Becomes a hazard after processing	
Condition for Growth: Foods kept at temperatures between 41°-139°F for extended periods of time, includes cooked foods.	
Sources:	
• Soil	• Fecal Contaminated Water
Processes of Concern:	*Examples:*
• Dishes made with meat and poultry held at temperatures between 41°-139°F for extended periods of time. Especially dishes made with rice, including wild rice.	• Wild Rice Dishes • Cooked Wild Leeks/Ramps • Cooked Wild Beach Peas • Venison Hot Dish • Turkey Gravy

Bacillus cereus, including other *Bacillus* bacteria, are a source of foodborne illness in starchy foods such as cooked rice (including wild rice) and rice dishes. *B. cereus* forms two types of toxins that cause two different illnesses. The CDC estimates that approximately 63, 400 cases of *B. cereus* illness occur annually in the United States. The first toxin is linked to many foods, including turkey and fish, which causes the following symptoms: diarrhea, nausea, and abdominal cramps. The onset time is about six to 15 hours after exposure and lasts about 24-36 hours. The second toxin is most often associated with cooked rice dishes and causes symptoms such as nausea and vomiting. The onset time of this second illness take 30 minutes to six hours and typically lasts about 24 hours. *B. cereus* is best controlled through freezing, refrigeration, good hygiene, and proper cooking (Abraham 2012). Individuals interested in consuming dishes made with turkey, fish, and/or wild rice may be at an elevated risk of exposure to *B. cereus* bacteria.

S. aureus Brief	
Habitat: N/A - Becomes a hazard after processing	
Condition for Growth: Foods kept at temperatures between 41°-139°F for extended periods of time, includes cooked foods.	
Sources:	
• Humans (esp. hair, nose, and throat)	• Fecal Contaminated Water
Processes of Concern:	*Examples:*
• Dehydrated foods. • Foods requiring handling, especially foods that require assembling after cooking. E.g. tuna salad, sandwiches with deli meat.	• Venison Jerky • Smoked Fish

Staphylococcus aureus (*S. aureus*) is a group of bacteria that is commonly found on the skin and nose of approximately 25% people and animals. These bacteria are harmless on healthy people, however, under certain circumstances, it creates a toxin which is heat resistant (CDC 2016b). The CDC estimates approximately 241,188 illnesses, 1,064 hospitalizations, and 6 deaths which occur annually are due to food related *S. aureus* infections (Abraham 2012). The toxin usually causes a reaction within 30 minutes, however, it can take up to six hours after exposure before symptoms develop. Symptoms typically include vomiting, nausea, stomach cramps, and diarrhea lasting for about 24 hours (Food Safety Working Group n.d.). Individuals interested in consuming smoked fish or dehydrated game are at an elevated risk of exposure to *S. aureus* bacteria.

C. Parasitic Pathogens:

Parasites eaten in undercooked fish and meat can present a potential human health hazard.[18] Among parasites, protozoans[19], roundworms (nematodes), tapeworms (cestodes), and flukes (trematodes) are of most concern. Many of these parasites cause only mild illness in humans, however in some cases, severe illness can occur.

Protozoans

***T. gondii* Brief**	
Habitat: Aquatic and Terrestrial	
Sources:	
• Cat Feces (including intestines) • Deer Meat • Contaminated Soil	• Fecal Contaminated Water • Cross-contamination
Primary Carriers:	
• Deer/Venison	

Toxoplasma gondii *(T.gondii)* is a common parasite found in mammals, especially cats (both wild and domestic), and contaminated water throughout the United States. *T. gondii* can contaminate aquatic habitats through fecal contamination such as sewage overflow, after a storm or flood, and animal related agricultural runoff**.** In terrestrial habitats, *T. gondii* is known to infect most warm-blooded animals, but it must infect cats and their wild feline relatives in order to multiply. The most common food sources in

[18] Freshwater fishes are not advised to be consumed raw under any circumstance.
[19]Protozoa are one-celled eukaryotes. Eukaryotes have membrane-bound organelles. Protozoa are in a subkingdom of the kingdom Protista (Yaeger 1996).

the United States are meat from pigs, sheep, and deer (CDC 2017), all of which can be infected by *T. gondii*.

According to the CDC *T. gondii* is the second leading cause of death from foodborne illnesses in the United States, and accounts for an estimated 327 deaths annually. *T. gondii* creates many hospitalizations related to foodborne illnesses, accounting for an estimated 4,428 hospitalizations annually. Symptoms occur within one to three weeks of exposure, and while symptoms in healthy people are uncommon, they can include enlarged lymph nodes in the head and neck, mild illness with fever, and rarely eye disease (CDC 2017).

Pregnant women who become infected with *T. gondii* soon before becoming pregnant or during pregnancy, can pass the infection on to the baby. Infected newborns do not always show symptoms, but newborns with symptoms may have serious brain or eye damage. Infants may not exhibit symptoms at birth but can develop symptoms, such as blindness or mental disability, later in life (CDC 2017).

T. gondii can be limited, but not necessarily destroyed, by freezing temperatures. Freezing meat at 0°F (home freezer temperature) for several days can decrease the chance of infection. (CDC 2017) Harvesters interested in plants eaten raw, white-tail deer, fish or waterfowl that may be in fecal contaminated water are at the most risk of exposure to the *T. gondii* parasite.

***Cryptosporidium* Brief**	
Habitat: Aquatic	
Sources:	
• Human Feces	• Fecal Contaminated Water • Cross-contamination
Primary Carriers:	*At Risk from Contaminated Water:*
Humans are the primary carrier of *Cryptosporidium spp*. Therefore, the risk is from contact with human feces or fecal contaminated water.	• Fish • Duck • Foods typically eaten raw: o Berries o Wild Leeks/Ramps

Cryptosporidium spp. is a common parasite that can be found in water throughout the United States or surfaces contaminated with fecal matter from humans and wild or domestic animals. Aquatic habitats can be contaminated by fecal matter containing *Cryptosporidium spp*. through flood water or storm run-off, agricultural run-off, or sewage overflow. Aquatic habitats, are a common source of the parasite in humans participating in recreational water activities. In terrestrial habitats, *Cryptosporidium spp*. can be found in fecal matter from humans and animals and in soil. (CDC 2015).

Each year, nearly 748,000 people in the United States become sick with cryptosporidiosis, the illness caused by this parasite, via consuming the parasite (CDC 2015). Populations with weakened immune systems that come in contact with *Cryptosporidium* can potentially encounter life threatening symptoms, as the parasite migrates from the intestines to the liver or lungs (Abraham 2012). Cryptosporidiosis symptoms can vary, as some individuals who come in contact with this parasite will not become ill. For individuals who become ill, the onset of symptoms occurs with two to 10 days and last for one to two weeks, but may last up to four weeks. Cryptosporidiosis symptoms include: stomach cramps, extreme diarrhea, nausea, vomiting, fever, decreased appetite, and headache (May 2010). *Cryptosporidium spp.* is resistant to chlorine, such as bleach, but can be inactivated by boiling untreated water for several minutes (Abraham 2012).

Harvesters interested in plants eaten raw, waterfowl or fish that may be in fecal contaminated water are at the most risk of exposure to the *Cryptosporidium* parasite.

***Giardia* Brief**	
Habitat: Aquatic	
Sources:	
• Animal Feces (including intestines)	• Fecal Contaminated Water • Cross-contamination
Primary Carriers:	*At Risk from Contaminated Water:*
Generally, a concern for only the harvester and any person handling the raw food. Killed by cooking.	• Fish • Duck • Foods typically eaten raw: o Berries o Wild Leeks/Ramps

Giardia lamblia is a relatively common parasite in the ceded territories, typically found in aquatic habitats (MDH 2018; WDHS 2017; Michigan Disease Surveillance System 2018). *Giardia* is transmitted in water or surfaces contaminated with fecal matter from infected animals, including deer, beaver, muskrat, fish, or humans (EPA 2000). In terrestrial habitats, *giardia* can live for weeks or even months in soil, on surfaces, and in fecal matter. Illness due to the *giardia* parasite is called giardiasis and is contracted by consuming contaminated material.

The CDC estimates that approximately 20,305 individuals become ill from giardiasis annually. Some individuals who contract giardiasis will not exhibit symptoms. The onset of symptoms occurs within one to three weeks of infection and can last from two to six weeks (Abraham 2012). Giardiasis symptoms include: diarrhea, flatulence, greasy stool that can float, abdominal cramps, nausea, and/or dehydration (CDC 2015). In

children with severe giardiasis, developmental delays and malnutrition can occur (CDC 2015). Harvesters interested in plants eaten raw, waterfowl or fish that may be in fecal contaminated water are at the most risk of exposure to the *Giardia* parasite.

Nematodes (Roundworms)

Nematodes Brief	
Habitat: Aquatic	
Sources:	
• Fish	• Fecal Contaminated Water • Cross-contamination
Primary Carriers:	*At Risk from Contaminated Water:*
Roundworms are most often associated with raw and under cooked fish. Typically killed by cooking or freezing.	• Fish

Nematodes, commonly known as roundworms, are a class of parasite found in both aquatic and terrestrial habitats worldwide. Roundworms in food are most typically associated with fish, however, they can be found in soil, and the feces of wild and domestic animals. Some examples of fish roundworms include: *Anisakis spp.*, *Pseudoterranova spp.*, and *Eustrongylides spp.* Each can be killed by proper cooking or freezing (DHHS 2011).

Once consumed, roundworms can embed within the wall of the human stomach or intestine (DHHS 2011; Abraham 2012). The frequency of diseases caused by roundworms in the United States is unknown, as it is not a reportable disease by the

CDC's standards and is therefore not required to be reported. The onset of symptoms occurs within 24 hours, or can take up to two weeks, and last about 3 weeks. Symptoms include: abdominal pain, nausea, vomiting, and diarrhea. In some cases, the roundworms can cause an allergic reaction (Abraham 2012). Individuals interested consuming in fish are the most risk of exposure to roundworm parasites.

Cestodes (Tapeworms)

Diphyllobothrium Brief	
Habitat: Aquatic	
Sources:	
• Animal Feces (including intestines) • Bird Feces •	• Fecal Contaminated Water • Cross-contamination
Primary Carriers:	*At Risk from Contaminated Water:*
Diphyllobothrium spp. is most often associated with raw and under cooked fish. Typically killed by cooking or freezing.	• Fish • Duck • Foods typically eaten raw: o Berries o Wild Leeks/Ramps

Diphyllobothrium spp. is a parasite found in fish throughout the United States, more commonly in freshwater fish than saltwater, which can infect humans, mammals, and birds which consume fish. Sometimes called "broad tapeworms" or "fish tapeworms", these are the largest tapeworms that can infect humans, potentially infecting 100-200 people annually in the United States (Abraham 2012; CDC 2017).

Diphyllobothrium is considered a minor public health concern and records of infection are no longer kept. Infections occur when the larvae are consumed, which can be found in the meat or viscera of fresh fish or of raw or undercooked fish. The onset of symptoms typically occurs 15 days after exposure, however, without symptoms or treatment, the parasite can live for years in the body. Symptoms are typically mild and include: abdominal discomfort, changes in appetite, and diarrhea. Typically, patients become aware of an infection when pieces of the tapeworm appear in stool (Abraham 2012). Individual interested in consuming fish are the most risk of exposure to *Diphyllobothrium spp.* parasites.

E. multilocularis Brief	
Habitat: Terrestrial	
Sources:	
• Fox Feces	• Fecal Contaminated Water • Cross-contamination
Primary Carriers:	*At Risk from Fox Fecal Contact:*
Fox are the primary carrier of *E. multilocularis.* Therefore, the risk is from contact with fox feces. Killed by cooking.	• Foods typically eaten raw: o Berries o Wild Leeks/Ramps

Echinococcus multilocularis is a type of tapeworm whose prevalence in North America is slowly increasing. *E. multilocularis* is a potential concern to people eating berries or mushrooms which have been contaminated with fox feces (Poulle et al. 2017).

Trematodes (Flukes)

Trematodes Brief	
Habitat: Aquatic	
Sources:	
• Fish • Deer Liver	• Cross-contamination
Primary Carriers:	
Fish can contain a variety of Flukes which can impact human health. Flukes are killed by cooking.	Deer can carry liver flukes which can impact human health. Deer liver with flukes may have secondary bacterial infection (WDNR 2012).

Trematodes can come from fish or deer. In human, intestinal flukes from fish can cause diarrhea and abdominal pain. Some flukes can migrate to the heart and central nervous system, causing damage to these systems. Some examples of intestinal flukes in fish include: *Heterophyes spp., Metagonimus spp.,* and *Nanophyetes salmincola*.

In humans, liver and lung flukes from fish can damage respective vital organs. *Paragonimus spp.* is an example of a lung fluke found in fish. Some examples of liver flukes found in fish include *Chlonorchis sinensis* and *Opisthorchis spp.* (DHHS 2011).

Liver flukes in deer are flat, grayish-purple, and resemble leeches or "bloodsuckers." People can consume meat from white-tailed deer infected with liver flukes, however, it is recommended to avoid consuming the liver of these deer. Deer liver flukes may be infected with a bacteria caused after the fluke attaches to the liver, which may impact human health (WDNR 2012).

D. Viral Pathogens

West Nile Virus Brief	
Habitat: Terrestrial	
Sources:	
• Mosquitos	• Birds
Primary Carriers:	*At Risk from Food:*
• Mosquitos • Birds *Current research suggest that harvesters are at the greatest risk due to greater exposure, especially to mosquitos carrying the disease.	• Mothers who are breastfeeding can pass the virus on to the breastfeeding infants. • Little or no evidence for foodborne risk to consumer.

West Nile Virus (WNV)[20] is transmitted mainly by mosquito bites.[21] Mosquitoes become infected with West Nile Virus by first biting infected animals, like birds,[22] white-tailed deer[23], and black bears. Viral antibodies have been found in Wisconsin black bears and medium-sized mammals,[24] which indicates that these animals have been exposed to the virus (Katz et al. 2007). Some species of ticks have also been found to carry the virus. It has been determined that West Nile Virus can survive in salt water at 30°F for 4 days, however, there is no documented cases of waterborne transmission to humans (Lund et al. 2017).

Waterfowl, such as wood ducks and mallards, live in habitats where they may be subjected to higher mosquito populations. Although most ducks do not appear to play a large role in disease transmission[25], or are documented in largescale West Nile Virus

[20] A virus is a microscopic agent that infects normal, host cells, and multiplies exponentially (EOL 2018). WNV is comprised of a single, linear strand of RNA (genetic material) called *Flavivirus* (Conover and Vail 2015, 327).
[21] *Culex* mosquitoes are mostly responsible for transmitting WNV (Conover and Vail 2015, 339).
[22] American crows (*Corvus brachyrhynchos*), common ravens (*Corvus corax*), and blue jays (*Cyanocitta cristata*), particularly, are susceptible to massive die-offs during WNV outbreaks (CDC 2018). All three are members of the Corvidae family. Some hawks, owls, songbirds, and other non-game bird species are also susceptible to WNV mortality (CDC 2017).
[23] In the United States, there has been one documented WNV mortality in a white-tailed deer in Georgia (Miller et al. 2005).
[24] Raccoons, opossums, red fox, and coyote were all found to have WNV-specific antibodies. Viral antibodies are blood proteins formed as an immune response to a virus (Docherty et al. 2006)
[25] One study found that wild mallards, American widgeon, northern pintail, and wood ducks tested only at 10 percent for WNV antibodies, indicating that these species are not as exposed as initially expected (Hoffmeister et al. 2016).

mortalities, they may serve as a possible reservoir for the virus to infect humans and other types of birds (Hofmeister et al. 2015 ; 2016).

Wild turkeys do not appear to be uniquely susceptible to death from West Nile Virus (Swayne et al. 2000), however, some wild turkeys that have died tested positive for the virus (CDC 2017; Zhang et al. 2006). Recent research from Pennsylvania has indicated that West Nile Virus may be stressing ruffed grouse populations within the state (Stauffer et al. 2018).[26]

FIGURE 4: COMPARISON OF BREAST MEAT OF GROUSE SUFFERING FROM WEST NILE VIRUS (LEFT) AND HEALTHY GROUSE BREAST MEAT (RIGHT).

PHOTO CREDIT: MILWAUKEE JOURNAL SENTINEL

Currently, no evidence exists that people can become infected with West Nile Virus from consuming infected meat which is properly cooked. However, harvesters cleaning infected game can obtain the virus from blood-to-blood contact with the infected animal (NH DHHS 2006).

Eight out of ten people infected have no symptoms, with approximately one in five infected people develop flu-like symptoms, including fever. Recovery time can range from several weeks to months. Rarely, people infected with West Nile Virus can develop serious complications of the central nervous system, including brain or spinal cord swelling, which sometimes results in death (CDC 2018).

[26] State natural resources agencies present in the ceded territories will be collaborating in the fall of 2018 to examine possible population-level effects of the West Nile Virus on ruffed grouse. (MI DNR 2018).

Pregnant women infected with West Nile Virus can transfer the virus to their developing child. Additionally, breastfeeding mothers can transfer the virus to their nursing child, however, this is not common (Conover and Vail 2015, 337). Harvesters interested in duck, fish, wild rice, wild leeks/ ramps, or prefer to hunt in areas where mosquitoes are abundant may be at an elevated risk of exposure to West Nile Virus.

Norovirus Brief	
Habitat: Aquatic and Humans Contact	
Sources:	
• Human Feces	• Fecal Contaminated Water • Cross-contamination
Primary Carriers:	*At Risk from Contaminated Water:*
Humans are the primary carrier of Norovirus and can easily spread from food handler to prepared food.	• All Identified traditional foods are at risk due to the nature of this virus. Harvesters may contract the virus from contaminated water.

Norovirus is a highly contagious virus which is transmitted when a small amount of feces or vomit contaminate water or food (CDC 2018). Norovirus can enter aquatic habitats through sewage overflow from a flood or contaminated storm water. Norovirus is the leading cause of vomit and diarrhea from acute gastroenteritis[27] in the United States; causing between 19 and 21 million cases, 56,00 to 71,000 hospitalizations, and 570 to 800 deaths annually (CDC 2018). Individuals that are ill or have recently been ill are known to transmit the virus, which enter the body through consumption of contaminated material (NRAEF 2012).

The onset of Norovirus symptoms occur within 24 to 48 hours and include vomiting, diarrhea, nausea, and abdominal cramps, generally occurring a few hours after exposure (NRAEF 2012). Symptoms last from 12 to 60 hours in healthy people and 72 to 96 hours in hospitalized patients, immunocompromised, and elderly populations. Harvesters interested in plants eaten raw, waterfowl or fish that may be in fecal contaminated water are at the most risk of exposure to Norovirus.

[27] Acute gastroenteritis is inflammation of the stomach and intestines.

Hepatitis A Brief	
Habitat: Aquatic and Humans Contact	
Sources:	
• Human Feces	• Fecal Contaminated Water • Cross-contamination
Primary Carriers:	*At Risk from Contaminated Water:*
Humans are the primary carrier of Hepatitis A and can easily spread from food handler to prepared food.	• All Identified traditional foods are at risk due to the nature of this virus. Harvesters may contract the virus from contaminated water.

Hepatitis A is a contagious virus that affects the liver which is transmitted by fecal matter from individuals whom have contracted the virus. Hepatitis A can enter aquatic habitats through sewage overflow from a flood or contaminated storm water. Unfortunately, it only takes a little bit of the Hepatitis A virus to make someone ill (NRAEF 2012). Hepatitis A is typically associated with eating prepared, ready–to-eat (RTE)[28] foods, however it is important to note that this virus is not destroyed by typical cooking temperatures during the preparation process (CDC 2018).

Hepatitis A symptoms include: mild fever, general weakness, nausea, abdominal pain, and jaundice. The onset of symptoms typically occurs about 4 weeks after exposure and can last up to 2 months for most people and 6 months for 10-15% of people. Children under the age of 6 do not generally show symptoms once infected (CDC 2018). Unlike many of the previously mention pathogens, a vaccine is available to prevent the Hepatitis A virus. Harvesters interested in plants eaten raw, waterfowl or fish that may be in fecal contaminated water are at the most risk of exposure to the Hepatitis A virus.

E. Prions

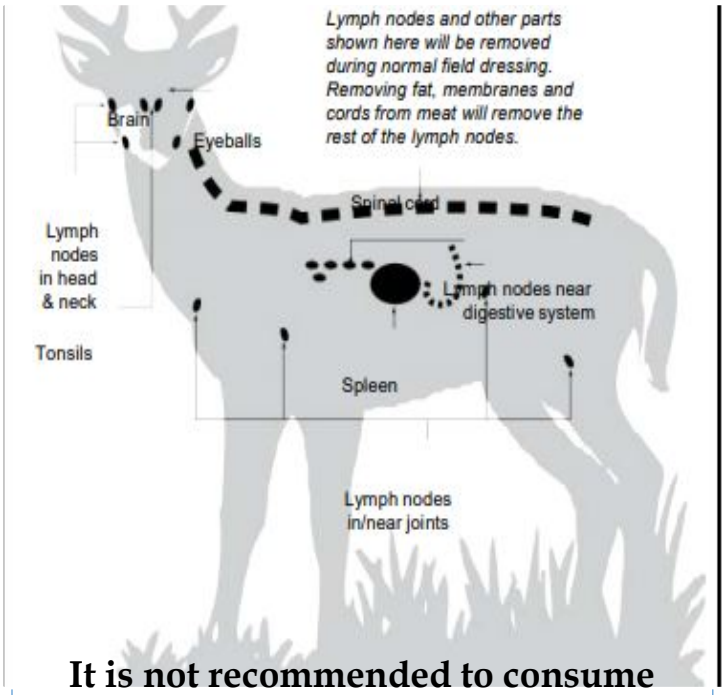
Chronic Wasting Disease (CWD) is the only prion disorder found within the ceded territories. A prion is an atypical, misfolded variety of a protein (Botzler and Brown 2014, 358). Prion disorders belong to a family of diseases called transmissible spongiform encephalopathies, or TSEs. TSEs are progressive disorders that are characterized by degeneration of the nervous system, including the brain. These types of diseases impact both humans and animals. TSEs have long incubation periods and cause the brain to have sponge-like holes in very advanced cases (CDC 2018).

[28] Ready-to-eat foods are foods that do not need cooking or have already been cooked and are ready for consumption.

Chronic Wasting Disease (CWD) is a fatal, prion disorder impacting wild and captive white-tailed deer, elk, and moose[29] (CDC 2018). Please see Appendix 3 for a map showing disease prevalence in the ceded territories. Prions tend to concentrate in tissues of the brain, lymph nodes, spinal cord, and spleen (Wisc. DPH 2018)[30] which are shed into the environment by infected animals through blood, saliva, feces, and urine (Geist et al. 2017, 2; CDC 2018; Mathiason 2015).[31]

A deer infected with CWD may not show any symptoms for several years. In time, CWD causes damage to the brain and other nervous system tissue. This results in significant behavioral changes, including isolation, head lowering, and repetitive walking patterns. Deer with advanced CWD become unusually thin, are constantly thirsty, copiously drool, and often grind their teeth. Elk with CWD have been known to become very nervous and hyperactive (CWD Alliance 2018).

The biological pathogens of CWD are not easily destroyed. The pathogens can remain present even after



It is not recommended to consume any meat from animals known to be infected with CWD (CDC 2018; CWD Alliance 2018).

FIGURE 5: CWD CONCENTRATES IN BRAIN, LYMPH NODES, SPINAL CORD, AND SPLEEN TISSUES. IN PARTICULAR, LYMPH NODES NEAR AND IN JOINTS ARE LIKELY TO BE ENCOUNTERED DURING PROCESSING (WISC. DPH 2018).

[29] The scientific names for white-tailed deer, elk, and moose, respectively, are *Odocoileus virginianus, Cervus canadensis, and Alces.*

[30] Prion numbers increase within a host, but do not multiply directly. Instead, prions cause the host's ordinary cell proteins to fold abnormally (Botzler and Brown 2014, 358).

[31] CWD is a highly infectious disease that persists on contaminated areas, in the soil, on plants, after passing through the digestive systems of CWD infected animals, and even after undergoing wastewater treatment (Hawkins et al. 2015; Johnson et al. 2007; Nichols et al. 2015; Hinckley et al. 2008; Geist et al. 2017,4).

treatments with common disinfectants, high temperatures, freezing, dehydration, and radiation (Geist et al. 2017, 2; Hughson et al. 2016; Brown et al. 2000).[32] Also, CWD prions can remain infectious in soil, bind to the outside of some plants, and even possibly be taken into plants via root systems (Geist et al. 2017, 4; Nichols 2016; Johnson et al. 2007).

To date, CWD infection in humans has not been found. Currently, research is conflicted about whether the disease is potentially transmissible to humans (Marsh et al. 2005; Waddell et al. 2018). Several studies have linked CWD in other mammals through eating infected meat, which indicates that the species barrier is able to be crossed by the pathogen (Geist et al. 2017, 3). However, other studies have contradicted this claim (Zabel and Ortega 2017; Race et al. 2018).

Due to this absence of knowledge, international, federal, and state agencies recommend that CWD positive meat be properly disposed of rather than consumed (Mathiason 2015; WDPH 2016; CDC 2018).[33] Additionally, human health impacts are not known concerning potential CWD exposure to small amounts of prions through eating contaminated plants or fungi in CWD-infected areas (Nichols 2016; Pritzkow et al. 2015).

Female White-tailed Deer

Photo credit:

Linda Freshwater Ardnt

It is believed among the Ojibwe that all animals, just like people, need to eat certain healing plants in order to maintain their overall health. CWD may be an indicator that white-tailed deer are not consuming enough white sage.[34] White sage on the ceded territories has declined over the years, mainly due to habitat loss (Enright and Doran n.d.). Tribal elders are encouraging tribal members to plant white sage in CWD-infected areas for wild deer. Sage grows best in prairies with dry to moderately moist soils (Meeker et al. 1993, 66).

[32] Biological inactivation by lichens, cleaning with relatively-inert hypochlorous acid (HOCl), and composting infectious materials all may help reduce infectivity of CWD prions. However, these methods do not completely eradicate them (Hughson et al. 2016; Rodriguez et al. 2012; Xu et al. 2014).
[33] Agencies include the World Health Organization, U.S. Centers for Disease Control and Prevention, the Wisconsin Division of Public Health, and other state natural resource agencies.
[34] The scientific name for white sage is *Artemisia ludoviciana* (Meeker et al. 1993, 66).

Many federal and state agencies have created herd certification plans for CWD management and monitoring on captive deer farms. Many of these regulations are intended to keep wild and captive deer separated to prevent the spread of disease from captive to wild deer populations and the spread of the disease between one captive deer herd to another.

In addition, Minnesota, Wisconsin, and Michigan have adopted regulations to restrict the movement of deer carcasses from known CWD-infected areas and carcass disposal regulations. There is more data that needs to be collected to understand the impact of these regulations on the spread of CWD.

Currently, the risk of CWD to humans is not fully understood. Other prion diseases, such as Mad Cow Disease (bovine spongiform encephalopathy), have caused disease in humans, therefore, it is reasonable to suspect that CWD may potentially have a similar impact to humans. Prions are very difficult to destroy during normal cooking methods and may be hard to remove from contaminated hands or clothing (Geist et al. 2017, 2; Hughson et al. 2016; Brown et al. 2000).

Sighting a Sick Deer:
If you observe or shoot a deer that appears to be sick, immediately report it to the nearest tribal registration clerk, GLIFWC biologist, conservation warden, or your local state DNR biologist (GLIFWC 2017).

CWD is a growing concern, yet, many counties in ceded territories have not been affected to date. Michigan, Minnesota, and Wisconsin's Natural Resource departments regularly update CWD affected counties list within their respective states.

Regulations

Regulations regarding CWD vary by state and jurisdiction. However, regulations generally apply to both deer and elk, where applicable, as both animals are affected by CWD and are in the cervid family. A compilation of regulations Michigan, Minnesota, Wisconsin, Colorado, Wyoming, and Canada has been provided in Appendix 4. The compilation includes regulations regarding the following for each jurisdiction:

- Baiting during hunting
- Deer farm fencing requirements
- Hunting preserve fencing requirements
- Intrastate movement of carcasses from CWD affected areas/management zones
- Action if CWD is verified – deer farm
- Action if CWD is verified – hunting preserve
- Testing requirements for hunting preserves

- Testing requirements for hunters in CWD Units
- Requirements for donated deer from non-CWD Units
- Requirements for donated deer from CWD Units

A table of deer farming regulations in Michigan, Minnesota, and Wisconsin has been provided in Appendix 5.

F. Allergens

Allergens are agents in food that cause or trigger an allergic reaction. There are more than 160 foods which can cause allergic reactions in people with food allergies, however, the FDA identifies the eight most common allergic foods. According to the FDA, these foods and their derivatives are implicated in approximately 90% of allergic reactions. The FDA requires food producers to specially label foods and or food ingredients containing one or more of these allergens (Nutrition 2017).

The eight most common allergens are:

- Milk
- Eggs
- Fish
- Crustacean shellfish
- Tree nuts
- Peanuts
- Wheat
- Soybeans

Of the 14 identified traditional foods, only three are major allergens: whitefish, walleye, and hazelnuts. It is important to note that allergic reactions can be triggered by foods that are not on the list. There are two additional foods from the identified traditional foods that are reasonably likely to cause allergic reactions: strawberries and morel mushrooms (fungi). These reactions are not as common as the reactions from the most common allergen above.

2. Chemical Hazards

Chemical hazards are non-biological contaminants which develop in or are added to foods that cause illness. These contaminants can be a naturally occurring chemical within the food, unnaturally occur due to tissue uptake from the environment, or are added to foods. The following sections outline natural toxins, heavy metal contaminants, pesticides, and industrial chemicals.

TABLE 5: AN OVERVIEW OF CHEMICAL HAZARDS OF IDENTIFIED TRADITIONAL FOODS. TO INCLUDE NATURAL TOXINS, HEAVY METALS, PESTICIDES AND INDUSTRIAL CHEMICALS.

Chemical Hazard Risk Overview	Deer	Rabbit/Hare	Duck	Turkey	Whitefish	Walleye	Berries	Wild Ramps	Beach Pea	Hazelnut	Morel Mushroom	Wild Rice	Maple Syrup	Berry Jam/Jelly	Animal Fats	Venison Jerky
NATURAL TOXINS																
Sambunigrin							X									
BOAA									X							
HEAVY METALS																
Lead	X		X	X					U		X	U	X			X
Mercury			X	X	X	X										
Arsenic							U				X	U				
Copper			X				X									
Zinc			X				X									
Manganese							X									
Cadmium																
Aluminum			X													
PESTICIDES & INDUSTRIAL CHEMICALS																
Toxaphene					X											
Dioxins & Furans—					X											
PCBs					X											
PFAs																
PFOs																
	Deer	Rabbit/ Hare	Duck	Turkey	Whitefish	Walleye	Berries	Wild Ramps	Beach Pea	Hazelnut	Morel Mushroom	Wild Rice	Maple Syrup	Berry Jam/Jelly	Animal Fats	Venison Jerky

'U' indicates unknown risk. See the companion document for more information.

A. Natural Toxins in Traditional Foods

Elderberries and wild beach peas contain natural plant toxins which could pose a human health hazard. Negative health effects would be exaggerated by consuming great quantities over a period of time. Moderate consumption and proper preparation are key to preventing hazardous impacts to human health.

Elderberries seeds, leaves, and twigs from elderberries[35] contain a cyanide-producing glycoside (CGG) called sambunigrin. In one study, elderberries at the bottom of hills were found to have slightly less CGGs in its berries overall, when compared to berries collected at the tops of hills (Senica et al. 2017). A toxic alkaloid, sambucine, is also present in unripe fruit and in its flowers.

The human digestive system can break down very small amounts of CGGs, however, overconsumption of elderberry seeds would result in symptoms of nausea, vomiting, and diarrhea. The sensitivity of people to these natural toxins will vary from person to person (Atkinson and Atkinson 2002).

Wild Beach Pea[36] Excessive and repeated consumption of *Lathryus spp.* leads to a disorder known since ancient times called lathyrism. This disease is caused by a neurotoxin, called beta-N-oxalyl-amino-L-alanine (BOAA). Lathyrism is characterized by painful muscle spasms, followed by permanent paralysis of the legs and buttocks in humans, and frequent urination. Young adult males are the most affected by excessive consumption of this neurotoxin. The onset of the illness can take anywhere from a few weeks or months from pea overconsumption. Lathyrism is also known to impact animals, causing animals to become crippled in extreme cases (Alm 2015; Manna et al. 1999).

From an ethnographic, or cultural, standpoint, the safety of beach pea consumption remains debated (Alm 2015; Chavan et al. 2003). Nutritionally speaking, however, the literature points toward the safety of beach pea as a wild, traditional food when consumed in moderation as part of a balanced diet. BOAA (neurotoxin) analysis of beach peas closely resembled that of the common soybean (Chavan et al. 2003).

[35] *Sambucus canadensis* and *Sambucus racemosa* are the two species of elderberries within ceded territories, with S. *canadensis* being more common overall (Meeker et al. 1993).
[36] *Lathyrus japonicus* is the scientific name for wild beach pea.

B. Heavy Metals

Heavy metals and metalloids are chemical elements; elements are chemicals that cannot be broken down further. Most heavy metals possess a high density or high weight compared to its volume. Once in the environment, heavy metals do not break down. Heavy metals are often released from human activities, such as manufacturing and mining (Lenntech 2018). Lead, a common metal used in gun ammunition, can contaminate game meat during the harvesting process. White-tailed deer, wild rice, maple syrup, rabbits, hare, whitefish, walleye, wild turkey, duck, beach pea, and some berries are all traditional foods that may be impacted by one or more heavy metals in some fashion.

Heavy metals are often toxic to the human body at relatively low concentrations, however, some metals are needed in trace amounts for proper body function, like copper and zinc. Others, like lead and cadmium, do not have a known nutritional function and can create problems when introduced into the body at all. Unfortunately, most of these elements bioaccumulate in tissues and biomagnify in the food web. Increasing concentrations of a harmful substance found within an individual is known as "bioaccumulation." When this happens when animals eat other animals, it is called "biomagnification" or "bioamplification (USGS n.d.)." Once in the human body, these elements often take a while to be reduced in concentration.

Human health effects from heavy metals exposure vary widely among specific elements and may be different depending on the length of exposure. However, impacts to the nervous system, liver, and kidneys are often associated with chronic, or long-term, heavy metals toxicity. Chronic exposure is much more likely to occur than high dose, acute (short-term) exposure from eating identified traditional foods. Certain metals, like mercury and lead, impact developing children, infants, and small children, more so than adults (ATSDR 2018).

Lead Brief	
At Risk Foods:	
• Deer/Venison (esp. ground) • Turkey • Wild Beach Pea — under review	• Morel Mushrooms • Maple Syrup • Wild Rice— under review
Maximum Allowable Limit (excerpt):	
0.1 ppm imported dried fruit	United States
0.5 ppm maple syrup	Canada
0.1 ppm poultry meat	European Union
0.3 ppm fish	World Health Organization

Lead is a naturally-occurring metal that creates a variety of health problems at even very low doses. [37] The nervous system, which includes the brain, is most damaged by lead exposure. This element becomes mobilizes primarily by human activities, such as manufacturing, mining, smelting, and the burning of fossil fuels (see Appendix 6 for a map of metallic mines in the ceded territories). Lead is commonly found in a wide variety of products, including fishing sinkers, weights, gun ammunition, and solder in spigots and valves. Once mobilized, lead persists and strongly binds to soil (Wani et al. 2015, 55; ATSDR 2018).

> Parts per million (ppm) basically means "one part in one million." It is also expressed as mg/L or mg/kg using the metric system. Parts per billion (ppb) is "one part in a billion." Ppb can be converted into ppm by moving the decimal place three places to the left to make the value smaller. For example, 1 ppb is also 0.001 ppm, or 0.001 mg/kg (Satterfield 2004).

For lead, no safe level of exposure exists (WHO 2018; EFSA 2010). Prevention and reduction of lead exposure remains the best course of action to reduce negative health impacts (US CDC 2017). Infants and young children are rapidly growing, making young children more sensitive to low concentrations of lead (Wani et al. 2015, 55; ATSDR 2018).[38] Lead exposure in children can cause devastating, lifelong impacts, such as brain damage that causes lowered I.Q. scores, violent outbursts, and learning problems (Wani et al. 2015, 55; ATSDR 2018).

Chronic lead exposure in adults can also result in noticeable health impacts, such as decreased mental function, anemia, and high blood pressure (Wani et al. 2015; ATSDR 2018). Kidney problems caused by lead can be worsened in people with Type 2 diabetes, a health issue that disproportionately affects Native Americans (Watson et al. 2009, 26). Ongoing lead exposure was also found to reduce male fertility (Wani et al. 2015).

High lead exposure may cause pregnant women to miscarry (Wani et al. 2015, Watson et al. 2009, 27). In both children and adults, severe brain and kidney damage from extreme lead exposure levels is linked to death (Wani et al. 2015; ATSDR 2018). However, the consumption of lead through traditional foods is unlikely to cause dramatic, acute health effects. Subtle impacts are more likely to occur from low dose, chronic ingestion of lead.

[37] The chemical symbol for lead is Pb (LANL 2018).
[38] Behavior, such as mouthing and crawling, puts infants and children in a position of potential increased exposure to lead (Watson et al. 2009).

Unfortunately, lead still has a wide variety of applications due to its abundance within the environment and its unique physical properties.[39] When products made with lead, such as gun ammunition and fishing line weights, are left or lost in the environment, it creates a perpetual cycle of contamination within that area (Watson et al. 2009).

TABLE 6: DIFFERENT ROUTES OF LEAD EXPOSURE POTENTIALLY IMPACTING IDENTIFIED TRADITIONAL FOODS.[40]

Identified Ojibwe Traditional Foods Potentially Impacted by Lead					
			Routes of Exposure		
			Ammo	*Processing Equipment*	*Tissue Uptake*
Common Name	**Scientific Name**	**Ojibwe Name**			
Big/Small Game					
White-tailed Deer	*Odocoileus virginiatus*	waawaashkeshiwi-wiiyaas	x		
Snowshoe Hare	*Lepus americanus*	waabooz	x		
Cottontail Rabbit	*Sylvilagus floridanus*	manidoo-waabooz	x		
Ducks/divers					
Scaup/Bluebill	*Aythya affinis; A. marila*	zhiishiib	x		x
Ring-necked Duck	*Aythya collaris*	dagwaagishiib	x		x
Duck/dabblers					
Blue-winged Teal	*Anas carolinensis*	kwishkwishibens	x		
Green-winged Teal	*Anas discors*	ozhaashkwinigwi-shibens	x		
Mallard	*Anas platyrhynchos*	ininishib	x		
Wood Duck	*Aix sponsa*	zii'amo	x		
Upland					
Wild Turkey	*Meleagris gallopavo*	mizise	x		
Ruffed Grouse	*Bonasa umbellus*	bine	x		
Plants					
Wild Rice	*Zizania palustris*	manoomin			x
Wild Beach Pea	*Lathyrus japonicus*	anijiimin (pea)			x
Fungi					
Morel Mushroom	*Morchella esculenta*	wazhashkwedoons (mushroom)			x
Value Added					
Maple Syrup	*Acer saccharum*	ziinzibaakwadwaaboo		x	
Venison Jerky	*Odocoileus virginiatus*	baatewaawaashkeshiwi-wiiyaas	x		

[39] Some unique physical properties include high density, malleability, corrosion resistance, and poor conductivity (Wani et al. 2015, 55).
[40] Ojibwe names were determined using the Ojibwe People's Dictionary from the University of Minnesota. These names are to be reviewed by GLIFWC's Advisory and Guidance Input Group of Elders in the Winter of 2019.

Routes of Exposure[41]

Ammunition

The most common cause of lead contamination in wild game meat occurs when hunters use lead ammunition shot, bullets, or slugs during an animal's harvest. Elevated exposure to lead from consuming game meat harvested with lead ammunition is widely documented as a potential human health hazard (Pain et al. 2010; MI DCH 2010; Fachehoun 2015; Hunt et al. 2009; Watson et al. 2009). In contrast, when rabbits are snared, the potential for lead exposure in the meat is virtually eliminated since there is no potential for ammunition containing the toxic metal to be used.

Lead fragments found in a whole cut of venison, weighing 982 mg.

Photo credit: Minnesota Department of Agriculture

Particular groups, including families with hunters, indigenous groups, and food pantry recipients, are more at risk for higher dietary exposure to lead (EFSA 2010; Knutsen et al. 2015; Hunt et al. 2009; ND DOH 2008). Blood lead levels are consistently higher in

[41] Lead can get deposited through the air by floating dust particles from fuel exhaust. The United States banned the use of lead as an additive in gasoline for passenger vehicles in 1996 (U.S. EPA 2016; Newell and Rogers 2003,6). Plants near roadways are exposed to lead contamination through accumulation of this dust. However, lead contamination of plants from road dust is not reasonably likely to accumulate to levels affecting human health (Trombulak and Frissell 2000, 22).

these groups than in the general population (Hunt et al. 2009; Watson et al. 2009; Johansen et al. 2006).

However, in a joint study by Fond du Lac Tribe and the Minnesota Department of Health (2014), only 3 out of 490 people tested had blood lead levels which exceeded the Level of Health Concern for lead, which is 5 micrograms/deciliter. Two of these respondents were likely exposed to this metal from their workplaces. In general, there did not appear to be a relationship between the consuming of game and blood lead levels. The exposure source remained largely undocumented, nonetheless, as information regarding a timeline of people consuming game meat in relation to giving blood samples was not gathered from participants.

Ammunition components separate differently depending on a variety of factors, including firearm design, metal composition, weight, and size. Rifle ammunition shatters more than shotgun ammunition, and muzzleloader bullets, respectively. Inexpensive lead bullets commonly used by center-fire rifles splinter far more than leaded-core and all-copper bullets (Cornicelli and Grund 2008). It is important to note that lead cannot be washed off a harvested animal. Rinsing the abdominal cavity may actually spread microscopic lead shards throughout the carcass, increasing the possibility of contamination (Grund et al. 2010).

Unfortunately, the type of ammo used also impacts the bioavailability of lead, meaning the smaller a lead fragment is, the easier it can be absorbed into the body (Barltrop and Meek 1979; Hunt et al. 2009). Additionally, the cooking method used to prepare harvested meat impacts the availability of lead for uptake into the body. Particularly in acidic recipes, lead from ammo in game meat becomes more accessible to the body after it is cooked (Mateo et al. 2011).

The cut of deer meat can also influence the amount of lead in venison. Ground venison is tested most often by agencies because it is a common way to consume white-tailed deer. However, the grinding processes mixes lead-contaminated meat with previously uncontaminated meat. Michigan Department of Community Health (2010) examined butterfly loins for lead, and found none. Lead ammunition placement would largely influence the presence of lead even in whole cuts of venison.

Deer jerky would contain the same levels of lead the raw meat originally contained. Ground meat jerky recipes would be at greater risk for higher lead levels than muscle jerky, if the deer was shot with a lead bullet.

Lead deposited in the environment by ammunition also likely harms animals, including those culturally significant to the Ojibwe people, such as the bald eagle. Northern-dwelling eagles scavenge more often during the cold, winter months. As scavengers,

bald eagles consume deer gut and organ (offal) piles, some of which can contain lead ammunition.

In an upper Midwest study, 36 % of offal piles sampled contained lead particles (Warner et al. 2014), and a study of Wisconsin bald eagle deaths found about 15 % died from lead poisoning. Death trends have been found to overlap with state hunting seasons (Watson et al. 2009, 194) with lead exposure rates for bald eagles remain consistently high (Warner et al. 2014, Watson et al. 2009).[42]

Bald Eagle. Photo credit: Linda Albor

Processing Equipment

Maple sap contains on average 1.1 microgram/L (ppb), or 0.001 ppm, of lead (Stilwell and Musante 1996). Lead contamination of **maple syrup** most often occurs through solder, spigots, and pumps containing lead (IMSI 2015).[43] However, any piece of older, lead-bearing processing equipment that the sap comes in contact with can leach into the finished product. This includes equipment, like buckets, pans, tanks, and drums (Willits and Tressler 1937; Stilwell and Musante 1996).

Tissue Uptake

Certain plants may uptake lead from the soil into their tissues (US FDA 2017). **Wild rice** has been documented to uptake elevated amounts of lead in its seeds (Bennett 2000; Pip 1993; Nriagu and Lin 1995). Wild rice in natural stands may potentially contain greater levels of lead compared to paddy-grown wild rice due to surrounding environmental factors (Nriagu and Lin 1995, 225; Pip 1993).

The roots of the grass pea[44] have the ability to uptake large amounts of lead into its roots. **Wild beach peas** are closely related to the grass pea, and are likely to possess this same quality. However, lead levels were not tested in the grass pea pod or seed (Brunet et al. 2008).

Lead uptake into **morel mushrooms** are a potential health hazard for people that consume this identified traditional food (Abdel-Aziz 2016).[45] Lead arsenate, a formerly-used insecticide containing both lead and arsenic, was widely used in commercial apple production. Soils in abandoned orchards still contain high amounts of lead from

[42] 38% of those bald eagles also had liver lead concentrations that suggest lead poisoning.
[43] Leaching of lead into maple syrup occurs more frequently during conditions of higher acidity and temperature (Willits and Tressler 1937; Stilwell and Musante 1996).
[44] The scientific name of grass pea is *Lathyrus sativus* (Brunet et al. 2008).
[45] The scientific name of morel mushroom is *Morchella esculenta*.

previous use of this insecticide. A relationship exists between higher levels of lead in the soil and higher amounts of lead found in morel fruiting bodies (Shavit and Shavit 2010).

Mercury Brief	
At Risk Foods:	
• Duck • Turkey	• Whitefish • Walleye
Maximum Allowable Limit (excerpt):	
1 ppm fish (edible portion)	United States
0.5 ppm; 1 ppm species dependent	Canada
0.01 duck meat	European Union
0.5 ppm; 1 ppm species dependent	World Health Organization

Mercury is a metal that occurs naturally in the environment and takes several forms, including the most toxic version is the organic (carbon-based) form: methylmercury. Methylmercury is most frequently encountered by people that consume a diet high in fish and shellfish. (ATSDR 2018).[46]

Mercury is bound in muscle tissue. It cannot be trimmed or cut off fish.

Inorganic mercury is released into the environment mostly through human activities, such as fossil fuel combustion, mining, metal smelting, waste incineration, and chlorine production. Smaller amounts of inorganic mercury can enter the environment through natural processes, such as erosion and volcanic activity (ATSDR 2018). Globally, it is estimated about 2/3 of mercury mobilized from the Earth's crust is due to the result of human activity (UNEP Chemicals Branch 2008).

Once mobilized, mercury does not break down, with inorganic forms transformed to organic methylmercury by bacteria in water and sediment.[47] The conversion of inorganic mercury to organic methylmercury occurs almost exclusively in aquatic environments. The more total mercury there is in the environment, the more methylmercury that can be created by bacteria (ATSDR 2018).

Developing fetuses, infants, and small children are the most sensitive to the effects of methylmercury exposure. Methylmercury in the mother's body passes to a developing child and can accumulate there. The compound can also be passed to a nursing infant through breast milk. In children, common symptoms of methylmercury exposure

[46] The chemical symbol for mercury is Hg. Methylmercury and metallic mercury vapor both can easily reach the brain (ATSDR 2018).
[47] This is a complex process involving the work of sulfate-reducing bacteria in mainly oxygen-poor conditions.

include: delays in fine motor skills, cognition, and speech and language development (ATSDR 2018).

Advanced methylmercury toxicity symptoms occur differently in adults. Those symptoms which include: clumsiness, muscle weakness, hearing and speech problems, nerve loss in hands and face, problems walking, and changes in vision. Other neurological effects include: depression, anxiety, irritability, problems with memory, shyness, numbness, and tremors. Substantial evidence also exists that methylmercury exposure increases the risk of cardiovascular disease (ATSDR 2018).

High-dose methylmercury exposure can cause permanent brain and kidney damage. However, acute methylmercury toxicity is very unlikely to result from traditional foods consumption.

Fish in the ceded territories have been extensively tested for methylmercury due to the important cultural and dietary role that fish have in Anishinaabe culture. Mercury is bound in muscle tissue, so trimming fat from fish fillets and removing skin do not reduce mercury levels.

Nearly 8,000 **walleye** fillets have been collected and tested for methylmercury since 1989 by GLIFWC. WDNR and tribes have also been collecting mercury data for walleye since the 1970s. A slight, regional decrease annually in walleye methylmercury of approximately 0.6 % annually was found between 1982 and 2005 (Madsen 2007). However, there was also evidence that the trend may have reversed in some areas, with mercury increasing (Monson et al. 2011).

Methylmercury-based walleye consumption advisories in the ceded territories are fairly common for inland lakes, especially for sensitive populations including infants, children, and women of childbearing age.

None of the Lake Superior fish sampled (**whitefish**, lake herring, lake trout, or siscowet trout) exceeded the United States FDA's methylmercury action limit of 1.0 ppm for commercially sold fish. However, the state of Michigan uses a lower level of 0.5 ppm (500 ppb). Siscowet samples in the 23-23 inch and 24.5-25.5-inch size groups exceeded Michigan's action level.[48]

Puddle, or dabbling, **ducks** do not accumulate substantial amounts of mercury. Dabblers averaged 0.09 ppm of total mercury in breast tissue, and 0.23 ppm of total mercury in livers. Correspondingly, diving ducks averaged 0.12 ppm in muscle, and 0.45 ppm in liver. The highest total mercury values observed came from certain duck livers, particularly diving ducks and grebes. These levels approached or exceeded 0.5 ppm (Kleinert and Degurse 1972, 6). In contrast, a 1987 study found male bluebills had

[48] GLIFWC memorandums from Matt Hudson, Dec. 30, 2005 and April 11, 2006.

higher mercury liver levels than females, but comparable, low levels to mallards and black ducks overall (Gochfeld and Burger 1987).

A study conducted by Fond du Lac Environmental Program tested mercury levels in duck breasts harvested by tribal members. Seventy percent of ducks tested were ring-necked ducks, a diving duck species. The study revealed 15% of sampled ducks exceeded 0.5 ppm in mercury concentrations. The Fond du Lac tribe recommended that children and women of childbearing age consume no more than one meal of duck per week. Other groups had no restrictions.[49]

[50]

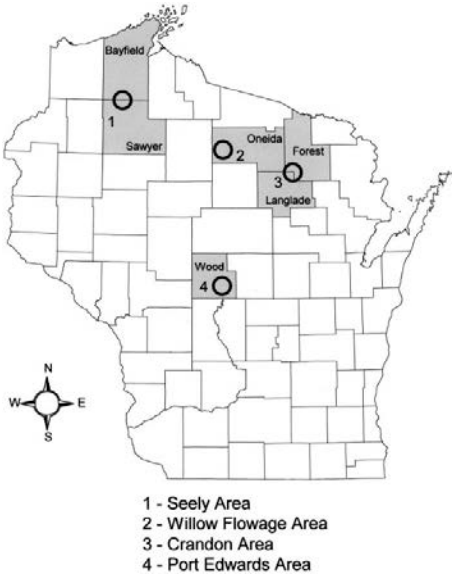


FIGURE 5: THIS MAP OF WISCONSIN SHOWS WHERE JAMES BENNETT AND HIS COLLEAGUES (2000) SAMPLED WILD RICE FOR VARIOUS HEAVY METALS, INCLUDING LEAD, MERCURY, AND ARSENIC.

Studies have consistently shown that wild rice does not uptake mercury into the seed head to any significant extent. One heavy metals study of Northern Wisconsin wild rice showed the highest total mercury average, 0.034 ppm, from the Seely-area rice beds (Bennett et al. 2000). The European Union has set a methylmercury consumption guideline for rice at 0.01 ppm. A study carried out by the Fond du Lac Environmental

[49] Personal communication with Nancy Schuldt, Fond du Lac Environmental Program, August 8, 2018.
[50] In general, diver ducks have large feet with short legs that are far back on the body in order to propel themselves underwater for food. In general, dabbler (puddle) ducks have smaller feet with legs situated farther forward on body. They often skim the water surface or tip forward to feed in the water (Ehrlich et al. 1988).

Program found no wild rice samples that exceeded 0.5 ppm, a fish consumption guideline set by United States EPA.[51] Thus, there is negligible risk of mercury exposure from consuming wild rice.

Arsenic Brief	
At Risk Foods:	
• Morel Mushrooms • Wild Rice — under review	• Berries — under review
Maximum Allowable Limit (excerpt):	
0.1 ppm infant rice cereal	United States
3.5 ppm fish protein	Canada
0.25 husked rice	European Union
0.1 edible fats and oils	World Health Organization

Arsenic is a metal-like element which is found naturally in the Earth's crust.[52] Two general types of arsenic exist: organic[53] and inorganic. Inorganic arsenic is more injurious to human health than organic arsenic. Compounds containing inorganic arsenic are mainly used in wood preservation and creation of pressure-treated lumber. Exposure to inorganic forms of arsenic are known to cause health problems in people, including: nausea, vomiting, decline in blood cell production, blood vessel damage, irregular heart rhythm, and prickling sensations on feet and hands. At very large doses of arsenic not likely to be associated with levels found in identified traditional foods, death can result. Limited research has been conducted on the human health effects of organic types of arsenic, but certain compounds caused diarrhea and kidney damage in laboratory animals (ATSDR 2018).

Wild rice and **blueberries** are two traditional Anishinaabe foods that may contain elevated amounts of arsenic in the ceded territories. Elevated amounts of total arsenic have been documented in wild rice seeds from natural areas (Pip 1993; Bennett et al. 2000).[54] However, amounts of the inorganic arsenic species, the variety more harmful to human health, was not evaluated in these studies. In addition, inorganic arsenic in cooked wild rice has not been examined to date (U.S. FDA 2013).

Wild blueberries in the Eagle Mine and Humboldt Mill area were found to contain amounts of total arsenic above the EPA's TDI value of 0.0003 ppm/day.[55] However, the

[51] Personal communication with Nancy Schuldt, Fond du Lac Environmental Program, August 8, 2018.
[52] The chemical symbol for arsenic is As (LANL 2018).
[53] The term 'organic' is defined as a chemical compound containing carbon.
[54] Personal communication with Abby Debiak, Superior Partnership & Land Trust, August 7, 2018.
[55] Eagle Mine and Humboldt Mill are in Marquette County of upper Michigan.

arsenic levels in the mining and mill area wild blueberries were approximately at the same arsenic level as in the control group.[56] This indicates that the geology of the area may naturally be high in arsenic overall.[57]

Arsenic uptake into **morel mushrooms** are a potential health hazard for people that consume this identified traditional food (Abdel-Aziz 2016). Lead arsenate, a formerly-used insecticide containing both lead and arsenic, was widely used in commercial apple production. Soils in abandoned orchards still contain high amounts of arsenic from past use of the insecticide. There is a relationship between higher levels of arsenic in the soil and higher amounts of arsenic found in morel fruiting bodies. About 94 percent of the arsenic stored in mushroom tissue was of the inorganic variety. Some morels exceeded consumption guidelines for long-term, oral ingestion of inorganic arsenic (Shavit and Shavit 2010).

Copper Brief	
At Risk Foods:	
• Duck (liver)	• Berries
Maximum Allowable Limit (excerpt):	
1 ppm bottled water	United States
1.3 ppm drinking water	Canada
2 ppm duck meat; 5 ppm duck fat	European Union
Limits have not been set	World Health Organization

Copper[58] is a naturally-occurring metal that is primarily released into the environment through mining and manufacturing operations. Smaller amounts of copper can also be released into the atmosphere from natural sources, like forest fires and decaying plants (ATSDR 2018). Trace levels of copper are essential for the proper function of the human body, such as cell energy generation and storage, wound healing, white blood cell formation, and enzyme function (Copper Development Association 2018).

Consuming excessive amounts of copper can cause negative health effects in both adults and children, such as diarrhea, vomiting, nausea, stomach cramps, and liver or kidney damage. At very large doses of copper not likely to be associated with levels found in identified traditional foods, death can result. (ATSDR 2018).

Blackberries sampled at the Eagle Mine and Humboldt Mill areas contained elevated copper concentrations of possible concern to human health, particularly at the mill site.

[56] Tolerable Daily Intake (TDI) refers to "an estimated amount of a potentially harmful substance in food or drinking water that can be ingested daily over the course of a lifetime without appreciable health risk."
[57] Personal communication with Abby Debiak, Superior Partnership & Land Trust, August 7, 2018.
[58] The chemical symbol for copper is Cu (LANL 2018).

Copper concentrations in blackberries during the 2-year study averaged around 10 ppm near the mill area. The control site berries were about half of this level. To compare, the European Union copper guideline is no more than 5 ppm in berries.

When examining copper exposure in **duck**, studies have shown that the livers of mallards, bluebills, and American black ducks from New Jersey all presented levels of possible concern to people who regularly consume duck liver. Male bluebills and female mallards have copper levels in their livers at 57 and 23 ppm wet weight, respectively. Copper levels in black ducks were slightly reduced compared to the other species, however, with males averaging 10 ppm in their livers (Gochfeld and Burger 1987). In contrast, the European Union's trigger levels are 5 ppm for duck fat, and 2 ppm for duck meat. Mallards and black ducks are considered dabbler ducks; bluebills are diving ducks. More recent studies of copper levels in duck liver in an area closer to the ceded territories have not been found.

Zinc Brief	
At Risk Foods:	
• Duck (liver)	• Berries
Maximum Allowable Limit (excerpt):	
Limits have not been established	United States
Limits have not been established	Canada
Limits have not been established	European Union
Limits have not been established	World Health Organization

Zinc[59] is a naturally-occurring metal and is frequently found in the crust of the Earth. It is present in many foods and needed in small amounts by the body for proper health. Most zinc is released as a result of from human activities, such as mining, steel production, and the burning of coal and industrial garbage. Zinc can form compounds with certain other elements, and can often be found near hazardous waste areas[60] (ATSDR 2018). Please see Appendix 7 for Comprehensive Environmental Response, Compensation and Liability Act (Superfund) areas.

When consumed in large amounts, zinc can cause nausea, stomach cramps, and vomiting. When zinc is consumed in excessive, long-term (chronic) amounts, it can decrease good cholesterol and cause anemia. While it is unknown if excess zinc can

[59] The chemical symbol for zinc is Zn (LANL 2018).
[60] Zinc compounds commonly found around hazardous waste areas are zinc sulfate, zinc sulfide, zinc oxide, and zinc chloride (ATSDR 2018).

cause any reproductive effects in humans, studies have shown infertility in rats that are fed very high concentrations of zinc (ATSDR 2018).

In 2015, **wild raspberries** sampled at the Eagle Mine and Humboldt Mill areas contained elevated zinc concentrations when compared to a control site, at values of 39, 43, and 26 ppm, respectively.[61] For comparison, the United States EPA's TDI value for oral zinc intake is 0.3 ppm/day. Wild raspberries sampled from the same areas the following year, however, did not demonstrate a consistent pattern of elevated zinc levels. Zinc concentrations in raspberries sampled from the mine, mill, and control areas were 25, 24, 25 ppm, respectively.[62]

When examining potential zinc exposure in **duck,** one study has shown that the livers of New Jersey mallards, bluebills,[63] and American black ducks all presented elevated levels of zinc that could be concerning for regular consumers of duck liver (Gochfeld and Burger 1987). For example, the average zinc levels in the livers of female mallards, male black ducks, and both sexes of bluebill were 92, 50, and 60 ppm wet weight. Mallards and American black ducks are considered dabbler ducks; bluebills are considered diving ducks.

Maple syrup is naturally high in zinc. Seasonal variation in zinc content included slightly higher levels in Canadian maple sap as the syrup season progressed. Zinc concentrations in resulting syrup reflected the change. The levels were not at amounts possibly harmful to human health (Robinson et al. 1989). However, zinc-coated processing equipment could potentially introduce excess zinc into maple syrup.

Manganese Brief	
At Risk Foods:	
• Berries	
Maximum Allowable Limit (excerpt):	
Limits have not been established	United States
Limits have not been established	Canada
Limits have not been established	European Union
Limits have not been established	World Health Organization

Manganese[64] is a metal commonly found in rocks, which is not able to break down in the environment (ATSDR 2018). Manganese is widely used in steel production and can

[61] The control site was located about 26 miles northeast of Humboldt Mill, and 28 miles southeast of Eagle Mine.
[62] Personal communication with Abby Debiak, Superior Partnership & Land Trust, August 7, 2018.
[63] Greater scaup was the specific bluebill species.
[64] The chemical symbol for manganese is Mn (LANL 2018).

also be found in modern gasoline additives (ATSDR 2018; US EPA 2016). Metallic sulfide mining activities can create acidic conditions that can mobilize this metal from the Earth as well (GLIFWC 2016). Please see Appendix 6 for a map showing metallic mining operations in the ceded territories.

Manganese is needed by the human body in trace amounts, and is naturally present in some foods, including shellfish and pine nuts. However, excess amounts of manganese negatively impact the nervous system. Some evidence suggests that children are more sensitive, especially to its effects on the nervous system. At toxic levels not likely to be found in traditional foods, manganese can cause brain damage, regardless of age. Individuals with iron deficiencies may uptake more of manganese than normally absorbed by healthy individuals (ATSDR 2018).[65] In animals that consume very high levels of manganese, reproductive effects have also been observed.

Wild blueberries, raspberries, and blackberries sampled around Eagle Mine or Humboldt Mill were consistently higher in manganese when compared to levels found in berries from the control site. The manganese levels in these berries were potentially harmful to human health over a period of time. The EPA's TDI manganese level for oral ingestion of berries is 0.14 ppm/day.

Wild blueberries from the Eagle Mine area possessed an average of 187 ppm of manganese, compared to the average at the control site, 160 ppm.[66] The difference between the manganese averages in raspberries was even more pronounced for the mine and control site at 245 and 34 ppm, respectively. Blackberries collected at Humboldt Mill site had much higher average manganese levels than berries at the control site, 217 and 78 ppm, respectively.

[65] Teenage girls, pregnant women, and women of childbearing years are more likely to be deficient in iron (ATSDR 2018).

[66] The control site was located about 26 miles northeast of Humboldt Mill, and about 28 miles southeast of Eagle Mine.

TABLE 6: THESE CALCULATIONS FOR AVERAGE MANGANESE LEVELS IN WILD RASPBERRIES ARE BASED UPON A PERSON WEIGHING 70 KG, OR ABOUT 154 POUNDS. ONE CUP OF RASPBERRIES EQUALS 125 GRAMS, OR 0.125 KG. TDI MEANS "TOLERABLE DAILY INTAKE," AND REFERS TO THE U.S. EPA STANDARD FOR ORAL INGESTION OF MANGANESE IN BERRIES. [67]

Superior Watershed Berry Monitoring Study: Manganese (Mn) Results for Raspberry			
2015			
	Eagle Mine	Humboldt Mill	Control Site
Ppm (mg/kg)	320	98	39
Kg to Exceed TDI	0	0.1	0.25
Equivalence in cups of berries	0.2	0.8	2.01
2016			
Ppm (mg/kg)	170	110	29
Kg to Exceed TDI	0.1	8.91	0.34
Equivalence in cups of berries	0.46	0.7	2.7

Cadmium Brief	
At Risk Foods:	
• Organ Meat (duck)	
Maximum Allowable Limit (excerpt):	
0.005 ppm bottled water	United States
0.005 ppm drinking water	Canada
0.05 poultry liver	European Union
0.01 ppm legumes	World Health Organization

Cadmium[68] is a soft, silvery metal associated with copper and zinc ores. Cadmium is released into the atmosphere from metallic sulfide mines, refineries, combustion of fossil fuels, and during waste disposal and incineration (ATSDR 2018). Mining activities also create acidic conditions which can mobilize cadmium into living organisms from the soil (Levit 2010). Please see Appendix 6 for a map showing metallic mining operations in the ceded territories.

[67] Personal communication with Abby Debiak, Superior Partnership & Land Trust, August 7, 2018.
[68] The scientific symbol for cadmium is Cd (LANL 2018).

Cadmium is known to accumulate in some crops, like Asian rice,[69] and aquatic organisms, such as birds, fish, and shellfish (ATSDR 2018). Cadmium is excreted from the body of aquatic organisms very slowly and has been documented to bioaccumulate in the food web (chain). People that consume contaminated foods from higher on the food web would, as a result, be exposed to higher levels of this heavy metal (Levit 2010). Also, people that regularly eat organ meat typically have higher rates of exposure (FdL and MN DoH 2014).

Currently, there is no known beneficial function of cadmium in the human body (Levit 2010). Consuming small amounts of cadmium over time can lead to buildup in the kidneys, with this high concentrations leading to damage in the kidneys (ATSDR 2018).[70] Additionally, fragile bones are another side effect of low-dose cadmium exposure. When lactating mothers are exposed to cadmium, small amounts are transferred to the infant from breastfeeding.

Ingestion of very high cadmium levels would not be very likely from eating identified traditional foods. However, those acute symptoms include: irritation of the stomach lining, causes vomiting and diarrhea, and even death, in some cases (ATSDR 2018). Individuals with iron deficiencies may absorb more cadmium from food sources more so than healthy individuals.

Animals that ingest cadmium develop liver disease, anemia, and brain and nerve damage. A few studies indicate that younger animals absorb more of cadmium than adult animals, which may result in bone loss from and have shown negative effects on learning and behavior (ATSDR 2018).

A study of New Jersey **ducks** found elevated cadmium concentrations in both diver and dabbler duck livers. The European Union has set a maximum level for poultry liver at 0.05 ppm. Not surprisingly, since diving ducks are higher on the food chain (web), greater scaup (bluebill) had the highest cadmium levels in their livers out of the three species, 1.09 and 0.897 ppm for female and male bluebill, respectively. In contrast, 0.565 ppm comprised the average for male American black duck livers, with averages for female livers being lower. Female mallards had an average of 0.566 ppm of cadmium in their livers, with male mallards having lower concentrations in their livers (Gochfeld and Burger 1987).

Forty-three people sampled in the Fond du Lac and Minnesota Department of Health (2014) human biomonitoring study exceeded the Level of Health Concern for cadmium

[69] *Oryza sativa* is the scientific name of Asian rice.
[70] High dietary cadmium exposure from Asian rice and *Tilapia* fish is the culprit for chronic kidney failure in a Sri Lankan farming region. As of 2008, more than 5,000 residents of the area were undergoing medical treatments for kidney failure (Levit 2010).

in blood, which is 1.7 micrograms/liter of blood. These results appeared to be related to cigarette smoking, however. There did not appear to be a relationship between blood cadmium levels and consumption of game meat or organs, yet only a few people reported eating organ meats.

There have been a number of studies concerning the potential cadmium exposure of **wild rice**, specifically to determine if cadmium affected the wild rice plant and/or the wild rice seed. Most studies have concluded that wild rice does not accumulate cadmium in its seeds to any significant extent.

Within one study, the majority of wild rice samples tested for cadmium came from Port Edwards and Crandon rice beds of northern Wisconsin, which are embedded within the ceded territory. This study determined that harmful concentrations of cadmium were not found within wild rice (Bennett et al. 2000). The median concentrations for cadmium were 0.016 ppm. The WHO consumption level recommendation for cadmium in rice is no more than 0.4 ppm.

Another study conducted on wild rice seeds in natural wild rice beds in Canada found cadmium concentrations no greater than 0.006 ppm. Within the study, it is also noted that the increased amount of cadmium found in wild rice typically means the wild rice will contain less copper, and could potentially affect the rice's nutritional composition (Pip 1993, 180).

Aluminum Brief	
At Risk Foods:	
• Blueberries	
Maximum Allowable Limit (excerpt):	
Limits have not been established	United States
Limits have not been established	Canada
Limits have not been established	European Union
Limits have not been established	World Health Organization

Aluminum[71] is the most abundant lightweight metal and is widely distributed in the Earth's crust. Aluminum is consistently found in combination with other elements in nature, such as oxygen. Aluminum can be mobilized by incinerators and coal-burning power plants (ATSDR 2018). Mining activities can create acidic conditions which can free aluminum from the soil to interact with the surrounding natural environment (Cronan and Schofield 1990).

[71] The chemical symbol for aluminum is Al (LANL 2018).

Individuals with kidney disease store aluminum within their bodies, as it cannot be effectively removed through urine. These people sometimes developed brain or bone diseases caused by high levels of this element. People with Type II diabetes may, consequently, be at a more elevated risk for aluminum exposure (ATSDR 2018).

In animal studies, test animals with aluminum toxicity performed lower than other test animals in grip-strength tests and presented with less mobility, showing that the nervous system is particularly sensitive to aluminum (ATSDR 2018).

Wild blueberries growing near Eagle Mine area were consistently higher in aluminum when compared to levels found in blueberries from the control site. The United States EPA's TDI for aluminum ingestion is 1 ppm/day. The average aluminum level for Eagle Mine blueberries was 29 ppm. The Humboldt Mill site levels were comparable to the control at about 16 ppm.

Elevated aluminum concentrations in **wintergreen** plants were found around the Eagle Mine area, of which the Ojibwe people use the plants and berries to make tea (Meeker et al. 1993). However, aluminum levels found in the wintergreen plants were not at a sufficient level to reasonably exceed the recommended EPA's TDI value of 1 ppm/day.[72] This is consistent with findings of elevated aluminum levels in tea made from other plants (Fung et al. 2009).[73]

Heavy Metal Safety Levels - Multijurisdictional

Safety and health of food supplies is a top priority for the United States, Canada, European Union member countries, and the World Health Organization. Each of these jurisdictions have set levels or limits to the amount or concentration of heavy metals in specific foods or food contact surfaces. Typically referred to as Maximum Level (ML), these levels are often based on the best available science and aimed at protecting human health. By setting limits, jurisdictions are creating parameters for food industries which are actionable and enforceable.

Appendix 8 provides tables of the current maximum allowable levels of heavy metals per country[74]. MLs vary from jurisdiction to jurisdiction and from food to food. Some countries have limits on only a few items per heavy metal, while others have set limits for a large quantity of foods. The MLs related or possibly related to traditional foods

[72] Superior Partnership did not infuse wintergreen tea, and only tested the whole plant. In the mine area, 1.76 pounds of wintergreen plant would have to be ingested to exceed TDI. In the control area, 2.43 pounds of plant would have had to be ingested. Personal communication with Abbie Debiak,Superior Partnership and Land Trust, August 7, 2018

[73] The tea plant, *Camellia sinensis,* has been widely researched in regards to aluminum levels.

[74] Maximum levels are revised often by each jurisdiction. For the most up to date information, refer to the jurisdiction's website or contact their outreach offices directly.

have been **bolded** for easier reference. For jurisdictions that have MLs for more than 5 non-traditional foods, only the traditional foods have been represented.

D. Pesticides & Industrial Chemicals

Pesticides and industrial chemicals can pose potential human health hazards, as they may contaminate animals living in the natural environment that people eat. Some of these chemicals, such as toxaphene, PCBs, dioxins, and furans, remain in the environment for long periods of time, biomagnify in the food web, and tend to accumulate in fat tissue. Fish and ducks, and the people that consume them, are often the most at risk from exposure to these types of pollutants. Some plants have been documented to uptake smaller amounts of certain chemicals from soil, but they are not likely to accumulate in plants at levels that would be hazardous to human health.

In a joint study conducted by Fond du Lac Environmental Program and Minnesota Department of Health (2015), people were assessed for exposure to certain organochlorine[75] chemicals. The chemicals tested for were DDT, DDE, hexachlorobenzene, mirex, PCBs, and toxaphene. In general, people that consumed wild rice, berries, fish, and game had similar chemical levels to people that did not consume traditional foods. However, people eating toxaphene from Lake Superior fish had small, but slightly elevated levels compared to the general population.

Older people in the study displayed higher concentrations of these chemicals than younger people, likely due to their extreme persistence. Since these pollutants are now banned in the United States, therefore, future generations will be less exposed than in the past (FdL and MN DOH 2015). However, lower levels of exposure can still occur when some of these chemicals are used elsewhere and travel around the world.

Perfluoroalkyl contaminants (PFCs), such as perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA), are chemicals of emerging concern with regards to their potential impacts on human health. The possible side effects of human exposure to these chemicals are largely unknown to date. However, animals exposed to these substances have experienced negative health effects.

Chlordane, DDT/DDE, mirex, chlordecone, aldrin, dieldrin, heptachlor, heptachlor epoxide, and hexachlorobenzene are organochlorine pesticides that no longer pose a threat to human health in the ceded territories, overall. They have significantly degraded over time to negligible levels. Glyphosate, 2,4-D, endothall, diquat dibromide, and chlorothalonil, although commonly used herbicides in the ceded territories, also

[75] Chemicals containing chlorine atoms on aromatic rings of carbon and hydrogen are called organochlorines or chlorinated hydrocarbons (U.S. EPA 2018).

generally do not present a significant threat to human health mainly due to lack of biomagnifying abilities. For more information about these chemicals, please see Appendix 9.

Organochlorine Pesticides

Toxaphene Brief	
At Risk Foods:	
• Ducks (particularly divers)	
Maximum Allowable Limit (excerpt):	
Limits have not been established	United States
0.1 ppm (default)	Canada
0.01 ppm (wild vertebrates)	European Union
Limits have not been established	World Health Organization

Toxaphene was an insecticide used heavily in the United States throughout the 1970s and into the early 1980s.[76] It is made up of a mixture of hundreds of specific chlorinated compounds. Most uses for toxaphene ceased in 1982, and it was completely banned in 1990 (ATSDR 2018). Toxaphene residues continues to persist in the environment, namely in Lake Superior (Xia et al. 2012).

Toxaphene can travel long distances in the air, contaminating sites where the chemical was not directly applied. This chemical strongly binds to soil, and in water, it tends to settle out onto the sediment as it does not dissolve well. Different types (congeners) of toxaphene break down at different rates, but all types break down quite slowly.

A common route of toxaphene exposure is by consuming contaminated food. Like many other persistent chemicals, toxaphene accumulates in the fat of fish, birds, and mammals. Studies in animals consuming toxaphene over time showed negative impacts to the kidneys, liver, and immune system. Several agencies have agreed that toxaphene likely causes cancer in humans (ATSDR 2018).

Consuming extremely high amounts of toxaphene would injure the liver, kidneys, and nervous system, and could cause death (ATSDR 2018). However, concentrations of toxaphene are not normally high enough to cause these acute illnesses from consuming traditional foods.

Although toxaphene levels are gradually declining over time (Xia et al. 2012), open-lake levels of toxaphene in Lake Superior continue to exceed water quality standards for

[76] Toxaphene was often used in the southern United States on cotton crops (ATSDR 2018).

certain jurisdictions. Higher concentrations of this chemical in Lake Superior compared to other Great Lakes can be explained by notable differences its unique physical properties, including large volume and cold temperature (Xia et al. 2011). Inland waters do not appear to have accumulation issues with this contaminant.

Since toxaphene biomagnifies in the environment, concern exists regarding the impacts in concentrations at higher trophic levels encompassing Lake Superior.[77] In particular, lake trout from Lake Superior generally contain the most total toxaphene out of fish species tested from the Great Lakes (Xia et al. 2012). This information is not entirely surprising considering the predatory status of the lake trout and higher trophic levels of these fishes.

Diving ducks collected in the southern Great Lakes were tested for this chemical and it was not detected in those samples. However, the southern Great Lakes are not afflicted with toxaphene persistence (Custer and Custer 2000). It is not entirely understood how toxaphene accumulates in the Lake Superior food web with respect to diving ducks, in particular, as testing has been primarily focused on fish.

Toxaphene 26 and 50 are the forms of the chemical commonly found in people. People that consume Lake Superior fish have elevated levels of toxaphene in their blood. Concentrations assessed in the blood were quite small overall, however. Both toxaphene congeners were more commonly found in people over 60 years of age. Median toxaphene 26 values for the 60+ year-old age group were 0.72 nanograms/gram of blood lipid. Median toxaphene 50 values for the 60+ year-old age group were 1.55 nanograms/gram of blood lipid (FdL and MN DOH 2015).

Dioxins & Dioxin-Like Compounds

Dioxins & Furans Brief	
At Risk Foods:	
• Whitefish	
Maximum Allowable Limit (excerpt):	
Limits have not been established	United States
20,000 ppm (under review)	Canada
0.000001 ppm (fish)	European Union
Limits may not be set at this time	World Health Organization

[77] A trophic level is an organisms' position in a food chain (web).

Dioxins and furans are contaminants that are created unintentionally through burning of garbage or coal. [78] In the United States, the greatest dioxin emission sources are electricity and heat-generating plants (Kanan and Samara 2018). They are also created as byproducts when the paper industry bleaches wood pulp, during herbicide manufacture, and in the creation of steel. Dioxins can be released during forest fires. These chemicals strongly bind to soil and sediment, but smaller amounts can evaporate (ATSDR 2018).

Dioxins and furans bioaccumulate and biomagnify up the food chain, primarily concentrating in fatty tissues of animals and humans. However, these chemicals have also been found on the surface of some produce. In addition, dioxins and furans can be taken up into squash family[79] plants in amounts smaller than found in animal-derived foods.[80] Consuming contaminated foods accounts for over 90 percent of human exposure to dioxins and related compounds.

Groups of people that are particularly sensitive to the effects of dioxins and dioxin-like compounds are developing fetuses, infants, and young children. They are also more highly exposed when their food intake per body mass is factored in. Other subgroups that are more highly exposed through the food supply include indigenous North Americans, people that fish, people in isolated areas whose food supplies are locally contaminated, and breastfed infants (IOM 2003).

The most toxic version of all the dioxins and furans is called TCDD.[81] Dioxin exposure at chronic levels in animals found negative effects, like liver damage, endocrine disruption,[82] and weakening of the immune system. Other studies in animals found birth defects and reproductive damage. TCDD is a known human carcinogen. High-dose TCDD exposure in people has caused acne-like lesions, skin rashes, excessive body hair, and changes in blood sugar metabolism. However, acute dioxin exposure is unlikely to occur from consumption of traditional foods.

In a GLIFWC study, measurable concentrations of dioxins and furans were found in fillet tissues of the largest sizes of tribal, commercially-harvested Lake Superior fish (lake herring, lake trout, **lake whitefish**, and siscowet trout). However, these concentrations were not particularly concerning, except for the untrimmed large siscowet.[83]

[78] There are 2010 different congeners, or varieties, of dioxins and furans. Seventeen of these have been found to be toxic (Kanan and Samara 2018).
[79] These foods were zucchini and pumpkin, specifically (IOM 2003).
[80] Carrots and peas also uptake small amounts of dioxin. However, most of the contaminant is found in the peel of the carrot and the pod of the pea (IOM 2003).
[81] The chemical name for TCDD is 2,3,7,8-tetrachloro-p-dibenzo-dioxin.
[82] The endocrine system regulates hormone use and production throughout the body.
[83] GLIFWC memorandums from Matt Hudson, Dec. 30, 2005 and April 11, 2006.

The sport fish dioxin and furan advisory level for the state of Michigan is 10 ppt toxic equivalency (TEQ).[84] The lowest TEQ concentrations were found in cisco and whitefish. Sampled lake herring averaged less than 0.5 ppt TEQ when the fillets were untrimmed and the skin was taken off. Comparatively, the sampled Lake whitefish averaged 1.8 ppt TEQ when the fillets were untrimmed and the skin was taken off, however, the whitefish muscle tissue averaged less than 0.6 ppt TEQ. Noticeably higher concentrations were found in both lake trout and sicowet. Lake trout averaged less than 5 ppt TEQ when the fillets were untrimmed and the skin was removed, while the lake trout muscle tissue averaged less than 4 ppt TEQ. Siscowet trout, which had the highest average of dioxins and furans concentrations, averaged 21 ppt TEQ when the fillets were untrimmed and the skin was taken off, with the siscowet muscle tissue averaging up to 7 ppt TEQ (Groetsch and Hudson 2005).

Fish consumption advisories for dioxin continue in Lake Superior. WHO, European agencies, and various states have established exposure guidelines for dioxins and furans in food to protect human health. However, FDA has not established Tolerance Levels or Action Levels for dioxin at this time.

PCBs Brief	
At Risk Foods:	
• Whitefish	
Maximum Allowable Limit (excerpt):	
2 ppm for fish	United States
2 ppm for fish — under review	Canada
0.00000175 ppm (cattle meat)	European Union
Limits may not be set at this time	World Health Organization

Polychlorinated biphenyls, or PCBs, are members of a broad chemical family, and are also known as dioxin-like compounds (DLCs).[85] They are a mixture of individual, manmade chemicals[86] that are no longer produced in the United States. PCBs were used mainly as coolants and lubricants in electrical equipment.[87] Other uses for these chemicals were in industrial adhesives, carbonless copy paper, hydraulic and motor oil, paint, plastics, floor finishes, and insulation. They were banned from use and

[84] TEQs are a weighted measure used to assess the relative toxicity of dioxins and dioxin-like compounds compared to the most toxic compound, TCDD (U.S. EPA 2016).
[85] PCBs are chemically composed of hydrocarbon rings with attached chlorines (US EPA 2018).
[86] These specific, identifiable chemicals are called congeners. There are 209 PCB congeners that can be subdivided even further into homologs that indicate the specific positions of chlorine on the ring (US EPA 2018).
[87] PCBs can be found in old fridges and televisions. They were used for this application because of unique physical properties, such as inflammability, thermal stability and resistance to corrosion.

production in 1979. Most people are exposed to PCBs through food, and fish are a common dietary source of PCBs (ATSDR 2018).

Developing fetuses and infants are believed to be more sensitive to the effects of PCBs. Children born to women that were exposed to higher amounts of the chemical had babies weighed less and showed abnormal responses in behavior and memory. Sometimes these symptoms lasted for several years. Immune system function in these children may have also been impacted. PCBs can be passed down from a nursing mother to an infant. However, prenatal exposure to these chemicals did not appear to cause structural birth defects.

Animals consuming smaller amounts of PCBs developed a variety of health effects, such as acne-like skin lesions, anemia, as well as stomach, liver, and thyroid gland injuries. Other chemical effects in animals include impairments to the immune system, behavior, and reproduction. Exposed workers had blood and urine results indicating impaired liver function. People exposed to large amounts of these chemicals often had acne[88] and rashes (ATSDR 2018). Recent research has also shown a link between PCBs and Type II diabetes (Faroon and Ruiz 2016).

Studies in workers[89] exposed to PCBs found an increased incidence of cancers in the bile duct,[90] liver, intestines, and skin. Rats eating high chemical amounts for two years got liver cancer. Based upon this information, the U.S. EPA has declared that PCBs likely cause cancer in humans. The International Agency for Research on Cancer has unquestionably decided that is a human carcinogen (ATSDR 2018).

Aquatic areas known to have high amounts of PCB contamination often have fish consumption advisories to protect the health of people eating fish from those areas. Tribal or state consumption advisories can sometimes be more restrictive than federal guidelines set by U.S. FDA (ATSDR 2018). Fish consumption advisories are sometimes in combination with other chemicals, such as mercury, dioxins, and toxaphene.

In a GLIFWC study, all Lake Superior fish sampled were did not exceed the FDA's action limit for PCBs, which is 2.0 ppm. The Lake Superior fish sampled during this study included **whitefish**, lake herring, lake trout, and siscowet. [91] Fish consumption advisories for this chemical continue in Lake Superior. However, people that consume

[88] This is a special type of severe acne called chloracne. It is caused by chlorinated chemical exposure (ATSDR 2018).
[89]In particular, male workers of capacitor manufacturing and/or repair facilities were examined after employment of greater than five years (ATSDR 2018).
[90] Biliary cancer is rare, and affects the tubes that take bile from the liver to the small intestine during the digestion of food (AGITG 2017)
[91] GLIFWC memorandums from Matt Hudson, Dec. 30, 2005 and April 11, 2006.

Lake Superior fish generally do not have concerning levels of PCBs in their blood (FdL and MN DOH 2015).

PCB levels can be reduced by trimming the fat from fillets, where PCBs are stored, which reduced PCB levels by 12 to 40 percent, depending on the fish species. Specifically, PCB levels in whitefish were reduced 32 percent, and 23-25 percent in lake trout. PCB concentrations in siscowet trout were lowered by 12-40 percent depending on the fish length. Removing skin from fillets further reduced concentrations of this chemical in whitefish, lake trout, and siscowet.[92]

Overall, harvested **waterfowl** do not uptake concerning amounts of PCBs in their breast muscle (Tsuji et al. 2007; Braune and Malone 2006). However, certain lakes are impacted more by past industrial use. For example, in one study, 80 percent of bluebill meat from Lakes Erie and Michigan exceeded the U.S. FDA's action level[93] during the years 1991 to 1993 (Custer and Custer 2000). PCB levels in the Laurentian Great Lakes continue to go down over time, decreasing impacts to human health for future generations (ECCC and U.S. EPA 2017).

Chemicals of Emerging Concern

Some persistent, manmade chemicals are being detected in increasing amounts within the environment. A few of these chemicals include perfluoroalkyl contaminants (PFCs), such as perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA). The potential side effects of human exposure to these chemicals are largely unknown, and more research is currently being conducted on them. Possible human health exposure from polybrominated diphenyl ethers (PBDEs) in fish was evaluated, but the risk to human health via traditional foods is negligible. For more information on PBDE, please see Appendix 11.

PFOS & PFOA Brief	
At Risk Foods:	
• Whitefish	
Maximum Allowable Limit (excerpt):	
Limits have not been established	United States
Limits have not been established	Canada
Limits have not been established	European Union
Limits have not been established	World Health Organization

[92] Ibid.
[93] The FDA action level was specific to consumption of poultry (3.0 mg/g lipid weight).

Perfluorooctane sulfonate (PFOS) and **perfluorooctanoic acid** (PFOA) are two specific compounds in a class of perfluorinated chemicals (PFCs). Out of the PFCs, PFOS and PFOA are the most widely studied. They are used in a wide variety of applications, predominately used in nonstick cookware, stain resistance for carpets and sofas, and waterproofing mattresses and clothes (NIH 2016). Other uses include paper coatings, cardboard packaging, leather products, industrial additives and coatings, and fire and chemical resistant tubing. PFOS and PFOA enter the environment from the manufacture and use of products that contain the chemicals. Degradation of similar chemicals can also turn into PFOS and PFOA (U.S. EPA 2017).

Studies of PFOA-exposed humans found links between exposure and increased liver enzymes, high cholesterol, thyroid disorders, preeclampsia, pregnancy-induced hypertension, kidney and testicular cancer, and decreased vaccination response. The WHO's International Agency for Research on Cancer (IARC) has categorized PFOA as possibly carcinogenic to humans. Research involving humans found connections between PFOS exposure and adverse developmental and reproductive effects, and high cholesterol. Laboratory animals exposed to PFOS and PFOA have exhibited detrimental developmental and reproductive effects (U.S. EPA 2017).

Although PFCs are not stored in body fat, they are persistent as they are resistant to environmental degradation (NIH 2016). PFOS and PFOA have been found in remote areas of the world, indicating that these chemicals are capable of long-range transport. In particular, PFOS is likely a bioaccumulating chemical and also able to biomagnify in the natural environment, such as in fish (U.S. EPA 2017). PFOS cannot be cooked or trimmed from fish, as it is bound in tissue (MDHHS 2016). PFOA can accumulate in species that breathe air, but not in fish (Vierke et al. 2012).

Wisconsin DNR evaluated various PFC congeners in different fish species from both the Laurentian Great Lakes and major rivers. PFOS was present in the highest concentrations and found in most samples. PFCs in fish sampled from the Great Lakes were lower overall than fish sampled from rivers, in particular the Mississippi River, which suggests that closeness to a PFC source is a major factor impacting contaminant levels. White bass and panfishes typically contain higher concentrations of PFOS than **walleye**. One of the lowest PFOS concentrations (2.0 ng/g, or 0.000002 ppm) was measured in Menominee River walleye (Williams and Schrank 2016).

Another study examined PFOS concentrations in the eggs and livers of **lake whitefish.** Average PFOS egg and liver concentrations in whitefish were 0.000263 and 0.000067 ppm wet weight, respectively (Kannan et al. 2005). Whitefish liver concentrations were below this standard, but whitefish eggs were nearly equal to the EPA's guideline. The United States EPA's drinking water maximum level for PFOS is 0.0002 ppm.

This study did not examine PFOS levels in whitefish tissue due to the negligible amount anticipated. The whitefish in this study were collected from Thunder Bay in Lake Huron, and PFOS levels differ between the Great Lakes (Kannan et al. 2005). For perspective, PFOS concentrations in lake trout from Lakes Huron, Michigan, and Superior are 0.000039, 0.000016, and 0.000005 ppm (Furdui 2007). Lake trout are situated within a higher trophic level than whitefish, therefore, it can be reasonably surmised that whitefish PFOS concentrations would be lower in Lake Superior than in Lake Huron. However, the interaction of factors that influence contamination from PFOS are still being investigated, and could be more complicated than expected (U.S. EPA 2017).

Pesticide and Industrial Chemical Safety Levels - Multijurisdictional

Safety and health of food supplies is a top priority for the United States, Canada, European Union member countries, and the World Health Organization. Each of these jurisdictions have set levels or limits to the amount or concentration of industrial chemicals in drinking but may not exist for foods. Available level or limits have been provided in Appendix 11 and Appendix 12. These levels are often based on the best available science and aimed at protecting human health. By setting limits, jurisdictions are creating parameters for food industries which are actionable and enforceable.

3. Physical Hazards

Physical hazards in food are foreign objects or materials that can enter food cause harm when consumed. Symptoms generally include but are not limited to: choking, dental damage, and laceration of the mouth or throat. Physical hazards specifically related to the identified traditional foods and outlined in this report include bullet fragments and shot pellets.

Physical Hazard Risk Overview	
	Bullet Fragmentation/ Shot Pellets
Deer	X
Rabbit/ Hare	X
Duck	X
Turkey	X
Whitefish	
Walleye	
Berries	
Wild Ramps	
Beach Pea	
Hazelnut	
Morel Mushroom	
Wild Rice	
Maple Syrup	
Berry Jam/Jelly	
Animal Fats	
Venison Jerky	

Bullet Fragmentation/Shot Pellets

A concern exists encountering metal fragments while consuming cooked game and or fowl meat. During consumption of meat, pellets or large bullet fragments could pose a choking hazard, cause damage to teeth, laceration hazard to the mouth or throat, and possibly damage the intestines (DHHS 2011). The FDA size standard for adulteration due to metal fragments is a minimum size of 0.3 inches (7 mm), however, it is unlikely that wild game killed with ammunition would exceed this threshold.

The potential for this hazard exists when using either non-lead or lead ammunition. However, it has been more widely studied in animals harvested with lead ammunition, mainly due to the significant health hazards associated with that metal. Agencies in Michigan, Wisconsin, Minnesota, and North Dakota X-rayed venison and all studies found some metal fragments, mostly in the form of lead (MI DCH 2010; WI DHFS 2008;

DNR 2008; ND DOH 2008). [94] The x-rays conducted by the Minnesota DNR found that metal shards spread as much as 18 inches,[95] or 1.5 feet, from where the bullet passed through. However, for the most part, citizens report that they rarely find metal fragments or shot in the wild game meat they consume (FSAS 2012).[96]

The largest concern would likely be in the form of pellets embedded in meat of fowl which are missed during cleaning and processing. As would be expected, harvesters perform a visual inspection to remove as much shot as possible from meat either during processing and before cooking (FSAS 2012). However, it is possible that pellets may be missed during the inspection process. Please see Figure 6 on page 67 for common pellet sizes for shotgun ammunition.

FIGURE 6 SHOT SIZES OF COMMON HUNTING AMMUNITION

Photo credit: IHEA-USA (https://www.hunter-ed.com/images/pdfs/ammo_shot_sizes.pdf)

[94] In Wisconsin, about 4 percent of x-ray results tested positive for lead. In N.D., about 12 percent tested positive for foreign material, with nearly 6 percent of that testing positive for lead. In the North Dakota study, other foreign particles found could have been bone shards, plastic, or metal fragments of other types, like copper. However, only lead was tested for due to funding constraints.
[95] This is the maximum distance that could be measured with x-ray (MN DNR 2008).
[96] This survey was conducted in Scotland.

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APPENDIX

Appendix 1: Excerpt from the Traditional Food Interest Survey

* 6. If safely available in your tribal community, what **large and small game** traditional foods would you be interested in having access to?

Examples: white-tail deer, black bear, moose, elk, bison, beaver, muskrat, hare, rabbit, badger, porcupine, raccoon, otter, lynx, woodchuck, etc.

	Would **STRONGLY** LIKE access to this food	Would **OCCASIONALLY** LIKE access to this food	Would **RARELY** LIKE access to this food	Would rather **NOT** access this food
White-tail Deer (Venison)	○	○	○	○
Black Bear	○	○	○	○
Moose	○	○	○	○
Elk	○	○	○	○
Rabbit/Hare	○	○	○	○
Porcupine	○	○	○	○
Beaver	○	○	○	○
Muskrat	○	○	○	○

Other large and small game I'd like access to:

* 7. If safely available in your tribal community, what **migratory birds** would you be interested in having access to?

Examples: ducks (mallard, wood duck), crane, swan, geese, snipe, mudhen/coot, sora & Virginia rails, doves, woodcock, etc.

	Would **STRONGLY** like access to this food	Would **OCCASIONALLY** like acces to this food	Would **RARELY** like acces to this food	Would rather **NOT** access this food
Geese	○	○	○	○
Duck	○	○	○	○
Crane (sandhill)	○	○	○	○
Swan	○	○	○	○
Snipe	○	○	○	○
Mudhen/coot	○	○	○	○
Rails (Sora & Virginia)	○	○	○	○
Mergansers	○	○	○	○

Other migratory birds I'd like to access:

APPENDIX 2 – Rare Zoonotic Diseases in the Ceded Territories

Brucellosis

Brucellosis in white-tailed deer, elk, and moose is caused mainly by a contagious bacterium called *Brucella abortus*.[1] The most common transmission of brucellosis is from ingesting undercooked meat or contact with skin wounds or mucous membranes. Additionally, harvesters can also catch brucellosis from inhaling bacteria while cleaning game (MI DNR 2018; CDC 2018). Rarely, brucellosis can be transmitted from person-to-person, also breastfeeding mothers can pass the illness to their nursing child (CDC 2018).

Symptoms of brucellosis vary, but typically include: fever, sweating, tiredness, weight loss, headache, backache, and muscle or joint pain. Recurrent symptoms may also result, such as depression, chronic fatigue, arthritis, organ swelling, and painful swelling of the testicles in males. Pregnant women who contract the illness may experience spontaneous abortion, therefore it is recommended to seek medical treatment for appropriate antibiotics (Conover and Vail 2015; CDC 2018).

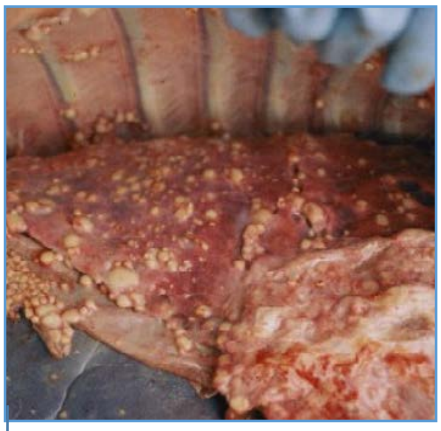
In the United States, brucellosis is relatively rare. In the ceded territories, only one human case has been reported since 2011 in Michigan (CDC 2018).[2] Brucellosis is not a very common disease in white-tailed deer. Michigan has extensively sampled the harvested deer populations and has found no evidence of brucellosis. In a study conducted nationwide, out of more than 17,000 white-tailed and mule deer[3] sampled, only 20 white-tailed deer tested positive for brucellosis (MI DNR 2018).

Bovine Tuberculosis (bTB)

Bovine tuberculosis (bTB) is a bacterial illness called *Mycobacterium bovis.*[4] It has been found in white-tailed deer,[5] elk, moose, and black bear.[6] People with the bovine version of TB have likely eaten contaminated meat or were infected through transmission via

[1] There are several species in the *Brucella* genus. Other animals able to become infected with *Brucella spp.*
[2] The case was found in Michigan. As this is a state we serve tribes in, I think it is important that this is mentioned in the sentence, not in a footnote.
[3] The scientific name for mule deer is *Odocoileus hemionus*.
[4] Most human tuberculosis (TB) cases are caused by *Mycobacterium tuberculosis,* not *M. bovis*.
[5] Due to its known infectivity of white-tailed deer and people, researchers experimentally inoculated wild turkeys (*Meleagris gallopavo*) with *M. bovis* to see if they serve as reservoir for the pathogen. They determined that young turkeys are resistant to *M. bovis* infection, and likely do not serve as a spillover host (Clarke et al. 2006, 131).
[6] The scientific name for the American black bear is *Ursus americanus.*

open wounds.[7] Direct animal-to-human transmission is believed to be quite rare. In these rare instances, people can become infected by inhaling air exhaled by animals that have the disease. Transmission of bTB can occur when an infected person coughs or sneezes onto an uninfected person (CDC 2011).



White-tailed deer chest cavity and lung infected with Bovine Tuberculosis. Photo credit: Michigan Department of Natural Resources.

Symptoms of tuberculosis vary depending on how a person was first exposed, and whether or not they have a latent form of the disease (Conover and Vail 2015, 45).[8] People that are exposed to bTB via ingestion or skin contact are more likely to have problems in the spleen, kidneys, liver, and digestive tracts, rather than issues within the lungs. Common universal symptoms include: unexplained weight loss, fever, excessive night sweating, and a constant cough (Conover and Vail 2015, 45).

Bovine tuberculosis is relatively uncommon, accounting for under 230 reported cases per year in the United States (CDC 2011), with incidents of tuberculosis higher in New England, Hawaii, and the southern United States. Throughout the ceded territories, incident rates of tuberculosis are less than 3.4 cases each year, per 100,000 people (Conover and Vail 2015, 43).

Eastern Equine Encephalitis (EEE)

Eastern Equine Encephalitis (EEE) in humans is very rare, more so than West Nile Virus. Humans typically become infected by EEE from a mosquito bite carrying the virus.[9] Mosquitos often get infected when feeding on carrier bird hosts, which are usually unaffected by the virus. White-tailed deer can become infected by EEE, but death from illness is rare. In Michigan, relatively higher mortality rates from EEE virus

[7] Bovine TB prevalence in Minnesota deer declined from 1.2 percent in 2005 to a level not detectable in 2010. Sharpshooting, a recreational deer feeding ban, and intensified hunting all helped decrease the disease in Minnesota (Carstensen and DonCarlos 2011).
[8] People who are infected, but have not developed symptoms, are termed as having a latent TB infection (CDC 2011). Infected individuals may get symptoms years later or not at all (Conover and Vail 2015, 45).
[9] EEE virus is one-stranded RNA (genetic material) with a spherical shape.

in deer has occurred, with seven dying in 2005, one in 2009, and two in 2010. One deer in Wisconsin died from this disease in 2004 (MI DNR 2018).

The last human case of this disease in Michigan occurred in 2014 in the southwest portion of lower Michigan. There were three cases reported, with no fatalities. The last reported EEE-related death occurred in 2001 in Michigan (MI DNR 2014). No specific information could be found regarding which portion of Michigan where this death occurred, but it was presumably in lower Michigan.

The majority of individuals that are infected exhibit no symptoms, or very mild symptoms that mimic other illnesses, including headache, tiredness, muscle aches, and fever (Conover and Vail 2015, 315). Only around 4 to 5 % of people infected with the virus develop serious brain swelling issues, typically affecting individuals under 15 years old or over age 50. Unfortunately, around a third of people who develop brain swelling issues die. Survivors of serious EEE infections often will have permanent neurologic damage, varying from mild to severe damage. Following the infection, affected individuals have immunity against the disease (CDC 2018).

People that hunt, fish, live, and/or work in hardwood swamps near the Great Lakes are at increased risk of infection with EEE (CDC 2018).[10] Although unlikely, harvesters could possibly become infected with the virus when field dressing and cleaning an infected deer. It is important for harvesters to avoid brain or spinal cord matter from the deer, taking extreme care to avoid with contact their eyes or open wounds during field dressing. Harvesters should also avoid inhaling droplets from the brain matter or spinal fluids (MI DNR 2018). Freezing meat will not kill the virus, so it should be cooked to the proper temperature (MI DNR 2014).

Highly-Pathogenic Avian Influenza (HPAI), or "Bird Flu"

Influenza is separated into three different classes, specifically A, B, C, and D.[11] "Bird flu," or "avian flu," is one specific type of influenza virus A. There are a number of different strains of HPAI in the United States which are different than strains that have caused outbreaks overseas.[12]. HPAI reached the United States from overlapping

[10] People that live or work in hardwood, freshwater swamps in the Gulf Coast and near the Atlantic Ocean are also at risk (CDC 2018).

[11] Influenza A is the class of viruses that can make people seriously ill or cause death. It also is a class of virus known to morph, or change, fairly easily. Viruses A, B, and C can infect humans with Viruses B and C typically cause short-lived, mild sickness. Virus D infects cattle, and is not known to make people ill (CDC 2017X).

[12] The deadliest strain is Asian H5N1, which is different than the North American H5N1 strain (CDC 2017X)

migratory bird flight pathways. These viruses do not usually infect humans, especially the North American varieties, however, in rare instances humans have become infected with bird flu (CDC 2017X).

Transmission of bird flu to humans is not completely understood, however, it seems to occur from close and continuous contact with infected birds. People can get infected when enough of the virus is present in air from water droplets, or dust, which is inhaled (Conover and Vail 2015; CDC 2017). Additionally, people can touch something infected, and can then transfer the virus to their eyes, nose, or mouth. However, in a few cases, direct contact with sick or dead birds was not thought to have occurred. The biggest concern exists regarding the ability of bird flu to morph into a form that is transmissible between humans (CDC 2017X).

Symptoms of bird flu include: eye inflammation, fever, cough, muscle aches, and sore throat, with symptoms ranging from mild to severe. In severe cases, symptoms include: diarrhea, vomiting, nausea, abdominal pain, shortness of breath, difficulty breathing, or seizures (CDC 2017).

It is important to note that bird meat or eggs containing HPAI are safe to eat if it is cooked to a proper temperature. However, there is the possibility of the HPAI virus contaminating the food after cooking, including exposure from contaminated hands, surfaces, or utensils (WHO 2005; Conover and Vail 2015). World Health Organization (2005) recommends that bird meat known to be diseased not be consumed, however.

In 2017, wild turkeys in Minnesota were assessed and found to not carry HPAI (Jennelle et al. 2017). However, different species of wild ducks[13] were experimentally infected with HPAI virus in a Dutch experiment (Keawcharoen et al. 2008, 600).[14] Researchers were interested in whether certain ducks were able to shed the virus while appearing unaffected, which would potentially allow these birds to carry the virus into areas further away.[15] Their findings suggested that some wild duck species, particularly

[13] Six species were chosen that are high-risk for HPAI, as well as common to Europe, Asia, and Africa. The species were mallard, gadwall, Eurasian widgeon, tufted ducks, Eurasian pochard, and common teal. Mallards and gadwall are species also found in the U.S. Tufted ducks and Eurasian pochards are closely related to bluebills. Eurasian widgeon is closely related to American widgeon, and common teal are closely related to blue-and green-winged teal.
[14] The subtype of HPAI virus used was Asian H5N1 (Keawcharoen et al. 2008, 600).

[15] Researchers found that Eurasian pochards, tufted ducks, and mallards shed much more of the virus than Eurasian wigeons, gadwalls, and common teals. However, only the ducks representing the diving duck family (tufted duck and Eurasian pochard) became gravely ill or died. Tufted duck had greater mortality than the pochard.

mallards, may be able to carry HPAI to previously uninfected areas (Keawcharoen et al. 2008, 600).

Deer Parapoxvirus is part of a viral group which can be found worldwide. While deer parapoxvirus typically infects sheep or goats, deer and other ungulates can become infected and potentially infect others. Deer with scabby, crusty lesions or sores in or around the mouth and on the face or antlers may have this virus, however, not all deer show symptoms (May 2010). Precaution should be made while field dressing deer, as the virus typically enters the body through open wounds in the skin on the hands or arms. To date, very few harvesters in the United States have been infected with this lesion-causing virus. Symptoms appear within 3 to 7 days, consisting of a discolored rash on the skin and which may continue to grow and swell (Roess et al. 2010).

Appendix 3: Maps of CWD prevalence in ceded territory

FIGURE 1: OVERVIEW OF CWD PREVALENCE IN CEDED TERRITORY.

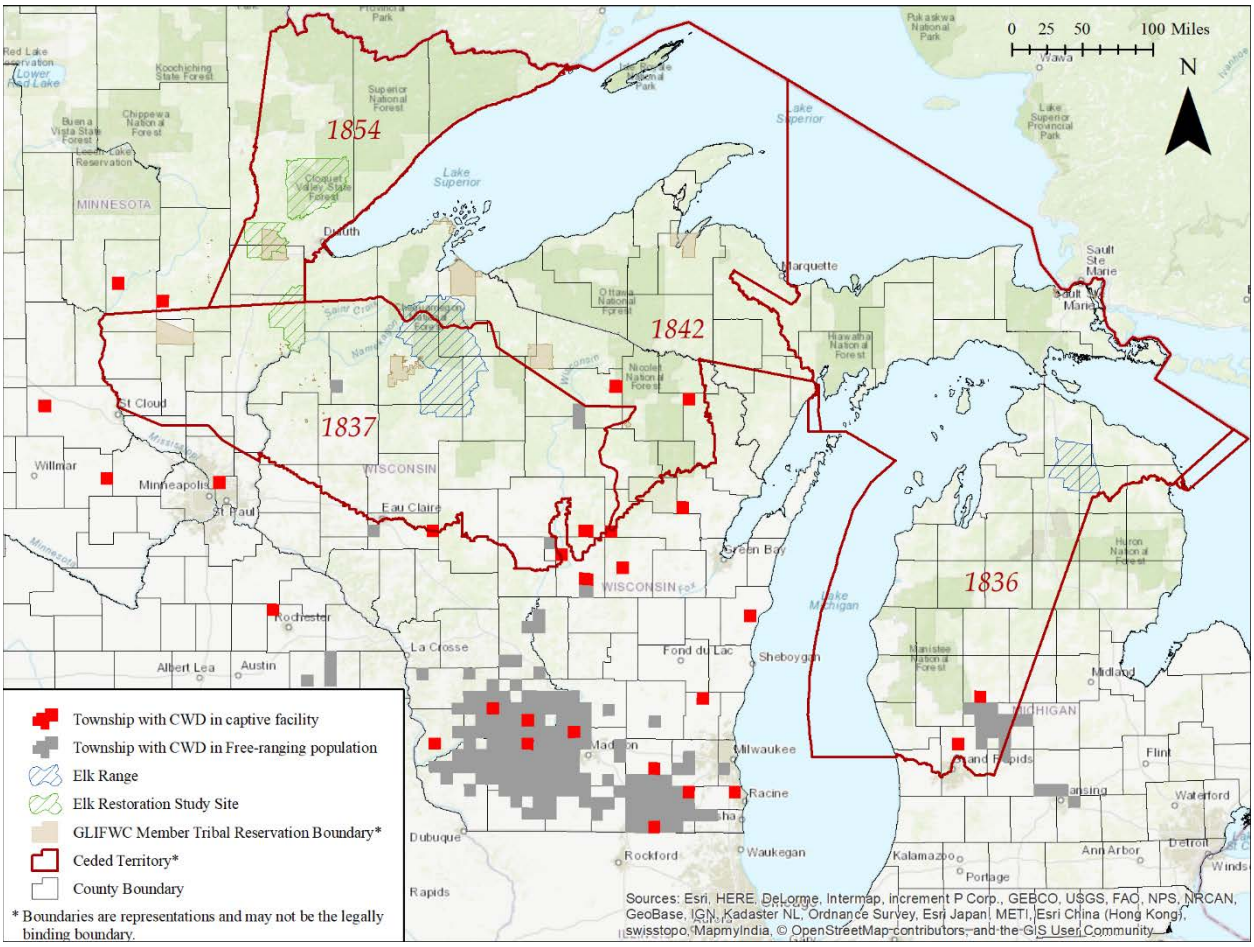


FIGURE 2: PREVALENCE OF CWD IN WISCONSIN.

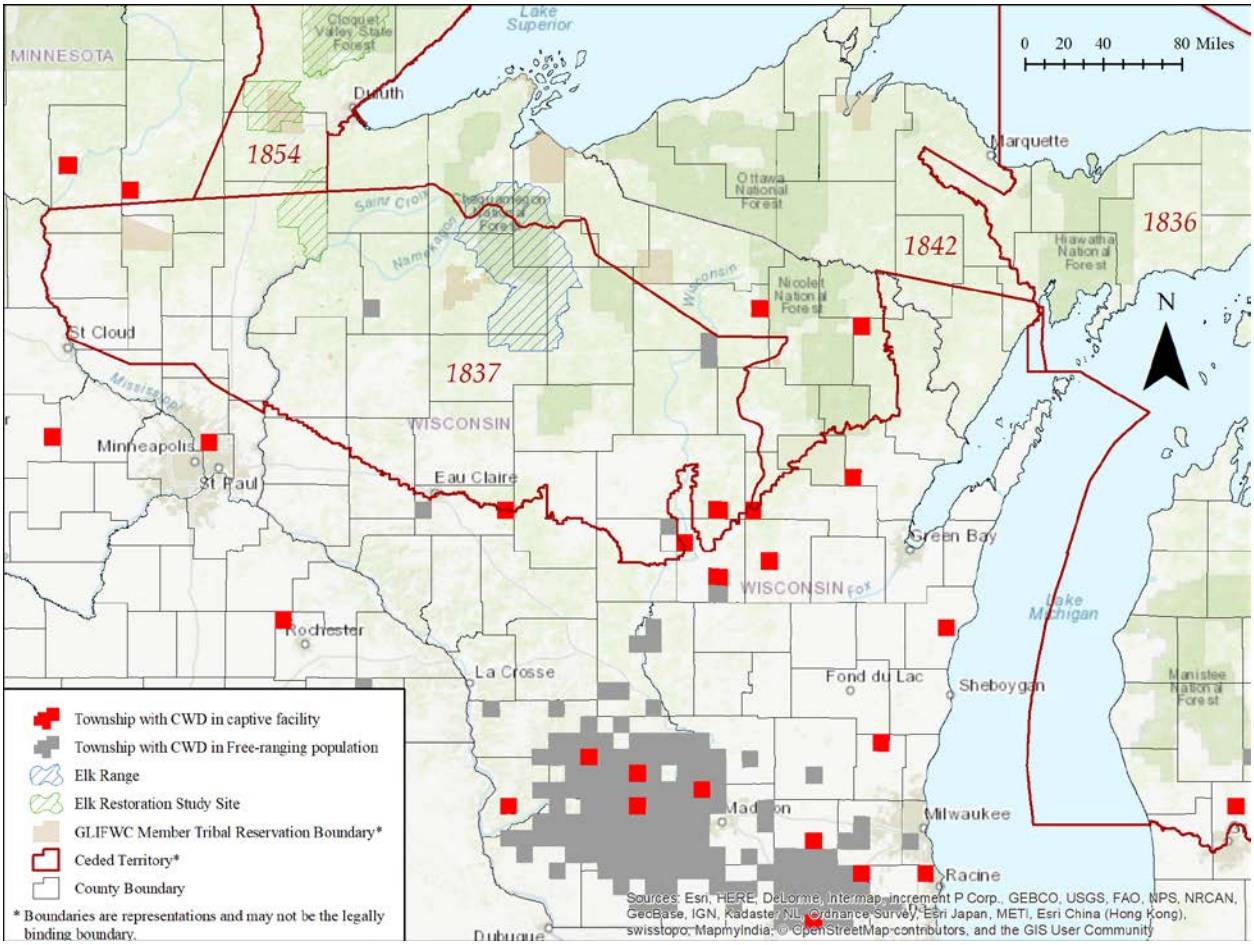


FIGURE 3: PREVALENCE OF CWD IN MICHIGAN.

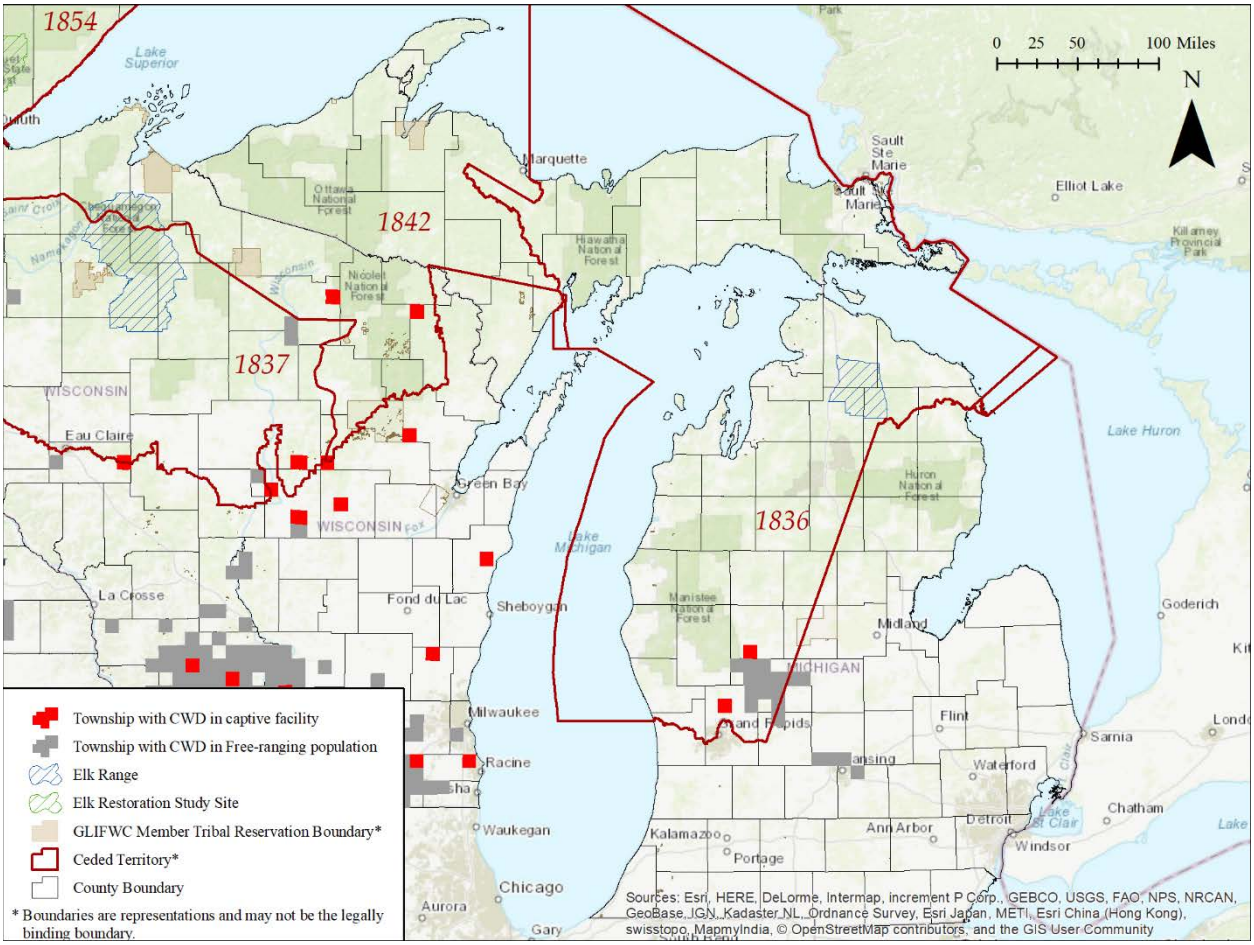
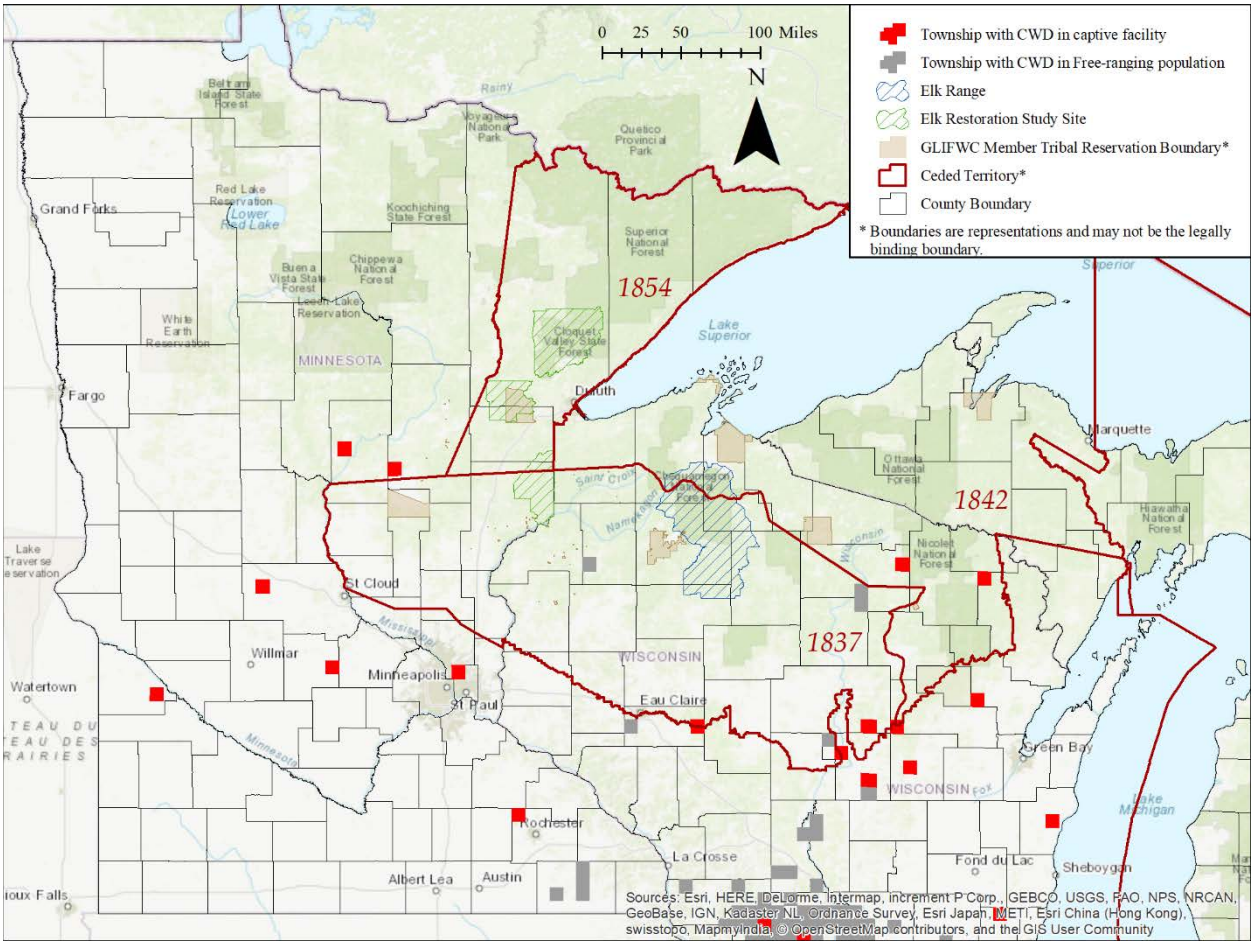


FIGURE 4: PREVALENCE OF CWD IN MINNESOTA.



Appendix 4: Regulations relating to CWD management in MN, WI, MI, WY, CO, and Canada.

First Documented CWD[1]	2002- on elk farm; 2011- confirmed in wild deer[1]	2002 – confirmed in wild deer[1]	2008- captive deer; 2015- confirmed in wild deer[1]	1979- in captive deer; 1985- confirmed in wild deer[2]	1967- captive deer; 1981- wild elk **first documented case of CWD in wild cervid;** 1985- first documented CWD in wild deer[1]	1981- in captive deer in zoo; [1]
Jurisdictional Agencies	MN DNR- wild cervid Board of Animal Health (BAH) – captive cervid	WI DNR- wild cervid and fencing DATCP- captive cervid	MI DNR- wild and captive cervid MI Agriculture and Rural Development (ARD): disease management and movement of captive cervid	Wyoming Game and Fish Dept. (WGFD)- wild cervid	Colorado Parks and Wildlife (CPW)- wild captive cervid; Dept. of Ag (CDA)- disease management of captive cervid	Canadian Food Inspection Agency: Voluntary Herd Certification Program (VHCP)
Baiting	**Banned** statewide[3]	**Partial Ban**: 43 counties banned; 29	**Partial Ban:** 11 counties banned; 72	**Banned** statewide with the exception	Big Game baiting is	3 provinces have baiting bans;

[1] Chronic Wasting Disease Alliance "Timeline" http://cwd-info.org/timeline/ accessed 7/3/2018
[2] Wyoming Game and Fish Department https://wgfd.wyo.gov/Wildlife-in-Wyoming/More-Wildlife/Wildlife-Disease/Chronic-Wasting-Disease Accessed 7/3/2018
[3] Chronic Wasting Disease Alliance "Chronic Wasting Disease and Cervidae Regulations in North America" Accessed 7/3/2018

		counties allowed (2 gallons/day archery season) Ban impacts is placed on any county within 10 miles of a captive or free-roaming deer that tests positive for either CWD or Bovine Tuberculosis (bTb). [4]	allowed (2 gallons/day from Sept. 15 - Jan 1)[3]	of permits provided by the WGFD[3]	**banned** statewide[3]	5 allow baiting; Baiting is an uncommon practice in the remaining 2 provinces; [3]
Fencing Requirements – Deer Farms	DNR-A **single fence is required.** Fencing must be 8 feet high and constructed "in a way that	DNR-a **single fence is required**. Since 2003, fence must be 8 feet tall, if build prior to 2003 it	DNR-A **single fence is required.** Must be 10 feet tall if newly constructed. Requires weekly	Deer farms are illegal in Wyoming.	CPW- **Double fencing is required**. Fences must be 8 feet tall. Fences must separated for ease of	National- **Single fence** must be 8 feet tall and in compliance with Provincial code.[9]

[4] Wisconsin Department of Natural Resources. "Wisconsin Deer Baiting and Wildlife Feeding Regulations (WM-456-2017)". https://dnr.wi.gov/topic/hunt/bait.html Accessed 7/3/2018

[9] Canadian Food Inspection Service. "National Standards for the CWD VHCP" document. Section 4.4.2 http://www1.agric.gov.ab.ca/$Department/deptdocs.nsf/all/rsb7193/$FILE/CWD_VHCP_NationalStandards2017.pdf Accessed 7/9/2018

	prevents the escape of farmed crevidae or entry… by free roaming crevidae"[5]	may be 7 feet, 10 inch tall. DATCP- **Double fence is required**. Specs: both solid barriers, 8 feet tall and no more than 16 feet apart.[6]	perimeter checks.[7] Michigan House Bill 5770 would require a second fence if passed. Submitted April 2018.		maintenance and vegetation should be controlled so as not to attract wild cervids. All gates shall be locked, consecutive, or self-closing.[8]	
Fencing Requirements – Hunting Preserves	MBAH- Under Minnesota law 35.153(3) ""Farmed cervidae" means cervidae that are: (1) **raised for any purpose**; and (2) registered in a manner	DNR- Must comply with the DNR regulations list for Deer Farms (see above). Preserves are a min. of 80 continuous acres.[10]	Same requirements as deer farms but the addition of a **double gating is also required**.[7]	Deer farms are illegal in Wyoming.	CPW- *Ranching for Wildlife:* 10,000 continuous acres privately owned. Must enter into a Cooperative Agreement with the State which includes a management	Requirements are set by each Province.

[5] Minnesota Statue 35.155 (4)
[6] Wisconsin ATCP 10.58
[7] Michigan Department of Natural Resources. "OPERATIONAL STANDARDS FOR REGISTERED PRIVATELY OWNEDCERVIDAE FACILITIES" document. Page 2. https://www.michigan.gov/documents/dnr/POC_OP_Standards_07_191455_7.pdf Accessed 7/5/2018
[8] Colorado Parks and Wildlife. "Chapter W-11 - Wildlife Parks and Unregulated Wildlife" Article III Section 1108 Subsection C
[10] Wisconsin ATCP 95.55 (5) (b) https://docs.legis.wisconsin.gov/statutes/statutes/95/55 7/5/2018

	approved by the Board of Animal Health."				plan. Must be open to the public. [11]	
Intrastate Movement of Carcasses from CWD affected areas or management units	DNR-1) *Whole Carcass:* Adult carcasses cannot be moved from CWD areas **until a negative CWD test is reported**. Fawns (1/2 year old) may only be moved after registered and tagged by a DNR official. 2) *Partial Carcass:* **Only the specific meat cuts and partial**	DNR- 1) *Professional Processing:* All parts and whole carcass may be transported from a CWD county to anywhere in the state as long as **they are transported to a licensed taxidermist or meat processor** within 72 hours of registering a deer or	DNR- **Whole carcasses and parts thereof may be moved within the state** after submitting the head to DNR official for testing (2017).[14]	WGFD- 1) *Whole Carcass:* **The spinal column and head must be left** at the kill site or disposed of at an approved landfill. 2)*Partial Carcass:* **Spinal column and head must be removed**. See next row for list.[15]	CPW- no regulations at this time	Requirements are set by each Province.

[11] Colorado Parks and Wildlife. Chapter W-2 "Big Game" Article 1 Section 210 Subsection B-D.
[14] Michigan Department of Natural Resources. "2017 Michigan Hunting and Trapping Digest". Page 62
[15] Wyoming Game & Fish Department. "Chapter 2: General Hunting Regulations". Section 15 (a)-(f) https://wgfd.wyo.gov/WGFD/media/content/REGULATIONS_CH2.pdf Accessed 7/4/2018

	carcasses may be moved prior to a negative test result. See next row for list.[12]	entering the state. 1) *Home Processing:* Whole carcass and specified parts **cannot be moved outside of CWD affect counties.** See next row for list.[13]				
Parts of a carcass that can be moved (within state): • Quarter without head or spinal column • Other portions of meat without head or	Carcass and partial carcass movement is the same as listed in first column.	Carcass and partial carcass movement is the same as listed in first column. *Teeth- allows only upper canines.	Carcass and partial carcass movement is the same as listed in first column.	Carcass and partial carcass movement is the same as listed in first column.	Carcass and partial carcass movement is the same as listed in first column.	Requirements are set by each Province.

[12] Minnesota Department of Natural Resources. Minnesota Hunting and Trapping Regulations. Page 65
[13] Wisconsin Department of Natural Resources webpage "Carcass Movement Restrictions". https://dnr.wi.gov/topic/wildlifehabitat/carcassmovement.html Accessed 7/4/2018

spinal column • Meat the is deboned and wrapped • Finished taxidermy heads • Teeth* • Hides cleaned of tissues • Antlers cleaned of tissues • Skull plate cleaned of tissues • Skulls cleaned of tissues						
Action if CWD is Verified – Deer Farm	BAH- Animal diagnose in late stage CWD is **euthanized**. [16]	DATCP- **Quarantine** the herd for up to 5 years after last positive	ARD- 1) **Complete epidemiological study to determine**	N/A	CAD: *During Slaughter-* carcass of suspected CWD will be	National- *HCP Enrolled Farms*: All cervids exposed to CWD positive

[16] Minnesota Statutes 1721.0370 (6)(b)

	Herds infected or exposed to CWD must be quarantined by BAH immediately. Movement from quarantine is only allowed by permit from BAH if determined not to endanger the health of other animals in the state. Quarantine is released based on level of environmental contamination and CWD	CWD result. After epidemiologic al study, a herd or individual deer can be quarantined for up to 5 years. DATCP may order **slaughter** or destruction of deer.[18]DATCP can **suspend** or **revoke** CWD Herd Plan status if a deer in the plan test positive for CWD[19]	**cause**; 2) **Quarantine** facility with depopulation and CWD testing; 3) "Trace Forward of exposed animal": exposed animals are depopulated and tested. If found positive the whole herd is positive; 4)"Traced back of exposed animals" Quarantine of remaining herd for 5 years from last		held for testing. If test is positive for CWD, carcass will be destroyed. CWD positive facility will be quarantined and a herd plan will be developed by the State Veterinarian and the Wildlife Division. No restocking will be allowed. Quarantine will remain until 5 years free of CWD is established.	deer are killed. Of the killed, all over 1-year-old will be tested for CWD. Positive carcasses must be disposed of by burial, incineration, or approved specified-risk material streams. *Non-Enrolled Farms:* Only and Epidemiologic al investigation will take place.[22]

[18] Wisconsin ATCP 10.52 (7)(8)
[19] Wisconsin ATCP 10.53 (8)(9)
[22] Canadian Food Inspection Agency. "Chronic wasting disease - What to expect if your animals may be infected" webpage. http://www.inspection.gc.ca/animals/terrestrial-animals/diseases/reportable/cwd/if-your-animals-may-be-infected/eng/1330188848236/1330189018195 Accessed 7/9/2018

	testing results. Quarantine can last up to 5 years and includes depopulation options.[17]		trace back date and monthly inspection by state or federal personnel.[20]		Depopulation will be required if the Division of Wildlife and CAD agree that there is substantial risk. [21]	
What is done if CWD is found – Hunting Preserve	See results for deer farm above	The results must be sent to the hunter.[23]	See results for deer farm above	N/A	No information available at this time.	Requirements are set by each Province.
Testing Requirements for Hunting Preserves	MBAH- See Testing Requirements for Deer Farms above.	DATCP- See Testing Requirements for Deer Farms above.	Same requirements as deer farms	WGFD- See Testing Requirements for Hunters below.	No information available at this time.	Requirements are set by each Province.
Testing Requirements for Hunters in CWD Units	DNR- "**Mandatory CWD testing continues** in southeast	DNR- **Voluntary.** Sample collection is offered at ~78	DNR- "If a deer is taken from a Core CWD Area, you **must**	WGFD- **Voluntary in 2018 but recently WGFD**	CPW- **Mandatory for some CWD Units due to lack of funds**	Requirements are set by each Province.

[17] Minnesota Rules: Deer and Elk 1721.0420 (2)
[20] Michigan Department of Natural Resources and Michigan Department of Agriculture and Rural Development. "MICHIGAN SURVEILLANCE AND RESPONSE PLAN FOR CHRONIC WASTING DISEASE (CWD) OF FREE-RANGING AND PRIVATELY OWNED CERVID" July 12.2012
[21] Code of Colorado Regulations 8 CCR 1201-17 (3.2), (3.4), and (3.5)
[23] Wisconsin ATCP 10.47 (4)

	Minnesota's disease management zone through … a late-season hunt that begins Saturday, Jan. 6."[24], [25]	stations throughout the state, however, the stations are concentrated in CWD affected counties. Testing is provided free of charge.[26]	**present the head at a deer check station** within the business hours of the next 72 hours after killing the deer."[27]	**received legal authority to mandate testing.[28]** Sample collection is offered at various stations throughout the state. Testing is provided free of charge.[29]	**not all can be tested.** New measures may be released in September 2018.[30] "All rifle season buck hunters licensed for Game Management Units (GMUs) … who harvest a buck are required to submit their	

[24] Minnesota Department of Natural Resources. "Deer Hunting Season Information" webpage. https://www.dnr.state.mn.us/hunting/deer/index.html Accessed 7/4/2018

[25] Minnesota Department of Natural Resources. "Testing required through Jan. 14, 2018" webpage. https://www.dnr.state.mn.us/cwd/603/index.html Accessed 7/5/2018

[26] Wisconsin Department of Natural Resources. "Sampling for chronic wasting disease" webpage. https://dnr.wi.gov/topic/wildlifehabitat/registersample.html Accessed 7/4/2018

[27] Michigan Department of Natural Resources webpage. "Deer". https://www.michigan.gov/dnr/0,4570,7-350-79119_79147_81438---,00.html Accessed 7/4/2018

[28] Wyoming Game and Fish Department. "New regulation to help measure effectiveness of future CWD management" https://wgfd.wyo.gov/News/New-regulation-to-help-measure-effectiveness-of-fu Accessed 7/9/2018

[29] Wyoming Game & Fish Department. "CWD Testing" webpage. https://wgfd.wyo.gov/Wildlife-in-Wyoming/More-Wildlife/Wildlife-Disease/CWD-in-Wyoming-Wildlife/CWD-Testing Accessed 7/4/2018

[30] Denver Post. "A disease that attacks the brains of deer, elk and moose has hit 16 percent of male animals tested in Colorado — and hunters need to be cautious". Published May 21, 2018. https://www.denverpost.com/2018/05/21/chronic-wasting-disease-deer-elk-moose-colorado/ Accessed 7/4/2018

					deer head or have a CWD sample taken. In addition, all deer hunters in GMU 33 who harvest a deer of either sex are required to submit their deer head or have a CWD sample taken."[31]	
Requirements for Donated Deer from Non-CWD Units	MDA- *Processor:* **All Firearm harvested venison product must be X-rayed** before serving. Any containing lead will be disposed of.	DNR- *Processor:* Accept only carcasses that appear clean and wholesome upon processor inspection.	Michigan Sportsmen Against Hunger- *Processor:* May accept whole carcass or customer may decide to donate 1-2 pounds from a	Currently there in not a statewide donation program.	Farmers and Hunters Feeding the Hungry: *Processor:* No testing is required.[37] CPW: *Hunter:* No testing is required. Must	Requirements are set by each Province.

[31] Colorado Parks and Wildlife Department. "" https://cpw.state.co.us/Documents/Research/CWD/Mandatory-CWD-FAQ-2017.pdf Accessed 7/4/2018
[37] Farmers and Hunters Feeding the Hungry. "BUTCHER & FEEDING PROGRAM PARTICIPATION" webpage. https://www.fhfh.org/butchers-and-feeding-programs.html Accessed 7/5/2018

	Accept only carcasses that appear clean and wholesome upon processor inspection.[32] *Hunter:* Must adhere to field dressing guidelines, sign donation form, provide proof of legal harvest, and hide must be intact. Processing is done at no cost to the hunter.[33]	*Hunter:* Deer must be legally harvested in WI and registered. Field dressed deer must be taken to a participating meat processor. The whole carcass (except the head and antlers) must be donated. Appears clean and wholesome upon processor inspection Complete a	deer the customer is having processed for the customer's personal use. Customer pays for the processing of the 1-2 pounds of donated meat. Accept only carcasses that appear clean and wholesome upon processor inspection. *Hunter:* No requirements were stated. Processing is		have proof of legal harvest.[38]	

[32] Minnesota Department of Agriculture. "Processor Participation Requirements - 2009 Venison Donation Program" webpage. http://www.mda.state.mn.us/licensing/inspections/meatpoultryegg/venisondonation/processorinfo.aspx Accessed 7/5/2108

[33]Minnesota Department of Agriculture. "Guide to donating hunter-harvested deer in Minnesota" brochure. https://files.dnr.state.mn.us/recreation/hunting/deer/venison-donation-guide.pdf Accessed 7/5/2018

[38] Colorado Parks and Wildlife. "2017 Colorado Big Game 2017" brochure. http://www.eregulations.com/wp-content/uploads/2017/08/biggame.pdf Accessed 7/5/2018

		donation form. Processing and donation are free to the hunter. Processing is done at no cost to the hunter.[34],[35]	done at no cost to the hunter if whole carcass is donated.[36]			
Testing Requirements for Donated Deer from CWD Units	There are no additional requirements at this time.	DNR- **Adult deer** harvested from 12[a] counties affected by CWD must be tested. **Adult deer and fawns** from the remaining 7[b] counties must be tested. The processed venison will be held until	There are no additional requirements at this time.	There are no additional requirements at this time.	There are no additional requirements at this time.	Requirements are set by each Province.

[34] Wisconsin Natural Resource Department. "Wisconsin Deer Donation" webpage. https://dnr.wi.gov/topic/hunt/donation.html Accessed 7/5/2018
[35] Wisconsin Statute 29.89 "Venison and wild turkey processing and donation program." Accessed 7/5/2018
[36] Michigan Sportsmen Against Hunger. "MSAH AFFILIATED PROCESSOR GUIDELINES MANUAL 2018" brochure. https://docs.wixstatic.com/ugd/a0a290_168f33569a0446e49fd48d32e1485af5.pdf Accessed 7/5/2018

		results are known. All other requirements are the same for the remainder of the state as outlined above.[32]				

[a] Adams, Crawford, Grant, Green, Jefferson, Juneau, Kenosha, Lafayette, Portage, Racine, Vernon, and Waukesha counties.

b Columbia, Dane, Iowa, Richland, Rock, Sauk and Walworth counties.

Appendix 5: Deer Farm regulations in Minnesota, Wisconsin, Michigan, and Canada

CWD Testing Requirements by State for Farm-Raised Deer	
Minnesota	Annual Requirements For Operation:
	• An animal inventory must be submitted annually (every 12 months) for each farmed cervidae[1] herd and include all identification, the age, sex, and type of animal. All tag numbers, letters, and colors must be included as they appear on each tag. • The accuracy of the inventory must be verified by the owner and an accredited veterinarian. • Fees: All cervidae producers are required to pay an annual inspection fee of $10 per animal in the herd, up to a $100 maximum by January 1. • Inspection: Each farmed cervidae facility must be inspected by an agent of the Board of Animal Health at least once each year to verify compliance with Minnesota statutes and rules. [2] CWD Herd Certification Program Enrollment: **Mandatory**
	CWD Testing Requirements:
	"**All farmed cervidae producers are required to test their herds for CWD**. From each herd, all farmed cervidae 12 months of age and older that die or are slaughtered, must be tested for CWD. Tissue samples are tested for CWD at the University of Minnesota Veterinary Diagnostic Laboratory" " All farmed cervid herds at a Level 6 Certified status must now submit both obex and lymph node tissues for testing."
Wisconsin	Annual Requirements For Operation:
	Farm Raised Deer (FRD) in Wisconsin, FRD Keeper (FRDK) must: • Register as a FRD Keeper (FRDK) with DATCP every year (registration expires March 15) and include any partial owner information on the registration • Register farm, free of charge, as a livestock premises every three years

[1] Cervidae is the biological Family classification for deer and elk. Cervid is a mammal from the cervidae family.
[2] Minnesota Board of Animal Health. "Minnesota Farmed Cervidae Handbook. Second Edition. 2017" booklet. https://www.bah.state.mn.us/media/FarmedCervidaeHandbk-Accessible.pdf Accessed 7/5/2018

	• Allow DATCP staff access to herd for disease testing and inspection upon request • Test FRD for CWD
CWD Testing Requirements by State for Farm-Raised Deer (continued)	
	• Report all escapes to DATCP and local DNR warden within 24 hours • Obtain a DNR fencing certificate if white-tailed deer are in the registered herd <u>Fees:</u> • 15 or fewer deer not enrolled in in CWD Herd Status Program that only move to slaughter: $85 • 15 or fewer deer enrolled in the CWD Herd Status Program: $162.50 • More than 15 deer: $325[3] CWD Herd Certification Program Enrollment: **Optional**
Wisconsin (cont.)	CWD Testing Requirements: "CWD testing of farm-raised deer is required regardless of whether or not the herd is enrolled in the CWD Herd Status Program, as follows: Herds enrolled in the CWD Herd Status Program with **LESS THAN 5 YEARS** of status must test the following deer that are <u>at least 12 months of age:</u> • 100% that die or are killed, including escapes • 100% that are shipped directly to a slaughtering establishment Herds enrolled in the CWD Herd Status Program with **AT LEAST 5 YEARS** of status must test the following deer that are <u>at least 12 months of age:</u> • 100% that die or are killed, including escapees • 25% that are shipped directly to a slaughtering establishment

[3] Wisconsin Department of Agriculture, Trade, and Consumer Protection. "Deer Farms" webpage. https://datcp.wi.gov/Pages/Programs_Services/DeerFarms.aspx Accessed 7/5/2018

	Herds **NOT ENROLLED** in the CWD Herd Status Program must test the following deer that are at least 16 months of age: • 100% that die by accident, natural causes, or escape
CWD Testing Requirements by State for Farm-Raised Deer (continued)	
	• 50% that are killed by hunt on a hunting ranch • 50% that are killed intentionally 25% that are shipped directly to a slaughtering establishment"[4]
Michigan	Annual Requirements For Operation:
	Every 3 years: • Register with Michigan Natural Resource Department in one of 4 classes (Hobby, Exhibit, Ranch, Full) • Records of animal identification, gender, age, test certificates, date and method of disposition from the herd and details, and escape details. Must be kept for 7 years. • Inventories must be kept Fees: • Class 1 (Hobby) unknown • Class 2 (Exhibition) $450 • Class 3 (Ranch) $750 • Class 4 (Full) $750 CWD Herd Certification Program Enrollment: **Optional**
	CWD Testing Requirements:
	• Upon the death of an animal in the herd, 12 months and older, or of an age determined by the state veterinarian, for any reason, the owner shall have the animal tested for CWD. • The tissue samples to be collected shall include obex and medial retropharyngeal lymph node. • The tissue samples must be collected by one of the following: an accredited veterinarian, an official laboratory, a veterinarian employed by the state or federal government.

[4] Wisconsin Department of Agriculture, Trade, and Consumer Protection. "CWD Testing Requirements" webpage. https://datcp.wi.gov/Pages/Programs_Services/CWDTestingRqmts.aspx Accessed 7/5/2018

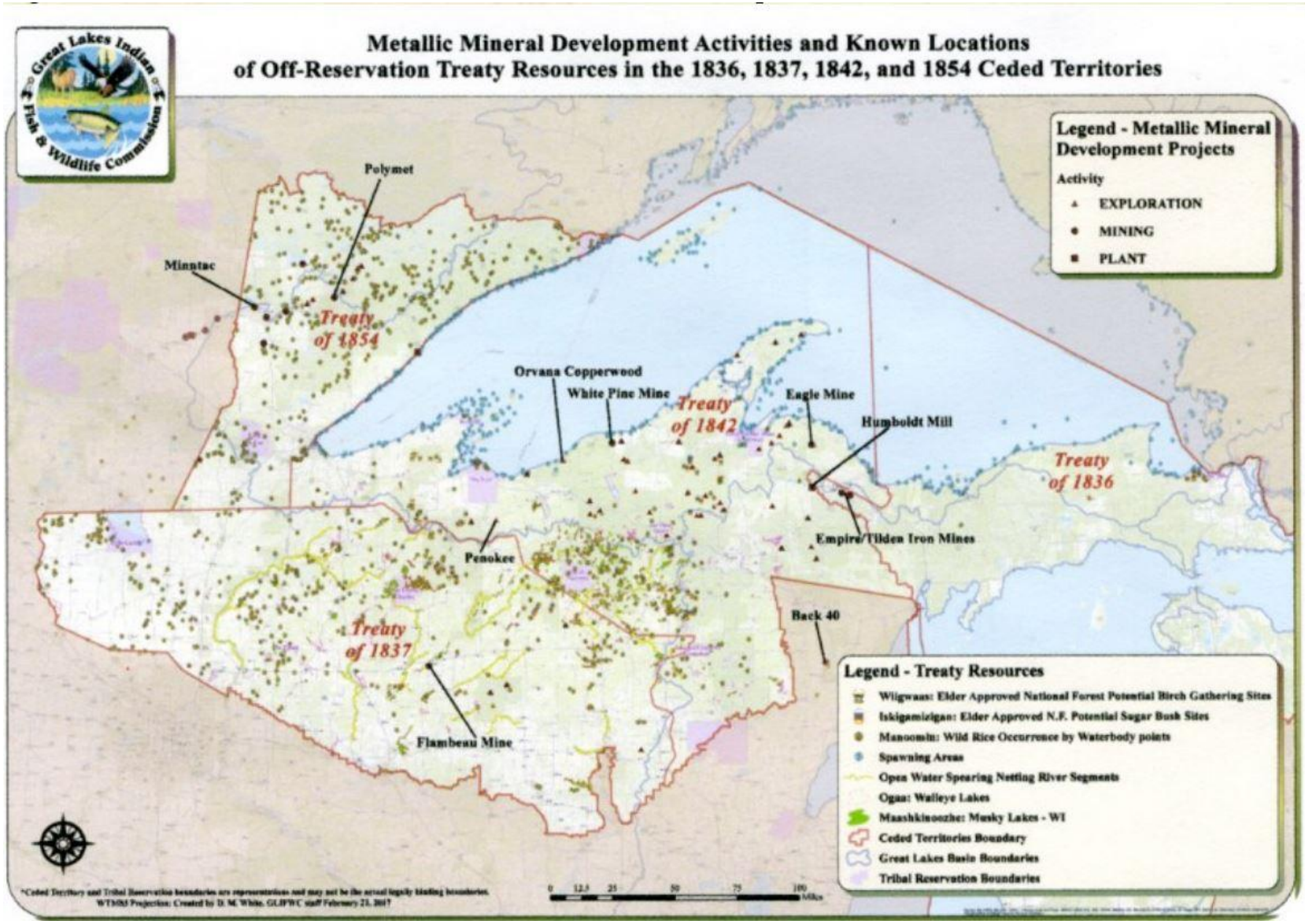
CWD Testing Requirements by State for Farm-Raised Deer (continued)	
Canada's, National Voluntary Herd Certification Program	Annual Requirements For Operation:

	• Voluntary enrollment in the program
	• Annual inspection by accredited veterinarian
	• Annual reports sign by owner, accredited veterinarian or qualified National Herd Certification staff.
	  • Annual inspection report
	  • Inventory reconciliation
	  • Documents for animal movement off of premise
	  • Necessary lab report

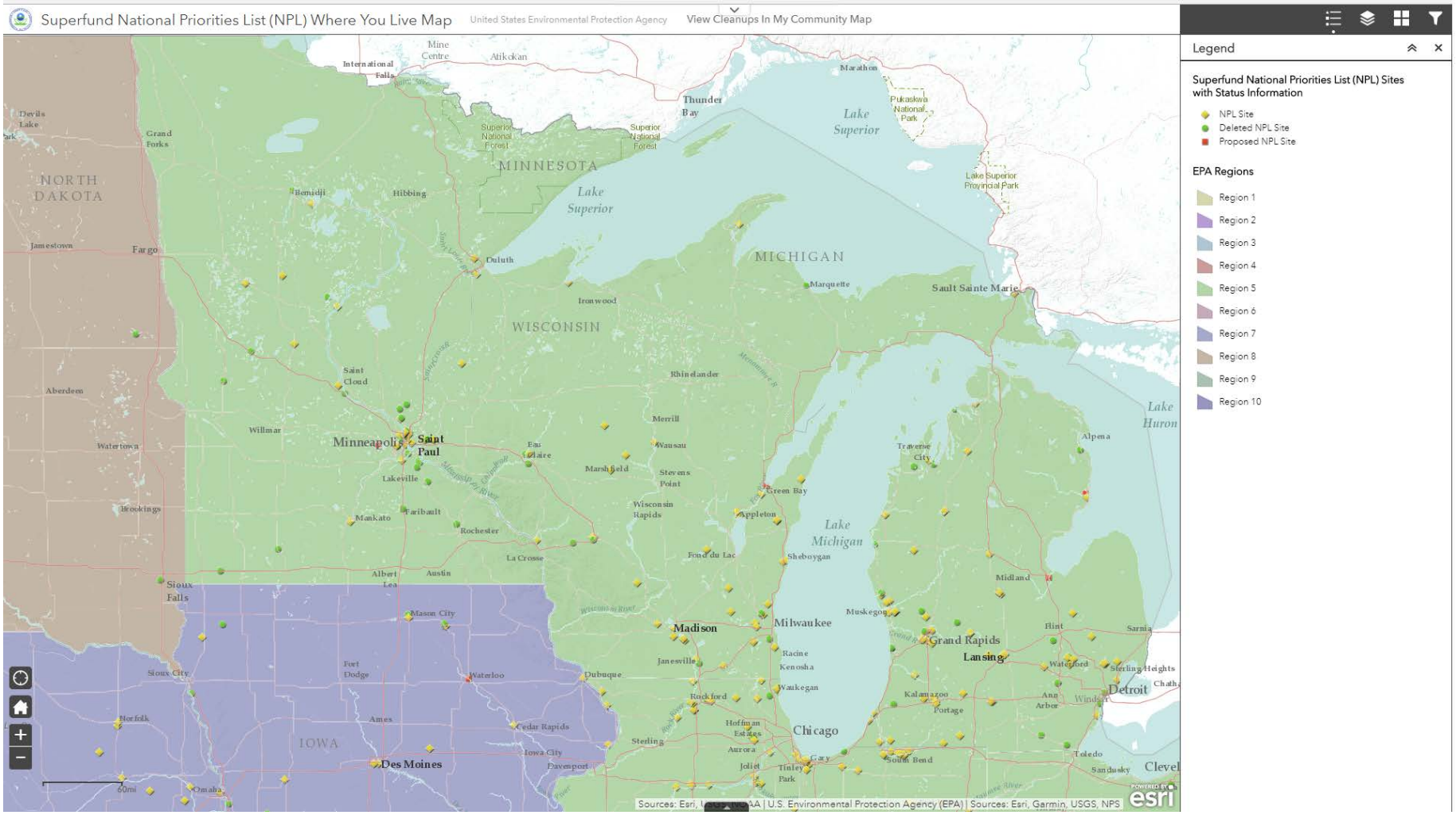
	• Perimeter fence report
	CWD Testing Requirements:
	• All deer 12 months and older that die of any cause, must be tested for CWD. • Beginning January 1, 2018, the requirement to submit samples for CWD testing will also include 50% of any cervids on the premises slaughtered at any abattoir (including US abattoirs) or on farm. • January 1, 2019, the slaughter requirement for CWD testing will increase to 75%, • January 1, 2020, the slaughter requirement for CWD testing will increase to 100%. • The obex and the RPLN must both be submitted for all farmed cervids tested for CWD[5]

[5] Canadian Food Inspection Service. "National Standards for the CWD VHCP" document. Section 4.2.1 http://www1.agric.gov.ab.ca/$Department/deptdocs.nsf/all/rsb7193/$FILE/CWD_VHCP_NationalStandards2017.pdf Accessed 7/9/2018

Appendix 6: Metallic Mineral Development in the Ceded Territories



APPENDIX 7: Map of Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) sites. These areas are commonly referred to as "Superfund" sites.



Appendix 8: Heavy Metal Limits in the United States, Canada, the European Union, and the World Health Organization.

Safety and health of food supplies is a top priority for the US, Canada, European Union member countries, and the World Health Organization. Each of these jurisdictions have set levels or limits to the amount or concentration of heavy metals in specific foods or food contact surfaces. Typically referred to as Maximum Level (ML), these levels are often based on the best available science and aimed at protecting human health. By setting limits, jurisdictions are creating parameters for food industries that are actionable and enforceable. Foods that are above the set limit are to be excluded from the food supply.

The following tables represent the maximum allowable levels of heavy metals per country at time of publication[1]. MLs vary from jurisdiction to jurisdiction and from food to food. Some countries have limits on only a few items per heavy metal and others have set limits for a large quantity of foods. The MLs related or possibly related to traditional foods have been bolded for easier reference. For jurisdictions that have MLs for more than 5 non-traditional foods only the traditional foods have been represented.

Note: Unless otherwise noted, the levels listed for the United States are set by the FDA unless otherwise listed.

Lead	
UNITED STATES	
0.1 ppm	Candy (likely to be consumed frequently by small children)[2]
0.1 ppm	**Imported Dried Fruits** (mostly raisins, dates, prunes/plums)
0.005 ppm	Bottled Water
0.05 ppm	**Fruit juice**
CANADA	
10 ppm	**Edible bone meal**
0.5 ppm	**Maple Syrup**
1.5 ppm	Tomato paste; Tomato sauce
0.5 ppm	**Fish protein**; Whole tomatoes
0.2 ppm	Beverages
0.15 ppm	Evaporated milk; Condensed milk; Concentrated infant formula
0.08 ppm	Infant formula when ready to serve

[1] Maximum levels are revised often by each jurisdiction. For the most up to date information refer to the jurisdiction's website or contact their outreach offices directly.
[2] https://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm557424.htm Accessed 6/20/2018

Lead (continued)

CANADA	
0.05 ppm	**Fruit juice; Fruit nectar**
0.01 ppm	Water sealed in containers
EUROPEAN UNION[3]	
0.02 ppm	Infant formula and follow-on formula
0.1 ppm	**Meat (excluding offal) of** bovine animals, sheep, pig, and **poultry**
0.5 ppm	**Offal of** bovine, sheep, pig, and **poultry**
0.3 ppm	**Muscle meat of fish**
0.2 ppm	**Legumes** and **pulses**
0.2 ppm	**Berries** and small fruit
0.1 ppm	**Fats and oils,** including milk fat
WORLD HEALTH ORGANIZATION[4]	
0.1 ppm	**Berries** and other small fruits
0.2 ppm	**Cranberries**
0.2 ppm	**Elderberries**
0.1 ppm	**Canned fruits**
0.4 ppm	**Jams, Jellies, Marmalades**
0.03 ppm	**Fruit juices and nectars**
0.1 ppm	**Bulb vegetables**
0.1 ppm	**Legumes** and **pulses**
0.1 ppm	Meat of cattle, pigs, and sheep
0.1 ppm	**Meat and fat of poultry**
0.5 ppm	**Edible Offal** (cattle, pigs, and **poultry**)
0.1 ppm	**Edible Fats and Oils**
0.3 ppm	**Fish**
2 ppm	Salt, food grade

[3] Commission Regulation (EU) 2015/1006 of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs
[4] Codex Alimentarius: International Food Standards. "General Standards for Contaminants and Toxins in Food and Feed" CXS 193-1995. Amended 2017.

Mercury	
UNITED STATES	
1 ppm	**methyl mercury in edible portion of fish**, shellfish, and crustaceans (CPG 540.600)
CANADA	
0.5 ppm	**In the edible portion of all retail fish**, with six exceptions (see the 1 ppm maximum level below).
1 ppm	The edible portion of escolar, orange roughy, marlin, fresh and frozen tuna, shark, and swordfish
0.5 ppm	**All fish products** (except swordfish, shark, fresh and frozen tuna, escolar, orange roughy and marlin)[5]
1 ppm	Swordfish, shark, fresh and frozen tuna, escolar, orange roughy and marlin[11]
EUROPEAN UNION[6]	
0.5 ppm	**Fishery products and muscle meat of fish**, excluding species listed in the following section. The maximum level for crustaceans applies to muscle meat from appendages and abdomen. In case of crabs and crab-like crustaceans (Brachyura and Anomura) it applies to muscle meat from appendages.
1 ppm	Muscle meat of the following fish: anglerfish (Lophius species) Atlantic catfish (Anarhichas lupus) bonito (Sarda sarda) eel (Anguilla species) emperor, orange roughy, rosy soldierfish (Hoplostethus species) grenadier (Coryphaenoides rupestris) halibut (Hippoglossus hippoglossus) kingklip (Genypterus capensis) marlin (Makaira species) megrim (Lepidorhombus species) mullet (Mullus species) pink cusk eel (Genypterus blacodes) **pike** (Esox lucius) plain bonito (Orcynopsis unicolor) poor cod (Tricopterus minutes) Portuguese dogfish (Centroscymnus coelolepis) rays (Raja species) redfish (Sebastes marinus, S. mentella, S. viviparus) sail fish (Istiophorus platypterus) scabbard fish (Lepidopus caudatus, Aphanopus carbo) seabream, pandora (Pagellus species) shark (all species) snake mackerel or butterfish (Lepidocybium flavobrunneum, Ruvettus pretiosus, Gempylus serpens) sturgeon (Acipenser

[5] http://www.inspection.gc.ca/DAM/DAM-food-aliments/STAGING/text-texte/fish_man_standardsmethods_appendix3_1406403090196_eng.pdf
[6] Commission Regulation (EU) 2015/1006 of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs

	species) swordfish (Xiphias gladius) tuna (Thunnus species, Euthynnus species, Katsuwonus pelamis)
Mercury (continued)	
EUROPEAN UNION[7]	
0.02 ppm	Other farmed terrestrial animals (Alpaca, Bactrian camel, Capybara, Cottontail/**American rabbit**, Dromedary, Eland, Elk/moose, Emu, Fallow deer, Guinea pig, Hare (farmed), Llama, Nandu/greater rhea, Ostrich, Peccari (collared), Rabbit, Red deer, Reindeer, Roe deer, **Other farmed terrestrial animals**,)[13]
0.01 ppm	**Duck**[13]
0.01 ppm	**Berries and small fruits**[13]
0.01 ppm	(b) strawberries (Musky strawberries, wild strawberries,)[13]
0.01 ppm	**Cranberries** (Cloudberries, Crowberries, Crowberries, Crowberries, Crowberries, Muntries, Partridge berries, Small cranberries/European cranberries,)[13]
0.01 ppm	SUGAR PLANTS: Others (2) (Birches (trunk sap), Manna ashes (trunk sap), **Maples (trunk sap**), Palms (trunk sap), Palms (trunk sap), Other sugar plants,)[13]
0.01 ppm	Rice (African rice, Hybrid Nerica®, Indian rice/**wild rice**,)[13]
0.02 ppm	**Hazelnuts**/cobnuts (Acorns, Filberts,)[13]
0.02 ppm	**Peas (with pods)** (Asparagus peas, Chickling vetches, Chickpeas/Bengal gram, Garden peas/green peas/mangetout/snow peas/split peas/sugar peas, Moringa/drumstick tree pods,)[13]
0.05 ppm	Cultivated fungi (Common mushrooms/button mushrooms/champignons mushrooms, Corn smuts/ Mexican truffles, Enokitake/winter mushrooms, Fusarium venenatum, Horse mushrooms, , Oyster mushrooms, Paddy straw mushroom, Pom-pom blancs/lion's mane mushrooms/monkeyhead mushrooms, Shiitake, Shimeji/bunashimeji/beach mushrooms, Snow mushrooms/white jelly mushrooms, Wood blewits/pied bleus, Other cultivated fungi, Other species of genus Pleurotus, not elsewhere mentioned,)[13]
0.01 ppm	**Bulb vegetables**[13]

[7] Commission Regulation (EU) 2015/1006 of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs

Mercury (continued)	
WORLD HEALTH ORGANIZATION	
0.5 ppm	**Fish**
1 ppm	**Predatory Fish** (shark, swordfish, tuna, pike, and others)

Arsenic (Inorganic)	
UNITED STATES	
0.1 ppm	**Infant Rice Cereal** (draft guidance)[8]
0.01 ppm	Apple juice[9]
0.35 ppm	Citrus Fruit (EPA)[10]
0.01 ppm	Bottled Drinking Water[11]
CANADA	
3.5 ppm	**Fish Protein**
1 ppm	**Edible Bone Meal**
0.1 ppm	Beverages; Fruit juice; Fruit nectar
EUROPEAN UNION (inorganic)[12]	
0.2 ppm	Non-parboiled milled rice (polished or white rice)
0.25 ppm	Parboiled rice and **husked rice**
0.3 ppm	Rice waffles, rice wafers, rice crackers and rice cakes
0.1 ppm	**Rice destined for the production of food for infants and young children**
WORLD HEALTH ORGANIZATION	
0.1 ppm	**Edible Fats and Oils**
0.35 ppm	**Rice, hulled**
0.5 ppm	Salt, food grade

[8] https://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm319870.htm Accessed 6/20/2018

[9] https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm360020.htm#action_level Accessed 6/20/2018

[10] EPA 2005j 40 CFR 180.289

[11] 21 CFR 165.110

[12] European Union. "COMMISSION REGULATION (EU) 2015/1006 of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs" 2015.

Copper	
USA	
1.3 ppm	Water (EPA)[13]
1 ppm	Bottled Water[14]
CANADA	
1.3 ppm	Drinking water[15]
EUROPEAN UNION[16]	
2 ppm	Others (2) (Bactrian camel, Dromedary, **Elk/moose**, Reindeer, Other milk producer animals,)[15] (Listed below "Horse (Species listed with code numbers 1015000-xxx,)")
5 ppm	**Duck fat[15]**
2 ppm	**Duck[15]**
5 ppm	**Strawberries (Musky strawberries, wild strawberries)[15]**
5 ppm	**Cranberries (Cloudberries, Crowberries, Crowberries, Crowberries, Crowberries, Muntries, Partridge berries, Small cranberries/European cranberries,)[15]**
5 ppm	SUGAR PLANTS: Others (2) (Birches (trunk sap), Manna ashes (trunk sap), **Maples (trunk sap)**, Palms (trunk sap), Palms (trunk sap), Other sugar plants,)[15]
10 ppm	Rice (African rice, Hybrid Nerica®, Indian rice/**wild rice**)[15]
30 ppm	**Hazelnuts**/cobnuts (Acorns, Filberts,)[15]
20 ppm	Peas (with pods) (Asparagus peas, Chickling vetches, Chickpeas/Bengal gram, Garden peas/green peas/mangetout/snow peas/split peas/sugar peas, Moringa/drumstick tree pods, Pigeon peas,)[15]
20 ppm	**Wild fungi** (Ceps/porcino mushrooms, Chanterelles, Hedgehog mushrooms, Horns of plenty/black trumpets, Morels, Périgord black truffles, Piemont white truffles, Saint George's mushrooms, Scotch bonnet mushrooms, Summer truffles, Other wild fungi, Other species of genus Tuber, not elsewhere mentioned,)[15]
5 ppm	**Bulb vegetables** [15]
WORLD HEALTH ORGANIZATION	
Maximum limits have not been developed for these copper in food.	

[13] EPA 2002d 40CFR141.51(b
[14] FDA 2001a 21CFR165.110
[15] http://www.odwac.gov.on.ca/reports/Lead%20Workshop/09%20lcr_revisions_white_paper_final_10.26.16.pdf
[16] Commission Regulation (EU) 2015/1006 of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs

Cadmium

UNITED STATES[17]	
0.005 ppm	Bottle Water[18]
	Pottery (ceramics)
0.5 ppm leaching solution	Flatware (average of 6 units)
0.5 ppm leaching solution	Small hollowware (any 1 of 6 units)
0.25 ppm leaching solution	Large hollowware (any 1 of 6 units)
CANADA	
0.005 ppm	Drinking water
EUROPEAN UNION[4]	
0.05 ppm	Vegetables and **fruit**, excluding root and tuber vegetables, leaf vegetables, fresh herbs, leafy brassica, stem vegetables
1 ppm	**Fungi**
0.05 ppm	**Meat** (excluding offal) of bovine, sheep, pig and **poultry**
0.05 ppm	**Liver** of bovine animals, sheep, pig, **poultry** and horse
1 ppm	**Kidney** of bovine animals, sheep, pig**, poultry** and horse
0.05 ppm	**Muscle meat of fish**, excluding mackerel (Scomber species), tuna (Thunnus species, Katsuwonus pelamis, Euthynnus species), bichique (Sicyopterus lagocephalus), bullet tuna (Auxis species), anchovy (Engraulis species), swordfish (Xiphias gladius), sardine (Sardina pilchardus)
	Infant formulae and follow on-formula:
0.01 ppm	powdered formulae manufactured from cows' milk proteins or protein hydrolysates
0.005 ppm	liquid formulae manufactured from cows' milk proteins or protein hydrolysates
0.02 ppm	powdered formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins
0.01 ppm	liquid formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins

[17] FDA. "Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed" 2000.
[18] CDC. "Cadmium Toxicity: What Are the U.S. Standards for Cadmium Exposure?" 2008. https://www.atsdr.cdc.gov/csem/csem.asp?csem=6&po=7

Cadmium (continued)	
WORLD HEALTH ORGANIZATION	
0.4 ppm	Polished, rice
0.05 ppm	**Blub Vegetables**
0.1 ppm	**Legumes** and **pulses**
0.5 ppm	Salt, food grade

Manganese, Zinc, & Aluminum
UNITED STATES
Maximum limits have not been developed for these metals in food.
CANADA
Maximum limits have not been developed for these metals in food.
EUROPEAN UNION[19]
Maximum limits have not been developed for these metals in food.
WORLD HEALTH ORGANIZATION
Maximum limits have not been developed for these metals in food.

µ Micro

[19] Commission Regulation (EU) 2015/1006 of 25 June 2015 amending Regulation (EC) No 1881/2006 as regards maximum levels of inorganic arsenic in foodstuffs

Appendix 9: Chemicals not of reasonable or likely concern.

Chlordane

Chlordane is a composed of a mixture of about 10 different chemicals.[1] It was used as a pesticide from 1948 to 1988 in the United States. Although it is banned in the United States, it is still used in other countries.

Chlordane strongly binds to soil's upper layers. Due to its insolubility in water, it is not likely to enter into groundwater. Breakdown of chlordane occurs in either water or sediment, but it is unknown where most of the degrading occurs. If this chemical breaks down in the soil, it happens very slowly (ATSDR 2018). Open-lake concentrations of chlordane continue exceeding water quality standards in certain areas (Lake Superior Partnership 2018).

Chlordane can remain in some types of soil for more than 20 years. Persistence of chlordane is less in sandy soil and greater in heavy soils or soils rich in organic matter. Volatilization is more rapid from light, sandy soils than from heavy soils. The half-life of this chemical from the soil surface is 2 to 3 days (ATSDR 2018).

A half-life is "the calculated time for loss of the first 50 percent of a substance." It is important to keep in mind, however, that the time needed for the loss of the remaining half of the substance could be longer. In other words, the remaining portion may degrade somewhat slower than the first half did (ATSDR 2018).

Most chlordane is lost by soil through evaporation. This chemical degrades easiest in the atmosphere where it reacts with light. However, it does stay intact enough to travel long distances and contaminate water or soil far from its source (ATSDR 2018).

Eating food contaminated with chlordane, such as fish, is the most common route of exposure to this chemical (ATSDR 2018).[2] This chemical bioaccummulates in fatty tissues, and also biomagnifies in the food web. As a result, chlordane strongly persists in the environment. Due to its former widespread use and long half-life in soil, it can still be found in animals and humans. However, levels continue to decline the longer chlordane has been banned (Venier et al. 2014).

Liver cancer was detected in rodents exposed to small amounts of chlordane through food over time. As a result, it has been classified as a probable human carcinogen. Humans that ingested large amounts of chlordane experienced digestive and nervous

[1] Major chemical components include beta-chlordene, trans-chlordane, cis-chlordane, and trans-nonachlor (ATSDR 2018).

[2] People that live in homes treated for termites using chlordane before it was banned are exposed to this chemical at higher rates than eating contaminated food (ATSDR 2018).

system problems, like seizures, confusion, stomach cramps, and diarrhea. Problems with the liver indicated by jaundice in these people were also detected (ATSDR 2018).

Lake Superior whitefish, lake herring, and lake trout sampled in a GLIFWC study did not exceed FDA's chlordane action limit of 0.3 ppm. However, siscowet from the 22-23 inch and 24.5-25.5-inch size groups did exceed the FDA's action limit. Action levels were not exceeded in other siscowet size groups.[3]

Trimming fillets reduced chlordane concentrations by 13 to 38 percent, depending on the fish species. Specifically, trimming reduced levels of this chemical 33 percent in whitefish and 34 percent in lake trout. Chlordane concentrations in siscowet were lowered between 13-38 percent, depending on the fish length. Overall, chlordane is no longer considered a consumption-limiting contaminant in Lake Superior fishes. [4]

Harvested waterfowl do not uptake chlordane levels in their breast muscle that would be concerning to human health (Tsuji et al. 2007; Braune and Malone 2006).

DDT & Related Compounds (DDE & DDD)

DDT is one of the first manmade insecticides developed in the modern day.[5] It had a wide usage in combating diseases carried by mosquitoes. DDT was also used extensively in insect control for farms, businesses, and home gardens. In 1972, its application as a pesticide was banned due to its adverse impacts to wildlife[6] and possible risks to human health (US EPA 2017).[7]

DDT is the most abundant, formerly-used organochlorine pesticide in all of the Great Lakes, with the exception of Lake Superior. Since the 1972 U.S. EPA ban, however, concentrations of DDT are steadily declining (ECCC and U.S. EPA 2017).

[3] GLIFWC memorandums from Matt Hudson, Dec. 30, 2005 and April 11, 2006.
[4] Ibid.
[5] The chemical name for DDT is dichloro-diphenyl-trichloroethane. Its widespread use started in the 1940s (US EPA 2017).
[6] DDT has been implicated in thinning of eggshells, interfering with the reproduction of large birds (Porter and Wiemeyer 1969). The thinning is caused by a disruption in enzyme activity involving calcium transport (Kolaja and Hinton 1977).
[7] In America, DDT is completely banned for all uses. In African countries, it is still used to control malaria. It is still used as an agricultural insecticide in some non-industrialized countries (EPA 2017).

DDE and DDD are chemically similar to DDT (ATSDR 2018).[8] DDE is created when DDT breaks down. DDD is a banned insecticide, and also a breakdown product of DDT (ATSDR 2018).

Eating foods that contain small amounts of DDT and related chemicals is how most people are exposed to this contaminant. Fish can contain low levels of DDT. This chemical bioaccummulates in fatty tissues, and also biomagnifies in the food web.

DDT and its related compounds bind strongly to sediment.[9] One scientist calculated DDT's half-life in American temperate soils to be 5.3 years. Other studies have calculated anywhere from 837 to 6,087 days. Highest residues of DDT are found in mucky soils and in unflooded fields that are deeply plowed (ATSDR 2018).

In animal studies, long-term exposure to small amounts of DDT caused liver dysfunction. DDE can raise the chance of a mother having an infant prematurely and cause a reduction in the length of milk production in lactating women. Harmful effects on reproduction were observed in animals that ingested small amounts of DDT over time (ATSDR 2018). DDE exposure has also been associated with instances of diabetes (Turyk et al. 2009).

High concentrations of DDT can affect the nervous system in humans, and cause moodiness, tremors, or seizures. However, the symptoms stop when exposure is removed (ATSDR 2018). These acute symptoms are not likely to occur from DDT or DDE exposure to levels that could be found in some wild, traditional foods. DDT is now considered to be a probable human carcinogen (U.S. EPA 2017).

People that eat Lake Superior fish generally do not have higher levels of DDT in their blood (FdL and MN DOH 2015). Harvested waterfowl do not uptake concerning amounts of DDT in their breast muscle, the portion of the duck most commonly consumed (Tsuji et al. 2007; Braune and Malone 2006).

Mirex and Chlordecone

Mirex and chlordecone and are chemically similar, man-made insecticides that have been banned for use in the U.S. since 1978.[10] These chemicals break down in the environment very slowly, staying for years in soil and water. They have a long half-life estimated to be about 10 years (ATSDR 2018).

[8] The chemical name for DDE is dichloro-diphenyl-dichloroethylene, and the chemical name for DDD is dichloro-diphenyl-dichloroethane (ATSDR 2018).
[9] The half-life of DDT in air exposed to sun is 2 days (ATSDR 2018).
[10] Mirex was also used sometimes as a flame retardant. (ATSDR 2018).

Mirex and chlordecone are not soluble in water, but bind closely to soil particles. As a result, they do not travel very far down into the soil. Also, these chemicals do not volatilize very easily from water or soil. Both mirex and chlordecone bioaccummulate and biomagnify in the environment. However, mirex breaks down more quickly than chlordecone (ATSDR 2018).[11]

A common route of low-level exposure to mirex and chlordane is by eating contaminated animals, particularly fish. These chemicals could occur in the environment from past use or be released from hazardous waste sites. Also, breastfeeding mothers may pass mirex through their milk to nursing infants (ATSDR 2018). Please see Appendix 7 for map of hazardous waste sites in the Ceded Territories.

Chlordecone has a tendency to bind to blood plasma proteins rather than fat tissues, which is unusual for an organochlorine pesticide. Mirex's biological half-life is estimated to be around 435 days. This chemical behaves as expected, however, and attaches to fat.

Animal studies have shown that ingestion of mirex and chlordecone can cause tumors in the liver, adrenal gland, and kidneys. However, short-term, irregular exposures to fairly low levels of mirex did not injure kidneys. Nevertheless, these chemicals are reasonably thought to be a human carcinogen based upon these studies. Kidney problems and negative impacts on development and reproduction in animals were also reported. Studies in workers exposed to chlordecone have found toxic effects on the nervous and reproductive systems, as well as on the liver (ATSDR 2018).

Mirex residues in various animals are much lower than those originally reported around the peak years of the chemical's production and use. All Lake Superior fish sampled by GLIFWC were far below the U.S. FDA's action limit for mirex, which is 0.1 ppm. Fish sampled were lake whitefish, lake herring, lake trout, and siscowet trout.[12]

Harvested waterfowl do not uptake mirex levels in their breast muscle that would be concerning for human health (Tsuji et al. 2007; Braune and Malone 2006).

Aldrin & Dieldrin

[11] Mirex degrades into photomirex, which also can cause harmful health effects. Photomirex is more poisonous than the parent chemical, mirex. Chlordecone breaks down into chlordecone alcohol, which less harmful (ATSDR 2018).
[12] GLIFWC memorandums from Matt Hudson, Dec. 30, 2005 and April 11, 2006.

Aldrin and dieldrin[13] are manmade compounds that have a similar chemical structure. Since 1970, these chemicals are no longer used as an agricultural pesticide, although they were commonly used in the past. In 1987, its use as a termite killer was also discontinued. Aldrin and dieldrin are still present in the environment from when they were commonly used as an insecticide. However, they can also leak from storage containers at waste areas. Please see Appendix 7 for Superfund sites.

Aldrin easily changes into dieldrin upon entering the environment or the human body. Bacteria and sunlight can transform aldrin into dieldrin. Dieldrin strongly binds to soil. It takes a long time for this chemical to break down in either water or soil. Dieldrin does not dissolve well in water. As a result, high concentrations are not found in water. However, it can travel through the air as dust, and settle on areas where it was not found before (ATSDR 2018).

Fish and birds that eat something contaminated with this chemical store it mostly in fat. Plants can uptake smaller amounts of dieldrin from the soil and store it in their roots and leaves.[14] As a result, dieldrin bioaccummulates and biomagnifies in the environment.[15]

All Lake Superior fish sampled in a GLIFWC study were far below the FDA's action levels for these chemical contaminants. Fish sampled in Lake Superior were whitefish, lake herring, lake trout, and siscowet.[16]

Harvested waterfowl do not seem to uptake concerning amounts of dieldrin in their breast muscle (Tsuji et al. 2007; Braune and Malone 2006).

Heptachlor & Heptachlor Epoxide

Heptachlor is a manmade insecticide used for agricultural, commercial, and residential applications until 1988.[17] Bacteria in the environment break down heptachlor into heptachlor epoxide, which is the form of the chemical most likely to be found. Heptachlor does not dissolve easily in water. Heptachlor epoxide is a more water-soluble than its parent chemical. Both chemicals bind strongly to soil, and slowly

[13] Aldrin's chemical name is 1,2,3,4,10,10-hexachloro-1,4,4α,5,8,8α-hexahydro-1,4-endo, exo-5,8-dimethanonaphthalene. The abbreviation of this name is HHDN. Dieldrin's chemical name is 1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,4α,5,6,7,8,8α-octahydro-1,4-endo,exo-5,8-dimethanonaphthalene. The abbreviation for this name is HEOD (ATSDR 2018).
[14] Barley and wheat seemed to have higher rates of chemical uptake (ATSDR 2018).
[15] Dieldrin has also been shown to thin eggshells (Porter and Wiemeyer 1969).
[16] GLIFWC memorandums from Matt Hudson, Dec. 30, 2005 and April 11, 2006.
[17] Heptachlor is now approved for only one use now: controlling fire ants in underground power transformers (ATSDR 2018).

evaporate into the air. The epoxide of heptachlor can remain in soil and water for many years (ATSDR 2018).

Eating fish or meat from other heptachlor-exposed animals is the most common way people come into contact with this chemical. However, certain types of plants, mostly root vegetables, have been found to uptake smaller amounts of heptachlor epoxide from the soil.[18] Nursing mothers that have been exposed to high concentrations of this chemical can also expose their infant through breast milk (ATSDR 2018).

The health effects to humans from heptachlor and its epoxide are largely unknown. Nervousness, liver damage, and fertility declines have been observed in animals that have ingested heptachlor. The effects worsened with high and long-term exposure, exposure not likely to occur from consumption of wild, traditional foods. Lifetime heptachlor exposure resulted in liver tumors in animals, which is a reason that heptachlor and heptachlor epoxide are classified as possible human carcinogens (ATSDR 2018).

All Lake Superior fish sampled by GLIFWC were far below the FDA's action levels for heptachlor and heptachlor epoxide. Fish sampled in Lake Superior were whitefish, lake herring, lake trout, and siscowet.[19]

Hexachlorobenzene (HCB)

Hexachlorobenzene (HCB) is a man-made fungicide used in the United States until it was banned in 1984.[20] It is formed as a waste product as other chemicals are manufactured. Smaller amounts of HCB can also be created during the large-scale combustion of household waste (ATSDR 2018).

HCB does not break down well in the air, and as a result, can be transported long distances in the atmosphere. It is insoluble in water, and binds strongly to soil. HCB's half-life in soil and water is 3 to 6 years. This chemical has been documented to bioaccummulate and biomagnify in aquatic environments (ATSDR 2018).

Most exposure to HCB occurs when people eat small amounts present in contaminated food. Long-term exposure to this chemical can cause liver disease, and negative impacts to the reproductive system. Mothers who are breastfeeding can pass HCB to their infant through milk. Infants and small children are particularly sensitive to the effects of

[18] Potatoes, carrots, beets, radishes, cucumbers, and tomatoes have all been found to uptake heptachlor epoxide to varying degrees (ATSDR 2018).
[19] GLIFWC memorandums from Matt Hudson, Dec. 30, 2005 and April 11, 2006.
[20] Commercial HCB production in the United States stopped in the late 1970s (ATSDR 2018).

highly-elevated HCB concentrations. Animal studies suggest that eating HCB-containing food for a long time can cause cancer of the kidney, liver, or thyroid. This chemical likely causes cancer in people (ATSDR 2018).

All Lake Superior fish sampled by GLIFWC were far below the FDA's action levels for HCB. Fish sampled in Lake Superior were whitefish, lake herring, lake trout, and siscowet. [21]

Harvested waterfowl do not uptake HCB levels in their breast muscle that would be concerning for human health (Tsuji et al. 2007; Braune and Malone 2006).

Chlorothalonil

Chlorothalonil is an organochlorine fungicide commonly used in commercial potato farming (USDA 2017).[22] A large swath of northeastern and west-central Wisconsin within the ceded territory falls within potato-growing country.[23] Overall, it is the most widely used pesticide for this crop, and was applied to 99 percent of the acres for planted potatoes within the state (USDA 2017).

The half-life of chlorothalonil in aerobic, or oxygen-abundant, soil is 1 to 3 months. Increased soil temperature or moisture increases the breakdown of this chemical, but it is not degraded by direct sunlight. Chlorothalonil binds more easily to soils containing a higher degree of organic matter. In sandier soils, this chemical is moderately mobile.

Chlorothalonil is not very soluble in water. Nearly 65 percent was degraded after 2.5 months in high pH water.[24] This chemical was found in one sample of surface water in Michigan at 6.5 ppm, which exceeded established levels. The EPA's reference dose is currently 0.015 ppm (U.S. EPA 1987).

Chlorothalonil is quickly excreted from the body, mostly in an unchanged form. Studies in rodents and dogs showed the chemical leaving the body via urine, feces, and in respiration. At low levels, it was found to be excreted within 24 hours. Therefore, it is not reasonably believed to accumulate in animal tissues.

Rats fed a range of chlorothalonil doses showed no impacts on physical appearance, behavior, and survival, overall. However, kidney enlargement of the rodents was common, which indicates organ dysfunction from large doses. The lowest amount of

[21] GLIFWC memorandums from Matt Hudson, Dec. 30, 2005 and April 11, 2006.
[22] Chlorothalonil is classified as an aromatic halogen compound.
[23] Wisconsin's Florence and Menominee counties do not engage in large-scale, commercial potato agriculture, as indicated on the map provided.
[24] The water was pH 9 (U.S. EPA 1987).

this chemical that was given to rats to eat without adverse symptoms was 60 ppm (US EPA 1987).

However, chlorothalonil is highly toxic to fish and aquatic insects, even at concentrations less than 1 ppm. Fishes, like rainbow trout, bluegill, and channel catfish,[4] exhibit noticeable effects (U.S. EPA 1987).[25] One study found 29 percent of the active ingredient was applied to non-target ground surfaces using typical applicator procedures. Small amounts of the chemical, 0.25 to 0.53 percent, were detected in runoff from sprayed area. Chemical concentrations ranged anywhere from 0.0012 to 0.5 mg/L (1.2 to 500 microgram/L) following the first runoff events (Wilson et al. 2010). However, runoff into a water body would be further diluted upon entrance.

Human health impacts from ingestion of chlorothalonil on wild, traditional foods are projected to be quite low overall. It does not accumulate in fish or animal meat. Direct application to a non-target plant would be unlikely, unless growing directly adjacent to a commercial potato field. This would be potential habitat for some types of berries, like blueberries and raspberries. However, non-target spraying at normal rates of application would likely not be at levels of concern to human health.

Glyphosate

Glyphosate is a widely-used, non-selective[26] herbicide first registered for American use in 1974 (Felsot 2011; Henderson et al. 2010). It is used in agriculture and forestry, and to kill weeds in commercial and residential settings. The largest applications are to corn and soybean fields, as well as pastureland and hay fields. It is also commonly applied to golf courses.

Glyphosate comes in a variety of formulations for either land or water applications.[27] In the U.S., over 750 glyphosate-containing formulations are sold (Henderson et al. 2010). This chemical kills plants by stopping the production of the EPSPS enzyme, which is essential for plant growth (Felsot 2011; Henderson et al. 2010).[28]

[25] LD is an abbreviation for "Lethal Dose". LD_{50} is the amount of a pollutant, given at one time, that causes 50 percent of a group of test animals to die. It is a common measure of acute, or short-term, toxicity. Rainbow trout's LD50 is 0.25 mg/L. Bluegill's LD50 is 0.3 mg/L. Channel catfish's LD50 is 0.43 mg/L. For reference, LD50 for mallards is 5,000 mg/L (U.S. EPA 1987).
[26] This means it will kill most plants it comes in contact with, that is, it does not select between plants.

[28] An enzyme is also a protein, increasing biological reaction times. The shikimic acid pathway requires the EPSPS enzyme, which is killed by glyphosate.

Glyphosate binds strongly to soil with high organic matter content. Glyphosate's half-life in soil is 1 to 174 days. However, the herbicide could be swept along by erosion and carried into water, if not directly applied to waterways. In ponds, the half-life of glyphosate is 12 days to 10 weeks. This chemical is broken down mainly by microbes. Its major metabolite is aminomethylphosphonic acid, or AMPA.

Studies were conducted that fed glyphosate to animals for long periods of time. Chickens, mice, rats, dogs, and rabbits were fed the chemical for as long as two years. There were, for the most part, no easily observable symptoms. Cell function, blood chemistry, and organ function were essentially not affected, even at the highest chemical concentrations tested (Henderson et al. 2010).

Researchers have debated for years whether glyphosate causes cancer. The evidence largely indicates that it does not cause cancer. Nonetheless, in 2015, this chemical was classified as "probably carcinogenic to humans" by IARC despite limited available evidence due to the ongoing debate.

Rats given the maximum glyphosate dose of 31 ppm/day tested did not exhibit toxic effects. Likewise, no ill effects were observed in a study of dogs eating the maximum dose tested, which was 500 ppm/day. Very high glyphosate amounts administered over the course of animals' lifetimes produced a minor reduction in body weight. However, slight changes to liver and kidney were observed in some animals (Henderson et al. 2010).

Two people that ingested large amounts of glyphosate had peak concentrations of the chemical in their blood plasma within 4 hours of ingestion. After 12 hours, glyphosate was nearly undetectable. Similar results have been found for AMPA, glyphosate's major metabolite. These findings indicate fairly rapid excretion of the actual chemical and AMPA from the human body.

Glyphosate can run off fields where it has been applied repeatedly, and at normal rates of application. It can also be taken up into the plant from roots. In this manner, glyphosate can impact plant functioning in plants found in agricultural ditches, including plant mortality. Some plants, however, are more tolerant of glyphosate residues (Saunders and Pezeshki. 2015).

Glyphosate is not the only chemical found in its formulations. Many formulations contain petroleum-based oxidized molecules, like POEA.[29] These chemicals are used in enhancing the ability of the herbicide to be applied to the plant, like as a surfactant.

[29] POEA stands for polyoxyethylene tallow amine. This chemical is a common surfactant in glyphosate formulations, and exhibits toxicity to aquatic organisms. (USGS 2018)

Surfactants help evenly spread the pesticide across the plant. Additional chemicals in the formulas are often considered inert, or chemically inactive. However, emerging evidence suggests that formulants may have more toxic effects on human cells than glyphosate itself. Traces of arsenic, cobalt, chromium, lead and nickel have also been found in some glyphosate-based herbicides (Defarge et al. 2018).

Glyphosate[30] uptake studies in forest blueberries and raspberries showed that less than 10 percent of the chemical entered fruit nine hours following application. A gradual decline in chemical residue levels over time were observed. The half-life of glyphosate on the berries were less than 20 days and less than 13 days for blueberry and raspberry fruit, in that order. Initial residue concentrations lowered to about 4 and 6 percent after 61 and 33 days for the blueberry and raspberry, respectively (Roy et al. 1989).

Glyphosate is not believed to bioaccumulate in animals or plants to any significant extent. Also, negative impacts in animals were at extremely high, repeated doses, which would not be typical at all in the human diet consisting of wild, traditional foods. However, people harvesting plants, rabbits, or hares next to golf courses and areas of intensive agriculture during the growing season are at increased risk of exposure. Wild turkeys are not typically eating green plant material when this chemical would be applied, so this species would be unlikely to be impacted.

2, 4-D

2,4-D is a selective, systemic[31] herbicide used to control plants with relatively broad, flat leaves. Major pesticide uses include residential lawns, roadways, pasture and rangeland, and cropland. It is also commonly applied to golf courses to control dandelions (Extension Toxicology Network 1993).

Once inside the plant, 2,4-D mimics a growth hormone called auxin, which causes uncontrolled and disorganized cell division within the target plant, typically within the stem region. This chemical can be found in several different forms depending on its specific formulation.[32] It has both land and water uses. Over 46 million pounds are applied annually in the U.S. for aquatic and terrestrial applications (Jervais et al. 2008).

2,4-D is one of the most common herbicides for aquatic invasive plant removal in the U.S. This chemical is commonly used in area lakes to control invasive Eurasian

[30] Vision® was the formulation used (Roy et al. 1989).
[31] Systemic herbicides are moved to other parts of the plant after first being absorbed by leaves or roots. 2,4-D has been registered for pesticide use since the 1940s.
[32] It can be an ester, amine or salt.

watermilfoil.[33] It is commonly applied for this application during spring or early summer when it is most effective (WDNR 2012).

As an aquatic herbicide, dimethylamine (DMA) salt and butoxyethyl ester (BEE) salt forms are used. The BEE formulation is more toxic to fishes and other aquatic organisms compared to the DMA form. Both forms are water soluble and break down rapidly to the 2,4-D acid in aquatic systems. The DMA salt is broken down to 2,4-D acid in less than 3 minutes. The BEE salt breaks down to 2,4-D acid within 1 to 3 days (WDNR 2012).

The 2,4-D acid itself is broken down in the aquatic environment primarily by microorganisms. Microbial degradation occurs mainly in sediments, with little taking place in the water column. The half-lives for 2,4-D acid in the field range from approximately 3 to 40 days. Half-lives under anaerobic conditions were over 300 days. Breakdown time increases with higher water and sediment temperatures, elevated dissolved oxygen levels, and increased nutrient loading. Breakdown rates for the chemical are slower in lakes that have not previously been treated, since bacteria present in the waterbody need to be able to break the chemical down (WDNR 2012).

Two low-dose (0.5 and 0.275 ppm), whole-lake treatments by the WDNR in Bayfield County found the 2,4-D (DMA) half-life to be 34 and 41 days in the water column, representing the upper end of recorded half-lives. 2,4-D remained at measurable concentrations in one lake for greater than 166 days after treatment (166 days after treatment was the final sample taken). Other studies have reported 2,4-D time to disappearance to be more typically 1 week to 2 months in water, and 2 weeks to 3 months in sediment. However, residues in sediment have been observed from 6 to 9 months (WDNR 2012).

2,4-D persistence in waterbodies is physically governed by transport of treated waters away from the treated area via water movement and circulation of water. This chemical does not bind strongly to sediments, though it can bind to a moderate degree to floating sediments with high organic content, especially in acidic lakes. This makes 2,4-D highly mobile and raises concerns about groundwater contamination. In fact, 2,4-D has been detected in groundwater throughout the U.S. and Canada, especially in rural areas where it is used as a terrestrial pesticide (WDNR 2012).

Liquid formulations will result in a higher initial 2,4-D water concentration. Granular (solid, grain-like) formulations have a longer persistence due to slow release and lead to lower water concentrations. Granules sink and release 2,4-D at the lake bottom. Liquid treatments take place at or near the surface of the water. As a result, sediment

[33] The scientific name for Eurasian watermilfoil is *Myriophyllum spicatum.*

concentrations are generally lower following liquid versus granular formulation treatments. Applications of granular formulations can result in excessive 2,4-D concentrations in sediment (WDNR 2012).

Some, but not all, studies have found an association between 2,4-D and non-Hodgkin's lymphoma in highly exposed populations. IARC determined the class of chemicals it is in (chlorophenoxy herbicides) to be possibly carcinogenic to humans in 1987. Based on limited evidence, EPA chose to place 2,4-D in the Group D category, meaning "not classifiable as to human carcinogenicity" in 2004 (Jervais et al. 2008).

There is also some evidence that 2,4-D may be an endocrine disruptor, having estrogen-like effects in humans. Two of the breakdown products of 2,4-D may also potentially affect male reproductive development. These impacts would not be expected at exposure levels occurring from occasional contact with treated water or consumption of fish from treated waters. However, exposure should be kept to a minimum since people could come in contact with this chemical from other sources, such as drinking water (Jervais et al. 2008; WDNR 2012).

The EPA states that there is no significant risk to recreational users of treated waters, though there is a 24-hour waiting period for swimming when the BEE formulation of 2,4-D is applied. There are no restrictions on fishing or boating in treated waters. Due to the low potential for bioaccumulation in animals, fish consumption from treated waters is not restricted. 2,4-D increases in edible fish tissue for a few days following application and is then rapidly eliminated (WDNR 2012).

Concern has arisen that 2,4-D may uptake into wild rice. No evidence exists that its systemic uptake into plants is harmful to human health, since the substance is not believed to bioaccumulate. However, wild rice is submergent during the application period for this chemical, and may be inadvertently injured or killed upon application. People harvesting berries would not have to worry about this chemical since the growing season is typically later than recommended timing of chemical application. Also, any berry or grape plant would likely be killed or significantly damaged by harvest time if accidentally sprayed.

Endothall

Endothall is the common name of endothal acid.[34] This chemical is a nonselective, contact herbicide.[35] In other words, it kills nearly all plants it comes into direct contact with.

Endothall is used in a variety of formulations to control both terrestrial and aquatic plants. Granular (solid) and liquid types of endothall are commonly used for aquatic weed control. It is also used on agricultural crops, like potato, sugar beet, hops, and alfalfa. On turf, it is used to annual grasses and broadleaf weeds (Extension Toxiology Network 1995). Annual grasses are more sensitive to the effects of endothall compared to perennial grasses (Koschnick et al. 2005). It is not really understood how endothall kills plants, but it is believed to interfere with plant respiration (Extension Toxiology Network 1995).

In waterways, this chemical is used mostly to treat invasive curly-leaf pondweed (*Potamogeton crispus*), although it is also effective against Eurasian watermilfoil (*Myriophyllum spicatum*) and a number of other invasive aquatic plants. It is normally applied in late spring and early summer, during active periods of growth (WDNR 2012).

Two types of endothall are available to use in aquatic applications: dipotassium salt and monoamine salts. The monomethylamine salt formulation of endothall is more toxic to fish and aquatic organisms than the dipotassium salt version (WDNR 2012).

The dipotassium and monomethylamine salt forms of endothall behave similarly in the environment. The dipotassium salt breaks down to the free acid immediately upon addition to water. In contrast, the monomethylamine salt can persist as the salt form to some degree in treated waters. This leads to the higher toxicity of the monomethylamine salt. Liquid formulations will result in a higher initial water concentration, whereas granular formulations have a longer persistence (WDNR 2012).

Endothall is dispersed by water movement. The herbicide is exceptionally stable in water, but is broken down in the environment by microorganisms. Low concentrations can persist in a treatment area for several days to several weeks, depending on environmental conditions. Persistence of greater 62 days has been reported. Its half-life ranges from less than 1 to 10 days. Complete microbial degradation takes between 30 and 60 days. Breakdown time increases with higher water and sediment temperatures, elevated dissolved oxygen levels, and increased nutrient loading (WDNR 2012).

[34] Endothaic acid's chemical name is 7-oxabicyclo[2,2,1] heptane-2,3-dicarboxylic acid.
[35] One formulation is approved for use as an algaecide.

The residence time of endothall in sediments is longer than in water, but sediment concentrations rarely reach levels as high as those in the water column. Because granules sink and release endothall at the lake bottom, in contrast to liquid treatments that take place at or near the surface of the water, sediment concentrations are generally lower following liquid versus granular formulation treatments. Endothall has a low probability of leaching to groundwater, but has been detected in groundwater where recharge areas with sandy or gravel bottoms have been treated (WDNR 2012).

Labels for products containing endothall specify wait times of up to 25 days before treated waters should be used for domestic purposes, for spraying food crops, or as livestock water. There are no restrictions on swimming, fishing, or boating in treated waters. Due to the low potential for endothall bioaccumulation, fish consumption from treated waters is not restricted (WDNR 2012).

Endothall would likely kill or injure wild rice seedlings during an optimal period of growth, but not be uptaken into the plant. Accordingly, low potential exists for significant human exposure via fish consumption from treated areas. Rabbits snared near large-scale potato growing operations during the growing season may be at increased exposure to endothall, but exposure is not at levels likely to impact human health.

Diquat Dibromide

Diquat, or diquat dibromide, is a swift-acting, contact herbicide. A contact herbicide kills just the area where it was applied, and is not taken up into the plant. The mode of action it uses to kill plants is by desiccation, or extreme drying of the plant. It is not selective, meaning it will kill most plants it comes in contact with. This chemical is commonly used in terrestrial and aquatic applications, including aquatic weed control, golf courses, and right-of-ways. It is also used on crops, including control of potato vines (Extension Toxicology Network 1993).

Diquat does not break down from bacterial activity, like many other pesticides used today. It is strongly bonded to silt or clay particles in soil or water, and accumulates in sediment. Its half-life in water is 1 to 35 days. In a waterbody with sandy sediments, it will remain in water longer (WDNR 2012).

A trace contaminant found in diquat products is ethylene dibromide (EDB). It comes about from the manufacturing process. EDB has been classified as a carcinogen. The EPA has set the maximum EDB level in diquat at 10 ppb. This contaminant degrades over time, and it does not persist like diquat itself (Extension Toxicology Network 1993)

Experiments show that walleye, particularly, are very sensitive to diquat, even at standard concentrations. In water treated with diquat at typical application rates, walleye displayed toxic symptoms. Other fish, like bass, northern pike, and bluegills, were not affected at normal rates of application. Bioaccummulation of diquat in fishes is minimal. In many fishes, the half-life of diquat is less than 21 days (Extension Toxicology Network 1993).

No restrictions exist for swimming or eating fish from diquat-treated aquatic areas. Water should not be used for drinking for 1 to 3 days following application, depending on the amount used. Water given to pets or livestock treated with diquat must be held for at least 1 day after treatment. For food crops, the irrigation restriction is 5 days. For lawn applications, it varies from 1 to 3 days depending on the amount used (WDNR 2012).

Long-term diquat exposure can produce cataracts, a clouding of the lens of the eye. When higher amounts were fed to test cats and dogs over a period of time, the instance of cataracts cases increased. In very large amounts not typically found in traditional foods, diquat can be fatal to humans. Studies in monkeys and massive human ingestions show that this chemical is mostly harmful to the digestive system, and the kidneys and liver (Extension Toxicology Network 1993).

Due to the low bioaccumulation potential, diquat ingestion from fishes is not of imminent concern (WDNR 2012). However, this chemical may be toxic to wild rice and walleyes during critical periods of growth. Rabbits snared near large-scale potato growing operations during the growing season are at increased exposure to diquat, but exposure is not likely to be at levels high enough to impact human health.

Appendix 10: Emerging chemicals not reasonably likely to be of concern

PBDE (Polybrominated Diphenyl Ethers)

Polybrominated diphenyl ethers (PBDEs) are a class of persistent, bioaccumulative compounds that are now understood to be environmental pollutants. These chemicals are used as flame-retardants in construction materials, electrical equipment, coatings, textiles and furniture padding. They enter the environment from manufacture and use of PBDE-containing products. PBDEs resist environmental degradation, as they are similar in chemical structure to PCBs (Siddiqi 2003).

PBDE toxicity is not entirely understood, yet these chemicals have been associated with neurodevelopmental delays, thyroid and liver problems, as well as tumors (Siddiqi 2003; ATSDR 2018). Negative neurological effects from PBDE exposure are similar to those observed for PCBs. Children exposed to PBDEs are prone to subtle, yet, measurable developmental problems (Siddiqi 2003). Studies of rodents and fish indicates that PBDE is likely an endocrine disruptor (Noyes and Stapleton 2014).

The tetra- and penta-BDE congeners are likely the most toxic of the PBDE compounds. The pentabromo formula is a mixture of tetra- and penta-PBDEs in nearly equal amounts. Pentabromo is banned by the European Union, but still widely used in North America. The United States is the top producer and user of pentabromo. However, the state of California has phased it out entirely (Siddiqi 2003).

Scientists evaluated PBDE concentrations in Great Lakes fishes to better understand the potential for human exposure through food. Overall, white sucker and common carp exhibited the highest total PBDE concentrations at 27–71 ng/g. Lake Superior's lake trout and whitefish contained higher levels than those from the other Great Lakes. However, fishes from Lake Ontario often had higher levels in tissue when not accounting for these outlying patterns. Whole body and egg contaminant loads are greater than in a corresponding fillet. Since PBDE levels have significantly declined since 2006, it will likely not result in appreciable fish accumulation of PBDEs (Gandhi et al. 2017). Therefore, it is not a significant human health hazard.

Appendix 11: Legally regulated limits of pesticide residues in foods in the United States, Canada, the European Union, and the World Health Organization.

Note: Canada has a default limit of 0.1 ppm for pesticide residues unless otherwise stated.

REGULATED PESTICIDE RESIDUE LIMITS IN FOODS		
Pesticide	**Maximum Residue Level**	**Agency**
Chlordane	0.3 ppm (fish)	United States
	0.1 ppm (berries)	United States
	0.1 ppm (bulb vegetables)	United States
	0.1 ppm (legumes)	United States
	0.1 ppm (default)	Canada
	0.01 ppm (berries)	European Union
	0.01 ppm (bulb vegetables)	European Union
	0.01 ppm (legumes)	European Union
	0.02 ppm (berries)	World Health Organization
	0.02 ppm (bulb vegetables)	World Health Organization
	0.02 ppm (legumes)	World Health Organization
DDT (DDE & DDD)	5 ppm (fish)	United States
	0.1 ppm (berries)	United States
	0.2 ppm (bulb vegetable)	United States
	0.2 ppm (legumes)	United States
	0.5 ppm (mushroom)	United States
	0.1 ppm (default)	Canada
	5 ppm (fish)	Canada
	0.5 ppm (bulb vegetable)	Canada
	0.5 ppm (legume)	Canada
	0.05 ppm (berries)	European Union
	0.01 ppm (wild raspberry)	European Union
	0.05 ppm (bulb vegetable)	European Union
	0.05 ppm (legume)	European Union
	0.05 ppm (rice)	European Union
	0.05 ppm (berries)	European Union
	0.1 ppm (rice)	World Health Organization
Mirex	0.1 ppm (fish)	United States
	0.1 ppm (fish)	Canada
	Limits have not been established at this time	European Union
		World Health Organization
Chlordecone	0.3 ppm (fish)	United States
	0.1 ppm (default)	Canada
	Limits have not been established at this time	European Union
		World Health Organization

REGULATED PESTICIDE RESIDUE LIMITS IN FOODS

Pesticide	Maximum Residue Level	Agency
Aldrin/ Dieldrin	0.3 ppm (fish-edible portion)	United States
	0.05 ppm (berries)	United States
	0.1 ppm (bulb vegetables)	United States
	0.03 ppm (legume)	United States
	0.1 ppm (default)	Canada
	0.01 ppm (berries)	European Union
	0.01 ppm (bulb vegetables)	European Union
	0.01 ppm (legumes)	European Union
	0.01 ppm (rice)	European Union
	0.05 ppm (bulb vegetable)	World Health Organization
	0.05 ppm (legume)	World Health Organization
	1 ppm (garden pea)	World Health Organization
	0.02 ppm (rice)	World Health Organization
Heptachlor	0.3 ppm (fish- edible portion)	United States
	0.05 ppm (berries)	United States
	0.03 ppm (rice)	United States
	0.1 ppm (default)	Canada
	0.01 ppm (berries)	European Union
	0.01 ppm (legumes)	European Union
	01 ppm (rice)	European Union
	0.02 ppm (rice)	World Health Organization
Hexachlorobenzene	0.05 ppm (berries)	United States
	0.05 ppm (bulb vegetable)	United States
	0.1 ppm (default)	Canada
	0.01 ppm (berries)	European Union
	0.01 ppm (bulb vegetables)	European Union
	0.01 ppm (legumes)	European Union
	0.01 ppm (rice)	European Union
	Limits have not been established at this time	World Health Organization
Glyphosate	0.25 ppm (fish)	United States
	0.2 ppm (berries)	United States
	0.2 ppm (wild leek)	United States
	0.1 ppm (wild rice)	United States
	310 ppm (aspirated fractions, wild rice)	United States
	8 ppm (pea)	United States
	1 ppm (tree nut)	United States
	5 ppm (liver- cattle)	United States
	0.1 ppm (meat- poultry)	United States
	1 ppm (liver- poultry)	United States

REGULATED PESTICIDE RESIDUE LIMITS IN FOODS		
Pesticide	**Maximum Residue Level**	**Agency**
Glyphosate (continued)	0.1 ppm (default)	Canada
	0.2 ppm (liver- cattle)	Canada
	0.08 ppm (meat- poultry)	Canada
	5 ppm (pea)	Canada
	0.1 ppm (berries)	European Union
	0.1 ppm (bulb vegetables)	European Union
	0.1 ppm (legumes)	European Union
	0.1 ppm (tree nut)	European Union
	0.2 ppm (liver- cattle)	European Union
	0.05 ppm (meat- polutry)	European Union
	0.05 ppm (liver- polutry)	European Union
	20 ppm (wild rice)	World Health Organization
	5 ppm (meat- mammalian)	World Health Organization
	5 ppm (offal- mammalian)	World Health Organization
	0.05 ppm (meat- polutry)	World Health Organization
	0.5 ppm (offal- poultry)	World Health Organization
2,4-D	0.1 ppm (fish)	United States
	0.2 ppm (berries)	United States
	0.2 ppm (tree nut)	United States
	0.3 ppm (meat- cattle)	United States
	40 ppm (wild rice)	United States
	0.1 ppm (default)	Canada
	0.3 ppm (meat- cattle)	Canada
	0.1 ppm (berries)	European Union
	0.2 ppm (tree nut)	European Union
	0.2 ppm (meat- cattle)	European Union
	0.1 ppm (wild rice)	European Union
	0.2 ppm (tree nut)	World Health Organization
	0.2 ppm (meat- mammalian)	World Health Organization
	5 ppm (offal-mammalian)	World Health Organization
Endothall	0.1 ppm (fish)	United States
	0.05 ppm (rice)	United States
	0.1 ppm (fish)	Canada
	0.1 ppm (default)	Canada
	0.01 ppm for all foods	European Union
	Limits have not been established at this time	World Health Organization

REGULATED PESTICIDE RESIDUE LIMITS IN FOODS		
Pesticide	**Maximum Residue Level**	**Agency**
Diquat dibromide	2 ppm (fish)	United States
	0.5 ppm (berries)	United States
	0.02 ppm (tree nut)	United States
	0.05 ppm (meat- cattle)	United States
	0.05 ppm (offal- cattle)	United States
	0.05 ppm (meat- poultry)	United States
	0.05 ppm (offal- poultry)	United States
	0.02 ppm (wild rice)	United States
	0.2 ppm (legumes)	Canada
	0.05 ppm (meat- cattle)	Canada
	0.05 ppm (offal- cattle)	Canada
	0.05 ppm (meat- poultry)	Canada
	0.01 ppm (berries)	European Union
	0.01 ppm (legumes)	European Union
	0.02 ppm (tree nut)	European Union
	0.05 ppm (meat- cattle)	European Union
	0.05 ppm (meat- cattle)	European Union
	0.05 ppm (meat- poultry)	European Union
	0.05 ppm (offal- poultry)	European Union
	0.02 ppm (wild rice)	European Union
	0.05 (berries)	World Health Organization
	0.3 ppm (legumes)	World Health Organization
	0.02 ppm (tree nut)	World Health Organization
	0.05 ppm (meat- mammalian)	World Health Organization
Chlorothalonil	1 ppm (blueberry)	United States
	5 ppm (berries)	United States
	5 ppm (wild leek)	United States
	0.1 ppm (legumes)	United States
	0.03 ppm (meat- cattle)	United States
	0.05 ppm (liver- cattle)	United States
	1 ppm (mushroom)	United States
	0.1 ppm (meat products)	Canada
	2 ppm (cranberries)	Canada
	0.6 ppm (berries)	Canada
	5 ppm (onion)	Canada
	0.1 ppm (legumes)	Canada
	1 ppm (mushroom)	Canada
	5 ppm (berries)	European Union
	0.01 ppm (bulb vegetable)	European Union
	3 ppm (legumes)	European Union

REGULATED PESTICIDE RESIDUE LIMITS IN FOODS		
Pesticide	**Maximum Residue Level**	**Agency**
Chlorothalonil (continued)	0.01 ppm (tree nut)	European Union
	0.15 ppm (meat- cattle)	European Union
	0.02 ppm (liver- cattle)	European Union
	5 ppm (berries)	World Health Organization
	10 ppm (spring onion)	World Health Organization
	1 ppm (legumes)	World Health Organization
	0.02 ppm (meat- mammalian)	World Health Organization
	0.2 ppm (offal- mammalian)	World Health Organization
Toxaphene	There are no established levels for food at this time.	United States
	0.1 ppm (default)	Canada
	0.01 ppm (wild vertebrates)	European Union
	0.01 ppm (poultry)	European Union
	0.01 ppm (poultry fat)	European Union
	0.01 ppm (berries)	European Union
	0.01 ppm (legumes)	European Union
	0.02 ppm (hazelnuts)	European Union
	0.01 ppm (bulb vegetables)	European Union
	0.01 ppm (wild fungi)	European Union
	0.01 ppm (cereals)	European Union
	There are no established levels for food at this time.	World Health Organization

Appendix 12: Legally regulated limits of industrial chemicals in foods in the United States, Canada, the European Union, and the World Health Organization

REGULATED INDUSTRIAL CHEMICAL RESIDUE LIMITS		
FOOD		
Pesticide	**Maximum Residue Level**	**Agency**
Dioxin & Furans	There are no established levels for food at this	United States
	20,000 ppm (under review)	Canada
	0.000001 ppm (fish)	European Union
	0.00000175 ppm (cattle meat)	European Union
	0.00000125 ppm (poultry meat)	European Union
	0.0000003 ppm (fruits and vegetables)	European Union
	No estabilished levels could be found at this time.	World Health Organization
Polychlorinated biphenyls (PCBs)	3 ppm fat basis (red meat)	United States
	3 ppm (poultry)	United States
	2 ppm (fish)	United States
	10 ppm paper food packaging	United States
	2 ppm (under review)	Canada
	0.0000025 ppm (fish)	European Union
	0.00000175 ppm (cattle meat)	European Union
	0.0000075 ppm (poultry meat)	European Union
	0.0000001 ppm (fruits and vegetables)	European Union
	No estabilished levels could be found at this time.	World Health Organization
Perfluorooctanoic acid (PFOA)	**There are no established levels for food at this time.**	United States
		Canada
		European Union
		World Health Organization
Perfluorooctane sulfonic acid (PFOS)	**There are no established levels for food at this time.**	United States
		Canada
		European Union
		World Health Organization

References:

Agency for Toxic Substances and Disease Registry. 2012. "Addendum to the Toxicological Profile for Chlorinated Dibenzo-p-dioxins (CDDs)". 66-69.

Code of Federal Regulation. Tolerances for polychlorinated biphenyls (PCB's). Title 21, Volume 2, Part 109.30 Subpart B.

Canada Food Inspection Agency. 2014. "Appendix 3 Canadian Guidelines for Chemical Contaminants and Toxins in Fish and Fish Products". 1-4.

European Union. 2013. "2013/711/EU: Commission Recommendation of 3 December 2013 on the reduction of the presence of dioxins, furans and PCBs in feed and food Text with EEA relevance".

Addendum to the GLIFWC Chippewa Ceded Territory Traditional Food Contaminant and Safety Report: A Scientific Evaluation of Possible Health Risks to Great Lakes Ojbwe Tribal Members from *manoomin* (wild rice), *zhiiwaagamizigan* (maple syrup) and *mizise* (wild turkey)

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List of Acronyms

AAS: Atomic Absorption Spectrometry

ANAB: ANSI-ASQ National Accreditation Board

ANSI: American National Standards Institute

ANA SEDS: Administration of Native Americans Social & Economic Development Strategies

BAL: Brooks Applied Labs

d.w.: Dry Weight

E.U.: European Union

GLIFWC: Great Lakes Indian Fish & Wildlife Commission

HACCP: Hazard Analysis and Critical Control Point

ICP-MS: Inductively Coupled Plasma-Mass Spectrometry

LOD: Limit of Detection

LOQ: Limit of Quantitation

LSRI: Lake Superior Research Institute

NRC-C: National Research Council-Canada

NIST: National Institute of Standards & Technology

MDL: Method Detection Limit

MRL_1: Method Reporting Limit

MRL_2: Maximum Residue Limit

Pace: Pace Analytical Services, LLC

ppm: parts per million = mg/L = mg/kg

QA/QC: Quality Assurance/Quality Control

RfD: Reference Dose

RPD: Relative Percent Difference

RSD: Relative Standard Deviation

SRM: Standard Reference Material

TEK: Traditional Ecological Knowledge

U.S. EPA: United States Environmental Protection Agency

U.S. FDA: United States Food & Drug Administration

w.w.: Wet Weight

INTRODUCTION

Ojibwe Bands entered into treaties with the United States government in 1836, 1837, 1842 and 1854. Within these treaties, the Bands ceded (sold) lands, mineral rights and timber to the United States but retained the right to harvest natural resources to continue traditional Ojibwe lifeways. These traditional Ojibwe lifeways incorporated seasonal harvests of fish, game, wild rice and other plant resources for spiritual, cultural, subsistence, and commercial purposes.

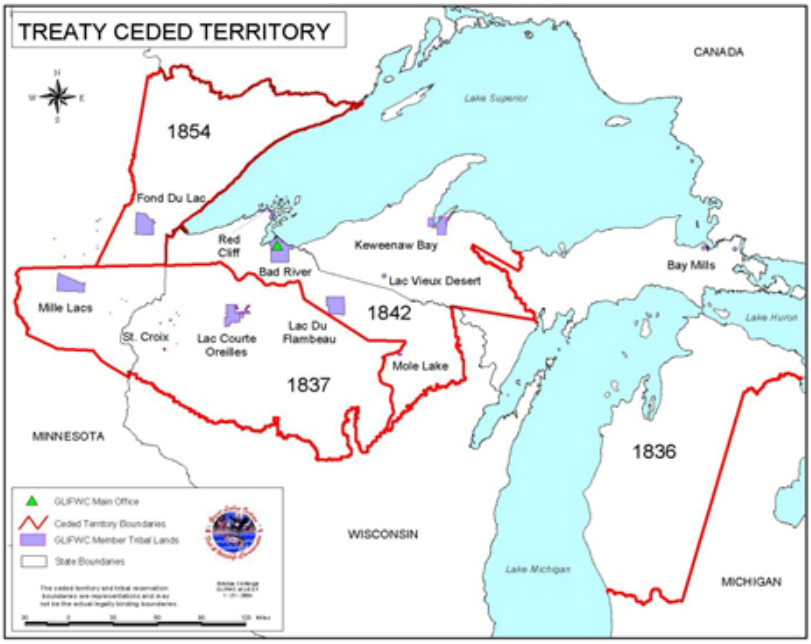

Figure 1: Boundaries of the territories ceded by the Ojibwe and year.

A series of federal and state court decisions re-affirmed off-reservation harvest rights of Ojibwe Bands including the 1981 *United States v. Michigan*, 1983 *Lac Courte Oreilles v. Wisconsin* and the 1999 U.S. Supreme Court Decision *Minnesota v. Mille Lacs Band*.

Eleven Ojibwe Bands in Minnesota, Wisconsin and Michigan established the Great Lakes Indian Fish and Wildlife Commission (GLIFWC) to implement court orders associated with the federal court decisions through inter-tribal protocols, delegated authorities and the development of tribal self-regulatory systems. The eleven Ojibwe Bands comprising the Great Lakes Indian Fish and Wildlife Commission include: *Nagaajiwanaag* (place were the water stops) commonly known as Fond du Lac, *Misi-zaagan'iganiing* (place of the big spread out lake) commonly known as Mille Lacs, *Wezaawaagami-ziibiing* (yellow river) commonly known as St. Croix, *Odaawaa-zaaga'iganing* (Ottawa Lake) commonly known as Lac Courte Oreilles, *Miskwaabikong* (place of steep rock of red material) commonly known as Red Cliff, *Mashkii-ziibing* (place of swampy river) commonly known as Bad River, *Waaswaaganing* (place of torch light) commonly known as Lac du Flambeau, *Zaka'aaganing* (place of torch-stick lake) commonly known as Sokaogon (Mole Lake), *Gete-gitgaaning* (old garden lake) commonly known as Lac Vieux Desert, *Gakiiwe'onaning* (or *Wiikwedong*) (place at the bay) commonly known as Keweenaw Bay, and *Ginoozhekaaning* (place of the pike) commonly known as Bay Mills. (GLIFWC 2018)

Traditional foods harvested by the Ojibwe have been documented to provide important sources of nutrition and have the potential to improve reservation health conditions. *"It is evident [from the above] that there is a relationship between the use of traditional Ojibwe food and the health and well-being of Band members. Band members recognize that traditional food is important for health, they would like to use more of it, and they wish this cultural knowledge to be taught to their children. Replacing some of the less-nutritious market food with traditional food will improve diet and nutrient*

intake, thus helping to prevent chronic disease; harvesting traditional food gives opportunity for activities in physical fitness and outdoor recreation; harvest and use of traditional food provides opportunity to experience, learn, and promote cultural activities·, it gives opportunity to develop personal qualities desired in Ojibwe culture such as sharing, self-respect, pride, self-confidence, patience, humility and spiritualty." (Kuhnlein 1995)

Federal courts have ruled State governments can only pre-empt tribal regulations governing the exercise of off-reservation treaty activities related to the harvest and sale of natural resources for conservation or safety purposes.

The *Voigt* and *Mille Lacs* cases both deferred a decision on the extent to which the States of Wisconsin and Minnesota, respectively, could regulate the off-reservation rights, including the sale and service of harvested food. (*Mille Lacs*, 124 F.3d 909). The issue of permissible state regulation was set for trial in subsequent phases and the parties later made stipulations to narrow the issues to be tried. The Deer Trial Stipulation provided that, as of 1989, the Tribes which were parties to *Voigt* did not have food regulations similar to enumerated provisions in Wisconsin law applicable to the processing of deer for human consumption, including the regulation of food processing and retail food establishments.(*Lac Courte Oreilles Band of Lake Superior Chippewa v. Wisconsin*, No. 74-C-313). The parties agreed, however, that Wisconsin law applied only until such time as a Tribe adopted "corollary regulations" and "employ[ed] trained and qualified personnel to enforce such regulations." (Pavel 2018)

Tribal leadership, and their communities, expressed desire to increase the availability of traditionally harvested foods within their communities and to integrate these foods into tribal community food systems. Tribes are particularly interested in increasing opportunities to sell traditionally harvested wild foods to the federal food programs operating within their reservation communities.

In response to community interest and tribal leadership directives, GLIFWC obtained a federal Administration of Native Americans Social & Economic Development Strategies (ANA SEDS) grant to develop a model traditional food code. The purpose of the tribal food code is to provide a regulatory structure governing the processing, distribution, labeling and sale of treaty harvested resources in a manner that effectively protects the health and safety of community members. Federal courts have ruled that Tribal off-reservation conservation codes must be based upon sound science to adequately protect natural resources. Similarly, tribal food codes must also be based upon sound science to adequately protect human health. In particular, food safety regulations need to identify and account for biological[1], chemical[2] and physical[3] food safety risks that are "reasonably likely" to occur.

GLIFWC utilized a systematic approach in identifying traditional Ojibwe foods of interest and potential food safety risks. GLIFWC first utilized a survey of tribal members and consultation with tribal elders and tribal leaders to identify and rank the 16 Ojibwe foods tribal members would most like

[1] Biological risks in food commonly consist of bacteria, virus, parasites and diseases such as Chronic Wasting Disease (CWD).
[2] Chemical risks in food commonly consist of lead, mercury and other heavy metals in addition to organochlorine chemicals such as PCBs and DDT.
[3] Physical risks in food commonly consist of metal fragments and glass.

to increase access to within their communities. Tribal members identified *manoomin* (wild rice), *zhiiwaagamizigan* (maple syrup) and *mizise* (wild turkey) through this process. (Kraft & Maroney 2018)

GLIFWC then conducted an extensive, peer review of scientific journals to ascertain possible food safety hazards associated with those Ojibwe foods identified as holding the greatest interest by tribal members in the survey. The scientific literature was compiled, analyzed and summarized in a report to identify potential biological, chemical and physical hazards to human health (Kraft 2018). Additional literature searches and analysis were then undertaken to verify which Ojibwe foods had limited or no published scientific research regarding chemical contamination. These foods were identified for further study.

Biology of Food Items for this Study and Identification of Potential Food Safety Concerns

manoomin (wild rice*, Zizania palustris*)

Manoomin is an annual grass that grows naturally in marshes, as well as on the fringes of lakes, streams, and rivers. These plants typically grow in calm, clear waters with soft, organic rich sediments at a relatively sensitive range of depths from 0.5 to 3 feet (Minnesota Department of Natural Resources 2018).

Manoomin has been a staple in the diet of native people in the upper Great Lakes region for over 1000 years (Johnson 1970). It has been an important component of the diet and the culture of the Ojibwe people since their immigration from the eastern seaboard into the heart of wild rice range at the west end of Lake Superior (Vennum 1988). With the arrival of Europeans, wild rice also became an important economic commodity, providing critical nutrition to the fur-trappers and traders moving into the area. Today, *manoomin* retains extraordinary significance to the Ojibwe, and is considered sacred food. The September moon is still referred to as Manoominike Giizis (the Rice Making Moon), and the harvest season is still celebrated with traditional pow-wows. (David 2013)

In addition to its value to Native Americans, wild rice provides a valuable food source for wildlife, and its presence increases the biological diversity of wetlands. *Manoomin* can also improve water quality by tying up nutrients and by decreasing the wind action across lakes that can suspend sediment particles and lead to water clarity and quality problems. (David 2013)

Unfortunately, wild rice is much less abundant than it was historically. The Great Lakes Indian Fish and Wildlife Commission (GLIFWC) conducts a *manoomin* (Zizania palustris) enhancement and research program in the territories ceded in the Treaties of 1836, 1837, and 1842 and works to restore the resource through cooperative projects with other natural resource agencies. (David 2013)

In 2014, tribal members were estimated to have harvested 18,605 pounds of *manoomin* in 520 trips. The total off-reservation harvest per active tribal license averaged 115 pounds. (David 2020)

Wild rice is commonly consumed by adults and children at tribal meals in cooked form as a side dish, or as an ingredient in casseroles or other main dishes. It is also sometimes ground into flour

or meal (GLIFWC 2014). It's general nutritional value surpasses cereal grains, such as wheat, oats, barley, and rye.

As an aquatic grain, or a cereal, wild rice contains more than 12 percent protein, is gluten free, and low in fat. It is also a good source of minerals, such as iron, potassium and phosphorus, as well as vitamins like thiamine, riboflavin and niacin. *Manoomin* has more overall nutrition than any other food in the Ojibwe diet. (*Manoomin* – Wild Rice the Good Berry).

Tribal members have experienced fish consumption advisories in ceded territory waters as these waters became polluted by mercury and organochlorine chemicals (i.e. PCBs, DDT, etc.) which bio-accumulated in fish tissue. (http://www.glifwc.org/Mercury/index.html)

As awareness of fish consumption advisories increased, tribal members became concerned pollutants could also enter the aquatic habitats growing *manoomin* (wild rice). These fears were augmented through scientific research, *"North American wild rice (Zizania aquatica L. and Z. palustris L.) grows in moderately soft and acidic freshwater wetlands. With the increasing pollution of such a habitat, there is some concern that the trace metal contents of the rice crop have become unduly elevated. This study finds moderately elevated levels of lead (0.5–11.5 µg/100 g dry wt.), cadmium (1.0–10.2 µg/100 g dry wt.) and arsenic (0.6–14.2 µg/100 g dry wt.) in 26 brands of wild rice sold in the United States".* (Nriagu 1995).

Tribal members have also historically utilized galvanized wash tubs to scorch wild rice as they process wild rice. Unfortunately, some of the galvanized wash tubs contain lead solder which necessitates testing to ensure food safety.

*zhiiwaagamizigan (*maple syrup*, boiled Acer spp. sap)*

Maple syrup is a traditional, Ojibwe sweetener made by evaporating sap from tapped *Acer spp.* trees, usually from sugar maples (*Acer saccharum*) or possibly red maple (*Acer rubrum*), due to the high sucrose concentration of sap from these particular species (Corbiere 2011). Sap (*ziinzibaadwadwaaboo*) is harvested by drilling through the bark and cambium into the sap wood of the tree and inserting a tube (spike) through which the sap drains into a pail. The sap is collected and dehydrated in an open pan with heat beneath the pan. The dehydration continues until the desired sugar concentration is accomplished. It was noticed during sample collection this particular traditional food is regularly bartered or gifted.

Lead contamination of maple syrup occurs predominantly from the use of lead-bearing processing equipment, and usually does not come from the sap itself (Ontario Ministry of Agriculture, Food, and Rural Affairs 2019). Under suitable conditions of acidity and temperature, lead mobilizes into sap when in contact with lead bearing materials (Willits and Tressler 1937). Therefore, concern existed that maple syrup may be contaminated with lead from old, inherited metal equipment used in processing and/or from lead-bearing mechanisms present in non-food grade equipment used by tribal members (Stilwell and Musante 1996; Willits and Tressler 1937; Ontario Ministry of Agriculture, Food, and Rural Affairs 2019).

Wisconsin regulatory rules expressly state that neither lead nor lead alloyed solder can be used in the assembly or repair of surfaces associated with food-contact for food sold in the private sector (Wisconsin Department of Agriculture, Trade and Consumer Protection 2019). This regulation could

potentially restrict the future sale of tribal maple syrup in retail establishments if lead-bearing equipment or repair material was inadvertently used by tribal harvesters.

*mizise (*wild turkey, *Meleagris gallopavo)*

Wild turkeys are large birds in the taxonomic order Galliformes that are four feet tall and weigh 18–24 pounds as adults. They are the largest wild bird in North America. Their young forage for food on the ground as soon as they are hatched. They feed on hard seeds and nuts as well as insects. They have a large and well developed gizzard (grinding organ at the entrance to the stomach) that grinds food prior to digestion (Wisconsin Department of Natural Resources 2015). Hunting of *miziseg* (turkeys) in the Wisconsin and Minnesota ceded territories has been a small but regular activity since the reaffirmation of off-reservation harvesting under the Voigt 1983 and Mille Lacs 1994 decisions. Once extirpated from the region, turkeys have again become established throughout much of the Wisconsin and Minnesota ceded territories and are now included in turkey management zones (David 2019).

Wild turkeys are customarily harvested with shotguns, presenting two, potential food hazards: physical and chemical. The possible physical hazard includes the presence of shot pellets or rifle bullet fragments embedded in turkey meat possibly causing damage to teeth or internal organs of the consumer. Most people attempt to remove visible pellets found in wild game when preparing meat for meal consumption (Food Standards Agency in Scotland 2012). However, placement of the pellets within meat may not always be visible during processing or before cooking.

The second possible hazard is lead contamination introduced by lead shot and is a possible chemical hazard from consumption of wild turkey meat. There is a large body of literature that exists to support this idea (Arnemo et al. 2016; Johansen et al. 2004; Pain et al. 2010; Tsuji et al. 1999). Lead is a well-studied element due to its known acute and chronic (lifetime) toxicity to the neurological system, particularly in children, pregnant women, and women of childbearing age (Agency for Toxic Substances and Disease Registry 2007). It is not known to what extent wild turkey meat retains this metal following harvest with lead ammunition, and after typical field dressing and butchering processes.

Research Objectives

Goals related to the chemical and/or physical contaminant inquiries regarding target Ojibwe foods:

- *Objectives regarding the inquiry into elemental contamination of wild rice*

1. Analyze total concentrations of nine elements in uncooked wild rice seeds gathered and processed within ceded territories by tribal harvesters (i.e., Pb, Zn, Cd, total Hg, Mg, total Cr, Cu, Se and As), and extrapolate these concentration results using moisture content information for cooked wild rice.
2. Analyze the proportion of wild rice's inorganic arsenic content in relation to total arsenic levels.
3. Compare elemental results to other published studies.
4. Compare elemental concentrations of Great Lakes Ojibwe harvested wild rice with regulatory action levels established to protect human health from excessive metal exposure.

 Objectives regarding the maple syrup lead inquiry

1. Analyze lead concentrations in maple syrup collected and processed within the ceded territories by tribal harvesters.
2. Compare lead concentrations in maple syrup with Canada's MDLs for lead in maple syrup and the State of California standard of 0.011 mg/kg.

 Objectives regarding wild turkey lead content

1. Evaluate how many pellets and/or fragments reside in wild turkey breast tissue
2. Analyze lead concentrations in individualized wild turkey breast tissue collected within the ceded territories by tribal harvesters.
3. Assess mean lead concentrations in wild turkey breasts per bird.
4. Compare lead concentrations in wild turkey breasts with regulatory action levels established to protect the human food supply and other wild game.

METHODS AND MATERIALS

Sample Collection

Several methods were used to disseminate information to GLIFWC-affiliated tribal harvesters regarding traditional foods to be collected for this study across the ceded territories. A call for samples was placed in the autumn 2018 edition of the *Mazina'igan*, a widely-distributed GLIFWC newspaper. Hard-copy, sample request posters were mailed to all member tribe offices, along with poster placement on GLIFWC's main webpage and social media accounts such as Facebook.

Known tribal harvesters and influential community members were subsequently contacted to request samples. Sample collection efforts were also announced at major GLIFWC meetings with tribal leadership for information dispersal. The various communication methods employed were used to reach the broadest Ojibwe audience, as well as diversify sample sources and methods used to harvest and/ or process samples within each of the 11 GLIFWC member tribes.

Most of the wild, traditional food samples came from within ceded territories (Fig. 1), with sample custody documented that included sample collection sites, how samples were harvested, and when collected by the tribal harvester. However, wild rice and maple syrup samples from institutions affiliated with tribal communities were also deemed acceptable. A select amount of comparable grocery store samples where tribal member would shop were also purchased for comparative analyses.

Wild rice sample collection

Forty wild rice samples were obtained by Ojibwe tribal harvesters within ceded territories; three commercial wild rice samples were purchased as comparative samples (Table 1). Package labels on cultivated (paddy) wild rice obtained from grocery stores indicated they were of Minnesota origin. Unfortunately, California grown paddy wild rice could not be found in the local grocery stores searched. Some of the wild rice from samples was selected at random and cooked to determine the moisture content of cooked wild rice.

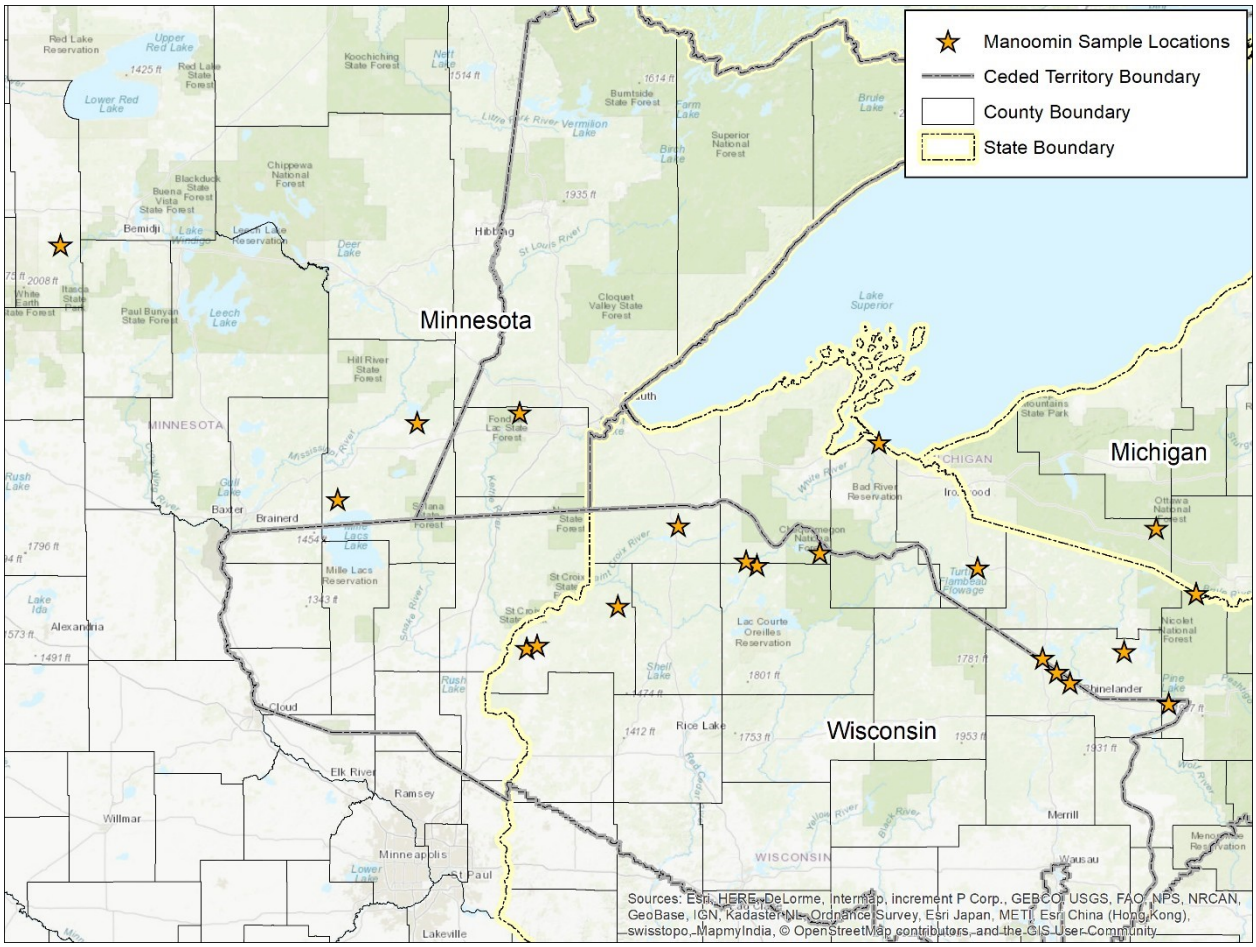

Figure 2. Wild rice samples for heavy metals testing were collected from natural beds located in the 1842, and 1854 treaty territories. However, three sample were collected outside ceded territory boundaries.

An additional wild rice sample was contributed by a Fond du Lac tribal member that was collected from Clearwater County Minnesota. Out of cultural respect and as a GLIFWC tribal member, that sample was also included for analyses, although technically outside the bounds of ceded territories. Some reservation localities experience a low abundance of wild rice resulting in samples obtained from both on-reservation and off-reservation harvest areas. A map of the general ceded territory boundaries (Fig. 2), with stars indicates wild rice source collection points identified by tribal harvesters. All samples were collected in northern regions of Minnesota, Wisconsin, and Michigan. Despite best staff efforts, it remained difficult to locate more samples from water bodies throughout the ceded territories. To increase sample size, wild rice purchased in previous years by GLIFWC was also submitted for analyses. "Finished" or "processed" wild rice throughout this document is defined as wild rice that has been dried, parched, threshed, and winnowed. "Unprocessed" or "green" rice refers to rice that has been collected but has not undergone any processing steps, therefore, containing more moisture.

Table 1. Wild rice sample locations identifying the water body, county, state of harvest and the number of samples from each site.

Lake / Water Body of Harvest	County of Harvest	Number of Samples
Wisconsin		
Bad River Sloughs	Ashland	2
Chippewa Lake	Bayfield	4
Cut-A-Way Dam	Douglas	1
Lee Lake	Rusk	1
Little Rice Lake	Forest	1
Little Turtle Flowage	Iron	1
Long Lake	Burnett	1
North Fork Flowage	Burnett	1
Pacwawong Lake	Sawyer	1
Phantom Lake Flowage	Burnett	1
Totagitic Lake	Bayfield	3
Rice Lake	Forest	5
Mixed Sources *		2
Michigan (Upper Peninsula)		
Brule River	Iron	1
Unknown Location**	Iron	1
Ontonagon River	Gogebic	1
Minnesota		
Deadfish Lake	St. Louis	1
Mallard Lake	Aitkin	1
Lake Minnewawa	Aitkin	1
Upper Rice Lake	Clearwater	1
Unknown Site & State		
		6
Cultivated Wild Rice from Unknown Harvest Locations		
MN paddies		3
Total		40

* Wild rice seeds from more than one source were combined by the harvester.
** Harvester wished to keep his source waterbody private to prevent others from harvesting there.

Maple syrup sample collection

Twenty-nine maple syrup samples were obtained by Ojibwe tribal harvesters within ceded territories and three commercial maple syrup samples were purchased as comparative samples.

The Ojibwe culture, as with many other indigenous tribes, customarily use items passed down to them from elders, e.g., harvesting or processing equipment. When possible, sample providers were asked whether they used any "old and/or inherited equipment from a previous generation," engendering a "yes" or "no" response. If the answer was "yes," more information regarding specific equipment was collected from the harvester. For purposes of this report, "old" is defined as having an age of more than 15 years old, i.e., one generation, and "inherited" means that it was passed down to the current harvester from a previous generation. This type of "old" and "inherited" equipment is more likely to have contained lead soldered connections or other non-food grade materials which come in contact with sap (International Maple Syrup Institute, 2015).

However, "old" and "inherited" are not necessarily interchangeable terms. An "old" piece of equipment may not necessarily be "inherited," but an "inherited" item is by default "old." If a processor did not classify their equipment as either "old and/or inherited," an assumption was made that the processor used all modernized equipment, even if not explicitly stated by them during sample collection.

In addition, finished wild rice and bottled maple syrup purchased from GLIFWC affiliated tribal harvesters in previous years were used to expand sample size and site selection. Scant or missing harvest and processing information remained a drawback to using samples from prior years. However, analyses of these samples provided valuable information of possible heavy metals exposure from consumption of those food items.

Wild turkey sample collection

Wild turkey samples were specifically collected in the fall 2018 and spring 2019 during tribal harvest seasons. Whole wild turkeys were collected from tribal hunters that contacted staff immediately upon harvest. The chain-of-custody record submitted with each bird contained information including the name of the harvester, shot size, type of shot, and gauge of shotgun used. Tribal harvesters submitting samples were required to freeze or refrigerate the birds no more than one hour after harvest. Whole birds were frozen by the harvester if turkey samples were held longer than 72 hours after harvest to maintain sample integrity. Whole wild turkeys were assigned a sample number and stored in an electronically-monitored freezer at ≤ -10°C until they underwent the breast removal process. Before breast removal, turkeys were thawed in a refrigerator at ~ 4°C for 48 to 72 hours.

Laboratories used for Processing and Analyzing Samples

Three laboratories were used for analysis of the metals of interest in this study for the assessment of chemical concentrations in the target Ojibwe foods. The laboratory at the University of Wisconsin-Superior, Superior, WI is a research laboratory of the Lake Superior Research Institute (LSRI) and was the primary laboratory for receiving and preparing samples for shipping to the other laboratories. LSRI ground the wild rice seeds and turkey breasts and analyzed a percentage of the wild

rice, turkey and maple syrup samples for moisture, and analyzed for the metals copper (Cu), magnesium (Mg), total mercury (Hg), and zinc (Zn) in wild rice. Pace Analytical (Pace) has its headquarters in Minneapolis, MN with many satellite laboratories of which one is located in Green Bay, WI and was utilized for this study. Pace analyzed samples for cadmium (Cd), chromium (Cr), lead (Pb), and selenium (Se). Brooks Analytical Labs (BAL) is located in Bothell, WA and specializes in trace metals analysis. BAL analyzed samples for arsenic (As); total and inorganic as well as the organic dimethylarsinic acid, and monomethylarsonic acid. BAL is an ANAB accredited analytical laboratory along with current certifications for environmental testing in eight states nationwide (BAL 2019b).[4] Specifically, BAL meets ANAB testing criteria for total and inorganic arsenic in biological tissues under the international standard ISO/IEC 17025:2005 using proprietary methods, processes, techniques, and standard operating procedures (BAL 2019b; ANSI 2019).

Sample processing and storage

Wild rice sample processing and storage

Upon arrival at GLIFWC's facility at Odanah, WI, plastic bags of wild rice seeds were labeled, a chain-of custody record was begun, and the sample placed in dry storage at room temperature (~18 to 21°C). Storing whole, finished wild rice seeds at an ambient temperature resembles typical finished wild rice storage by tribal consumers. Select aliquots of wild rice were cooked for later moisture analysis. These nonrandom cooked samples were chosen for moisture analysis based upon geographical location of harvest to represent the entire area from which samples were collected.

The cooked wild rice samples were prepared according to a standardized protocol developed at GLIFWC in a manner typical to that of tribal consumers. The resulting cooked wild rice was then stored in clean glass bottles in a temperature monitored freezer at ≤ -10°C. One moisture content sample included a can of grocery store purchased cooked paddy wild rice, drained and subsequently frozen. No other canned, commercial brands could be found in a variety of grocery stores explored. Both finished (uncooked) and cooked wild rice samples were then delivered to LSRI.

Maple syrup sample processing and storage

Labeled, sealed maple syrup bottles and the single maple sugar sample were placed in locked, dry storage at room temperature (~18 to 21°C), a typical storage procedure of these food items by tribal consumers. Glass maple syrup sample bottles were packed securely in plastic containers and delivered to LSRI. LSRI examined moisture content in all maple syrup samples and transferred an aliquot of each sample to critically clean bottles prior to delivering them to Pace in coolers on ice for lead analysis.

Wild turkey sample processing and storage

Before pectoral muscle removal from the birds, total length was measured from the end of the beak to the end of the tail. Right and left breasts of wild turkeys were extracted using a standardized protocol. "Right" and "left" breast orientation refers to the extractor's left and right sides with the

[4] ANSI-ASQ National Accreditation Board (ANAB) is an independent accreditation body that oversees the quality of laboratory test results for specific matrices, methods, and analytes, among other tasks (ANSI 2019).

bird's head facing away from the extractor. The breasts were separated at the sternum. Any shot pellets observed on or in breast tissue was manually removed using forceps, and accompanied the sample in a separate plastic bag for later analysis. After breast removal, samples were labeled with the sample number and an alphabetic letter (R for right or L for left) for each individual breast. Each breast was examined by x-ray to locate any hard objects obstructed from view by tissue and the objects removed for analysis. The breast samples were then returned to frozen storage and delivered to LSRI for tissue grinding and homogenizing. LSRI examined moisture content in 16 turkey breasts and transferred an aliquot of each sample to critically clean bottles prior to delivering them to Pace in coolers on ice for lead analysis.

All grinding equipment used in the preparation and analyses of samples were critically-cleaned with 0.1 M hydrochloric acid. All glassware and plastic labware that were not used in the homogenization process were critically-cleaned using a 10% solution of nitric acid. Due to a property of high solubility, maple syrup and maple sugar were not homogenized. Equipment and labware cleaned in any acidic solutions were subsequently rinsed with copious amounts deionized water. Decontamination procedures at Pace included similar critical-cleaning practices for reusable labware. BAL utilized proprietary critical-cleaning practices that third-party accreditation bodies have determined as acceptable.

Sample homogenization and storage

Wild rice sample homogenization and storage

Uncooked wild rice samples were ground into a fine powder at LSRI using a stainless-steel, commercial grinding blender. Homogenized aliquots were then placed in certified-clean, high-density polyethylene containers and secured in a locked cabinet at room temperature (~18-21 ºC). At the start of digestion at LSRI, samples were taken out of storage, the sample aliquot weighed with an analytical balance which had been verified daily with Class 1 weights.

Homogenized wild rice samples to be analyzed by Pace or BAL were stored in a locked cabinet at room temperature at LSRI until the time of transfer. Samples were kept in this manner to simulate as much as possible the typical storage method of wild rice flour by tribal households. Wild rice flour was transferred to Pace on ice and BAL with silica gel packs in coolers to preserve sample integrity in transit.

Maple syrup sample homogenization and storage

Labeled, sealed maple syrup glass bottles and the single maple sugar sample were placed in locked, dry storage at room temperature (~18 to 21°C), a typical storage procedure of these food items by tribal consumers. LSRI examined moisture content, and then shipped sample aliquots in coolers on ice to Pace for lead analysis.

Wild turkey sample homogenization and storage

Frozen wild turkey breast samples in individual plastic bags were transported to LSRI where the samples were homogenized. The night before the samples were to be processed, the breast samples

were removed from the freezer and were allowed to thaw at room temperature until the next morning. The sample was passed through the tissue grinder three times. A small amount of the initial tissue that passed through the grinder was discarded. The grinder attachment was disassembled after each breast sample was ground and the unit was washed according to the labware cleaning procedure. A subsample of each ground wild turkey breast was placed into a labeled, certified clean, high density polyethylene (HDPE) bottle and stored in a refrigerator until all samples were processed (three days). A sub-sample from each HDPE bottle was then placed into a certified clean four-ounce glass bottle received from Pace and shipped on ice to Pace with sample custody documentation.

Upon receipt at Pace, homogenized aliquots of wild rice flour, maple syrup, and wild turkey were placed in frozen storage until digestion commenced. A 1 g portion of sample was digested in nitric acid with subsequent additions of hydrochloric acid and hydrogen peroxide, diluted to a 50 mL volume with reagent water, and heated in a HotBlock®.

Tissue Moisture analysis

Wild rice tissue moisture analysis

Moisture content of samples was measured at LSRI. Moisture in both uncooked (finished) and cooked wild rice seeds were gravimetrically determined for 25% and 100% of samples, respectively. Since only a portion of the finished wild rice samples were analyzed for moisture, the samples were chosen randomly. Cooked wild rice samples were stored in a temperature monitored freezer until moisture analysis while the uncooked (finished) rice samples were stored at room temperature in a locked cabinet. The samples were placed into individual dried and weighed aluminum weighing pans. The pans were placed into an oven (60 ± 10 ºC) for ≥ 24 hours. Dried samples were cooled, and then weighed to three significant digits using an analytical balance. Randomized samples were placed back in the oven for a second period of equal time to confirm complete water loss. During moisture analysis of wild rice, one of the wild rice seed samples was analyzed in duplicate while two of the cooked seed samples were analyzed in duplicate.

Maple syrup moisture analysis

Moisture content in maple syrup was gravimetrically determined for all samples. Each sample was placed into individual, dried and weighed aluminum weighing pans. The pans were placed into an oven (60 ± 10 ºC) for 98 hours. Dried samples were cooled, and then weighed to three significant digits using an analytical balance. Randomized samples were returned to the oven for an additional 90 hours of drying before being weighed a second time. Then, samples were placed into the oven a third and final time, and allowed to dry for an additional 144 hours before being weighed. Maple sugar moisture analysis was similarly done.

Wild turkey tissue moisture analysis

Moisture content in wild turkey breast tissue was also gravimetrically determined by LSRI on ~26% of randomly chosen samples. Homogenized samples were individually placed into dried and weighed aluminum weighing pans. The pans were placed into an oven (60 ± 10 ºC) for 24 to 43 hours. Dried samples were cooled, and then weighed to three significant digits using an analytical balance.

Approximately 19% of randomized samples were placed back in the oven for another 24 hours to confirm complete water loss.

Radiographic Analysis of Wild Turkey Breasts

Ashland Area Veterinary Clinic (AAVC) is a small- and large-animal care clinic located in Ashland, WI. The clinic possesses and maintains a Summit Nova 360 x-ray unit, and provides digital radiographical services to its clients, as one component of animal care services. The clinic examined each wild turkey breast sample via x-ray (Fig. 3) using appropriate settings, and visually scanning subsequent images for dense matter.

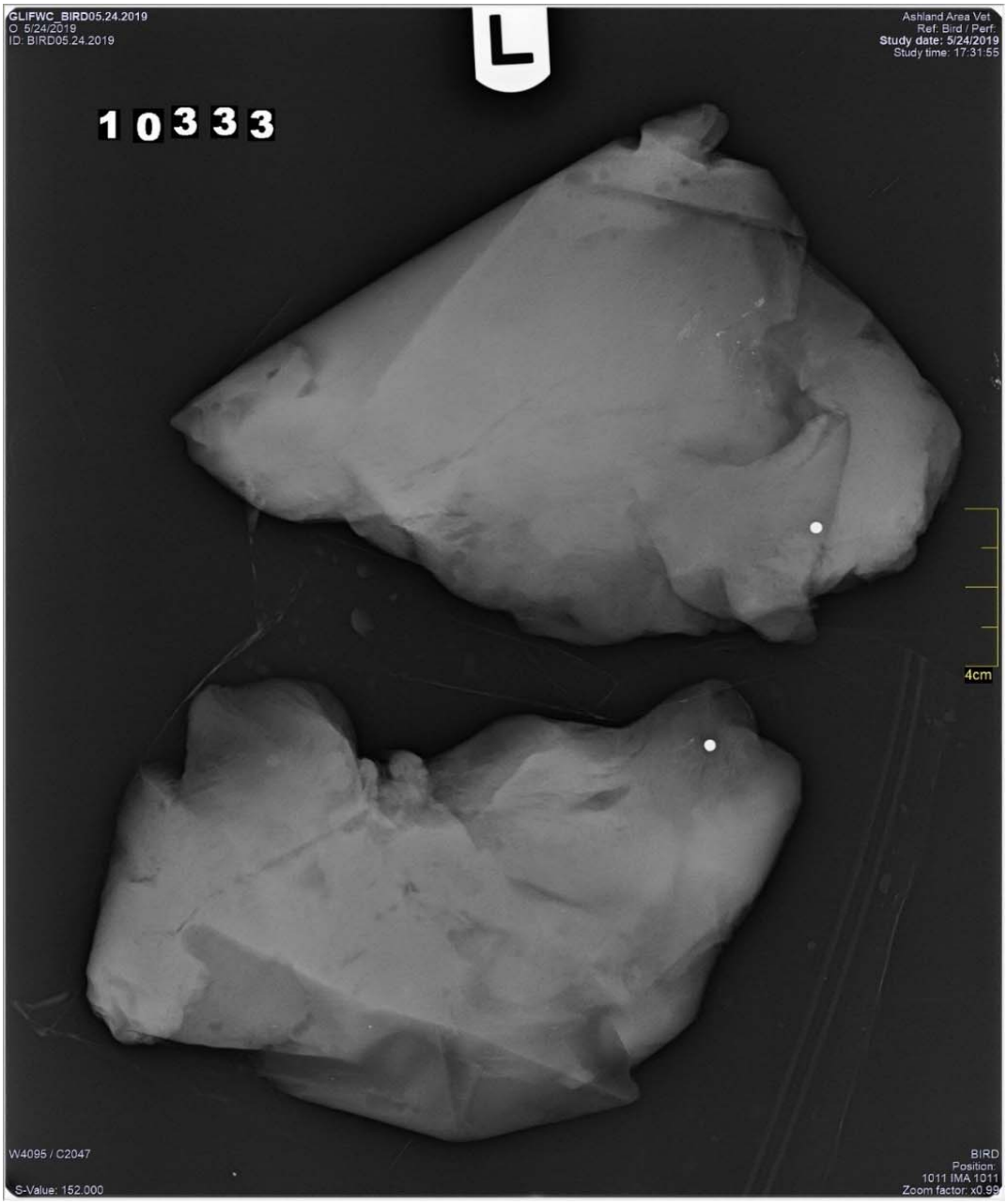

Figure 3. X-Ray radiograph image of a pair of wild turkey breast (pectoral muscle) samples showing hard metal objects embedded (white dots).

Shot pellets or larger fragments not initially observed at breast dissection were later removed utilizing radiographic images provided by AAVC. Once all conspicuous pellets and/or fragments were removed from the birds, the metallic pieces were tested for magnetism. Lead shot, bismuth-alloy, and some tungsten-matrix shot are nonmagnetic; steel and tungsten-polymer with iron in the shot possess magnetic qualities (Mann et al. 1994). Bird remains were always properly disposed of in a culturally-sensitive manner in accordance with Ojibwe customs, with certain salvageable parts saved for ceremonial purposes for tribal members upon request.

Shot Pellet/fragment Lead analysis

Shot and/or large fragments recovered from several turkey breast samples were analyzed to determine if the pellet was primarily lead or made of other metals. These metallic pieces were weighed, placed into a digestion vessel, with an addition of 3 mL of nitric acid, and then heated in a HotBlock® at 95 ± 5°C for 15 minutes. Samples were cooled and diluted to 50 mL of deionized water. Since not all of the samples were digested, remaining solid material was recovered, dried, and weighed. LSRI used the flame option on their Atomic Absorption Spectrometry (AAS) instrument for lead analysis. Lead percentages in the portions of the metal dissolved during digestions of pellets were calculated.

Quality Assurance and Quality Control (QA/QC)

Specific level of detection[5] (LOD) and level of quantitation[6] (LOQ) values were determined for each metal analyzed at LSRI, Pace, and BAL laboratories (Table 2).

Detection limits for Hg, Zn, Cu, and Mg are established annually at LSRI, with samples of each metal in particular matrices analyzed on a quarterly basis for calculation and/or adjustment. Detection limits for Pb, Cd, total Cr, and Se were determined by Pace, and utilized criteria they deemed as acceptable. BAL specializes in arsenic speciation analysis and has calculated their own detection limits for total and inorganic arsenic using proprietary methods. All analytes were measured as total of each metal except arsenic where inorganic was separated from total arsenic.

[5] Limit of detection (LOD) is the lowest level or amount of an analyte (analyte is the target chemical or element being measure i.e. mercury) which can reliably and feasibly be detected by the instrument used for measuring.
[6] Level of quantitation is a calculated value which factors in known and predefined bias or imprecision within the instrument used for measuring. LOQ represents the lowest reliable measurable concentration with known imprecision factored in.

Table 2. LOD and LOQ values for the ten analytes of interest and the analytical instrument used for analysis. LSRI used two Atomic Absorption Spectrometry (AAS) options: cold-vapor for Hg and flame for the other metals analyzed. Pace utilized Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) for analyses. BAL used inductively coupled plasma collision reaction cell mass spectrometry (ICP-CRC-MS).

Analyte	**LOD values*** **(mg/kg or ppm)**	**LOQ values**** **(mg/kg or ppm)**	**Analytical Instrument**	**Analytical laboratory**
Zn	0.600	2.000	Flame AAS	LSRI; UW-Superior, WI
Mg	0.467	1.567		
Cu	0.433	1.443		
Hg	0.015	0.050	Cold-Vapor AAS	
Cd	0.014	0.047	ICP-MS	Pace Analytical Services; Green Bay, WI
Se	0.049	0.163		
Cr	0.088	0.293		
Pb	0.026	0.087		
Total As	0.003	0.011	ICP-CRC-MS	Brooks Analytical Labs, Bothell, WA
Inorganic As	0.004	0.012		

* As, Cd, Cr, Pb, and Se biota detection limits are based on 1 g tissue. Cu, Mg, and Zn biota detection limits are based on 3 g tissue. Hg biota detection limit is based on 0.232 g tissue.
** LOQ values are calculated as 10/3 of LOD.

During analyses at each laboratory, blanks, spikes, duplicates, as well as standard reference materials (SRM) from the National Institute of Standards & Technology (NIST) and/or the National Research Council of Canada (NRC-C), were utilized to ensure unbiased and accurate measurements. Where possible, an SRM was chosen that was of similar tissue make up to the samples being analyzed (i.e. rice flour and apple leaves are plant tissue and were analyzed concurrently with the wild rice). The NIST SRM, 1568b (rice flour) possessed certified concentrations for Cd, Zn, Mg, Cu, and Se, and was used at all three labs in conjunction with analysis of wild rice.

BAL analyzed blank spikes, matrix spikes, and duplicate spikes for each sample series. They also used As (III) and As (V) in separate matrix spike runs. Rice flour (NIST 1568b TM/SP) was also analyzed by BAL as a standard reference material. BAL only analyzed wild and commercial rice for total As, inorganic arsenic, monomethylarsonic acid (MMAs), and dimethylarsinic acid (DMAs).

Additionally, NIST SRM 1515 (apple leaves) and TORT-3 (lobster hepatopancreas) from NRC-C were used at Pace. TORT-3, a SRM routinely used at Pace, possessed certified concentrations for

Pb, Cd, Cr, and Se. The SRM used at LSRI for total Hg testing included DORM-4 (dogfish shark tissue) from NRC-C, as it had an appropriate certified concentration for that particular element.

Spikes, duplicates, and SRMs were evaluated during each analytical run for each metal analyzed at Pace and LSRI. Ten percent of the samples were analyzed in duplicate and ten percent of the samples were spiked with known concentrations. One reagent blank was run per digestion set for testing of the metals (other than mercury) analyzed by LSRI and Pace.

Analysis of Cu, Mg, Total Hg, and Zn

At LSRI a 3 g portion of ground sample was digested in nitric acid and 30% hydrogen peroxide, diluted to a 100 mL volume, and heated in a HotBlock®. The digested sample was filtered prior to analysis. Individually, Cu, Mg, and Zn analyses were performed using the flame option on a Perkin Elmer PinAAcle 900T AAS .

Mercury was analyzed for total Hg using 0.2 – 0.3 g of homogenized tissue samples digested with concentrated sulfuric and nitric acids in a HotBlock®. Potassium permanganate and potassium persulfate were used to convert organic mercury to inorganic mercury and stannous chloride converted inorganic mercury to elemental mercury which is analyzed by cold vapor AAS (Lobring and Potter 1991).

Analysis of Pb, Cd, Cr and Se

A slightly different digestion procedure was used at Pace than that used by LSRI. A 1 g portion of ground sample was digested in nitric acid with subsequent additions of hydrochloric acid and hydrogen peroxide, diluted to a 50 mL volume with reagent water, and heated in a HotBlock®. The digested sample was filtered prior to analysis. Pb, Cd, and Cr were analyzed as a multi-elemental suite utilizing ICP-MS.

Analyses of Total Arsenic and Arsenic Species

BAL digested the wild rice and commercial rice samples in a HotBlock® using known mass of tissue placed into a microwave digestion vessel and then aliquots of concentrated hydrogen peroxide and nitric acid were added to the samples. All samples at BAL were digested in sealed vessels at elevated temperature and pressure. BAL analyzed only wild and commercial rice samples for total arsenic, inorganic arsenic, dimethylarsinic acid (DMAs), and monomethylarsenic acid (MMAs).

The digestion method involves converting the As(V) to As(III) in the samples themselves, as well as the matrix spike samples. Inorganic arsenic was reported as the sum of As(III) and As(V). After digestion, the arsenic speciation analysis was performed using an Ion Chromatography (IC) ICP-MS. The ICP-MS used in that analysis was also equipped with an interference removal technology, collision reaction cell, to ensure data accuracy by reduction of polyatomic interferences and high sensitivity of results (BAL 2019a).

Arsenic is an element prone to polyatomic interferences (BAL 2019a). Polyatomic interferences are triggered by polyatomic ions formed from precursors with numerous sources, e.g., the sample

matrix, preparation reagents, and plasma gases (May & Wiedmeyer 1998). Thus, advanced interference removal technology was employed during total As analysis. The samples were analyzed on a triple quadrupole-equipped ICP-MS (BAL 2019a). Each sample for arsenic speciation and quantitation was extracted on a HotBlock® with an aliquot of trifluoroacetic acid (TFA) solution. Arsenic species were chromatographically separated on an ion exchange column and then quantified using inductively coupled plasma collision reaction cell mass spectrometry (ICP-CRCMS). Two sets of laboratory control samples and matrix spikes were prepared during arsenic speciation extraction to monitor for any potential interference.

Data analysis

All metal concentrations from LSRI and Pace Lab were expressed on a wet-weight (w.w.) basis upon reporting to GLIFWC, and later converted to dry weight for comparison to BAL concentrations which were reported as dry weight results. The conversion formula used was $C_d = (C_w / P_s) \times 100$, where C_d represents dry weight concentration, C_w is the wet weight concentration, and P_s is percent solids. Percent solids, or P_s was calculated for each analyte analyzed by Pace and LSRI by subtracting the percent moisture from 100.

A simple substitution method was utilized for values that were below either the LOD or LOQ values when calculating summary statistics. Where values were below the LOD value for each particular metal analyzed, a value of zero was used in its place. When values were below the LOQ value for each particular metal analyzed, the substituted value used was that element's LOQ value divided by the square root of two. Division of the LOQ values by the square root of two (1.414) reduced the LOQ values by 29.3%.

Total and inorganic arsenic, as well as copper, were calculated using the simple substitution method. Only one sample analysis for each of these analytes resulted in a value less than the LOD. Pace originally analyzed the rice samples for total arsenic and measured values above the LOQ in four samples. As a result, the samples were sent to BAL for the more sensitive analytical measurements reported for total arsenic. BAL also analyzed for the analytes of organic arsenic, monomethylarsoinic acid and dimethylarsinic acid. The analysis of total arsenic by Pace was not used although in general agreement with the BAL results.

All values for magnesium and zinc were above LOQ values, so no substituted values were necessary to assess summary statistics for those elements. However, due to measured values of <LOD, descriptive statistics were unable to be generated for Pb, Cd, total Hg, total Cr, and Se for wild rice.

RESULTS

Moisture analysis

Wild rice moisture analysis results

Ten of the finished wild rice seed samples were analyzed for moisture content. Moisture analysis occurred immediately following rice homogenization at LSRI. Moisture values ranged from 6.1 to 11.7%, with a mean value of 7.8 ± 1.8 % moisture. The data obtained by drying and weighing

the samples twice indicates that drying for 24 hours remained sufficient in removing moisture from the samples. Eleven cooked wild rice samples were measured for moisture content. Mean and standard deviation of moisture content in cooked rice was 59.2 ± 7.3 %. The relative percent difference for the three samples measured in duplicate ranged from 0.2 to 0.7% (Polkinghorne et al. 2019a).

Maple syrup moisture analysis results

Maple syrup samples obtained from tribal harvesters had moisture values that ranged from 24.4 to 52.5% with a mean value of 32.5 ± 7.0 % moisture. Commercial obtained maple syrup samples had measured moisture of 27.3 ± 3.3 % moisture. Higher variability found in the tribal samples likely reflects the culinary preferences of the processors and/or intended recipients of the syrup (Table 5). The moisture value for the single maple sugar sample was 0.7%.

Wild turkey moisture analysis results

Percent moisture was measured in 16 wild turkey breast samples. Moisture values ranged from 69.0 to 73.4% with a mean value of 71.0 ± 1.1%. Moisture analysis took place immediately following homogenization of the turkey breasts. The data obtained by drying and weighing the samples twice indicates that drying for 24 hours is sufficient to remove the moisture from the samples. Two of the samples were analyzed in duplicate, yielding relative percent differences of 0.4 and 0.5%.

Metals Measured in Wild and Commercial Wild Rice

Copper, magnesium, and zinc are elements essential to plant growth and, consequently, were the most abundant metals quantified in processed wild rice seeds. Copper in finished wild rice ranged from 1.013 to 5.683 mg/kg d.w. with mean and standard deviation values of 2.299 ± 1.520 mg/kg d.w. in the 37 samples measured (Table 3). Magnesium in wild rice ranged from 712.6 to 1108.7 mg/kg d.w. with a mean of 923.5 ± 97.4 mg/kg d.w. Zinc values ranged from 18.98 to 70.72 mg/kg d.w. with a mean of 34.98 ± 3.30 mg/kg d.w. A Totagatic Lake (WI) sample possessed the highest zinc concentration.

Total mercury had two values greater than the LOQ of 0.050 mg/kg and they ranged from 0.061 to 0.064 mg/kg d.w., there were three samples with total mercury concentration greater than the LOD of 0.015 mg/kg but less than the LOQ. The remaining 31 samples had total mercury values less than the LOD.

Only three samples of commercial wild rice seeds were analyzed and they had higher concentrations of copper (mean of 4.013 ± 3.159 mg/kg d.w.), magnesium (1009.2 ± 14.57 mg/kg d.w.), and zinc (55.04 ± 2.53 mg/kg d.w.) than wild rice. All three samples of commercial wild rice had total mercury concentrations less than the LOQ of 0.050 mg/kg.

Pace analyzed the 40 samples of wild rice and commercial wild rice seeds for lead (Table 3), cadmium, chromium, and selenium (Table 4). Lead in wild rice seeds had two measured concentrations (0.063, 0.26) above the LOD of 0.026 mg/kg. Of the two samples, one sample was

less than the LOQ of 0.087 mg/kg and other sample had a lead concentration value of 0.26 mg/kg d.w. The remainder of the samples were less than the LOD. The lead sample with the highest lead concentration (Table 3) was collected from the Bad River Sloughs (sample 3A). A second sample was collected from Bad River Sloughs (sample 20A) and the lead concentration measured in that sample was less than the LOD. All commercial wild rice samples had lead concentrations less than the LOD.

Cadmium in wild rice seeds had three measured concentrations (0.021, 0.024, 0.079 mg/kg w.w.) greater than the LOD of 0.014 mg/kg and the remainder were less than the LOD (Table 4). Commercial wild rice seeds had cadmium concentrations measured above the LOD but less than the LOQ of 0.047 mg/kg in all three samples.

Chromium had two measured values for wild rice (0.094, 0.120 mg/kg w.w.) above the LOD of 0.088 mg/kg but less than the LOQ of 0.293 mg/kg (Table 4). Commercial wild rice had all chromium values below the LOD of 0.088 mg/kg. Of valence states of chromium compounds, hexavalent chromium, or Cr(VI), most negatively impacts human health (NIH 2018). The proportion of hexavalent chromium from total chromium in wild rice was not measured.

Selenium in wild rice seeds was not measured at concentrations above the LOD of 0.049 mg/kg in any of the 41 samples of wild and commercial rice (Table 4).

Pace also measured total arsenic in the wild and commercial rice samples (Table 4) and in general had good agreement with the BAL results (Table 3) for total arsenic concentrations. The wild and commercial rice samples prepared at LSRI were shipped to BAL for speciation of arsenic and the resulting concentrations of each arsenic analyte.

BAL measured arsenic as total, inorganic, dimethylarsenic acid (DMAs) and monomethylarsonic acid (MMAs) in the wild and commercial rice samples. DMAs had five measured values above the Method Detection Limit (MDL_1) of 0.005 mg/kg and the remainder were below the Method Reporting Limit (MRL_1) of 0.011 mg/kg. All measured values for MMAs were below the MDL of 0.005 mg/kg d.w. Inorganic arsenic was the major analyte in samples with measured concentrations above the MRL_1 of 0.012 mg/kg and represented 66.3 % of the arsenic measure in wild rice (Table 3). Inorganic arsenic represented all (101.7 %) the arsenic in commercial rice samples. Total arsenic in the 17 wild rice samples with measured concentrations above the LOQ ranged from 0.023 to 0.108 mg/kg d.w. with a mean of 0.047 ± 0.026 mg/kg d.w. Commercial rice samples had higher total arsenic concentrations than wild rice. The mean concentration in commercial rice was 0.114 ± 0.057 mg/kg d.w.

Table 3. Measured, wild rice elemental concentrations (dry weight) with water body source of sample.

Sample Number	Source Water Body Location	LSRI				Pace	BAL		
		Cu (mg/kg)	Mg (mg/kg)	Zn (mg/kg)	Total Hg (mg/kg)	Pb (mg/kg)	InOrg As (mg/kg)	Total As (mg/kg)	% of InOrg As of Total As
1A	Unknown	1.013*	992.4	32.65	<0.015**	<0.026**	0.038	0.064	59.8
2A	Mixed Source (WI)	1.013	1039.1	43.53	<0.015	<0.026	0.008*	0.008*	
3A	Bad River Sloughs (WI)	1.013	1031.5	28.09	<0.015	0.260	0.021	0.030	69.5
4A	Mixed Source (WI)	2.397	995.7	32.65	<0.015	<0.026	0.024	0.037	64.5
5A	Long Lake (WI)	1.608	974.4	33.65	<0.015	<0.026	0.008	0.008	
6A	Chippewa Lake (WI)	1.013	904.6	36.66	<0.015	<0.026	0.008	0.008	
7A	North Fork Flowage (WI)	2.028	968.5	40.13	<0.015	<0.026	0.038	0.055	68.8
8A	Phantom Lake Flowage (WI)	1.013	930.8	46.75	<0.015	<0.026	0.075	0.105	71.4
9A	Pacwawong Lake (WI)	2.798	984.8	31.89	<0.015	<0.026	0.008	0.008	
10A	Upper Rice Lake (MN)	2.061	1052.1	53.04	<0.015	<0.026	0.023	0.046	50.4
11A	Lake Minnewawa (MN)	1.013	938.2	27.66	<0.015	<0.026	0.016	0.027	59.5
12A	Mallard Lake (MN)	1.013	892.6	35.90	<0.015	<0.026	0.019	0.035	54.4
13A	Rice Lake (WI)	4.698	827.7	31.61	<0.015	<0.026	0.008	0.008	
14A	Totagitic Lake (WI)	1.822	836.2	70.72	<0.015	<0.026	0.008	0.008	
15A	Chippewa Lake (WI)	1.013	798.3	36.88	<0.015	<0.026	0.008	0.008	
16A	Totagitic Lake (WI)	3.415	869.6	40.30	<0.015	0.062	0.016	0.008	
17A	Ontonagon River (MI)	3.872	901.3	38.40	<0.015	<0.026	0.058	0.066	88
18A	Lee Lake (WI)	1.013	954.4	43.82	<0.015	<0.026	0.008	0.023	51.5
19A	Chippewa Lake (WI)	1.013	770.1	39.15	<0.015	<0.026	0.008	0.008	
20A	Bad River Sloughs (WI)	1.013	879.6	23.43	<0.015	<0.026	0.030	0.038	79.8

21A	Unknown	1.013	937.1	42.73	<0.015	<0.026	<0.004**	0.008	
22A	Unknown	1.013	953.4	18.98	<0.015	<0.026	0.021	0.025	85
23A	Unknown	1.013	772.2	43.71	<0.015	<0.026	0.008	0.008	
24A	Rice Lake (WI)	3.279	770.2	26.14	<0.015	<0.026	0.008	0.008	
25A	Rice Lake (WI)	2.657	805.9	32.10	<0.015	<0.026	0.017	0.028	59.9
26A	Totagitic Lake (WI)	5.456	874.2	52.93	<0.015	<0.026	0.008	0.008	
27A	Unknown	1.013	811.3	42.95	<0.015	<0.026	0.017	0.027	62.7
28A	CutAway Dam (WI)	3.330	972.3	33.52	<0.015	<0.026	0.017	0.008	
29A	Rice Lake (WI)	1.714	972.9	26.57	<0.015	<0.026	0.008	0.008	
30A	Brule River (MI)	3.364	1108.7	36.47	<0.015	<0.026	0.008	0.008	
31A	Rice Lake (WI)	5.683	712.6	33.62	0.035*	<0.026	0.008	0.008	
32A	unknown (MI)	4.913	826.5	43.38	0.061	<0.026	0.040	0.050	79.8
33A	Chippewa Lake (WI)	1.013	894.2	36.64	0.064	<0.026	0.008	0.008	
34A	Little Rice Lake (WI)	1.013	764.3	36.60	<0.015	<0.026	<0.004	0.008	
35A	Little Turtle Flowage (WI)	5.152	921.9	34.71	0.035	<0.026	0.021	0.028	75.3
40A	Deadfish Lake (MN)	3.796	1084.6	39.05	0.035	<0.026	0.050	0.108	46.3
41A	Unknown	3.796	854.7	37.31	0.035	<0.026	0.008	0.008	
	Mean	2.299	923.5	34.98	0.007***	0.009***	0.018	0.026	66.3
	Std. Dev.	1.520	97.4	3.30	0.017	0.045	0.016	0.026	12.4
Commercial Grown Wild Rice									
36A	Unknown (MN)	6.247	1019.5	53.25	0.035	<0.026	0.164	0.177	92.7
37A	Unknown (MN)	5.434	1022.8	59.54	0.035	<0.026	0.093	0.099	93.8
38A	Unknown (MN)	1.779	998.9	56.83	0.035	<0.026	0.144	0.066	*118.5***
	Mean	4.013	1009.2	55.04	0.035	<0.026	0.134	0.114	101.7
	Std. Dev.	3.159	14.6	2.53	0	0	0.037	0.057	14.6

* Value used when LOQ was reported (LOQ / square root of 2).
** Value used when LOD was reported (0 was used when calculating statistics).
*** Values were less than LOD values due to the use of 0 in place of the LOD.
**** Value is acceptable when the relative percent difference (RPD) is <20%.

Table 4. Concentrations (mg/kg) of four metals (wet weight) in wild and commercial rice seeds measured by Pace.

Wild Rice				
Sample ID	Cd	Cr	Se	As (Total)
1A	<0.014	<0.087	<0.050	0.071
2A	<0.013	<0.081	<0.046	<0.028
3A	<0.014	<0.087	<0.050	<0.030
4A	0.024	<0.088	<0.100	0.080
5A	<0.013	<0.080	<0.046	<0.027
6A	<0.014	<0.086	<0.049	<0.029
7A	<0.014	<0.087	<0.050	<0.056
8A	<0.013	<0.080	<0.046	0.093
9A	<0.014	<0.088	<0.051	<0.030
10A	<0.013	<0.079	<0.045	0.041
11A	<0.014	<0.088	<0.051	0.034
12A	<0.014	<0.086	<0.049	0.048
13A	<0.013	<0.082	<0.047	<0.028
14A	<0.014	<0.086	<0.049	<0.029
15A	<0.014	<0.088	<0.050	<0.030
16A	0.021	<0.079	<0.045	0.042
17A	<0.010	0.120	<0.047	0.078
18A	<0.011	<0.085	<0.049	<0.029
19A	<0.010	<0.081	<0.047	<0.028
20A	<0.010	<0.079	<0.045	0.033
21A	<0.010	<0.084	<0.048	<0.029
22A	<0.011	<0.088	<0.050	0.034
23A	<0.011	<0.086	<0.049	<0.029
24A	<0.011	<0.086	<0.049	<0.029
25A	<0.010	<0.080	<0.046	0.036
26A	0.079	<0.088	<0.051	0.130
27A	<0.010	0.094	<0.048	0.039
28A	<0.010	<0.083	<0.047	<0.028
29A	<0.010	<0.080	<0.046	<0.027
30A	<0.010	<0.082	<0.047	<0.028

31A	<0.014	<0.088	<0.051	<0.030
32A	<0.013	<0.084	<0.048	0.047
33A	<0.014	<0.085	<0.049	<0.029
34A	<0.014	<0.087	<0.050	<0.030
35A	<0.014	<0.088	<0.050	0.071
40A	<0.014	<0.086	<0.049	0.056
41A	<0.013	<0.082	<0.047	<0.028
Commercial Rice				
36A	0.040	<0.084	<0.048	0.180
37A	0.031	<0.083	<0.048	0.097
38A	0.033	<0.083	<0.046	0.120

Lead measured in maple syrup and maple sugar

Lead concentrations were measured in 29 samples of maple syrup harvested by tribal members in the ceded territories (Table 5). Only one sample had a lead concentration measured above the LOQ of 0.087 mg/kg. The lead concentration in the sample was 0.27 mg/kg and the harvester identified the equipment used as "old" or "inherited" metal equipment. The single maple sugar sample had a lead concentration less than the LOD of 0.026 mg/kg. Commercial maple syrup samples were analyzed for lead content but none had lead concentrations measured above the LOD (Polkinghorne et al. 2019b).

Table 5. Lead concentrations and moisture content in maple syrup and maple sugar. Sample number, harvest year, state and county of harvest, and the equipment used by harvester or processor. LOD and LOQ values for lead were 0.026 mg/kg and 0.087 mg/kg, respectively.

Sample #	Year of Harvest	State	County	Pb Levels (mg/kg d.w.)	Moisture Content (%)	Usage of Old and/or Inherited Metal Equipment
5A	2018	WI	Bayfield	<0.026*	29.8	No
7A	2019	WI	Bayfield	<0.026	31.9	No
8A	2019	WI	Bayfield	<0.026	29	No
13A	2019	WI	Bayfield	<0.026	37.2	No
24A	2019	WI	Bayfield	<0.062**	26.4	Yes
6A	2019	WI	Sawyer	<0.026	28.4	No
12A	2019	WI	Bayfield	<0.026	45.65	No
14A	2019	WI	Sawyer	<0.026	27.1	Yes
15A	2019	WI	Sawyer	<0.026	32.9	No
33A	2019	WI	–	<0.026	24.6	–
9A	2019	WI	Burnett	0.27	28.9	Yes

10A	2019	WI	Ashland	0.062**	52.5	Yes
11A	2019	WI	Ashland	<0.026	31.9	Yes
16A	2019	WI	Ashland	<0.026	27.2	Yes
20A	—		—	<0.026	26.9	—
34A	2019	WI	Ashland	<0.026	40.3	No
17A	2019	MN	Carlton	<0.026	37.3	No
18A	2019	MN	Carlton	<0.026	30.9	No
19A	2019	Iron	WI	<0.026	31.7	No
27A	2018	Vilas	WI	<0.026	42.2	No
28A	2019	Vilas	WI	<0.026	24.4	Yes
21A	2019	WI	WI	<0.026	27.8	No
22A	2019	WI	WI	<0.026	34	No
32A	2019	WI	WI	<0.026	28.2	Yes
25A	2019	MI	Baraga	<0.026	29.1	No
25C***	2019	MI	Baraga	<0.026	0.7	No
26A	2019	MI	Baraga	<0.026	27.1	No
29A	2019	MN	Mille Lacs	<0.026	36.3	Yes
30A	2019	MN	Mille Lacs	<0.026	46	Yes
31A	2019	MI	Chippewa	0.062**	27.4	No
Commercial Maple Syrup						
1A	—	—	WI	<0.026	22.5	—
2A	—	—	MI	<0.026	28.5	—
4A	—	—	WI	<0.026	28.6	—
23A	2019	—	WI	<0.026	29.7	—

— indicates missing and/or unknown information.
* LOD value.
** LOQ value.
*** Sample 25C is a corresponding sugar sample with 25A.

<u>Lead concentrations measured in wild turkey breasts</u>

Sixty wild turkey breast samples from 30 birds were analyzed for lead concentrations. Only twelve of the breasts had lead concentrations measured above the LOD of 0.026 mg/kg. Ten of the breasts had concentrations between the LOD and LOQ of 0.087 mg/kg. Two breasts had high lead concentrations of 15.9 and 16.2 mg/kg d.w. Wild turkey sample number 10394 had been shot with a high power rifle using a single bullet and did not have a lead concentration above the LOD. Ten breast samples had pellets or metal fragments found in the tissue. Five of the breasts containing metal pellets

or fragments did not have lead concentrations measured above the LOD indicating that all pellets were removed or did not contain lead. Six breast samples had measured lead concentrations without detected pellets or fragments.

A small percentage (8.3 %) of total breast samples that did not have pellets/fragments detected had measured lead values above the LOD value of 0.026 mg/kg d.w. It is possible that x-ray analysis did not identify microscopic fragmentation too small for observation. Wild turkeys are omnivorous, but primarily eat vegetation and are, therefore, unlikely to ingest lead in their diets.

Table 6. Lead concentrations in wild turkey breast samples grouped by size of shot used for harvest with sample identification number, county and state of harvest, total length of bird, and shotgun used with shot size of ammunition.

Sample Number w/turkey breast side (left/right)	County of Harvest	State of Harvest	Bird* Length (in.)	Gun	Shot Size	Shot Type	# of shot fragments noted & shot/bullet fragmentation notes	Lead Concentrations (mg/kg d.w.)
Samples harvested with copper plated lead shot								
10334L	Burnett	WI	32	20 gauge	5 shot	copper plated lead	0	<0.026
10334R	Burnett	WI	32	20 gauge	5 shot	copper plated lead	0	<0.026
10398L	Burnett	WI	30	20 gauge	5 shot	copper plated lead	0	<0.026
10398R	Burnett	WI	30	20 gauge	5 shot	copper plated lead	0	<0.026
10399L	Ashland	WI	26	20 gauge	5 shot	copper plated lead	0	<0.026
10399R	Ashland	WI	26	20 gauge	5 shot	copper plated lead	0	<0.026
10400L	Ashland	WI	31	Unknown	5 shot	copper plated lead	0	<0.026

10400R	Ashland	WI	31	Unknown	5 shot	copper plated lead	0	<0.026
Lead Level by reported shot size								
223 Caliber								
10394L**	Ashland	WI	---	223 rifle	Unknown	Unknown	1 lg. gray fragment and small fragments	<0.026
10394R**	Ashland	WI	---	223 rifle	Unknown	Unknown	small microscopic fragments	<0.026
00 Buck								
10336L	Ontonagon	MI	33	12 gauge	00 Buck	Unknown	0	<0.026
10336R	Ontonagon	MI	33	12 gauge	00 Buck	Unknown	0	<0.026
10337L	Ontonagon	MI	32	12 gauge	00 Buck	Unknown	1 large pellet found (nonmagnetic & gray)	<0.026
10337R	Ontonagon	MI	32	12 gauge	00 Buck	Unknown	0	0.100
#4 shot								
10388L	Iron	MI	34	12 gauge	4 shot	Unknown	0	<0.026
10388R	Iron	MI	34	12 gauge	4 shot	Unknown	0	<0.026
10389L	Iron	MI	32	12 gauge	4 shot	Unknown	0	<0.026
10389R	Iron	MI	32	12 gauge	4 shot	Unknown	0	<0.026
#5 shot								
10338L	Gogebic	MI	34	12 gauge	5 shot	Unknown	0	<0.026
10338R	Gogebic	MI	34	12 gauge	5 shot	Unknown	0	<0.026
10339L	Gogebic	MI	29	12 gauge	5 shot	Unknown	0	<0.026
10339R	Gogebic	MI	29	12 gauge	5 shot	Unknown	0	<0.026
10340L	Gogebic	MI	33	12 gauge	5 shot	Unknown	0	<0.026
10340R	Gogebic	MI	33	12 gauge	5 shot	Unknown	0	<0.026
10341L	Gogebic	MI	35	12 gauge	5 shot	Unknown	1 small fragment found	<0.026
10341R	Gogebic	MI	35	12 gauge	5 shot	Unknown	0	<0.026

10342L	Gogebic	MI	31	12 gauge	5 shot	Unknown	0	<0.026
10342R	Gogebic	MI	31	12 gauge	5 shot	Unknown	0	<0.026
10343L	Gogebic	MI	32	12 gauge	5 shot	Unknown	0	<0.026
10343R	Gogebic	MI	32	12 gauge	5 shot	Unknown	0	<0.026
10387L	Bayfield	WI	36	Unknown	5 shot	Unknown	2 large pellets found (nonmagnetic)	0.110[J]
10387R	Bayfield	WI	36	Unknown	5 shot	Unknown	0	<0.026
10390L	Gogebic	MI	36	Unknown	5 shot	Unknown	microscopic fragmentation found	1.41
10390R	Gogebic	MI	36	Unknown	5 shot	Unknown	0	<0.026
10393L	Gogebic	MI	36	Unknown	5 shot	Unknown	0	<0.026
10393R	Gogebic	MI	36	Unknown	5 shot	Unknown	0	<0.026
10395L	Bayfield	WI	40	Unknown	5 shot	Unknown	0	<0.026
10395R	Bayfield	Wi	40	Unknown	5 shot	Unknown	0	<0.026
#6 shot								
10333L	Ashland	WI	34	20 gauge	6 shot	Unknown	3 large pellets found (all nonmagnetic & gray) and small fragments found	2.83
10333R	Ashland	WI	34	20 gauge	6 shot	Unknown	1 large pellet (nonmagnetic & gray)	0.260[J]
#8 shot								
10344L	Ashland	WI	32	Unknown	8 shot	Unknown	0	0.45
10344R	Ashland	WI	32	Unknown	8 shot	Unknown	0	<0.026
10391L	Ashland	Wi	33	Unknown	8 shot	Unknown	0	<0.026
10391R	Ashland	WI	33	Unknown	8 shot	Unknown	0	<0.026
10392L	Ashland	WI	34	Unknown	8 shot	Unknown	0	1.00
10392R	Ashland	WI	34	Unknown	8 shot	Unknown	0	<0.026
Unknown Shot Size								
10331L	Gogebic	MI	33	Unknown	Unknown	Unknown	microscopic fragments found on x-ray	16.2
10331R	Gogebic	MI	33	Unknown	Unknown	Unknown	0	<0.026

10332L	Gogebic	MI	22	Unknown	Unknown	Unknown	0	0.380
10332R	Gogebic	MI	22	Unknown	Unknown	Unknown	0	0.240[J]
10335L	Vilas	WI	36	Unknown	Unknown	Unknown	0	<0.026
10335R	Vilas	WI	36	Unknown	Unknown	Unknown	0	<0.026
10345L	Ashland	WI	37	12 gauge	Unknown	Unknown	0	<0.026
10345R	Ashland	WI	37	12 gauge	Unknown	Unknown	0	<0.026
10346L	Ashland	WI	37	12 gauge	Unknown	Unknown	0	<0.026
10346R	Ashland	WI	37	12 gauge	Unknown	Unknown	0	<0.026
10396L	Ashland	WI	38	Unknown	Unknown	Unknown	0	<0.026
10396R	Ashland	WI	38	Unknown	Unknown	Unknown	0	<0.026
10397L	Ashland	WI	37	Unknown	Unknown	Unknown	0	15.9
10397R	Ashland	WI	37	Unknown	Unknown	Unknown	2 large fragments	2.38

* Bird length measured from tip of beak to end of tail.
** Killed with a centerfire 223 rifle
[J] Value between the LOD and LOQ

The current study examined birds that were harvested as meat intended for human consumption. This investigation also operated under the assumption that most birds were harvested using lead-containing ammunition, or some combination of metals including lead, due to the lower cost and high commercial availability of lead-based ammunition. According to Winchester Ammunition (2017), the best shot size to use for wild turkey hunting is either No. 4, No. 5, or No. 6 (Fig. 4). All wild turkeys acquired for this study were harvested with a firearm. Unfortunately, archery (bow or crossbow) harvested samples were unable to be obtained from tribal harvesters as a control group. Although turkey hunters typically aim for the bird's head, other factors, such as gun gauge, shot size, metallic composition of ammunition, distance, and shooting skill, all ultimately influence shot placement. Gathering birds from different hunters helped reflect this variability. However, turkey hunting remains either a niche or opportunistic harvest for tribal hunters, so the overall number of hunters obtaining this particular avian species was expected to be relatively low.

From the limited firearms data gathered from Ojibwe harvesters, shot size 5 appeared to be the most common shot size employed, although shot sizes 4, 6, and 8, as well as double-0 buckshot were also reportedly used. Not all firearms information was able to be collected from the hunter. In addition, not all tribal harvesters were able to provide reliable data regarding firearm caliber and/or shot size used. All pellets/fragments were tested for magnetism and all were nonmagnetic, indicating that the shot was composed primarily of either lead, iron, tungsten, or bismuth alloy. Color of pellet/fragments was documented for further inquiry (Mann et al. 1994). An observation was made of the data ranked by shot size (Table 6) that the smaller the shot size there was a tendency for more samples to contain a measurable lead concentration. The speculation is that the x-ray analysis did not identify the smaller shot and it remained in the tissue during lead analysis.

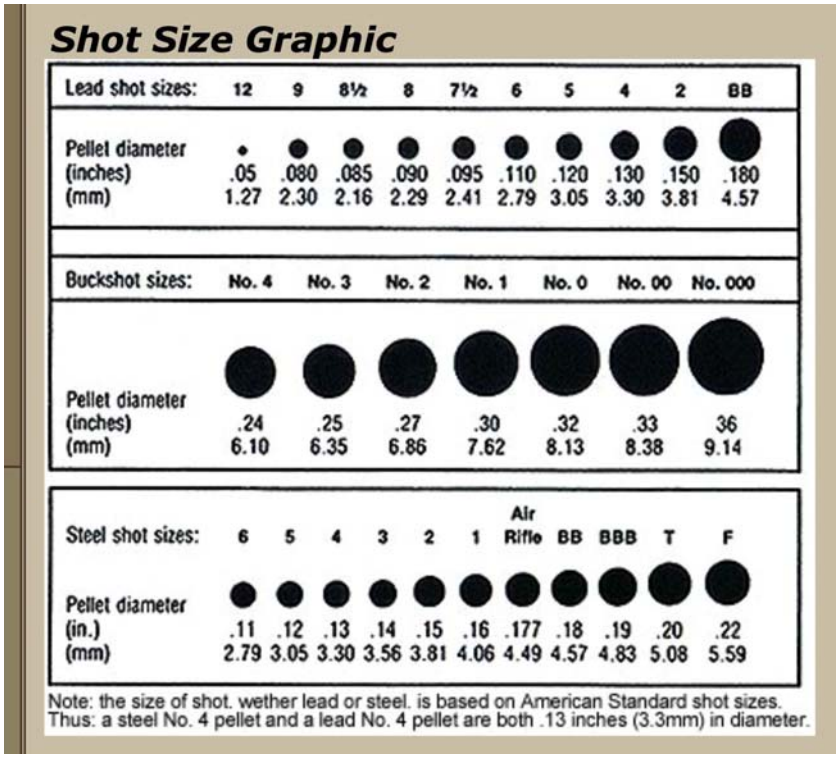

Figure 4. Description of shot size used in shotgun ammunition.

Lead percentages in the shot pellets or fragments that dissolved during digestion ranged from less than 1% to 93%. The greater the lead percentages from the dissolved pellets/fragments after digestion indicate that those samples were predominately composed of lead, not another metal. Furthermore, the possibility remains that pellets collected from some wild turkey breasts came from more than one firearm.

Ten wild turkeys had metal embedded in one or both of their pectoral muscles. Metal from five of the breast samples were analyzed for lead. Two breast samples had two shot pellets analyzed and one had three pellets analyzed for lead concentration. Three other breast samples had single pellets/fragments analyzed. Not all metal in pellets or fragments dissolved during digestion. Remaining metallic material was weighed, and resulting solutions were analyzed by flame AAS for lead content. Lead concentrations in solutions varied widely from <1 to 93 percent of weight (Table 7). Pellet color was also noted for comparison with lead concentrations. Color did not correlate well with lead concentrations. Gray color is the color of lead and the highest lead concentrations were in gray colored pellets/fragments. Copper color was the color of the lowest lead concentration in pellets/fragments. However, four of the gray colored pellets/fragments had intermediate concentrations of lead that matched two of the copper colored pellets/fragments. Turkey number 10394L was harvested with a rifle and the gray colored fragments were likely the lead portion of the projectile. The likelihood is that much of the shot used to kill wild turkeys was not pure lead rather a mixture of metals such as copper, bismuth, tungsten, or iron.

Table 7. Lead analysis of shot pellets found in wild turkey breasts.

Sample ID	Initial Sample Weight (mg)	Final Sample Weight (mg)	Weight of Portion Dissolved (mg)	Pb Conc. in Solution* (mg/L)	Lead Dissolved (mg)	% Lead in Portion of Shot That Dissolved	Qualitative Pellet / Fragment Color
10333L-1	124	45	79	1450	72.5	92	Gray
10333L-2	133	61	72	590	29.5	41	Gray
10333L-3	128	50	78	720	36	46	Gray
10333R	124	54	70	460	23	33	Gray
10337L	227	122	105	720	36	34	Gray
10387L-1	150	70	80	580	29	36	Copper
10387L-2	158	91	67	430	21.5	32	Copper
10394L	67	14	53	990	49.5	93	Gray
10397R-1	21	0	21	0.2	0.01	<1	Copper
10397R-2	11	0	11	7.7	0.39	4	Copper

* Solution was 20 mL in volume; therefore the concentration was divided by 20 to achieve the dissolved lead concentration.

Discussion

GLIFWC has undertaken this project to comply with the FDA food safety requirements that incorporate Hazard Analysis and Critical Control Point (HACCP) to determine if certain tribal wild harvested foods are safe for child nutrition under the National School Lunch Program (NSLP) and sale of these foods to the public. HACCP guidance is concerned with points during food acquisition and processing that identify potential biological, chemical and physical risks that may contribute to unsafe food.

National and International Health Standards

The United States Food & Drug Administration (U.S. FDA), and other health organizations worldwide, have established Maximum Residue Limit (MRL_2) to halt the flow of excessively contaminated foods from entering the human food chain. According to Australia's Agriculture Victoria (2019), a MRL_2 is "the maximum concentration of a chemical residue that is legally permitted to be present in food…" Any concentration above a MRL_2 is deemed unacceptable by the responsible regulatory agency. The use of a Canadian MRL_2 are utilized in this document, where a U.S. MRL_2 is not available, as they are considered comparable to U.S. standards. Also, commerce occurs regularly between these countries.

The U.S. Environmental Protection Agency (U.S. EPA) established health standards in foods, and other modes of ingestion exposure, as oral Reference Doses (RfD) to protect human health. A

RfD, according to the U.S. EPA (2018), is "an estimate … of a daily oral exposure to the human population (including sensitive subgroups) … likely to be without an appreciable risk of deleterious effects during a lifetime." The RfD is useful in gauging potential toxicity of foods (among other routes of intake) from chemicals, heavy metals, and other elements, as in the case of cooked wild rice (U.S. EPA 2005; 1991).

Table 8: MRL_2 values from various health organizations for rice, rice products and maple syrup.

Arsenic (Inorganic)*	
United States	
0.1 ppm	Infant rice cereal (draft guidance)
European Union	
0.1 ppm	Rice destined for the production of food for infants & young children
0.25 ppm	Parboiled & husked rice
0.3 ppm	Rice waffles, rice wafers, rice crackers, & rice cakes
World Health Organization	
0.35 ppm	Hulled rice
Lead	
.011 ppm	Maple syrup State of California labeling standard
.500 ppm	Maple syrup Canadian standard
≥.500 ppm	Maple Syrup is considered adulterated 3715.59 of the Revised Ohio Food Code
European Union	
0.25 ppm	Legumes & pulses (non-rice food staples)
Cadmium	
World Health Organization	
0.4 ppm	Polished rice
Copper	
United States	
10 ppm	Rice (African rice, Nerica hybrids, & Indian/wild rice)
*Total As, Zn, Mg, Cr, and Se do not have comparable MRL_2 values for rice, and are therefore not included in this table. No total Hg MRL_2 exists, but the MRL_2 for methylmercury in rice (*Oryza spp.*) and wild rice is 0.01 ppm. However, no published information exists regarding the proportion of methylmercury from total Hg in wild rice.	

Wild Rice

Arsenic concentration in naturally occurring wild rice is one of the primary concerns of this investigation. Arsenic is an element that occurs in the environment from both natural and man-made sources. Arsenic is not an essential element for plant or human growth. Inorganic arsenic (As III) is considered more toxic to humans than organic arsenic (As V) according to U.S. FDA (2016a). Rice (*Oryza sativa*) and rice-based products tend to have higher levels of inorganic arsenic than do other cereal crops such as wheat and barley. Though wild rice (*Zizania palustris*) is not a true rice but an

aquatic grass, it is commonly served as a rice and little information about the concentration of inorganic arsenic wild rice is available. The U.S. FDA has set action level of 0.1 mg/kg in rice.

Table 9. Comparison of metal concentrations (mg/kg d.w.) in wild rice and processed wild rice from four investigations.

	Cu Mean ± Std. Dev. (n=)	Mg Mean ± Std. Dev. (n=)	Zn Mean ± Std. Dev. (n=)	T. Hg Mean ± Std. Dev. (n=)	Pb Mean ± Std. Dev. (n=)	T. As Mean ± Std. Dev. (n=)	Cd Mean ± Std. Dev. (n=)	Cr Mean ± Std. Dev. (n=)	Se Mean ± Std. Dev. (n=)
Nriagu and Lin 1995 (Processed) seed)	8.7 ±0.32 (26)	--	23.2 ±0.78 (26)	--	0.042 ±2.58 (26)	0.066 ±3.89 (26)	0.053 ±1.48 (26)	–	--
Bennett et al. 2000 (unprocessed seed w/hulls)	5.27 (29)	1175 (44)	43.9 (44)	0.035 (7)	0.96 (32)	0.11 (4)	0.021 (24)	0.49 (3)	0.21 (3)
Brooke et al. 2004* (unprocessed seed)	1.65 ±0.61 (36)	879.4 ±107.7 (36)	22.4 ±5.91 (36)	0.002** ±0.002 (32)	0.063 ±0.033 (36)	<0.054** ±0.004 (36)	<0.163** ±<0.002 (36)	0.403 ±0.124 (36)	<0.058** ±0 (36)
This Study (processed seed-Tribal)	2.30 ±1.52 (37)	923.5 ±97.4 (37)	34.98 ±3.30 (37)	0.007** ±0.017 (37)	0.009** ±0.045 (37)	0.026 ±0.026 (37)	0.003** ±0.014 (37)	0.006** ±0.025 (37)	<0.049** ±0 (37)
This Study (Commercial grown & processed seed)*	4.013 ±3.159 (3)	1009.2 ±14.6 (3)	55.04 ±2.53 (3)	0.035 ±0.017 (3)	<0.026 ±0 (3)	0.114 ±0.057 (3)	0.035 ±0.005 (3)	<0.084** ±0 (3)	<0.048** ±0 (3)

* Value used when LOQ was reported = (LOQ / square root of 2).
** When an LOD was reported, 0 was used when calculating statistics.

In 1997 and 1998, GLIFWC, in cooperation with the University of Wisconsin–Madison, collected whole wild rice plants from northern Wisconsin to measure several heavy metal elements in roots, stems, leaves, and seeds. This study identified the location of these metals within the plants (Bennett et al. 2000). Wild rice roots contained the highest concentrations of arsenic, cadmium, chromium, lead and selenium while rice seeds (included hulls) contained the highest concentrations of copper and zinc. Stems and leaves had concentrations intermediate to the roots and seeds of these elements. Mercury and magnesium were evenly distributed in the plants.

In 2004, GLIFWC collected wild rice plants from eight water bodies near potential metal mining sites. The roots and seeds (included hulls) were removed and analyzed for metals. Samples were collected and processed according to a U.S. EPA-approved quality assurance project plan. The results of that study were reported to the U.S. EPA Region V Environmental Justice Department (Brooke et al., 2004). Both of these GLIFWC affiliated research studies examined unprocessed wild rice seeds, with the encasing hull. They agreed in rank order of concentrations of the nine measured metals; however, the 1998 study reported higher concentrations of each metal. In slight contrast, this current study evaluated elemental concentrations in processed (without hulls and beards) wild rice seeds.

Another study (Nriagu and Lin 1995) of wild rice measured metal concentrations in finished (processed) wild rice and long-grain commercial brown or white rice. The rice samples (n=26) were purchased from retail stores with labeling naming sources as from Minnesota, California, and Saskatchewan, Canada. Some of the samples were pure wild rice and some were mixtures of wild rice and commercial brown and white rice. Concentration of six metals (cadmium, lead, total arsenic copper zinc and iron) were measured.

Inorganic arsenic was an average of 66.7% of the total arsenic in the three paddy wild rice seed samples tested in the U.S. FDA (2013) rice and rice product study. Arsenic has been found in white rice grown in the U.S. (Lamont 2003). In our study, where arsenic was detected in concentrations near or above the LOQ value, the average proportion of inorganic arsenic in total arsenic was calculated at 66.3% in tribal harvested rice and 101.7% in the three commercial wild rice samples (Table 3). This study agrees with the U.S. FDA study that indicates when arsenic is present in wild rice, inorganic arsenic is the most dominant species.

The current study of 37 measured samples of tribal harvested wild rice had a mean and standard deviation of inorganic arsenic of 0.018 ± 0.016 mg/kg d.w. Total arsenic had a mean and standard deviation of 0.026 ± 0.026 mg/kg d.w. in the same study. The earlier studies by Bennett et al. (2000), Brooke et al. (2004), and Nriagu and Lin (1995) found total arsenic seed concentrations of 0.11, 0.054 and 0.066 mg/kg d.w., respectively (Table 8). The U.S. FDA has set a MRL_2 for rice and rice products of 0.10 mg/kg. Australia has determined a limit of 1.0 mg/kg arsenic in cereals.

Table 10. Comparison of tribal and commercial harvested wild rice samples for total and inorganic arsenic content.

Inorganic Arsenic Concentrations (mg/kg d.w.)		
	Tribal Harvested Wild Rice (n=37)	*Commercial Wild Rice (n=3)*
Mean	0.018	0.134
Standard Deviation	0.016	0.037
Maximum	0.075	0.164
Minimum	0.000	0.093
Total Arsenic Concentrations (mg/kg d.w.)		

	Tribal Harvested Wild Rice (n=37)	*Commercial Wild Rice (n=3)*
Mean	0.026	0.144
Standard Deviation	0.026	0.057
Maximum	0.108	0.177
Minimum	0.000	0.066

Mean inorganic arsenic concentrations in tribal wild rice are considerably (87%) lower when compared to mean inorganic arsenic commercial wild rice concentrations (Table 9). The mean total arsenic concentration (0.026 mg/kg d.w.) in tribal wild rice is only 18% of the concentration in commercial rice of 0.144 mg/kg d.w. It must be cautioned that the data for commercial wild rice is derived from only three samples. Ingestion of cooked tribal wild rice or commercial wild rice is not likely to impact human health due to the volume of rice needed to be consumed to exceed safe limits (Table 10).

However, arsenic compounds present in the cooking water, and the acidity of the recipe used when cooking, among other unknown factors, would also likely impact the final arsenic content of cooked wild rice, and subsequent dietary arsenic intake. Additionally, while rinsing and cooking other rice varieties in excess water may potentially lower inorganic arsenic content in wild rice (Raab et al. 2009), this cooking method would likely not be necessary based upon inorganic arsenic results of tribal obtained wild rice.

Table 11. Consumption of wild and commercial harvested rice needed to exceed the adult oral RFD (U.S. EPA 1991; 2005).

Oral Reference Doses (RfD) for Cooked Wild Rice*			
Element	*RfD (mg/kg-day)*	*Consumption/day (lbs.)*	*Consumption/day (oz.)*
Inorganic Arsenic (As) Tribal Harvest	0.0003	4.12	65.8
Inorganic Arsenic (As) Commercial Harvest	0.0003	0.25	4.01
Cadmium (Cd)**	0.001	3.13	50.0
Zinc (Zn)	0.03	0.13	2.12
Magnesium (Mg)	11	1.84	29.41

* Maximum daily consumption was derived using a body weight of 70 kg (~154 lbs.) and a cooked moisture value of 60% for wild rice. Consumption/day = [(RfD mg/kg/day X Body weight kg) / (Mean element concentration mg/kg)] X 1.60 (percent moisture).
** Highest value measured above the LOD of 0.079 mg/kg was used to calculate consumption/day.

Wild rice has been documented to contain lead in unhulled seeds (Pip 1993; Bennett et al. 2000, Brooke et al. 2004) and processed wild rice (Nriagu and Lin 1995). The Bennett et al. (2000) study

found a mean lead concentration in unprocessed wild rice seeds with attached hulls at 0.94 mg/kg d.w. Brooke et. al. (2004) found the mean lead concentration in unhulled wild rice seeds of 0.063 mg/kg d.w., and Nriagu and Lin (1995) measured a mean lead concentration of 0.042 mg/kg d.w. The European Union (E.U.) has set a lead MRL_2 of 0.25 mg/kg for legumes, but does not have one established for rice. The U.S. FDA has not set a lead action limit for either rice or legumes. The U.S. EPA (1988) has not determined a RfD for lead or its inorganic compounds because as a known neurotoxin at extremely low blood levels, particularly in children, it was deemed inappropriate to establish one.

However, the highest lead value from this study is from the Bad River Slough of 0.26 mg/kg d.w. and is between the average lead concentrations in unprocessed wild rice seeds with attached hulls from the two previous northern Wisconsin studies (Bennet et al. 2000, Brooke et.al. 2004). A second sample from the Bad River Slough had no detectable lead concentration indicating possible processing contamination. The only detectable lead value found in this study remained comparable to the E.U.'s legume action limit of 0.25 ppm. However, legumes are not taxonomically related to rice, but provided the only comparable action level from either national or international health organizations. The U.S. EPA (1988) decided it was not appropriate to establish a RfD, so cooked wild rice information could not be calculated for this heavy metal.

Magnesium is an essential element for plant and animal growth (Cakmak 2013) and these results indicate that natural wild rice is also a rich source of dietary magnesium. Bennet et al. (2000) measured a mean concentration in unhulled wild rice seeds of 1152 mg/kg d.w. and Brooke et al. (2004) measured a mean concentration of 879.4 mg/kg d.w. In the current study, magnesium values ranged from 712.58 to 1,108.72 mg/kg d.w. with a mean of 923.5 mg/kg d.w. An adult would have to eat 1.84 lbs. of cooked wild rice per day in order to exceed the magnesium RfD (Table 10).

Copper is another essential element for plant and animal growth. Bennett et al. (2000) found an average copper concentration of 5.27 mg/kg d.w. in unfinished wild rice seeds, Brooke et al. (2004) measured a mean concentration of 1.65 mg/kg d.w. in unfinished wild rice. Copper concentrations in finished tribal wild rice seeds in this study ranged from 1.013 to 5.68 mg/kg d.w. with an average of 2.23 ± 1.52 mg/kg d.w. and Nriagu and Lin (1995) measured copper concentrations at a mean value of 8.7 mg/kg (Table 8). All were below the 10 mg/kg copper action level for rice established by the U.S. FDA. Commercial wild rice in the current study had a 42.7% higher mean copper concentration than tribal harvested wild rice with a mean concentration of 4.0 mg/kg d.w. (Table 3).

Six of the 40 analyzed wild rice samples had cadmium values that were greater than the LOD value of 0.014 mg/kg, but all of those concentrations were less than the LOQ value of 0.047 mg/kg. The cadmium values are comparable (Table 8) to average unhulled wild rice seed findings from northern Wisconsin of 0.021 mg/kg d.w. (Bennett et al. 2000) and <0.163 mg/kg d.w. (Brooke et al. 2004). Nriagu and Lin (1995) found a mean concentration of 0.053 mg/kg d.w. in 26 samples of wild rice and mixed wild rice with brown and white rice. A typical adult would have to ingest over 3.13 lbs. of cooked wild rice per day to exceed the cadmium RfD (Table 10).

Selenium is an essential element for plant and animal growth. Concentrations in all wild rice samples remained less than the LOD value of 0.049 mg/kg in this study. Bennett et al. (2000) found an

average concentration of 0.21 mg/kg d.w. in unfinished wild rice seeds, and Brooke et al. (2004) measured selenium in unhulled wild rice seeds of <0.058 mg/kg d.w. There is no action level or RfD for selenium.

Zinc is essential for plant and animal growth. This study shows that natural wild rice is a rich source of dietary zinc. Bennett et al. (2000) measured a mean value of 43.9 mg/kg d.w. for unhulled wild rice, Brooke et al. (2004) measured a mean value of 22.4 mg/kg d.w. for unhulled wild rice, and Nraigu and Lin (1995) measured a mean of 23.2 mg/kg d.w. in wild rice and mixed wild, brown, and white rice (Table 8). A mean concentration for zinc of 34.98 mg/kg d.w. for unfinished wild rice and 55.04 mg/kg d.w. for finished wild rice was measured in this study (Table 3). Some concern exists regarding elevated zinc concentrations in finished wild rice may be introduced during processing. The parching process did not influence zinc concentrations as the levels are fairly comparable between parched (processed) and unparched (unprocessed) samples demonstrated from this study and the earlier studies (Table 8). Zinc safe concentrations have not been determined by U.S. FDA, but a RfD has been established by U.S. EPA of 0.3 mg/kg/day. However, a typical adult would have to ingest 0.13 pounds of cooked wild rice per day to exceed the RfD for zinc (Table 10).

Chromium compounds exist in either of two valence states (III and VI). Chromium (III) is an essential element for plant and animal life. Hexavalent chromium, or Cr (VI), most negatively impacts human health (National Institute of Health 2018). Bennet et al. (2000) and Brooke et al. (2004) reported mean chromium concentrations of 0.49 and 0.40 mg/kg d.w., respectively. This study did not differentiate the valence state for chromium. Only two wild rice samples were above the LOD value of 0.088 mg/kg total chromium, yet both values were less than its LOQ value of 0.293 mg/kg. The proportion of hexavalent chromium to total chromium in wild rice is not presently known. An MRL_2 for chromium has not been established.

Wild rice seed samples were analyzed for total mercury concentrations. Mercury is a neurotoxin especially when it is in the organic methylmercury form. Measurement of methylmercury is a difficult measurement and not usually done. In the current study, a majority of the total mercury values remained below the LOD value of 0.015 mg/kg. Four samples had mercury concentrations between the LOD the LOQ value of 0.050 mg/kg. Three samples had measured total Hg concentrations at or above the LOQ value. The highest total mercury concentration of 0.064 mg/kg d.w. came from Chippewa Lake in Wisconsin. The other mercury value above the LOQ value came from an unknown site in Michigan with a concentration of 0.061 mg/kg d.w. Deadfish Lake, Minnesota, had a concentration of 0.035 mg/kg d.w. which was at the LOQ value for mercury.

Mercury concentrations in the current study and in previous studies were similar. Bennett et al. (2000) measured a mean concentration of 0.035 mg/kg d.w. in eight water bodies which equalled the concentration of total mercury in the current study for commercial wild rice (Table 8). Brooke et al. (2004) measured a mean concentration of 0.002 mg/kg d.w. in wild rice seeds from eight different water bodies which is similar to the mean mercury value measured in this study of 0.007 mg/kg d.w. The samples for the previous studies were unfinished (not parched) and the current study wild rice seeds were finished (parched) showing that the parching process does not significantly reduce the total mercury content of the seeds. The previous studies examining dried

wild rice seeds, including hulls, from northern Wisconsin that possessed similar average total mercury concentrations to the Deadfish Lake sample at 0.035 mg/kg d.w. and lower concentrations than the other two samples from Chippewa Lake and Iron County, Michigan samples. The proportion of methylmercury in total Hg of wild rice is not presently known.

Maple Syrup

Maple syrup is a traditional, Ojibwe sweetener made by evaporating sap from tapped *maple* trees, usually from sugar maples (*Acer saccharum*), due to the high sucrose concentration in the sap (Corbiere 2011). Lead contamination of maple syrup is a concern and occurs predominantly from the use of lead-bearing processing equipment. Lead does not come from the sap itself (Ontario Ministry of Agriculture, Food, and Rural Affairs 2019). Under suitable conditions of acidity and temperature, lead mobilizes into sap when in contact with leadbearing materials (Willits and Tressler 1937). Hence, concern exists that maple syrup may be contaminated with lead from old, inherited metal equipment used in processing and/or from lead containing equipment present in nonfood grade equipment used by tribal members (Stilwell and Musante 1996; Willits and Tressler 1937; Ontario Ministry of Agriculture, Food, and Rural Affairs 2019).

Wisconsin rules expressly state that neither lead or lead-alloy solder can be used in the assembly or repair of surfaces associated with food sold in the private sector (Wisconsin Department of Agriculture, Trade and Consumer Protection 2019). Several other states have similar rules/guidance for commercial maple Syrup production. The State of California has set a maximum limit for lead in maple syrup of 0.011 mg/kg enforced by their Proposition 65 law (Table 11)[7]. This regulation could potentially hinder the future sale of tribal maple syrup in retail establishments if lead-bearing equipment or repair material was inadvertently used by tribal harvesters. It could require a lead warning label on maple products sold in California. Lead contamination can be eliminated from maple syrup using the guidance offered by the maple syrup organizations of Canada and the U.S. (International Maple Syrup Institute, 2015; Manufacturers of Maple Sugaring Equipment, 2002).

Past, peer-reviewed studies have only examined large-scale, commercial maple syrup enterprises. Lead concentrations in sap samples from plastic commercial tanks in Connecticut ranged from less than 0.0005 to 0.0054 mg/kg, with an average of 0.0011 mg/kg. Whereas, the lead content in all grove sap samples using both plastic and metal equipment ranged from <0.0005 to 0.019 mg/kg, averaging 0.0026 mg/kg. Higher values corresponded with samples procured from galvanized receptacles. The lead content of resultant maple syrup samples from State of Connecticut producers ranged from 0.038 to 0.948 mg/kg, averaging 0.291 mg/kg (Stilwell and Musante 1996).

Unintended sap contamination in the Stilwell and Musante (1996) study was caused by a bronze gear pump used in sap transfer steps. This contamination resulted in an average lead level of 0.019 mg/kg in sap from the terminal stainless-steel storage tanks (Stilwell and Musante 1996). The U.S. FDA does not have a specific regulatory guideline for lead in maple syrup, but Canada's MRL_2 is 0.5 mg/kg w.w. (Health Canada 2018).

[7] October 1, 2014 the Superior Court of the State of California, County of Humboldt stipulated a consent judgment in the case between Mateel Environmental Justice Foundation vs Anderson's Maple Syrup, Inc. et al. and set the lead limit for maple syrup at 11 ppb requiring that the lead content in syrup be measured before bottling to assure compliance.

This study included 29 maple syrup samples from tribal harvesters. Twenty-seven samples had lead concentrations measured as <LOD of 0.027 mg/kg. Commercial processed maple syrup (four samples) had the same result. One sample of maple syrup had a measured concentration of lead between the LOD and LOQ of 0.091 mg/kg. A single sample had a lead concentration measured above the LOQ at 0.27 mg/kg. The harvester/processer reported using old or inherited equipment. Lead was not detected in the single maple sugar sample. Moisture concentrations in the syrup samples varied and reflects the personal preference of the processor. It would be safe to conclude that maple syrup gathered and processed using plastic pails and new welded stainless steel evaporators would be safe for human consumption.

Wild Turkey

Concern for consuming wild turkey meat is due to the possibility of lead contamination from the methods commonly used to harvest wild turkeys. Published studies on metal contamination have not been found for wild turkeys although some x-ray and lead analyses data exist regarding other avian species. Three, peer-reviewed research studies were compared regarding lead contamination of other game bird tissues. A study on the effects of white-tailed deer (*Odocoileus virginianus*) also showed the effects of lead containing ammunition on the contamination of rifle harvested wild game (Hunt et al. 2009). They fed rifle-killed deer that had been commercially processed with the removal of tissues around the wound channel to swine and measured their blood lead concentrations. Swine fed meat from these deer had significantly elevated lead blood concentrations in two days after feeding began.

Scheuhammer et al. (1998) collected nearly 4000 game birds from every province in Canada harvested mostly by shotgun using lead shot. The samples included 44 avian species (mostly waterfowl) with the pectoral muscles analyzed for lead. Ten gram portions of each right pectoral muscle were pooled (827 pools of 1-12 birds per pool) by species and geographic location and analyzed the tissue for lead. Pectoral muscle tissue from both the right and left sides of some birds were examined, with visually detectable pellets or fragments removed before x-ray and lead analyses. Random, individual birds from various pools were also analyzed for lead content.

Lead concentrations averaged ~4.7 ± 43 mg/kg d.w. for all 827 sample pools. There were 735 sample pools with lead concentration averaging ≤2 mg/kg d.w. and 92 sample pools from the upper 10 percentile of lead concentrations that averaged 40 ± 125 mg/kg d.w.

In addition, two American woodcocks (*Scolopax minor)* sampled in the Scheuhammer et.al. (1998) study had measured lead concentrations of 14.2 and 844 mg/kg (d.w.) in the right breasts. In two spruce grouse *(Falcipennis canadensis) samples*, no lead was detected in one bird's left breast and its corresponding right breast possessed a lead level of 104 mg/kg (d.w.). The other spruce grouse had high lead concentrations in each of its breasts. X-rays were also taken of selected samples before lead analysis and, in some instances, indicated lead fragment and/or pellet presence. Scheuhammer et al. (1998) concluded "This form of dietary lead exposure in people is completely unnecessary, and can be avoided by the use of non-toxic shot for hunting."

Greenland seabirds were evaluated by x-ray and subsequently analyzed for lead content. Shot pellets were removed from tissue if visually observed or detected in x-ray. Using common eiders (*Somateria mollissima*) drowned in fishing nets as a control group and common eiders harvested by

shotgun as the experimental group, common eiders and thick-billed murres (*Uria lomvia)* were boiled according to a recipe common to the region. Whole, right pectoral breasts were removed and analyzed for lead content (Johansen et. al. 2004). Among eiders shot, one to 42 pellets were found radiographically in the whole bird and 0 to 3 pellets were found in breast tissue alone. Among eiders drowned, 0 to 3 pellets were found radiographically in whole birds, and 0 to 1 pellet was found in breast tissue alone. The average lead concentration in shotgun-harvested common eiders was 6.1 mg/kg w.w., and the mean lead concentration for drowned eiders were 0.14 mg/kg w.w. Murres harvested by shotgun had 0 to 12 pellets embedded within the whole bird, and 0 to 5 pellets in breast tissue alone. Murres harvested by shotgun had an average lead concentration in breast tissue of 0.73 mg/kg w.w. (Johansen et al. 2004).

Common eiders are overall larger than thick-billed murres, at about 20-28 inches and 18 inches, respectively (Cornell Laboratory of Ornithology 2017a; 2017b). In contrast, adult wild turkeys are 43 to 45 inches long (Cornell Laboratory of Ornithology 2017c). Therefore, due to their size, eiders would theoretically be more comparable in size to wild turkey than thick-billed murres, although the turkey is roughly twice the size as eider.

In another study, Pain et.al. (2010) examined a wide range of variables potentially impacting lead levels in European wild fowl meat, such as radiographic pellet presence and cooking methods. Through qualitative identification techniques regarding the composition of recovered pellets, 91% of birds were identified as having been shot with lead ammunition, rather than ammunition composed of non-lead materials. These qualitative methods included: notation of the pellet's color and malleability, determinations of magnetism and melting points, as well as chemical analysis for metal in shot. Nitric acid combined with potassium iodide were used to determine if the shot contained lead or bismuth alloys. Known pellet types were used as positive controls

In the study by Pain et.al. (2010), two groups of birds with approximately the same amount of pellets detected via x-ray were sampled from each of six game bird species examined. Afterwards, entire birds were cooked using either an acidic or nonacidic recipe which included the whole bird. After cooking, the edible muscle tissue was removed from the skeleton and analyzed for lead content. Grocery store chicken breasts were cooked using the acidic or nonacidic recipes, as control groups. Cooked game bird samples exceeding the E.U. lead action limit of 0.1 mg/kg w.w. for red grouse *(Lagopus lagopus scotica)*, ring-necked pheasant *(Phasianus colchicus*), and red-legged partridge (*Alectoris rufa*) by an estimated 6%, 8%, and 20%, respectively. Of these three species, ring-necked pheasants would be the most comparable in size to wild turkey (Ring-necked pheasant measure a length of nearly 20 to 28 inches), although wild turkey is roughly twice the size and four times heavier than pheasant (Cornell Laboratory of Ornithology 2017c). A significant positive correlation was found between the number of shot detected by x-ray and lead concentrations in total muscle tissue of cooked birds, even upon removal of shot pellets and/or fragments after cooking.

Pain et. al. (2010) did not find any statistically significant difference between lead concentrations in game meat cooked in acidic and non-acidic recipes. The researchers did not measure the pH of the cooking broth, but categorized acidic and non-acidic recipes based upon primary ingredients added. This finding contrasts with a previous study, in which lead levels increased when cooked as part of an acidic recipe (Mateo et al. 2007), and is possibly due to the pH levels of the

recipes used in the different studies. The current study did not examine cooked wild turkey breast tissue. However, wild turkey is typically prepared in a nonacidic manner by Ojibwe tribal harvesters.

The potential exists for physical harm to consumers from metal contamination in wild turkey from shotgun shot. A U.S. FDA (2005) investigation of hard and/or sharp foreign objects in foods prompted guidance to protect human health. "The investigation Board found that foreign objects that are less than 7 mm (0.276 in. which is about the diameter of no. 4 buckshot) maximum dimension, rarely cause trauma or serious injury except in special risk groups such as infants, surgery patients, and the elderly." Shot would not exceed the 7 mm size needing guidance for safe consumption of wild turkey.

The Canadian MRL_2 for lead in fish tissue is 0.5 mg/kg (Health Canada 2014), but the E.U.'s lead action limit for farmed poultry meat is 0.1 mg/kg. The U.S. FDA does not have an action limit for lead in poultry tissue. As in the case of maple syrup, Canada's MRL_2 for lead in fish tissue is used to evaluate lead concentrations in relation to possible impact on human health.

In our study, not all analyzed breast tissue containing pellets and/or fragments possessed lead concentrations above the LOD or LOQ values. Out of the 60 total breast samples from 30 different wild turkeys, four breast samples with pellets or fragmentation found in them possessed lead concentration values under the LOD value of 0.026 mg/kg. Two tissue samples containing pellets/fragments had lead levels under the LOQ value of 0.087 mg/kg (Table 6). Forty percent of total wild turkey breast samples where metallic material or fragments were found generated lead values over the LOQ value, with two of those values above the Canadian MRL_2 (0.5 mg/ kg) for lead in fish tissue.

Five (8.3%) of total breast samples where no pellets/fragments were discovered had detectable lead values above the LOQ value of 0.087 mg/kg, and ranged from 0.240 to 15.9 mg/kg d.w. It is possible that x-ray analysis did not capture microscopic shot fragmentation too small for observation. Wild turkeys are omnivorous, but primarily eat vegetation and are, therefore, unlikely to bio-accumulate significant concentrations of lead in their muscle tissues. Nonetheless, further investigation using wild turkey samples harvested with non-lead containing methods should be conducted to determine the sources of lead exposure in wild turkeys other than lead shot.

Ultimate lead concentrations in individual pectoral tissue samples were highly variable, ranging from 16.2 mg/kg d.w. to levels below the detection limit of 0.026 mg/kg. Notably, microscopic fragmentation was associated with the highest lead value from the 60 breast samples (10331-L). The mean lead concentration in tissue samples of wild turkey with concentrations above the LOD is 3.44 mg/kg d.w. This highest lead value in breast tissue is over thirty-two times the Canadian MRL_2 in fish muscle (0.5 mg/kg). This is a concerning finding, and warrants a change in ammunition used to harvest wild turkey. Smaller shot (size 8) may have resulted in higher lead concentrations due to greater difficulty finding the shot by sight or in x-ray examination. Due to the permanent impacts of lead exposure on children's cognitive and neurological development, harvest techniques need to be evaluated. In total, three individual samples contained lead concentrations greater than the Canadian MRL_2.

Conclusion

Wild rice (*manoomin*), maple syrup (*zhiiwaagamizigan*), and wild turkey (*mizise*) were all analyzed to better understand potential chemical and/or physical contamination associated with these traditional, Ojibwe foods.

Wild rice

Finished wild rice seeds harvested and processed by Ojibwe tribal members do not contain amounts of lead, zinc, cadmium, total mercury, copper, magnesium, total chromium, selenium, and total and inorganic arsenic concentrations that would be of negative impact to human health, in either cooked or dry form. Naturally-derived wild rice met current and/or proposed MRL_2 or a RfD identified by national health organizations.

While limited to three samples, testing results of cultivated (commercial) wild rice was found not to contain amounts of lead, zinc, cadmium, total mercury, copper, magnesium, total chromium, selenium, and total arsenic concentrations that would be of negative impact to human health. Two of the three cultivated (commercial) wild rice samples tested above the 0.1 ppm action level proposed by the U.S. FDA as being harmful to infants consuming cereals. An extensive review of arsenic in rice and rice products has been developed by the U.S. FDA (2016) in developing a risk assessment of consuming these products. Additional research is needed before any definitive conclusions can be made regarding health risks to infants in relation to inorganic arsenic levels in cultivated wild rice.

Consumption of wild rice, harvested and processed by tribal members, does not pose a chemical risk to tribal communities and should be made available to tribal members being served in federally-funded food programs to improve reservation health conditions.

Maple Syrup

Maple sap harvested and processed by Ojibwe tribal members into syrup does not contain lead concentrations that would be harmful to human health using the Canadian MRL_2 for lead in maple syrup. Only one out of 29 tribally-obtained maple syrup samples analyzed contained a detectable lead concentration, yet the sample did not exceed Canada's MRL_2 of 0.5 ppm for lead in maple syrup.

Approximately 1/3 of tribal harvesters and processors indicated they used "old and/or inherited" equipment in procuring or processing of maple sap into syrup. Despite the intrinsic sentimentality of inherited equipment, use of modernized equipment by tribal members will further ensure undetectable concentrations of lead in maple syrup. Therefore, maple syrup processed by tribal members does not pose a chemical risk, from lead, to tribal communities and should be made available to tribal members served in federally-funded food programs, as well as made available for retail sale within their tribal communities. Using the guidelines produced by maple syrup producing organizations will eliminate lead contamination (Health Canada 2018; International Maple Syrup Institute 2015, Manufacturers of Maple Sugaring Equipment 2002).

Wild Turkey

Wild turkey breast meat should be further studied, as results from this study indicate that ammunition used to harvest the birds was the main source of lead in the meat. The potential for lead contamination of wild turkey breasts due to lead ammunition usage represents a greater human health hazard than that of natural contamination. If wild turkey meat is eaten, a consideration of the irreversible neurological impacts lead exposure can have on sensitive populations, such as children, must be considered.

With regards to metallic contamination of wild turkey breast meat, harvesting of this avian species with smaller size No. 8 and No. 6 shot increased lead content found in the breast meat. Furthermore, turkey harvested with larger size No. 5 copper coated lead shot were found to test below laboratory detection limits. The risk of lead contamination from shot pellets can further be reduced by tribal hunters utilizing either crossbow, archery, or waterfowl shotgun ammunition which is lead free. It should also be noted that the risk of fragments in breast meat, cannot be completely eliminated because it cannot be ascertained that the bird had not been shot before and subsequently survived.

While bow or crossbow usage by tribal harvesters would assist in reducing physical risk, all submitted samples were harvested with a firearm. Crossbow or bow archery harvesting appears to be a harvest technique that not many tribal hunters use today. Future research involving lead contamination of wild turkeys from lead-bearing ammunition would require a control group of turkeys harvested by archery or shotgun with waterfowl ammunition.

For Ojibwe members wishing to harvest with firearms, using the recommend shot sizes for wild turkey hunting, either No. 4, No. 5, or No. 6, would assist in keeping meat beneath the U.S. FDA hard and/or sharp foreign object threshold of 7 mm. However, shot pellets or fragments may not always be visually detectable during normal processing or meal preparation. Therefore, care should be exercised to remove any metallic components before consumption.

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GREAT LAKES INDIAN FISH & WILDLIFE COMMISSION
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ADDRESSING LAKE SUPERIOR FISH CONTAMINANT LEVELS IN REGARD TO FDA HACCP GUIDELINES

Date: December 31, 2017

Prepared by: Jim Thannum,
Director of Planning and Development
Great Lakes Indian Fish and Wildlife Commission

Lake Superior fish species within the Fish and Fishery Products Hazards and Control Guide – April 2011 – Table 3-2

Pg. #	Market Name in Hazards Guide	Scientific Name	Identified as a Hazard – Environmental Chemicals	Names also referred to in the industry
34	Chub	*Coregonus Kiyi*	Yes	Big-eyed chub, deepwater cisco, chub
	Not listed	*Coregonus hoyi*	Not listed	Bloater, deepwater cisco, chub
35	Chub or Cisco	*Coregonus zenithicus*	Yes	Shortjaw cisco
35	Cisco or Tullibee	*Coregonus artedi*	Yes	Cisco, Lake Herring
	Not listed	*Couesius plumbeus*	Not listed	Lake Chub
47	Perch, Lake or Yellow	*Perca flavescens*	Yes	
58	Trout Aquacultured	*Salvelinus namaycush*	Yes for contaminants– also listed for Aquaculture Drugs as a Hazard	Lean trout, siscowet trout, humpers
	Wild Lake Trout - Not listed in the table	*Salvelinus namaycush*	Not listed	Lean trout, siscowet, humper
59	Walleye	*Sander vitreus*	Yes	Walleye
60	Whitefish	*Coregonus spp. & Coregonus clupeaformis*	Yes	Whitefish, Lake Whitefish
60	Not listed	*Prosopium coulteri*	Not listed	Pigmy Whitefish
60	Whitefish	*Prosopium cylindraceum*	Yes	Menomonie Whitefish, Round Whitefish

Fish and Fishery Products Hazards and Control Guide – April 2011 – Table 9-1

ENVIRONMENTAL CHEMICAL CONTAMINANTS AND PESTICIDES TOLERANCE AND ACTION LEVELS

Tolerance Levels			
DELETERIOUS SUBSTANCE	LEVEL IN EDIBLE TISSUE	FOOD COMMODITY	REFERENCE
PCBs	2 ppm	All fish	21 CFR 109.30
Carbaryl	0.25 ppm	Oysters	40 CFR 180.169
Diquat	2 ppm	Fish	40 CFR 180.226
Diquat	20 ppm	Shellfish	40 CFR 180.226
Diuron and its metabolites	2 ppm	Farm-raised,	40 CFR 180.106
Endothall and its monomethyl ester	0.1 ppm	All fish	40 CFR 180.293
Fluridone	0.5 ppm	Finfish and	40 CFR 180.420
Glyphosate	0.25 ppm	Fish	40 CFR 180.364
Glyphosate	3 ppm	Shellfish	40 CFR 180.364
2,4-D	0.1 ppm	Fish	40 CFR 180.142
2,4-D	1 ppm	Shellfish	40 CFR 180.142

Action Levels			
DELETERIOUS SUBSTANCE	LEVEL IN EDIBLE TISSUE	FOOD COMMODITY	REFERE
Aldrin/Dieldrin[1]	0.3 ppm	All fish	"Compliance Policy Guide," Sec. 575.100
Benzene hexachloride	0.3 ppm	Frog legs	"Compliance Policy Guide," Sec. 575.100
Chlordane	0.3 ppm	All fish	"Compliance Policy Guide," Sec. 575.100
Chlordecone[2]	0.3 ppm	All fish	"Compliance Policy Guide," Sec. 575.100
Chlordecone[2]	0.4 ppm	Crabmeat	"Compliance Policy Guide," Sec. 575.100
DDT, TDE, and DDE[3]	5 ppm	All fish	"Compliance Policy Guide," Sec. 575.100
Methylmercury[4]	1 ppm	All fish	"Compliance Policy Guide," Sec. 540.600
Heptachlor and Heptachlorepoxide[5]	0.3 ppm	All fish	"Compliance Policy Guide," Sec. 575.100
Mirex	0.1 ppm	All fish	"Compliance Policy Guide," Sec. 575.100

1. The action level for aldrin and dieldrin is for residues of the pesticides individually or in combination. However, in calculating a total, amounts of aldrin or dieldrin found at below 0.1 ppm are not counted.
2. Previously listed as Kepone, the trade name of chlordecone.
3. The action level for DDT, TDE, and DDE is for residues of the pesticides individually or in combination. However, in calculating a total, amounts of DDT, TDE, and DDE found below 0.2 ppm are not counted.
4. See Chapter 10 for additional information.
5. The action level for heptachlor and heptachlor epoxide is for the pesticides individually or in combination. However, in calculating a total, amounts of heptachlor and heptachlor epoxide found below 0.1 ppm are not counted

Fish Contaminant Trends in the Great Lakes

Fish Consumption Assessment Highlights[1]

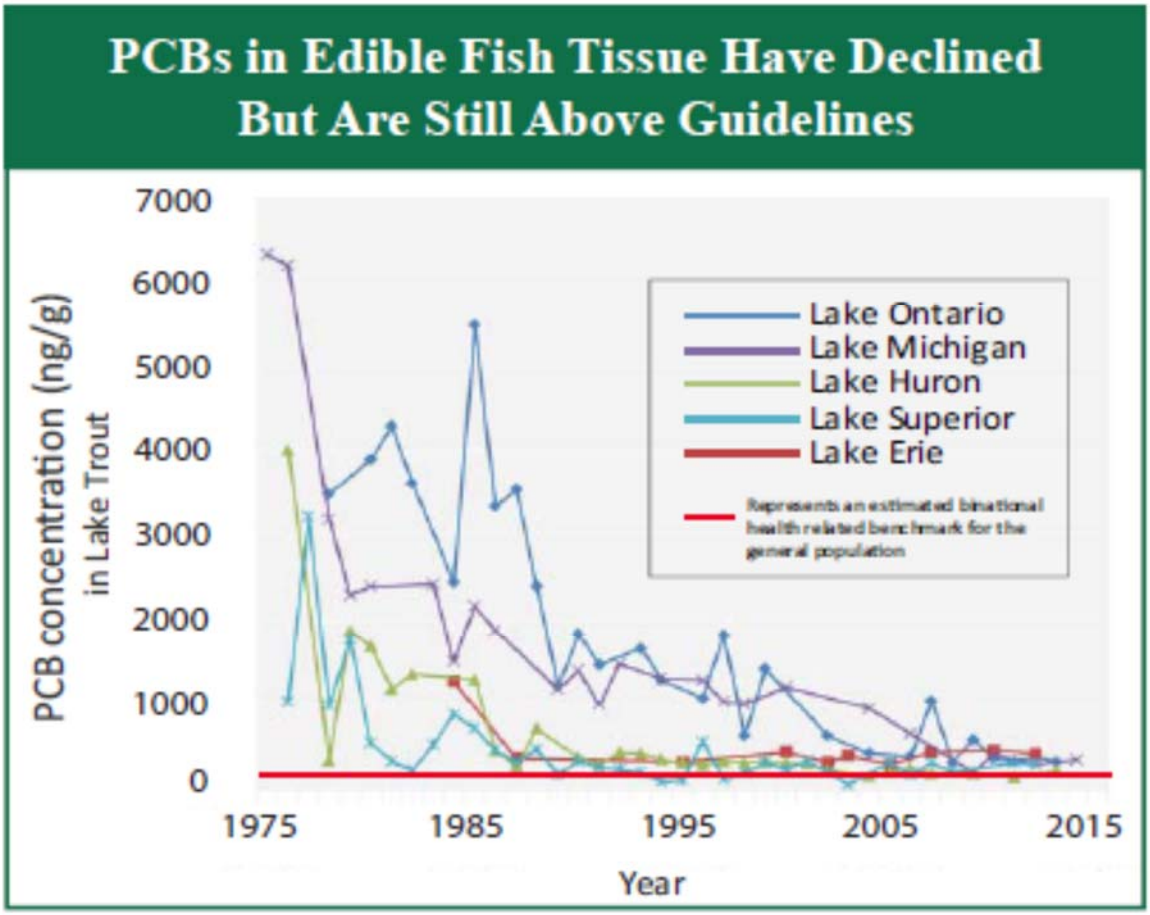
The Fish Consumption indicator reveals that in all the Great Lakes contaminants in edible portions of fish have declined over time. However, in Lakes Erie and Huron, recent concentrations of PCBs and mercury are stable or slightly increasing. The status of contaminants in edible portions of fish is assessed as **Fair** and the trend is **Unchanging** since last reported in 2011.

Contaminants causing consumption restrictions of Great Lakes fish typically include PCBs, mercury, and dioxins. PCBs drive the majority of fish consumption advice in both the U.S. and Canada. PCB levels in edible portions of fish tissue have decreased by 90% in some cases, but are still above consumption benchmarks.

Mercury levels have generally declined over the last four decades and, depending on the fish species and lake, are lower than most fish consumption advisory benchmarks. However, in Lakes Erie and Huron, PCBs and mercury have remained stable or are slightly increasing.

Non-legacy contaminants, such as Perfluorooctanesulfonic acid or PFOS (a stain repellent), continue to be a monitoring priority and will be included in future State of the Great Lakes reporting as necessary. Additional stressors such as warming waters and invasive species will likely continue to complicate the cycling of contaminants in the Great Lakes and may impact the levels of contaminants in fish.

[1] **Error! Main Document Only.STATE OF THE GREAT LAKES 2017 - *HIGHLIGHTS REPORT- EPA and Canada***
https://binational.net/wp-content/uploads/2017/06/SOGL_17-EN.pdf



GLIFWC's Lake Superior Fish Contaminant Testing Program

GLIFWC's Lake Superior fish contaminant studies included: 1) Lake Superior Fish Contaminants/HACCP Project, Administration for Native Americans Grant # 90NR0096/01, sampled in 1998/1999 and reported in February 2000, 2) Polychlorinated Dibenzo-p-Dioxin (CDD) and Polychlorinated Dibenzofuran (CDF) Concentrations in Fillet Tissue of Five Species of Lake Superior Fish, U.S. EPA Grant #X97567001, sampled in 1998/1999 and reported March 2005, 3) Lake Trout Contaminant Testing, U.S. EPA Grant #EQ-97598601-0, sampled in 2003 and reported April 2006, 4) Lake Whitefish Contaminant Testing, U.S. EPA Grant # EQ-98538501, sampled in 2004 and reported in December 2005, and 5) Cisco Contaminant Testing, U.S. EPA Grant #GL00E06501 Cisco Contaminant Testing, sampled in 2006 and reported in September 2007.

Lake Superior Fish Contaminants/HACCP Project - Administration for Native Americans Grant # 90NR0096/01:

Note – See Exhibit 1 for more detailed information and tables and graphs.

Overall Findings

- All lake trout, whitefish, and herring samples tested under this project were below U.S. FDA action limits that restrict commercial sales for chemical contaminants.
- Concentrations of chemical contaminants varied between Lake Superior fish species. Fish lower in the food chain, such as whitefish and lake herring, had significantly lower PCB, chlordane, and mercury concentrations than predators such as lake trout and siscowet trout.
- The concentration of chemical contaminants such as PCBs, chlordane, and mercury increased with age and length of the fish.
- Trimming fillets and removing skin significantly reduced the concentration for PCBs, chlordane, and other organic persistent contaminants.
- Trimming fillets and removing skin did not reduce mercury concentrations in Lake Superior fish due to mercury being bound to muscle tissue.

Polychlorinated biphenyls (PCBs) findings

- None of the Lake Superior fish samples (lake herring, whitefish, lake trout, or siscowet trout) exceed the U.S. FDA's PCB action limit for commercial sales for PCBs of 2000 ppb (2.0 ppm).
- Trimming fillets lead to reduced PCB contaminant levels by 12% to 40% depending on the fish species. For example, PCB contaminant levels in whitefish were reduced 32% and in lake trout 23-25%. PCB contaminant levels in siscowet trout were reduced between 12-40% depending upon the length of the fish. (See Trimmed Skin-On figures in Table 7.)
- Removing skin from fillets further reduced PCB concentrations in whitefish, lake trout, and siscowet trout between 17 and 20.5 inches. (See Trimmed Skin-Off figures in Table 7.)

Chlordane findings

- None of the Lake Superior fish samples of lake herring, whitefish, or lake trout exceeded the U.S. FDA's chlordane action limit of 300 ppb (0.3 ppm) for commercial sale.
- Siscowet samples in the 17-18 inch size group and the 19.5-20.5 inch size group **did not** exceed the U.S. FDA's chlordane action limit of 300 ppb (0.3 ppm).
- Siscowet from the 22-23 inch size group and 24.5-25.5 inch size group **did** exceed the U.S. FDA's chlordane action limit of 300 ppb (0.3 ppm).
- Trimming fillets led to reduced chlordane concentration levels by 13% to 38% depending on the fish species. For example, chlordane concentration levels in whitefish were reduced 33% and in lake trout 34%. Chlordane concentration levels in siscowet trout were reduced between 13-38% depending upon the length of the fish. (See Trimmed Skin-On figures in Table 8.)

- Removing skin from fillets further reduced chlordane concentrations in whitefish, lake trout, and siscowet trout between 17 and 20.5 inches. (See Trimmed Skin-Off figures in Table 8.)

Using test results from 22 composite samples and linear regression, GLIFWC has determined that Lake Superior commercial fishermen could harvest and process siscowet trout up to 22 inches without exceeding FDA's action limit for chlordane of 300 ppb (0.3 ppm), **if the belly and back fat is removed from the fillet.** (Note: see Total Chlordane Concentrations in Untrimmed and Trimmed Skin-on Siscowet Fillets from the South Shore of Lake Superior, See Exhibit # 1 - Graph 5, page 7)

If belly and back fat is not removed from Siscowet trout fillets, fishermen should utilize gill net mesh sizes that would limit their harvests to Siscowet trout less than 20 inches in length. Fish processors have the option to meet FDA restrictions on chlordane levels by:

- 1) culling out all siscowet trout over 20 inches if they intend to market whole fish or process whole smoked fish, or
- 2) culling out all siscowet trout over 21.5 inches in length if they decide to remove belly and back fat during the filet process and then use those filets for smoking or sale.

Mercury findings

- None of the Lake Superior fish samples (lake herring, whitefish, lake trout, or siscowet trout) exceed the U.S. FDA's methylmercury action limit for commercial sales of 1000 ppb (1.0 ppm).
- Only siscowet samples in the 22-23inch size group and 24.5-25.5inch size group exceeded 500 ppb (.5 ppm), a lower level used by Michigan for fish caught and sold in that state.

Benzene hexachloride, DDT, aldrin/dieldrin, mirex, and heptachlor/heptachlor epoxide findings

All Lake Superior fish samples (lake herring, lake whitefish, lake trout, or siscowet trout) were far below the U.S. FDA's action limit for these chemical contaminants. (See Table 11.)

Fish Contaminant Testing Results - Administration for Native Americans Grant # 90NR0096/01

Chemical		Mercury	PCBs	Chlordane	DDT, DTE, DDE	Aldrin Deildrin	Benzene hexachloride	Heptachlor and Heptachlorepoxide	Mirex
FDA Action Level ppm		1	2	0.3	5	0.3	0.3	0.3	0.1
FDA Action Level ppb		1,000	2,000	300	5,000	300	300	300	100
Lake Superior Fish	**Size (inches)**	Mean Trimmed Skin-off Filets	Mean Untrimmed skin-on filets	Mean Untrimmed skin-on filets	Mean Untrimmed skin-on filets	Mean Untrimmed skin-on filets	Mean Untrimmed skin-on filets	Mean Untrimmed skin-on filets	Mean Untrimmed skin-on filets
Cisco-Lake Herring	15-17	107	68	22	3.8	7.2	0	0	0
Whitefish	22-24	65	57.8	26.5	4.8	0	1.5	10	0
Lake Trout	25-26	163	313	93	130	26	6.2	5.9	0
Lake Trout	27-28	355	551	164	230	35	5.8	6.8	0
Siscowet Trout	17-18	220	216	133					
Siscowet Trout	19.5-20.5	360	407	233					
Siscowet Trout	22-23	515	1078	**502**	630	79	4.4	12	7.8
Siscowet Trout	24.5-25.5	610	1145	**557**	680	78	12	12	17

Lake Superior Fish Contaminants/HACCP Project - Administration for Native Americans Grant # 90NR0096/01

Additional GLIFWC Lake Superior Fish Contaminant Studies:

- Polychlorinated Dibenzo-p-Dioxin (CDD) and Polychlorinated Dibenzofuran (CDF) Concentrations in Fillet Tissue of Five Species of Lake Superior Fish, U.S. EPA Grant #X97567001, sampled in 1998/1999 and reported March 2005,
    - FDA has not established Tolerance Levels or Action Levels for Dioxin at this time.

Lake Trout Contaminant Testing, U.S. EPA Grant #EQ-97598601-0, sampled in 2003 and reported April 2006 – Note page 24 of the report. ND = none detect.

Chemical	Sample	Size - cm	Size- inches	Tested Results Mean	FDA Level ppb
Total Mercury	Muscle tissue	46	18	135	1000
Total Mercury	Muscle tissue	54	21	207	1000
Total Mercury	Muscle tissue	62	24	230	1000
Total Mercury	Muscle tissue	71	28	292	1000
Total PCBs	Untrimmed-skin on filets	46	18	61	2000
Total PCBs	Untrimmed-skin on filets	54	21	84	2000
Total PCBs	Untrimmed-skin on filets	62	24	120	2000
Total PCBs	Untrimmed-skin on filets	71	28	330	2000
Total Chlordane	Untrimmed-skin on filets	46	18	26	300
Total Chlordane	Untrimmed-skin on filets	54	21	36	300
Total Chlordane	Untrimmed-skin on filets	62	24	46	300
Total Chlordane	Untrimmed-skin on filets	71	28	92	300
Total DDT	Untrimmed-skin on filets	46	18	29	5000
Total DDT	Untrimmed-skin on filets	54	21	50	5000
Total DDT	Untrimmed-skin on filets	62	24	72	5000
Total DDT	Untrimmed-skin on filets	71	28	170	5000
Aldrin/Dieldren	Untrimmed-skin on filets	46	18	10	300
Aldrin/Dieldren	Untrimmed-skin on filets	54	21	12	300
Aldrin/Dieldren	Untrimmed-skin on filets	62	24	12	300
Aldrin/Dieldren	Untrimmed-skin on filets	71	28	17	300
Heptachlor	Untrimmed-skin on filets	46	18	2.4	300
Heptachlor	Untrimmed-skin on filets	54	21	2.7	300
Heptachlor	Untrimmed-skin on filets	62	24	2.7	300
Heptachlor	Untrimmed-skin on filets	71	28	3.3	300
Mirex	Untrimmed-skin on filets	46	18	ND	100
Mirex	Untrimmed-skin on filets	54	21	2.1	100
Mirex	Untrimmed-skin on filets	62	24	5.3	100
Mirex	Untrimmed-skin on filets	71	28	8.2	100

Lake Whitefish Contaminant Testing, U.S. EPA Grant # EQ-98538501, sampled in 2004 and reported in December 2005 – Note page 25 of the report. ND = none detect.

Chemical	Sample	Size - cm	Size- inches	Tested Results Mean	FDA Level ppb
Total Mercury	Muscle tissue	43-46	17	56	1000
Total Mercury	Muscle tissue	48-51	19	61	1000
Total Mercury	Muscle tissue	53-56	21	90	1000
Total Mercury	Muscle tissue	58-61	23	98	1000
Total PCBs	Untrimmed-skin on filets	43-46	17	29	2000
Total PCBs	Untrimmed-skin on filets	48-51	19	47	2000
Total PCBs	Untrimmed-skin on filets	53-56	21	75	2000
Total PCBs	Untrimmed-skin on filets	58-61	23	86	2000
Total Chlordane	Untrimmed-skin on filets	43-46	17	23	300
Total Chlordane	Untrimmed-skin on filets	48-51	19	39	300
Total Chlordane	Untrimmed-skin on filets	53-56	21	58	300
Total Chlordane	Untrimmed-skin on filets	58-61	23	76	300
Total DDT	Untrimmed-skin on filets	43-46	17	20	5000
Total DDT	Untrimmed-skin on filets	48-51	19	33	5000
Total DDT	Untrimmed-skin on filets	53-56	21	57	5000
Total DDT	Untrimmed-skin on filets	58-61	23	65	5000
Aldrin/Dieldren	Untrimmed-skin on filets	43-46	17	10	300
Aldrin/Dieldren	Untrimmed-skin on filets	48-51	19	19	300
Aldrin/Dieldren	Untrimmed-skin on filets	53-56	21	20	300
Aldrin/Dieldren	Untrimmed-skin on filets	58-61	23	33	300
Heptachlor	Untrimmed-skin on filets	43-46	17	4.2	300
Heptachlor	Untrimmed-skin on filets	48-51	19	7.3	300
Heptachlor	Untrimmed-skin on filets	53-56	21	8.9	300
Heptachlor	Untrimmed-skin on filets	58-61	23	13	300
Mirex	Untrimmed-skin on filets	43-46	17	ND	100
Mirex	Untrimmed-skin on filets	48-51	19	ND	100
Mirex	Untrimmed-skin on filets	53-56	21	ND	100
Mirex	Untrimmed-skin on filets	58-61	23	ND	100

Cisco Contaminant Testing, U.S. EPA Grant #GL00E06501, sampled in 2006 and reported in September 2007 – Note page 23 of the report. ND = none detect.

Chemical	Sample	Size - cm	Size- inches	Tested Results Mean	FDA Level ppb
Total Mercury	Muscle tissue	33-34	13	37	1000
Total Mercury	Muscle tissue	36-39	15	50	1000
Total Mercury	Muscle tissue	41-42	16.14	58	1000
Total Mercury	Muscle tissue	45-47	17.71	94	1000
Total PCBs	Untrimmed-skin on filets	33-34	13	ND	2000
Total PCBs	Untrimmed-skin on filets	36-39	15	ND	2000
Total PCBs	Untrimmed-skin on filets	41-42	16.14	ND	2000
Total PCBs	Untrimmed-skin on filets	45-47	17.71	36	2000
Total Chlordane	Untrimmed-skin on filets	33-34	13	7.1	300
Total Chlordane	Untrimmed-skin on filets	36-39	15	10	300
Total Chlordane	Untrimmed-skin on filets	41-42	16.14	13	300
Total Chlordane	Untrimmed-skin on filets	45-47	17.71	14	300
Total DDT	Untrimmed-skin on filets	33-34	13	6.5	5000
Total DDT	Untrimmed-skin on filets	36-39	15	7.8	5000
Total DDT	Untrimmed-skin on filets	41-42	16.14	9.2	5000
Total DDT	Untrimmed-skin on filets	45-47	17.71	10	5000
Aldrin/Dieldren	Untrimmed-skin on filets	33-34	13	5.3	300
Aldrin/Dieldren	Untrimmed-skin on filets	36-39	15	5.5	300
Aldrin/Dieldren	Untrimmed-skin on filets	41-42	16.14	5.7	300
Aldrin/Dieldren	Untrimmed-skin on filets	45-47	17.71	5.4	300
Heptachlor	Untrimmed-skin on filets	33-34	13	ND	300
Heptachlor	Untrimmed-skin on filets	36-39	15	ND	300
Heptachlor	Untrimmed-skin on filets	41-42	16.14	ND	300
Heptachlor	Untrimmed-skin on filets	45-47	17.71	ND	300
Mirex	Untrimmed-skin on filets	33-34	13	ND	100
Mirex	Untrimmed-skin on filets	36-39	15	ND	100
Mirex	Untrimmed-skin on filets	41-42	16.14	ND	100
Mirex	Untrimmed-skin on filets	45-47	17.71	ND	100

WISCONSIN STATE – LAKE SUPERIOR WATERS FISH CONSUMPTION GUIDELINES

Advisory Area

Advice for eating fish from the area you selected:

County:	Ashland, Bayfield, Douglas, Iron
Advisory Area:	LAKE SUPERIOR INCLUDING TRIBUTARIES UP TO THEIR 1ST IMPASSABLE BARRIER (DAM OR FALLS)
Includes:	LAKE SUPERIOR

Women up to age 50 (child bearing age) and children (under age 15) may safely eat:

Unrestricted	rainbow smelt, brown trout, burbot, chinook salmon less than 32", chubs, coho salmon,
1 Meal Per Week	lake herring, lake trout less than 22", lake whitefish, rainbow trout, yellow perch
and	
1 Meal Per Month	chinook salmon larger than 32", lake sturgeon larger than 50", lake trout 22" to 39", siscowet lake trout less than 29", walleye
Do Not Eat	lake trout larger than 39", siscowet lake trout larger than 29"

All men (15 and older) and older women (50 and older) may safely eat:

Unrestricted	coho salmon, lake herring, rainbow smelt, rainbow trout, yellow perch
1 Meal Per Week	brown trout, burbot, chinook salmon less than 32", chubs, lake trout less than 22", lake whitefish, walleye
and	
1 Meal Per Month	chinook salmon larger than 32", lake sturgeon larger than 50", lake trout 22" to 39", siscowet lake trout less than 29"
Do Not Eat	lake trout larger than 39", siscowet lake trout larger than 29"

The above advice is due to the following pollutants: MERCURY, PCB

Date of Query: December 12 201

http://dnr.wi.gov/FCSExternalAdvQry/FishAdvisorySrch.aspx

MICHIGAN STATE – LAKE SUPERIOR WATERS FISH CONSUMPTION GUIDELINES

Lake Superior

Type of Fish	Chemicals of Concern	Size of Fish (length in inches)	MI Servings per Month*
Brown Trout	PCBs	Any	1[2x]
Burbot	PCBs	Any	Limited▲
Chinook Salmon	PCBs	Any	6 Per Year[2x]
Coho Salmon	PCBs & Toxaphene	Any	4[2x]
Lake Herring	Mercury	Any	8
Lake Trout	PCBs & Toxaphene	Under 24"	2[2x]
	PCBs	24" to 28"	1[2x]
		Over 28"	6 Per Year[2x]

(continued on the next page)

* See page 6 ▲ See page 7 [2x] See page 8 Best Choice! =

Lake Superior (continued)

Type of Fish	Chemicals of Concern	Size of Fish (length in inches)	MI Servings per Month*
Lake Whitefish	PCBs, Dioxins, Toxaphene	Any	2[2x]
Northern Pike	Mercury	Any	2
Rainbow Trout	PCBs	Any	2[2x]
Siscowet	PCBs & Toxaphene	Any	Limited▲
Steelhead	PCBs	Any	2[2x]
Suckers	Toxaphene	Any	2[2x]
Walleye	Mercury	Any	2
Yellow Perch	Mercury	Any	2

Limited

If you:

- are under the age of 15,

-or-

- have health problems, like cancer or diabetes,

-or-

- are planning on having children in the next several years, currently pregnant, or breastfeeding,

MDHHS suggests you **avoid eating all fish listed as "*Limited*"** because of higher levels of chemicals.

If **NONE** of the above apply to you, it is usually OK to eat fish listed as "*Limited*" **1 or 2 times each year**.

http://www.michigan.gov/documents/mdch/MDCH_EAT_SAFE_FISH_GUIDE_-_UPPER_PENINSULA_WEB_455361_7.pdf

Lake Superior Fish											
	WI - Unrestricted consumption and fish size - (Mercury, PCBs)	WI -1 meal per week consumption and fish size = 4 meals per month x 12 months = 48 meals per year (Mercury, PCBs)	WI - 1 meal per month consumption = 12 meals per year and fish size (Mercury, PCBs)	WI - Do not eat and fish size (Mercury, PCBs)	MI - Servings per month x 12 months and fish size (Mercury, PCBs, Toxaphene, Dioxins)	MI - Servings per month x 12 months - trimming filets with back/belly fat removed and broiling/grilling	MI - Servings per month x 12 months and fish size (Mercury, PCBs, Toxaphene, Dioxins)	MI - Servings per month x 12 months - trimming filets with back/belly fat removed and broiling/grilling	MI - Servings per year and fish size (Mercury, PCBs, Toxaphene, Dioxins)	MI - Servings per year and fish size - trimming filets with back/belly fat removed and broiling/grilling	MI - Do not eat and fish size (Mercury, PCBs, Toxaphene, Dioxins)
Women up to age 50 (child bearing age) and Children (under age 15)											
Commercial											
rainbow smelt	any size- unlimited										
lake herring (cisco)		any size - 48 meals per year			any size - 96 meals per year - (8 fish/month x 12 months)	any size - 96 meals per year - (8 fish/month x 12 months)					
chubs		any size - 48 meals per year									
lake whitefish		any size - 48 meals per year			any size - 24 meals per year - (2 fish/month x 12 months)	any size - 48 meals per year - (4 fish/month x 12 months)					
lake trout		<22" - 48 meals per year	22"-39" - 12 meals/year	any fish > 39"	< 24" - 24 meals per year - (2 fish/month x 12 months)	< 24" - 48 meals per year - (4 fish/month x 12 months)	24" - 28" 12 meals per year - (1 fish/month x 12 months)	24" - 28" 24 meals per year - (2 fish/month x 12 months)	> 28" - 6 meals per year	> 28" - 12 meals per year	
siscowet lake trout			< 29" - 12 meals/year	any fish > 29"							any size
walleye			any size - 12 meals/year		any size - 24 meals per year - (2 fish/month x 12 months)	any size - 24 meals per year - (2 fish/month x 12 months)					
Subsistence											
yellow perch		any size - 48 meals per year			any size - 24 meals per year - (2 fish/month x 12 months)	any size - 24 meals per year - (2 fish/month x 12 months)					
coho salmon		any size - 48 meals per year			any size - 48 meals per year - (4 fish/mon. x 12 months)	any size - 96 meals per year - (8 fish/month x 12 months)					
rainbow trout		any size - 48 meals per year			any size - 24 meals per year - (2 fish/month x 12 months)	any size - 48 meals per year - (4 fish/month x 12 months)					

	WI - Unrestricted consumption and fish size - (Mercury, PCBs)	WI -1 meal per week consumption and fish size = 4 meals per month x 12 months = 48 meals per year (Mercury, PCBs)	WI - 1 meal per month consumption = 12 meals per year and fish size (Mercury, PCBs)	WI - Do not eat and fish size (Mercury, PCBs)	MI - Servings per month x 12 months and fish size (Mercury, PCBs, Toxaphene, Dioxins)	MI - Servings per month x 12 months - trimming filets with back/belly fat removed and broiling/grilling	MI - Servings per month x 12 months and fish size (Mercury, PCBs, Toxaphene, Dioxins)	MI - Servings per month x 12 months - trimming filets with back/belly fat removed and broiling/grilling	MI - Servings per year and fish size (Mercury, PCBs, Toxaphene, Dioxins)	MI - Servings per year and fish size - trimming filets with back/belly fat removed and broiling/grilling	MI - Do not eat and fish size (Mercury, PCBs, Toxaphene, Dioxins)
brown trout		any size - 48 meals per year			any size - 12 meals per year - (1 fish/month x 12 months)	any size - 24 meals per year - (2 fish/month x 12 months)					
burbot		any size - 48 meals per year									any size
chinook salmon		< 32" - 48 meals per year	> 32" - 12 meals per year						any size - 6 meals per year	any size - 12 meals per year	
lake sturgeon			> 50" - 12 meals per year								
Northern Pike					any size - 24 meals per year - (2 fish/month x 12 months)	any size - 24 meals per year - (2 fish/month x 12 months)					
Steelhead					any size - 24 meals per year - (2 fish/month x 12 months)	any size - 48 meals per year - (4 fish/month x 12 months)					
Suckers					any size - 24 meals per year - (2 fish/month x 12 months)	any size - 48 meals per year - (4 fish/month x 12 months)					

Lake Superior Fish											
	WI - Unrestricted consumption and fish size - (Mercury, PCBs)	WI -1 meal per week consumption and fish size = 4 meals per month x 12 months = 48 meals per year (Mercury, PCBs)	WI - 1 meal per month consumption = 12 meals per year and fish size (Mercury, PCBs)	WI - Do not eat and fish size (Mercury, PCBs)	MI - Servings per month x 12 months and fish size (Mercury, PCBs, Toxaphene, Dioxins)	MI - Servings per month x 12 months - trimming filets with back/belly fat removed and broiling/grilling	MI - Servings per month x 12 months and fish size (Mercury, PCBs, Toxaphene, Dioxins)	MI - Servings per month x 12 months - trimming filets with back/belly fat removed and broiling/grilling	MI - Servings per year and fish size (Mercury, PCBs, Toxaphene, Dioxins)	MI - Servings per year and fish size - trimming filets with back/belly fat removed and broiling/grilling	MI - Do not eat and fish size (Mercury, PCBs, Toxaphene, Dioxins)
Men (15 and older) and women (50 and older)											
Commercial											
rainbow smelt	any size- unlimited										
lake herring (cisco)	any size- unlimited				any size - 96 meals per year - (8 fish/month x 12 months)	any size - 96 meals per year - (8 fish/month x 12 months)					
chubs		any size - 48 meals per year									
lake whitefish		any size - 48 meals per year			any size - 24 meals per year - (2 fish/month x 12 months)	any size - 48 meals per year - 4 fish/month x 12 months)					
lake trout		<22" - 48 meals per year	22"-39" - 12 meals/year	any fish > 39"	< 24" - 24 meals per year - (2 fish/month x 12 months)	< 24" - 48 meals per year - (4 fish/month x 12 months)	24" - 28" 12 meals per year - (1 fish/month x 12 months)	24" - 28" 24 meals per year - (2 fish/month x 12 months)	> 28" - 6 meals per year	> 28" - 12 meals per year	
siscowet lake trout			< 29" - 12 meals/year	any fish > 29"					any size - 1 meal per year	any size - 2 meals per year	
walleye		any size - 48 meals per year			any size - 24 meals per year - (2 fish/month x 12 months)	any size - 24 meals per year - (2 fish/month x 12 months)					
Subsistence											
yellow perch	any size- unlimited				any size - 24 meals per year - (2 fish/month x 12 months)	any size - 24 meals per year - (2 fish/month x 12 months)					
coho salmon	any size- unlimited				any size - 48 meals per year - (4 fish/month x 12 months)	any size - 96 meals per year - (8 fish/month x 12 months)					
rainbow trout	any size- unlimited				any size - 24 meals per year - (2 fish/month x 12 months)	any size - 48 meals per year - (4 fish/month x 12 months)					

	WI - Unrestricted consumption and fish size - (Mercury, PCBs)	WI -1 meal per week consumption and fish size = 4 meals per month x 12 months = 48 meals per year (Mercury, PCBs)	WI - 1 meal per month consumption = 12 meals per year and fish size (Mercury, PCBs)	WI - Do not eat and fish size (Mercury, PCBs)	MI - Servings per month x 12 months and fish size (Mercury, PCBs, Toxaphene, Dioxins)	MI - Servings per month x 12 months - trimming filets with back/belly fat removed and broiling/grilling	MI - Servings per month x 12 months and fish size (Mercury, PCBs, Toxaphene, Dioxins)	MI - Servings per month x 12 months - trimming filets with back/belly fat removed and broiling/grilling	MI - Servings per year and fish size (Mercury, PCBs, Toxaphene, Dioxins)	MI - Servings per year and fish size - trimming filets with back/belly fat removed and broiling/grilling	MI - Do not eat and fish size (Mercury, PCBs, Toxaphene, Dioxins)
brown trout		any size - 48 meals per year			any size - 12 meals per year - (1 fish/mon. x 12 months)	any size - 24 meals per year - (2 fish/mon. x 12 months)					
burbot		any size - 48 meals per year							any size - 1 meal per year	any size - 2 meals per year	
chinook salmon		< 32" - 48 meals per year	> 32" - 12 meals per year						any size - 6 meals per year	any size - 12 meals per year	
lake sturgeon			> 50" - 12 meals per year								
Northern Pike					any size - 24 meals per year - (2 fish/month x 12 months)	any size -24 meals per year - (2 fish/month x 12 months)					
Steelhead					any size - 24 meals per year - (2 fish/month x 12 months)	any size - 48 meals per year - (4 fish/month x 12 months)					
Suckers					any size - 24 meals per year - (2 fish/month x 12 months)	any size - 48 meals per year - (4 fish/month x 12 months)					

Exhibit 1

GLIFWC's Lake Superior fish sampling and contaminant testing programs

Overall Findings

- All lake trout, whitefish, and herring samples tested under this project were below U.S. FDA action limits that restrict commercial sales for chemical contaminants.
- Concentrations of chemical contaminants varied between Lake Superior fish species. Fish lower in the food chain, such as whitefish and lake herring, had significantly lower PCB, chlordane, and mercury concentrations than predators such as lake trout and siscowet trout.
- The concentration of chemical contaminants such as PCBs, chlordane, and mercury increased with age and length of the fish.
- Trimming fillets and removing skin significantly reduced the concentration for PCBs, chlordane, and other organic persistent contaminants.
- Trimming fillets and removing skin did not reduce mercury concentrations in Lake Superior fish due to mercury being bound to muscle tissue.

Realizing that the treaty fishery and its markets are impacted by publicity surrounding fish contaminant issues and FDA's new Seafood safety regulations, GLIFWC contracted funding from the Administration for Native American's (ANA) program to undertake a contaminant study of Lake Superior fish and develop a tribal regulatory structure in compliance with FDA's Hazard Analysis Critical Control Point (HACCP) seafood safety regulations.

Tribes were particularly interested in determining how the removal of belly and back fat from Lake Superior fish could reduce chemical contaminant levels in the edible portion of fish sold by tribal fishermen.

Project design

In designing the project, GLIFWC realized the study needed to address the following:

- Adequate sample size and statistical power to determine if the test results were less than the FDA action levels and state contaminant guidelines;
- Analyzed fish tissue needed to be representative of the edible portion that is to be sold;
- Analytical results needed to be supported by good quality control and quality assurance procedures including documentation.

Furthermore, in order to limit the number of samples needed to be analyzed, the following were considered:

- Within a species, larger and older fish tend to have higher contaminant concentrations;
- Species of fish at the top of the food chain tend to have higher contaminant concentrations than species of fish lower in the food chain;
- A single species of fish from a given water body tends to be exposed to similar amounts of environmental contaminants.

Collecting Lake Superior fish samples

Sample size ranges were selected after analyzing data of the lengths of Lake Superior fish measured from the tribal commercial catch from 1986 to 1999. Within a species, up to 48 fish were collected per size range.

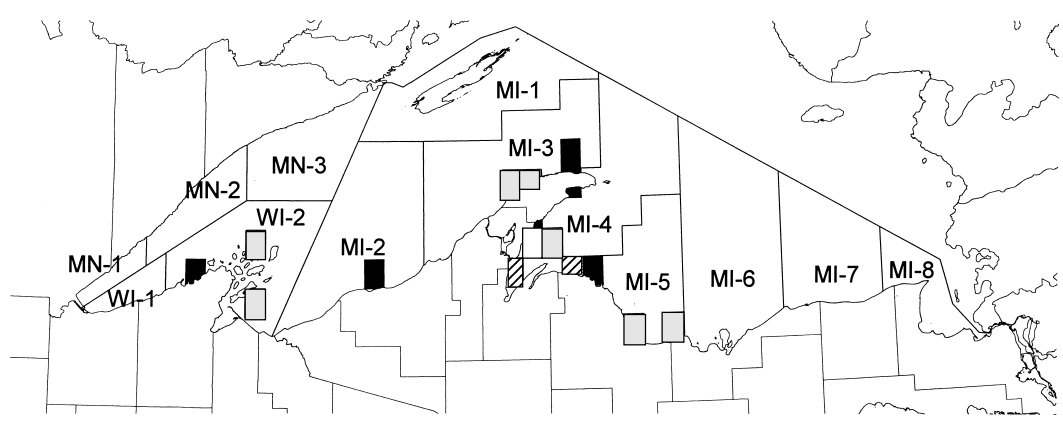
Common Name	Size Range (in)	No. Composites (C)	No. Fish/C	Total No. Fish
siscowet	17.0-18.0	4	12	48
siscowet	19.5-20.5	4	12	48
siscowet	22.0-23.0	4	12	48
siscowet	24.5-25.5	4	12	48
siscowet	24.5-25.5	4	12	48
lake trout	25.0-26.0	4	12	48
lake trout	27.0-28.0	4	12	48
lake trout	27.0-28.0	3	8	24
whitefish	22.0-24.0	4	12	48
lake herring	15.0-17.0	4	12	48

(Table 6)

With the help of tribal fishermen, GLIFWC and tribal biologists collected four species of fish from the southern shore of Lake Superior (See map). Fisheries biologists then measured fish for total length, recorded their round weight, determined their sex, and collected otoliths and scales for aging purposes. Each fish collected was then tagged, placed into a specialized storage bag, cooled, and placed into a freezer.

A chain-of-custody form was also started for each species of fish collected from a given location on a given date and updated as samples were transferred between freezers and laboratories. This enabled GLIFWC to trace back testing results to the specific fish collected and at a specific sampling location.

Lake Superior management units in U.S. waters and areas of collection for ANA-HACCP contaminant analysis



Species collected in area

Lake Trout | Siscowet Trout | Whitefish | Lake Herring

Tribally licensed commercial fishermen assisted GLIFWC in collecting 431 fish samples for contaminant testing during numerous Lake Superior assessments. Above are fisheries biologists Sean Sitar, MIDNR, and Bill Mattes, GLIFWC, working aboard Gilmore Peterson's fishing tug. (Photo by Sue Erickson.)

Processing Lake Superior fish samples

All fish were aged using standardized techniques adopted by the Lake Superior Technical Committee of the Great Lakes Fishery Commission. Each set of 48 similarly-sized fish was then divided into 4 groups of up to 12 similarly-aged fish.

Fish samples were then processed at the Lake Superior Research Institute (LSRI), UW- Superior, Superior Wisconsin. Larry Brooke, LSRI research chemist, and Joe Duffy, Red Cliff tribal fisherman, teamed their talents to process the fish samples. Two fillets were collected from each fish. One fillet was processed raw and divided into three separate tissues of skin, muscle and fatty tissue and the other fillet was saved for commercial smoking. During this process, data was also recorded on weights and water content of samples.

Laboratory staff then cut skin and fat tissue into small pieces, froze the tissue with liquid nitrogen, and ground the tissue into a coarse powder. Muscle tissue was also ground. Similar tissues (i.e. skin, muscle, or fatty tissue) were then combined from twelve fish of similar age to form a single composite sample.

An equal weight of each set of tissues (skin, muscle or fatty tissue) was combined (composited) into a single sample and placed into several special sample bottles and stored in a freezer. Chain-of-custody forms were then updated and samples were sent to EN CHEM, Inc. analytical laboratory in Madison, Wisconsin for chlorinated organic chemical analysis. Samples were also archived for future research.

(See Sampled Lake Superior fish, page 6)

All lake trout, whitefish, and herring samples tested under this project were below U.S. FDA action limits that restrict commercial sales for chemical contaminants.

Sampled Lake Superior fish below FDA restrictions for both PCBs and chlordane

Continued from page 5)

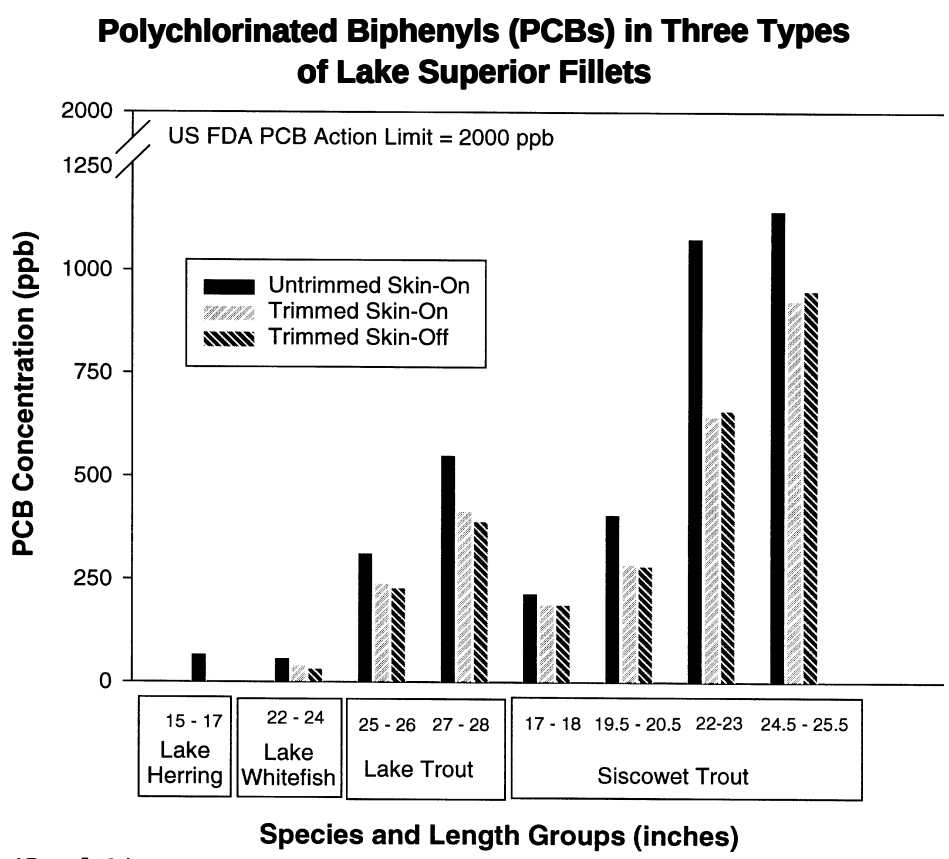
Joe Duffy, Red Cliff commercial fisherman, (left) assisted by Ben Pfaff, University of Wisconsin-Superior student, processes fish samples for contaminant testing at the Lake Superior Research Institute, UW-Superior. (Photo by Charlie Otto Rasmussen.)

Testing Lake Superior fish samples

Each composite sample was analyzed for total mercury, polychlorinated biphenyls as aroclor mixtures, and a suite of chlorinated pesticides. Mercury testing was completed at the Lake Superior Research Institute at the U.W. Superior and the University of Minnesota-Duluth. Chlorinated organic analyses were conducted by EN CHEM, Inc. of Madison, Wisconsin.

Polychlorinated biphenyls (PCBs) findings

- None of the Lake Superior fish samples (lake herring, whitefish, lake trout, or siscowet trout) exceed the U.S. FDA's PCB action limit for commercial sales for PCBs of 2000 ppb (2.0 ppm).
- Trimming fillets lead to reduced PCB contaminant levels by 12% to 40% depending on the fish species. For example, PCB contaminant levels in whitefish were reduced 32% and in lake trout 23-25%. PCB contaminant levels in siscowet trout were reduced between 12-40% depending upon the length of the fish. (See Trimmed Skin-On figures in Table 7.)
- Removing skin from fillets further reduced PCB concentrations in whitefish, lake trout, and siscowet trout between 17 and 20.5 inches. (See Trimmed Skin-Off figures in Table 7.)



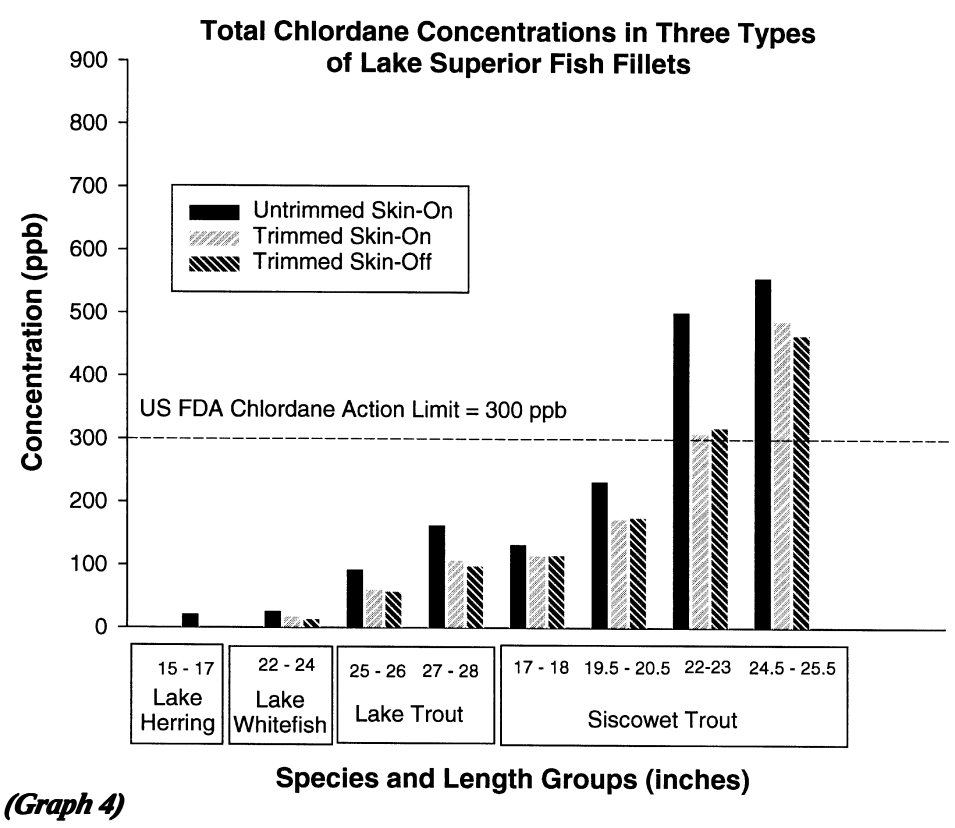
(Graph 3.)

Length Group *Inches*	Processing *Fillets*	Age (Range) *years*	Location (see map) *Management Unit*	Number of Composites *(4 - 12 fish each)*	Processing Reduction *Percentage*	Total Polychlorinated Biphenyls *Mean*	*Lower*	*Upper*	Exceeds US FDA Action Limit
Lake Herring (Total = 48 fish)									
15.0-17.0	Untrimmed Skin-On	9 (7 to 13)	MI-4	4		68	61	75	No
Lake Whitefish (Total = 47 fish)									
22.0-24.0	Untrimmed Skin-On	9 (7 to 12)	MI-4	4		57.8	49	67	No
22.0-24.0	Trimmed Skin-On				32%	39.4	28	51	No
22.0-24.0	Trimmed Skin-Off				44%	32.3	20	45	No
Lake Trout (Total = 128 fish)									
25.0-26.0	Untrimmed Skin-On	9 (6 to14)	MI-4	4		313	244	382	No
25.0-26.0	Trimmed Skin-On				23%	241	186	297	No
25.0-26.0	Trimmed Skin-Off				27%	229	178	280	No
27.0-28.0	Untrimmed Skin-On	10 (6 to 16)	MI-2,3,4,5; WI-2	8		551	378	724	No
27.0-28.0	Trimmed Skin-On				25%	415	279	551	No
27.0-28.0	Trimmed Skin-Off				29%	391	274	509	No
Siscowet Trout (Total = 208 fish)									
17.0-18.0	Untrimmed Skin-On	13 (10 to 17)	MI-4	4		216	177	255	No
17.0-18.0	Trimmed Skin-On				12%	190	152	227	No
17.0-18.0	Trimmed Skin-Off				13%	189	151	226	No
19.5-20.5	Untrimmed Skin-On	15 (9 to 20)	MI-4	4		407	326	487	No
19.5-20.5	Trimmed Skin-On				30%	286	249	324	No
19.5-20.5	Trimmed Skin-Off				31%	283	260	305	No
22.0-23.0	Untrimmed Skin-On	16 (11 to 24)	MI-4; WI-2	8		1078	422	1734	No
22.0-23.0	Trimmed Skin-On				40%	647	375	919	No
22.0-23.0	Trimmed Skin-Off				39%	660	383	937	No
24.5-25.5	Untrimmed Skin-On	18 (15 to 23)	MI-3,4,5; WI-2	6		1145	890	1401	No
24.5-25.5	Trimmed Skin-On				19%	926	780	1071	No
24.5-25.5	Trimmed Skin-Off				17%	952	802	1101	No

(Table 7)

Chlordane findings

- None of the Lake Superior fish samples of lake herring, whitefish, or lake trout exceeded the U.S. FDA's chlordane action limit of 300 ppb (0.3 ppm) for commercial sale.
- Siscowet samples in the 17-18 inch size group and the 19.5-20.5 inch size group **did not** exceed the U.S. FDA's chlordane action limit of 300 ppb (0.3 ppm).
- Siscowet from the 22-23 inch size group and 24.5-25.5 inch size group **did** exceed the U.S. FDA's chlordane action limit of 300 ppb (0.3 ppm).
- Trimming fillets led to reduced chlordane concentration levels by 13% to 38% depending on the fish species. For example, chlordane concentration levels in whitefish were reduced 33% and in lake trout 34%. Chlordane concentration levels in siscowet trout were reduced between 13-38% depending upon the length of the fish. (See Trimmed Skin-On figures in Table 8.)
- Removing skin from fillets further reduced chlordane concentrations in whitefish, lake trout, and siscowet trout between 17 and 20.5 inches. (See Trimmed Skin-Off figures in Table 8.)



(Graph 4)

Length Group *Inches*	Processing *Fillets*	Age (Range) *years*	Location (see map) *Management Unit*	Number of Composites *(4 - 12 fish each)*	Processing Reduction *Percentage*	Total Chlordane *Mean*	*Lower*	*Upper*	Exceeds US FDA Action Limit
Lake Herring (Total = 48 fish)									
15.0-17.0	Untrimmed Skin-On	9 (7 to 13)	MI-4	4		22	21	23	No
Lake Whitefish (Total = 47 fish)									
22.0-24.0	Untrimmed Skin-On	9 (7 to 12)	MI-4	4		26.5	25	28	No
22.0-24.0	Trimmed Skin-On				33%	17.6	15	21	No
22.0-24.0	Trimmed Skin-Off				47%	14.1	11	17	No
Lake Trout (Total = 128 fish)									
25.0-26.0	Untrimmed Skin-On	9 (6 to14)	MI-4	4		93	71	115	No
25.0-26.0	Trimmed Skin-On				34%	61	46	76	No
25.0-26.0	Trimmed Skin-Off				38%	58	43	72	No
27.0-28.0	Untrimmed Skin-On	10 (6 to 16)	MI-2,3,4,5; WI-2	8		164	119	210	No
27.0-28.0	Trimmed Skin-On				34%	108	75	141	No
27.0-28.0	Trimmed Skin-Off				40%	99	72	127	No
Siscowet Trout (Total = 208 fish)									
17.0-18.0	Untrimmed Skin-On	13 (10 to 17)	MI-4	4		133	112	153	No
17.0-18.0	Trimmed Skin-On				13%	116	95	137	No
17.0-18.0	Trimmed Skin-Off				13%	116	94	137	No
19.5-20.5	Untrimmed Skin-On	15 (9 to 20)	MI-4	4		233	167	299	No
19.5-20.5	Trimmed Skin-On				25%	174	131	216	No
19.5-20.5	Trimmed Skin-Off				24%	176	131	220	No
22.0-23.0	Untrimmed Skin-On	16 (11 to 24)	MI-4; WI-2	8		502	207	797	Yes
22.0-23.0	Trimmed Skin-On				38%	310	180	440	Yes
22.0-23.0	Trimmed Skin-Off				36%	319	186	452	Yes
24.5-25.5	Untrimmed Skin-On	18 (15 to 23)	MI-3,4,5; WI-2	6		557	393	721	Yes
24.5-25.5	Trimmed Skin-On				12%	488	309	666	Yes
24.5-25.5	Trimmed Skin-Off				16%	466	353	579	Yes

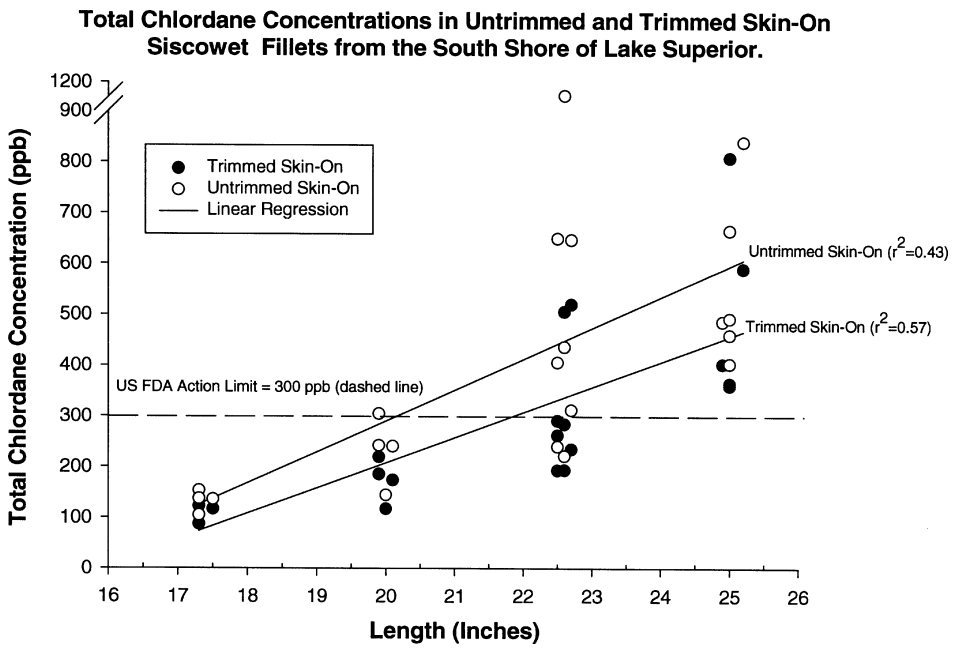
(Table 8)

(See Lake Superior fish, page 7)

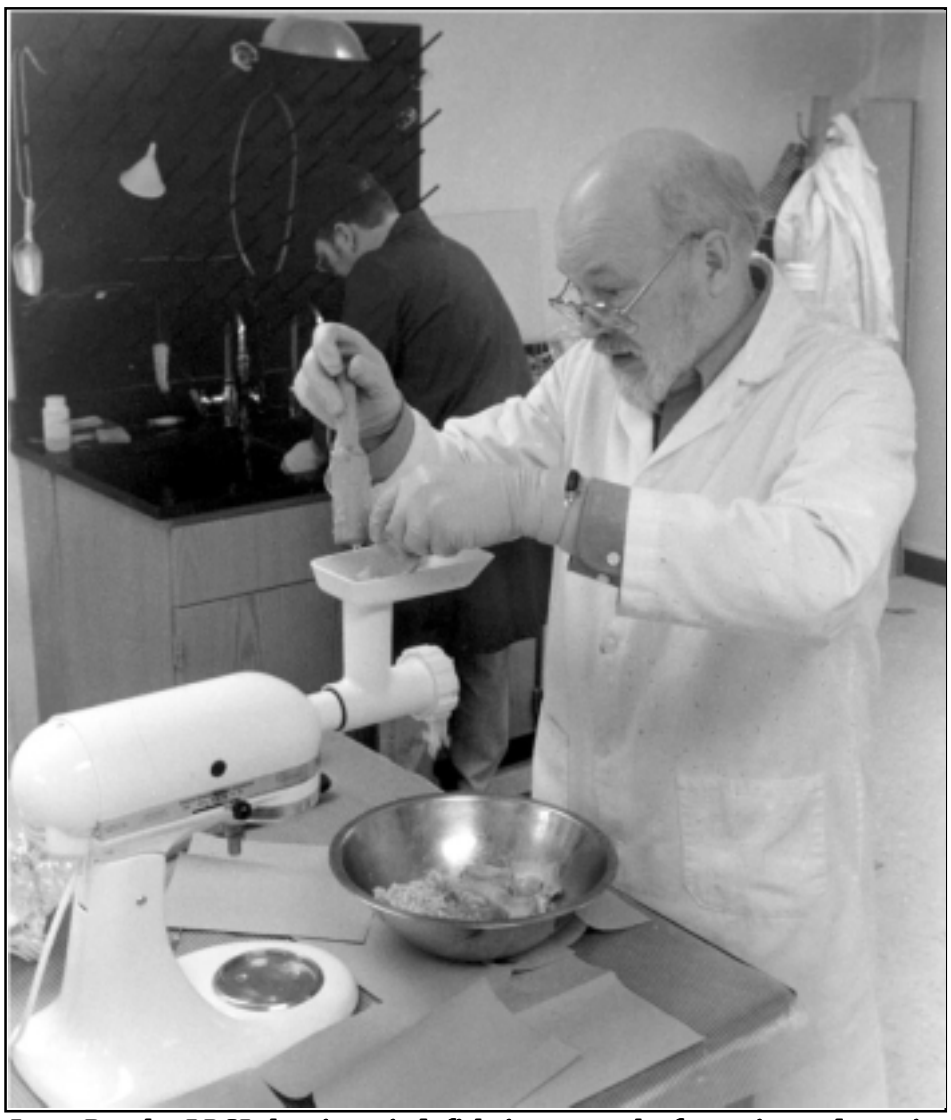
Lake Superior fish are tested for mercury

(Continued from page 6)

Using test results from 22 composite samples and linear regression, GLIFWC has determined that Lake Superior commercial fishermen could harvest and process siscowet trout up to 22 inches without exceeding FDA's action limit for chlordane of 300 ppb (0.3 ppm), **if the belly and back fat is removed from the fillet.** (note: see Total Chlordane Concentrations in Untrimmed and Trimmed Skin-on Siscowet Fillets from the South Shore of Lake Superior, Graph 5)



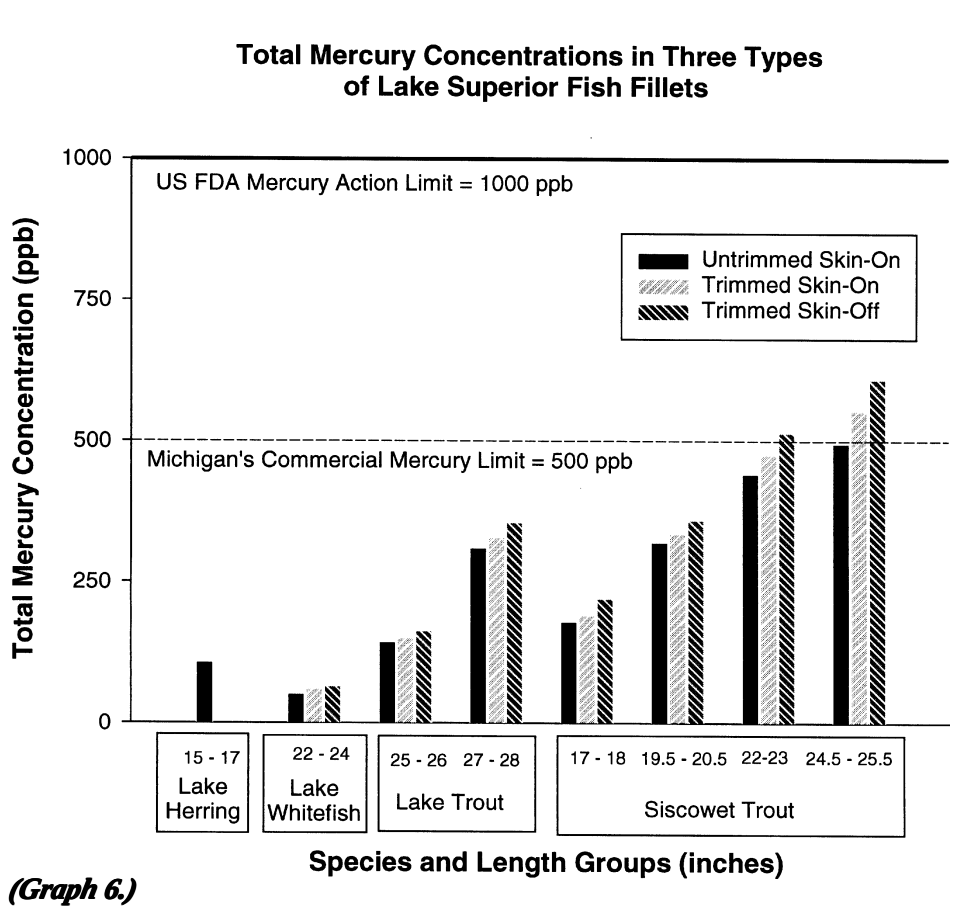
(Graph 5. Trimming 22 inch siscowet fillets (closed circles) reduced the estimated average total chlordane concentrations from around 420 ppb to at or below 300 ppb, and thus allowed 22 inch siscowet to be at or below the U.S. FDA's no-sale action limit (300 ppb).)



Larry Brooke, LRSI chemist, grinds fish tissue samples for testing to determine the mercury levels in Lake Superior fish. None of the Lake Superior whitefish, lake trout, lake herring, or siscowet trout samples exceed the U.S. FDA's methylmercury action limit for commercial sales of 1000 ppb (1.0 ppm). (Photo by Charlie Otto Rasmussen.)

Mercury findings

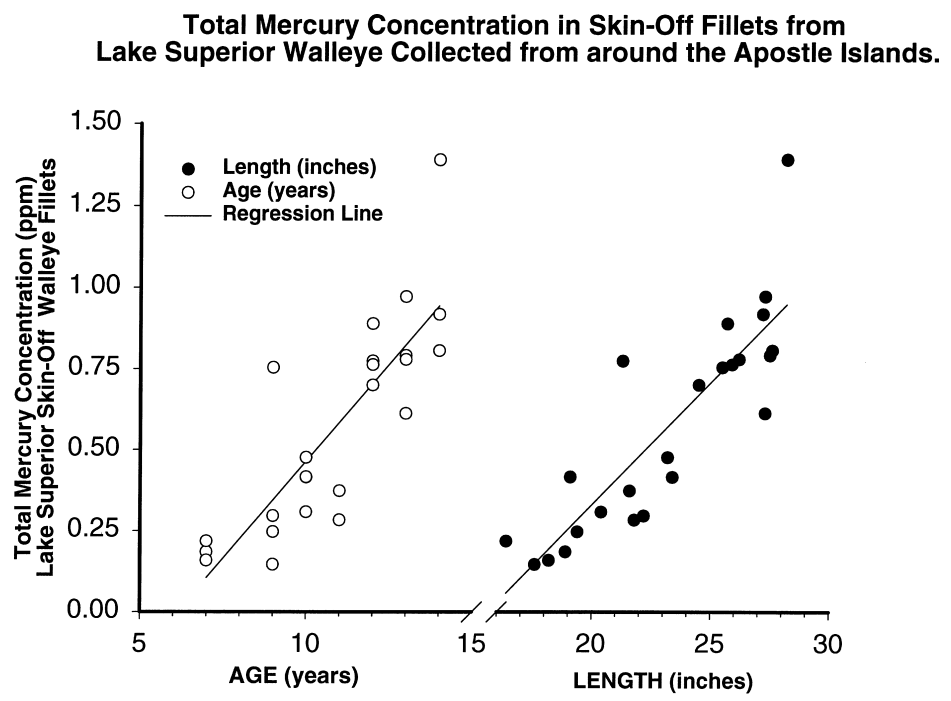
- None of the Lake Superior fish samples (lake herring, whitefish, lake trout, or siscowet trout) exceed the U.S. FDA's methylmercury action limit for commercial sales of 1000 ppb (1.0 ppm).
- Only siscowet samples in the 22-23 inch size group and 24.5-25.5 inch size group exceeded 500 ppb (.5 ppm), a lower level used by Michigan for fish caught and sold in that state.



(Graph 6.)

Length Group Inches	Processing Fillets	Age (Range) years	Location (see map) Management Unit	Number of Composites (4 - 12 fish each)	Total Mercury Mean	Lower	Upper	Exceeds US FDA Action Limit
Lake Herring (Total = 48 fish)								
15.0-17.0	Untrimmed Skin-On	9 (7 to 13)	MI-4	4	107	65	149	No
Lake Whitefish (Total = 47 fish)								
22.0-24.0	Untrimmed Skin-On	9 (7 to 12)	MI-4	4	51	44	58	No
22.0-24.0	Trimmed Skin-On				61	52	70	No
22.0-24.0	Trimmed Skin-Off				65	60	70	No
Lake Trout (Total = 128 fish)								
25.0-26.0	Untrimmed Skin-On	9 (6 to14)	MI-4	4	143	115	171	No
25.0-26.0	Trimmed Skin-On				150	122	179	No
25.0-26.0	Trimmed Skin-Off				163	133	193	No
27.0-28.0	Untrimmed Skin-On	10 (6 to 16)	MI-2,3,4,5; WI-2	8	310	204	415	No
27.0-28.0	Trimmed Skin-On				328	211	446	No
27.0-28.0	Trimmed Skin-Off				355	227	484	No
Siscowet Trout (Total = 208 fish)								
17.0-18.0	Untrimmed Skin-On	13 (10 to 17)	MI-4	4	179	148	210	No
17.0-18.0	Trimmed Skin-On				190	158	221	No
17.0-18.0	Trimmed Skin-Off				220	186	255	No
19.5-20.5	Untrimmed Skin-On	15 (9 to 20)	MI-4	4	320	265	376	No
19.5-20.5	Trimmed Skin-On				335	277	393	No
19.5-20.5	Trimmed Skin-Off				360	301	418	No
22.0-23.0	Untrimmed Skin-On	16 (11 to 24)	MI-4; WI-2	8	441	345	536	No
22.0-23.0	Trimmed Skin-On				476	360	592	No
22.0-23.0	Trimmed Skin-Off				515	396	633	No
24.5-25.5	Untrimmed Skin-On	18 (15 to 23)	MI-3,4,5; WI-2	6	496	437	556	No
24.5-25.5	Trimmed Skin-On				554	486	621	No
24.5-25.5	Trimmed Skin-Off				610	535	684	No

(Table 9.)



(Graph 7. Twenty-four walleye (16-28 inches) were collected from around Lake Superior's Apostle Islands and only one of the largest walleye (28 inches) of the 24 collected exceeded the U.S. FDAs 1.0 methylmercury action limit.)

Concentrations of chemical contaminants varied between Lake Superior fish species. Fish lower in the food chain, such as whitefish and lake herring, had significantly lower PCB, chlordane, and mercury concentrations than predators such as lake trout and siscowet trout.

(See Testing reveals good news, page 11)

Tips for keeping smoked fish safe

Smoked Lake Superior fish has been enjoyed by the Anishinaabe and their visitors for hundreds of years. This regional delicacy remains available today at numerous locations along Lake Superior's south shore (See Tribal retail & wholesale outlets, page 12).

Smoked fish customers are often under the impression that smoked fish is "preserved" and does not need to be refrigerated. This is wrong and could be a deadly mistake. Remembering a few important points will protect the health and safety of your family when transporting and storing smoked fish.

Botulism toxins can be deadly

Clostridium botulinum, commonly referred to as botulism, is found in soil, water, vegetables, meats, dairy products, and fish. The botulism toxin develops from spores of the botulism bacteria. These spores grow and produce a toxin when non-acid food (e.g., meat, fish, poultry, and vegetables) is held in an air-tight container such as a plastic bag or cans.

Botulism is both deadly and hard to detect since it produces little noticeable evidence of spoilage. Because botulism produces heat-resistant spores and requires the absence of oxygen for growth, it has been commonly associated with improperly canned food (usually home canning).

Botulism toxins are easily controlled

While the botulism toxin can be deadly, it is easily controlled. Using Hazard Analysis Critical Control Point (HACCP) techniques, Lake Superior fish smokers ensure proper salt content in their brining solutions. Fish smokers also ensure adequate cooking times (i.e. a minimum of 30 minutes) and temperatures (i.e. a minimum of 145°F) to destroy the bacteria that produces the botulism toxins.

Refrigerate smoked fish

Lake Superior fish smokers also use HACCP techniques to ensure that smoked products are stored at proper temperatures (38°F or below) and are properly labeled. Customers reading the labels provided on smoked fish products will find these products must be:

- **kept refrigerated at or below 38°F, and**
- **eaten by a specified expiration date.**

Ensuring that your smoked fish **is in a refrigerated condition** will keep you and your family safe and returning for more of Lake Superior's famous smoked fish.

Newago's smoked fish products contain labels stressing the importance of keeping smoked fish refrigerated. These labels help to ensure the safety of their customers and promote family owned businesses. Newago's Fish Market is located in Chassell, Michgan. (Photo by Jim Thannum.)

Freezing freshwater fish

(Continued from page 10)

- Keep your freezer cold. A storage temperature of -20° F or colder is strongly recommended by food scientists. When stored at 0° F, fish have only half the storage life possible at -20° F.
- Thawing fish in still air is not recommended—the surface of the fish will warm, become soft and begin to spoil before the center thaws. Thawing fish under refrigeration (35 to 40° F) or submersing securely packaged fish in cold running water is recommended. It is important to remember that thawed fish deteriorate rapidly due to the release of enzymes and nutrients for bacteria growth.
- Avoid thawing and refreezing fish. The flesh becomes mushy and dry when cooked.

Testing reveals good news on Lake Superior fish contaminant levels

(Continued from page 7)

Benzene hexachloride, DDT, aldrin/dieldrin, mirex, and heptachlor/heptachlor epoxide findings

- All Lake Superior fish samples (lake herring, lake whitefish, lake trout, or siscowet trout) were far below the U.S. FDA's action limit for these chemical contaminants. (See Table 11.)

GLIFWC's Lake Superior study was conducted in the western and central portions of Lake Superior. ITFAP's study was conducted in the eastern portion of Lake Superior. (See story below.)

Chemical	FDA Action Level (ppb)	Lake Herring (15-17 in.) n = 4 Mean (Range)	Lake Whitefish (22-24 in.) n = 4 Mean (Range)	Lake Trout (25-26 in.) n = 4 Mean (Range)	Lake Trout (27-28 in) n = 8 Mean (Range)	Siscowet Trout (22-23 in.) n = 8 Mean (Range)	Siscowet Trout (24.5-25.5 in.) n = 6 Mean (Range)
Benzene hexachloride	300	0 (0-0)	1.5 (0-7.0)	6.2 (5.4-7.3)	5.8 (4.7-8.1)	4.4 (1.6-6.9)	12 (10-18)
DDT & metabolites	5000	3.8 (0-20)	4.8 (0-30)	130 (85-170)	230 (150-380)	630 (260-1300)	680 (470-1000)
Aldrin/Dieldrin	300	7.2 (0-9.6)	0 (0-0)	26 (23-32)	35 (28-48)	79 (32-130)	78 (60-120)
Heptachlor/ Heptachlor epoxide	300	0 (0-0)	10 (3.4-15)	5.9 (5.4-6.3)	6.8 (5.7-8.6)	12 (2.3-26)	12 (8.5-20)
Mirex	100	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	7.8 (0-27)	17 (10-38)

(Table 12. n = number of composite samples each containing 7 to 13 fish.)

Contaminant results good in Whitefish Bay

Sault Ste. Marie, Mich.—There's good news for people who like to eat fish. Lake Superior fish are well below government guidelines for safe consumption. Lake Superior whitefish and take trout collected from commercial catches in the Whitefish Bay area (MI-8) recently tested well below state and federal guidelines.

Contaminant levels of the Lake Superior fish were analyzed as part of a long-term fish contaminant monitoring program conducted by the Inter-Tribal Fisheries and Assessment Program (ITFAP) in order to determine contaminant levels in commercially caught fish. Results from an independent laboratory analysis are compared to contaminant levels determined to be safe by various government agencies. ITFAP, also shares the results with these agencies, including the Michigan Department of Public Health.

Lake Superior fish were tested for a wide range of contaminants, including mercury, PCBs, dioxins and pesticides such as DDT. All fish were considerably below the guidelines for commercial fish issued by the U.S. Food and Drug Administration (FDA) and below the Michigan Department of Public Health's guidelines for consumption of sport fish by the general public.

Lake Superior fish were remarkably low in mercury, especially when compared to levels of mercury found in fish from most inland lakes. Mercury, mostly from sources such as coal burning electrical plants, accumulates in rain and snow and then concentrates in Lake Superior and in the smaller inland lakes.

Levels of pesticides such as DDT, which was banned in the United States in the 1970s, are also remarkably low in Lake Superior fish. Contaminant levels in fish from all of the Great Lakes have declined dramatically since the 1970s, when regulations were put in place to reduce pollution.

These results are encouraging for those who enjoy eating Great Lakes fish, especially since studies show that most Americans eat a diet high in saturated animal fats.

Most Americans could dramatically reduce their risk of heart attack and stroke by switching to a more lean protein source, such as properly prepared fish (fillet and cook with no additional fat).

Other studies also show that a different type of fat, Omega-3 fatty acids, significantly reduces the risk of heart disease and may actually reduce the risk of cancer. Great Lakes fish (like whitefish, lake trout, or chub) are especially high in Omega-3 fatty acids.

For more information, contact Mike Ripley, ITFAP Environmental Coordinator, at 906-632-0072.

Exhibit 2

GREAT LAKES INDIAN FISH & WILDLIFE COMMISSION

P. O. Box 9 • Odanah, WI 54861 • 715/682-6619 • FAX 715/682-9294

• MEMBER TRIBES •

MICHIGAN
Bay Mills Community
Keweenaw Bay Community
Lac Vieux Desert Band

WISCONSIN
Bad River Band
Lac Courte Oreilles Band
Lac du Flambeau Band
Red Cliff Band
St. Croix Chippewa
Sokaogon Chippewa

MINNESOTA
Fond du Lac Band
Mille Lacs Band

To: Ann McCammon-Soltis, Policy Analyst

From: Matt Hudson, Environmental Biologist

Date: April 11, 2006

Re: Lake Trout Contaminant Testing Project – Final Memo Revised to Incorporate Corrected Data in Three Tables.

The attached memo is an updated and corrected version of my May 18th, 2005 memo to you entitled, "Reporting Results for U.S. EPA Grant Number: EQ97598601-0". This updated memo replaces the one from May 18th, 2005.

Table 13 has been updated with corrected tissue weight values for whole fillet, muscle, fat, and skin samples for all lake trout except those in the smallest size group. In addition, an error was found in the calculations used to estimate chemical concentrations in skin-on trimmed (SOT) and skin-on untrimmed (SOUT) fillets. Tables 15 and 17 were updated to include these corrections. The muscle tissue concentrations reported in these tables were correct.

The data corrections did not affect any conclusions that would result from the data as presented in the memo. For instance, all muscle tissue, SOT, and SOUT fillets were still below all FDA chemical concentration limits for the commercial sale of fish.

cc Neil Kmiecik, Biological Services Director
John Coleman, Environmental Section Leader
James Thannum, Planning Director

GREAT LAKES INDIAN FISH & WILDLIFE COMMISSION

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• MEMBER TRIBES •

MICHIGAN	WISCONSIN		MINNESOTA
Bay Mills Community	Bad River Band	Red Cliff Band	Fond du Lac Band
Keweenaw Bay Community	Lac Courte Oreilles Band	St. Croix Chippewa	Mille Lacs Band
Lac Vieux Desert Band	Lac du Flambeau Band	Sokaogon Chippewa	

To: Ann McCammon-Soltis, Policy Analyst

From: Matt Hudson, Environmental Biologist Matt Hudson

Date: April 11, 2006

Re: Reporting Results for U.S. EPA Grant Number: EQ97598601-0

Attached are results for U.S. EPA Grant Number: EQ97598601-0. Also included are brief descriptions of the fish processing and analytical methods used to produce the data.

The objectives of this study were to:

1. Determine the wet weight of each fillet's skin, lipid dense trimmings, and muscle tissue collected from lake trout (*Salvelinus namaycush namaycush*) captured in management units MI-2, MI-3 and MI-4.

2. Determine the concentration of chemicals listed in Table 1 in 16 composite muscle samples; lipid and moisture content in 16 composite muscle, 16 lipid-dense, and 16 skin samples; and archive these 48 composite samples from management units MI-2, MI-3 and MI-4.

3. Based on tissue wet weights and chemical concentrations, mathematically estimate the chemical concentrations in skin-on trimmed fillets (SOT) and skin-on untrimmed fillets (SOUT).

4. Compare the mean chemical composite concentrations of the skin-off trimmed fillet (muscle), SOT and SOUT fillets to the U.S. Food and Drug Administration's environmental chemical concentration limits for the sale of fish.

Methods

Lake Trout Collection and Storage

Lake trout collections occurred in November 2003 using gillnets along the central south shore of Lake Superior in lake trout fisheries management units MI-2, MI-3, and MI-4 (Figure 1). Four length ranges of lake trout were collected: 43-48, 52-54.5, 61-63.5, and

70-72.5 centimeter (cm). The length ranges selected span the length range of lake trout commonly harvested by tribal commercial fishermen (Figure 2). Samples were handled in a similar manner to commercially harvested fish and placed on ice within hours of collection. Samples were frozen intact within 24 hours of collection and remained frozen (at temperatures at or below -10°C) until processing at the analytical laboratory. The date, time, and conditions of collection and storage were documented on chain-of-custody forms.

Lake Trout Processing into Composites

Total length, round weight, and aging material (sagittal otolith) were collected from each fish prior to freezing. The Great Lakes Indian Fish and Wildlife Commission's Great Lakes Fisheries Section aged the fish to the nearest year. Fish were selected for each composite group based on length and age. Lake trout were processed into composites at the Lake Superior Research Institute, University of Wisconsin-Superior in February and March of 2003. Mean length (cm) and age (yr) ± one standard deviation are given for each composite size group in Table 2.

Fish were thawed before processing. Individual lake trout were filleted using a stainless steel knife. Fillets were segmented into skin, dorsal/ventral fatty tissue (fat), and muscle tissue. Laboratory personnel were trained by an experienced tribal fisherman during a previous GLIFWC study on the technique used to trim the fillets. Each individual fillet component was weighed separately before grinding and compositing, based on equal tissue weights, according to the pre-assigned groups. On each processing day, a can of commercial chunk light tuna (*Thunnus sp*.) was divided in half. One half was processed in the same manner as the lake trout composites and the other half was transferred directly to an amber sample jar. These samples were used as procedural blanks to check for contamination that may have been introduced during processing. All lab utensils and glassware were critically cleaned between composites of different tissue types and species. Moisture analyses were conducted on the composites. Remaining composite tissues were transferred to critically cleaned amber glass jars with Teflon lids and archived at in a freezer at temperatures at or below -10°C.

Chemical Extraction and Analysis

The muscle tissue composite of each sample was analyzed for 37 chemicals (Table 1). In addition, three skin and three fat composites were analyzed for the 36 organic chemicals between January and February of 2005 in order to compare measured organic chemical concentrations in the skin and fat tissue to the predicted values used to estimate concentrations of organic chemicals in skin-on trimmed fillets and skin-on untrimmed fillets.

Mercury was analyzed by LSRI according to LSRI SOP SA/13, *Cold Vapor Mercury Analysis in Biota*, based on EPA Method 245.6. Percent moisture was determined by LSRI using LSRI SOP H *Procedures for Determining Percent Moisture in Tissue Samples*. The organic chemicals were extracted according to EnChem SOP SOV-60

(based on EPA SW846 Method 3540C). Percent lipid was determined by EnChem SOP SOV-59, based on Standard Methods for the Examination of Water and Wastewater # 5520, 1992. Lipids were removed from the sample extracts using gel permeation chromatography (EnChem SOP 3-SOV-26, based on EPA SW846 Method 3640A). Following removal of lipids, the samples were filtered through a silica gel column to separate the chlorinated pesticides from the PCBs (EnChem SOP SOV-58, based on EPA SW846 Method 3630C). The final extracts were analyzed for PCBs according to EnChem SOP SOV-52 (based on EPA Method 8082) and chlorinated pesticides according to EnChem SOP SOV-51 (based on EPA Method 8081A).

A more complete description of the methods can be found in the Quality Assurance Project Plan (QAPP) for this project entitled "Lake Trout Collection, Compositing, and Environmental Chemical Contaminant Analysis Quality Assurance Project Plan".

Results

Quality Control

Results from quality control (QC) analyses used to monitor data quality for the organic chemical analyses can be found in Tables 3 - 8. QC results from the total mercury analyses can be found in Tables 9 - 12.

Objective #1 - Determine the wet weight of each fillet's skin, lipid dense trimmings, and muscle tissue collected from lake trout captured in management units MI-2, MI-3 and MI-4.

Table 13 lists descriptive data including tag number, sex, age, and length, along with the weight of muscle, skin, and fat tissues for the lake trout that make up each composite. Each fish was represented equally by weight in the composites, so the tissue weights listed in Table 13 are not the weight of tissue used for each fish in the composites. Weights of tissues from each fish in each composite were recorded by LSRI.

Objective #2 - Determine the concentration of chemicals listed in Table 1 in 16 composite muscle samples; lipid and moisture content in 16 composite muscle, 16 lipid-dense, and 16 skin samples; and archive these 48 composite samples from management units MI-2, MI-3 and MI-4.

Objective #3 - Based on tissue wet weights and chemical concentrations mathematically estimate the chemical concentrations in skin-on trimmed fillets (SOT) and skin-on untrimmed fillets (SOUT).

Table 14 displays skin and fat tissue composite mean ± one standard deviation percent moisture and percent lipid measurements. Table 15 displays the lake trout data by chemical. Table 15 also includes mean ± one standard deviation of muscle composite chemical concentrations for each size group and estimated mean ± one standard deviation of chemical concentrations in SOT and SOUT fillets. These estimates were calculated

using the assumption that organic, PBT contaminants partition primarily to the lipid tissue of organisms (Mackay 1982) and were based on tissue weights recorded during fish tissue processing, and percent lipid measured in each tissue.

Figures 3-11 display mean ± one standard deviation of composite muscle tissue concentrations by lake trout size group for seven of the nine chemicals targeted for zero discharge by the Lake Superior Binational Program.

In an effort to compare the PBT lipid partitioning assumptions used to calculate concentrations of chemicals in the SOT and SOUT fillets to measured data in those same tissues, three skin and three fat composite samples were analyzed for the same 36 organic chemicals as the muscle composites. Relative percent differences between the measured and predicted concentrations are given in Table 16. A plot of the measured and predicted concentrations in the fat composites is given in Figure 12 and a plot of the measured and predicted concentrations in the skin composites is given in Figure 13.

All tissue composites have been archived at LSRI in critically cleaned amber glass jars with Teflon lids, frozen at temperatures at or below -10°C.

Objective #4 - Compare the mean chemical composite concentrations of the skin-off trimmed fillet (muscle), SOT and SOUT fillets to the U.S. Food and Drug Administration's environmental chemical concentration limits for the sale of fish.

The United States Food and Drug Administration (FDA) regulates the sale of fish based on concentrations of various chemicals measured in fish fillets that are to be sold commercially. Table 17 compares Lake Superior lake trout muscle tissue concentrations of chemicals and chemical groups to FDA action levels for those chemicals/groups.

GLIFWC conducted a study of PBT contaminants in Lake Superior fish (including lake trout) in 1999. Table 18 compares concentrations of three chemicals measured in lake trout muscle tissue composites in 1999 to those measured in the current study (2003).

References

Mackay, D. Correlation of bioconcentration factors. Environmental Science and Technology. 1982. 16: 274-278.

cc Neil Kmiecik, Biological Services Director
John Coleman, Environmental Section Leader
James Thannum, Planning Director

TABLES

Table 1. Chemical and non-chemical analyses conducted on muscle tissue (e.g. trimmed, skin-off fillets) composite samples of Lake Superior lake trout (*Salvelinus namaycush namaycush*).

No	Chemical Analyses	Lab Conducting Analysis	No	Chemical Analyses	Lab Conducting Analysis
1	**Total Chlordane**	Calculated by GLIFWC	22	Toxaphene	En Chem
2	Cis-Chlordane	En Chem	23	Aldrin	En Chem
3	Trans-Chlordane	En Chem	24	Dieldrin	En Chem
4	Cis-nonachlor	En Chem	25	Heptachlor	En Chem
5	Trans-nonachlor	En Chem	26	Heptachlor epoxide	En Chem
6	Oxychlordane	En Chem	27	Endrin Ketone	En Chem
7	**Total PCBs**	En Chem	28	Methoxychlor	En Chem
8	1016	En Chem	29	Hexachlorobenzene	En Chem
9	1221	En Chem	30	Mirex	En Chem
10	1232	En Chem	31	Pentachloroanisole	En Chem
11	1242	En Chem	32	Endosulfan	En Chem
12	1248	En Chem	33	Endrin	En Chem
13	1254	En Chem	34	Endosulfan sulfate	En Chem
14	1260	En Chem	35	Endrin aldehyde	En Chem
15	**Total DDT**	Calculated by GLIFWC	36	α-benzene hexachloride	En Chem
16	4,4'-DDT	En Chem	37	β-benzene hexachloride	En Chem
17	4,4'-DDE	En Chem	38	δ-benzene hexachloride	En Chem
18	4,4'-DDD	En Chem	39	γ-benzene hexachloride	En Chem
19	2,4'-DDT	En Chem	40	Total mercury	LSRI
20	2,4'-DDE	En Chem	41	Lipid Determination	En Chem
21	2,4'-DDD	En Chem	42	Moisture Determination	LSRI

Table 2. Mean length and age (± one standard deviation) of each lake trout (*Salvelinus namaycush namaycush*) composite size group.

Size Group (cm)	**Mean Length (cm)**	**Mean Age**
43-48	45.7 ± 1.8	4.9 ± 1.4
52-54.5	53.6 ± 1.0	11.3 ± 1.3
61-63.5	62.0 ± 1.0	11.4 ± 1.4
70-72.5	70.6 ± 1.0	14.5 ± 1.2

Table 3. Relative Percent Agreement (RPA) of lipid concentration in duplicate lake trout (*Salvelinus namaycush namaycush*) samples analyzed by EnChem. No criteria given for acceptance.

Date of Analysis	Composite No.	Sample 1	Sample 2	RPA*
5/19/2004	SN61-63.5-L2	22.8	20.6	89.9%
5/19/2004	SN70-72.5-L4	16.7	18.5	89.8%
5/19/2004	SN61-63.5-S3	9.61	9.64	99.7%
5/19/2004	SN70-72.5-S4	11.8	10.9	92.1%
5/19/2004	SN52-54.5-TF2	6.05	5.77	95.3%
5/19/2004	SN61-63.5-TF1	6.50	5.66	86.2%

*RPA is: 1 – (absolute value of the difference between the two samples/mean of the two samples)

Table 4. Relative Percent Agreement (RPA*) of PCB and pesticide concentrations in duplicate samples analyzed by EnChem. No criteria given for acceptance.

Compound	SN54-TF2	SN62-TF1
Arochlor 1016	NC	NC
Arochlor 1221	NC	NC
Arochlor 1232	NC	NC
Arochlor 1242	NC	NC
Arochlor 1248	NC	NC
Arochlor 1254	NC	NC
Arochlor 1260	94.9%	98.1%
Total PCBs	94.9%	98.1%
2,4'-DDD	NC	NC
2,4'-DDE	NC	NC
2,4'-DDT	NC	NC
4,4'-DDD	NC	NC
4,4'-DDE	68.4%	68.4%
4,4'-DDT	33.3%	63.0%
Aldrin	NC	NC
alpha-BHC	71.4%	92.6%
alpha-Chlordane	81.0%	56.5%
beta-BHC	NC	NC
cis-nonachlor	88.9%	67.1%
delta-BHC	NC	NC
Dieldrin	93.3%	95.3%
Endosulfan I	NC	NC
Endosulfan II	NC	NC
Endosulfan Sulfate	NC	NC
Endrin	NC	NC
Endrin Aldehyde	NC	NC
Endrin Ketone	NC	NC
gamma-BHC (Lindane)	NC	55.1%
gamma-Chlordane	NC	NC
Heptachlor	NC	NC
Heptachlor Epoxide	94.3%	90.5%
Hexachlorobenzene	95.3%	95.9%
Methoxychlor	NC	NC
Mirex	NC	NC
Oxychlordane	88.2%	89.8%
Pentachloroanisole	NC	NC
Toxaphene	73.2%	91.3%
Trans-nonachlor	90.7%	91.3%

NC - Not Calculable, because one or both of the samples was below detection limit

*RPA is: 1 – (absolute value of the difference between the two samples/mean of the two samples)

Table 5. Spike Recovery of PCBs and Pesticides in Lake Trout (*Salvelinus namaycush namaycush*) Samples Analyzed by EnChem.

Compound	SN54-TF1	SN62-TF2	QC Limits
Arochlor 1254	120	128	43-130
alpha-BHC	113	108	69-123
beta-BHC	100	110	35-128
delta-BHC	110	120	57-126
gamma-BHC (Lindane)	110	115	52-126
Aldrin	105	115	52-122
Heptachlor	60	110	50-128
Heptachlor epoxide	96	109	51-130
Endosulfan I	85	110	45-140
Dieldrin	106	115	42-135
4,4'-DDE	128	168*	46-152
Endrin	112	112	43-136
Endosulfan II	108	116	46-147
4,4'-DDD	124	132	48-160
Endosulfan sulfate	105	118	54-132
4,4'-DDT	90	103	49-148
Methoxychlor	93	110	36-159
Endrin ketone	102	120	61-139
Endrin aldehyde	50	70	6-115
alpha-Chlordane	115	127	52-139
gamma-Chlordane	105	115	55-136
2,4'-DDD	160	160	40-160
2,4'-DDE	135	135	40-160
2,4'-DDT	92	92	40-160
cis-Nonachlor	188*	188*	40-160
trans-Nonachlor	148	148	40-160
Oxychlordane	123	123	40-160
Hexachlorobenzene	107	107	40-160
Pentachloroanisole	86	86	40-160
Mirex	130	130	40-160
Toxaphene	116	116	40-160

* Spiked sample recovery not within control limits.

Table 6. Procedural Blank Samples Before and After Grinding Analyzed for PCBs and Pesticides.

Compound	Tuna before grinding on 4/7/04	Tuna after grinding on 4/7/04	Tuna before grinding on 5/5/04	Tuna after grinding on 5/5/04
Arochlor 1016	ND	ND	ND	ND
Arochlor 1221	ND	ND	ND	ND
Arochlor 1232	ND	ND	ND	ND
Arochlor 1242	ND	ND	ND	ND
Arochlor 1248	ND	ND	ND	ND
Arochlor 1254	ND	ND	ND	ND
Arochlor 1260	ND	ND	ND	ND
Total PCBs	ND	ND	ND	ND
2,4'-DDD	ND	ND	ND	ND
2,4'-DDE	ND	ND	ND	ND
2,4'-DDT	ND	ND	ND	ND
4,4'-DDD	ND	ND	ND	ND
4,4'-DDE	ND	ND	ND	ND
4,4'-DDT	ND	ND	ND	ND
Aldrin	ND	ND	ND	ND
alpha-BHC	ND	ND	ND	ND
alpha-Chlordane	ND	ND	ND	ND
beta-BHC	ND	ND	ND	ND
cis-nonachlor	ND	ND	ND	ND
delta-BHC	ND	ND	ND	ND
Dieldrin	ND	ND	ND	ND
Endosulfan I	ND	ND	ND	ND
Endosulfan II	ND	ND	ND	ND
Endosulfan Sulfate	ND	ND	ND	ND
Endrin	ND	ND	ND	ND
Endrin Aldehyde	ND	ND	ND	ND
Endrin Ketone	ND	ND	ND	ND
gamma-BHC (Lindane)	ND	ND	ND	ND
gamma-Chlordane	ND	ND	ND	ND
Heptachlor	ND	ND	ND	ND
Heptachlor Epoxide	ND	ND	ND	ND
Hexachlorobenzene	ND	ND	ND	ND
Methoxychlor	ND	ND	ND	ND
Mirex	ND	ND	ND	ND
Oxychlordane	ND	ND	ND	ND
Pentachloroanisole	ND	ND	ND	ND
Toxaphene	ND	ND	ND	ND
Trans-nonachlor	ND	ND	ND	ND

ND - Not Detectable.

Table 7. Spike recovery of PCBs and pesticides in lab control spikes (LCS) and lab control spike duplicates (LCS dup) analyzed by EnChem. Samples BBLK53, SVK1079-041, and SVK1079-046 were analyzed along with the additional skin and fat samples (1-2/2005). All other samples were part of the original muscle tissue composite analysis (5-6/2004).

Compound	BBLK43 LCS	BBLK43 LCS dup	BBLK49 LCS	BBLK44 LCS	BBLK44 LCS dup	BBLK53 LCS	BBLK53 LCS dup	SVK1079-041F2MB LCS	SVK1079-041F2MB LCS dup	SVK1079-046F2MB LCS	SVK1079-046F2MB LCS dup	QC Limits 5-6/2004	QC Limits 1-2/2004
Arochlor 1254	100	96		108	112			100	97	105	109	40-128	40-128
alpha-BHC	115	110		115	115			95	95	85	105	65-117	65-117
beta-BHC	90	85		95	95			85	80	80	95	58-109	58-115
delta-BHC	115	110		115	115			85	75	75	95	63-117	63-117
gamma-BHC (Lindane)	110	100		115	110			95	90	85	105	65-115	65-115
Aldrin	110	100		115	115			100	95	120*	120*	60-115	60-115
Heptachlor	60	60		115	110			95	80	100	100	58-118	58-118
Heptachlor epoxide	105	100		110	105			95	90	90	105	63-118	63-118
Endosulfan I	90	85		105	100			90	85	80	95	54-129	54-129
Dieldrin	108	100		115	110			90	85	82	100	63-117	63-117
4,4'-DDE	138	130		170*	168*			108	105	138	135	60-150	60-150
Endrin	110	102		110	105			88	82	82	100	55-116	55-116
Endosulfan II	102	95		102	95			82	85	78	92	57-120	57-120
4,4'-DDD	125	118		122	120			90	90	82	100	63-128	63-128
Endosulfan sulfate	105	95		105	102			82	80	75	88	61-123	61-123
4,4'-DDT	72	85		95	85			70	90	72	22*	62-127	62-127
Methoxychlor	95	90		100	95			85	85	80	100	33-141	33-141
Endrin ketone	102	95		105	102			90	90	80	98	64-132	64-132
Endrin aldehyde	65	65		68	60			60	48	60	68	16-75	16-115
alpha-Chlordane	100	100		120	115			90	95	80	90	58-125	58-125
gamma-Chlordane	100	100		110	105			85	85	80	85	64-120	64-120
2,4'-DDD			158*			120	122					60-150	70-130
2,4'-DDE			145			92	92					60-150	70-130
2,4'-DDT			100			125	125					60-150	70-130
cis-Nonachlor			182*			162*	165*					60-150	70-130
trans-Nonachlor			148			115	115					60-150	70-130
Oxychlordane			128			100	100					60-150	70-130
Hexachlorobenzene			110			85	85					60-150	70-130
Pentachloroanisole			90			100	95					60-150	70-130
Mirex			122			98	95					60-150	70-130
Toxaphene			120			105	105					60-150	60-140

* Spiked sample recovery not within control limits.

Table 8. Results of Standard Reference Material (SRM) analysis. SRM-1946 was the Certified Standard Reference Material used. SRM 43, 44, and SRM S&F refer to the SRM 1946 samples analyzed by EnChem. Results are compared to Quality Control (QC) ranges issued for SRM 1946 and to En Chem's QC ranges for the same analytes.

Compound Name	SRM 1946	SRM 1946	SRM QC					En Chem Matrix	En Chem QC				
	Conc. µg/Kg	Uncertainty	Range (ug/kg)		SRM 43	SRM 44	SRM S&F	spike QC limits	Range (ug/kg)		SRM 43	SRM 44	SRM S&F
Hexachlorobenzene	7.25	±0.83	8.08	6.42	9.1*	10*	9.5 J*	60-150	4.4	10.9	9.1	10	9.5 J
Alpha-BHC	5.72	±0.65	6.37	5.07	6.1	6.1	5.3 J	65-117	3.7	6.7	6.1	6.1	5.3 J
Gamma-BHC	1.14	±0.18	1.32	0.96	0.92*	0.94*	1.1 J	65-115	0.7	1.3	0.92	0.94	1.1 J
Heptachlor epoxide	5.50	±0.23	5.73	5.27	7.1*	7.6*	5.7	63-118	3.5	6.5	7.1*	7.6*	5.7
Oxychlordane	18.9	±1.5	20.4	17.4	17*	16*	18	60-150	11.3	28.4	17	16	18
Alpha-chlordane	32.5	±1.8	33.33	30.7	32	36*	27*	58-125	18.9	40.6	32	36	27
Gamma-chlordane	8.36	±0.91	9.27	7.45	11*	12*	9.8*	55-136	4.6	11.4	11	12*	9.8
Cis-nonachlor	59.1	±3.6	62.7	55.5	55*	83*	74*	60-150	35.5	88.7	55	83	74
Trans-nonachlor	99.6	±7.6	107.2	92	110*	140*	120*	60-150	59.8	149.4	110	140	120
Dieldrin	32.5	±3.5	36	29	37*	44*	31	63-117	20.5	38.0	37	44*	31
Mirex	6.47	±0.77	7.24	5.7	5.2*	10*	6.7 U	60-150	3.9	9.7	5.2	10*	6.7 U
4,4'-DDE	373	±48	421	325	430*	460*	360	60-150	223.8	559.5	430	460	360
2,4'-DDD	2.20	±0.25	2.45	1.95	1.6 U	1.6 U	1.9 U	60-150	1.3	3.3	1.6 U	1.6 U	1.9 U
4,4'-DDD	17.7	±2.8	20.5	14.9	8.4 U	30*	4.6 J*	60-150	10.6	26.6	8.4 U	30*	4.6 J*
4,4'-DDT	37.2	±3.5	40.7	33.7	30*	52*	35.0	62-127	23.1	47.2	30	52*	35.0
% Lipid	10.2	±0.48	10.7	9.72	10.6	10.6	10.5						

U- Analyte was not detected at or above the reporting limit.
J – Analyte was above method detection limit but below estimated quantitation limit.
* Analyte concentration was outside of given quality control (QC) range.

Table 9. Relative Percent Agreement (RPA) of Procedural Blank Samples [Commercial Tuna Fish (*Thunnus sp.*) Before and After Grinding] for Total Mercury Analysis by the Lake Superior Research Institute.

Date of Analysis	Grinding Date	Before Grinding (μg Hg/g)	After Grinding (μg Hg/g)	RPA
6/29/2004	4/7/2004	0.066	0.070	94.1
7/7/2004	4/13/2004	0.027	0.028	96.4
6/29/2004	4/23/2004	0.083	0.103	78.5
6/29/2004	4/28/2004	0.079	0.078	98.7
6/29/2004	5/5/2004	0.100	0.090	89.5

*RPA is: 1 – (absolute value of the difference between the two samples/mean of the two samples)

Table 10. Mercury Concentration of Dogfish Tissue Supplied by the National Research Council Canada (DORM-2) and analyzed by the Lake Superior Research Institute. The Tissue has a Certified Mercury Concentration of 4.64±0.26 μgHg/g Tissue.

Date of Analysis	Sample 1 (μg Hg/g)	Sample 2 (μg Hg/g)	Mean	Std. Dev.	Percent of Expected
6/29/2004	3.85	4.02	3.94	0.11	84.8
6/29/2004	4.21	4.35	4.28	0.09	92.3

Table 11. Relative Percent Agreement (RPA) Between Duplicate Analysis for Total Mercury (Wet Weight) Content in Skinless Fillet Tissue of Composited Lake Trout (*Salvelinus namaycush namaycush*) Analyzed by Lake Superior Research Institute.

Date of Analysis	Sample ID	Sample 1 (μg Hg/g)	Sample 2 (μg Hg/g)	RPA*
6/29/2004	SN43-48TF4	0.181	0.16	87.7
6/29/2004	SN61-63.5TF1	0.23	0.224	97.4

*RPA is: 1 – (absolute value of the difference between the two samples/mean of the two samples)

Table 12. Percent of Mercury Recovered from Skinless Fillet Tissue of Composited Lake Trout (*Salvelinus namaycush namaycush*) Spiked with a Known Quantity of Mercury by the Lake Superior Research Institute.

Date of Analysis	Sample ID	Spike #1	Spike #2	Mean	Std. Dev.
6/29/2004	SN43-48TF4	101.9	97.3	99.6	3.34
6/29/2004	SN61-63.5TF1	103.0	75.3	89.1	19.58

Table 13. Individual Lake Superior lake trout (*Salvelinus namaycush namaycush*) descriptive data for fish contained in each composite. Tissue weights are wet weight values. Each fish was represented equally by weight in the composites, so the tissue weights listed here are not the weight of tissue used for each fish in the composites.

Sample ID	Length* Range	Tag Num	Mgmt Unit	Sex	Age (yr)	Length (cm)	# Fillets in Sample	Round Wt (g)**	Whole Fillet Wt (g)	Muscle Wt (g)	Fat Wt (g)	Skin Wt (g)
846447-037	43-48-1	1410	MI-2	F	4	43.2	2	750	173.0	122.4	30.9	16.4
846447-037	43-48-1	1442	MI-2	F	3	43.9	2	700	163.7	113.4	26.0	18.0
846447-038	43-48-2	1425	MI-2	M	4	44.7	2	900	192.2	135.9	32.0	21.3
846447-038	43-48-2	1449	MI-2	M	4	47.0	2	900	227.9	161.6	37.7	25.4
846447-039	43-48-3	5	MI-3	F	7	46.2	2	650	185.5	145.1	22.4	17.6
846447-039	43-48-3	14	MI-3	M	5	47.2	2	1000	259.8	193.2	41.1	24.2
846447-040	43-48-4	3	MI-3	M	6	48.0	2	700	172.4	124.6	26.2	20.7
846447-040	43-48-4	13	MI-3	M	6	46.0	2	1050	291.0	219.3	42.5	26.3
846447-041	52-54.5-1	825	MI-4	M	10	53.8	1	1500	414.7	319.2	47.9	45.2
846447-041	52-54.5-1	890	MI-4	M	10	53.8	1	1350	361.0	274.5	46.3	40.7
846447-041	52-54.5-1	814	MI-4	M	10	55.4	1	1200	338.0	248.2	46.9	33.9
846447-041	52-54.5-1	319	MI-4	M	9	54.4	1	1500	392.3	307.2	46.2	42.0
846447-042	52-54.5-2	820	MI-4	M	11	51.6	1	1000	312.4	232.0	43.0	34.3
846447-042	52-54.5-2	822	MI-4	M	11	51.3	1	1000	311.9	232.6	40.7	34.8
846447-042	52-54.5-2	125	MI-3	M	11	53.1	1	1100	333.7	250.6	49.7	30.8
846447-042	52-54.5-2	1	MI-3	F	11	53.3	1	1350	379.0	282.8	60.9	33.8
846447-043	52-54.5-3	10	MI-3	F	11	53.8	1	1450	386.8	293.4	50.9	32.6
846447-043	52-54.5-3	8	MI-3	M	11	54.9	1	1450	320.6	248.5	35.9	33.3
846447-043	52-54.5-3	2	MI-3	M	11	54.6	1	1200	328.9	248.6	40.3	37.6
846447-043	52-54.5-3	6	MI-3	M	11	54.1	1	1200	348.3	255.1	58.3	32.8
846447-044	52-54.5-4	7	MI-3	F	14	53.3	1	1150	252.3	170.5	49.1	30.9
846447-044	52-54.5-4	332	MI-4	M	13	52.3	1	1000	269.0	203.2	38.7	25.2
846447-044	52-54.5-4	11	MI-3	F	13	54.4	1	1100	352.9	266.7	44.8	38.2
846447-044	52-54.5-4	9	MI-3	F	13	53.3	1	1250	298.8	208.9	52.7	34.4
846447-045	61-63.5-1	1409	MI-2	M	9	61.5	1	2100	567.8	420.8	76.0	50.4
846447-045	61-63.5-1	122	MI-3	M	10	62.2	1	2000	520.6	394.1	67.3	52.0
846447-045	61-63.5-1	326	MI-4	M	9	61.7	1	2100	561.2	414.4	93.2	48.2
846447-045	61-63.5-1	329	MI-4	M	10	61.7	1	2000	523.2	403.8	67.8	49.6
846447-046	61-63.5-2	123	MI-3	M	11	62.2	1	1800	502.3	369.9	77.7	47.3
846447-046	61-63.5-2	1431	MI-2	M	11	63.5	1	2300	629.8	475.5	97.9	49.8
846447-046	61-63.5-2	811	MI-4	M	11	61.0	1	2000	559.4	384.4	116.1	49.9
846447-046	61-63.5-2	120	MI-4	M	11	61.0	1	2000	547.7	406.4	82.3	56.8
846447-047	61-63.5-3	895	MI-3	M	12	61.2	1	1800	551.3	429.8	70.4	48.1
846447-047	61-63.5-3	341	MI-4	M	12	61.0	1	1700	473.2	363.0	43.1	50.5
846447-047	61-63.5-3	315	MI-4	F	12	61.0	1	2000	433.9	329.6	60.7	38.7
846447-047	61-63.5-3	345	MI-4	M	12	61.5	1	2000	496.5	385.1	64.7	43.9
846447-048	61-63.5-4	121	MI-3	M	13	63.5	1	2000	498.4	377.6	70.5	47.8
846447-048	61-63.5-4	126	MI-3	U	13	63.5	1	2000	457.6	351.2	60.1	42.5
846447-048	61-63.5-4	807	MI-4	M	13	63.0	1	2000	468.9	349.6	71.6	45.1
846447-048	61-63.5-4	342	MI-4	M	13	64.0	1	2000	604.2	456.6	89.8	48.4

Table 13 continued…

Sample ID	Length Range	Tag Num	Mgmt Unit	Sex	Age (yr)	Length (cm)	# Fillets in Sample	Round Wt (g)	Whole Fillet Wt (g)	Muscle Wt (g)	Fat Wt (g)	Skin Wt (g)
846447-049	70-72.5-1	124	MI-3	M	13	70.6	1	2500	758.2	597.6	96.2	58.5
846447-049	70-72.5-1	896	MI-3	M	13	70.9	1	3200	829.1	614.9	137.1	71.8
846447-049	70-72.5-1	891	MI-4	M	13	70.4	1	2750	750.5	585.4	96.2	61.1
846447-049	70-72.5-1	340	MI-4	M	13	72.4	1	3500	926.3	659.3	147.6	98.5
846447-050	70-72.5-2	128	MI-3	M	14	71.1	1	2600	766.3	581.7	109.6	70.9
846447-050	70-72.5-2	350	MI-4	M	14	69.1	1	2600	710.5	530.6	103.4	68.6
846447-050	70-72.5-2	826	MI-4	M	14	69.3	1	2500	700.0	546.2	82.8	66.1
846447-050	70-72.5-2	823	MI-4	M	14	69.6	1	2700	790.5	584.8	122.8	78.2
846447-051	70-72.5-3	129	MI-3	M	15	71.4	1	3500	968.1	769.7	107.0	85.6
846447-051	70-72.5-3	313	MI-4	M	15	70.4	1	3000	826.9	670.2	83.7	67.7
846447-051	70-72.5-3	323	MI-4	M	15	71.1	1	3000	738.5	600.2	75.3	57.7
846447-051	70-72.5-3	322	MI-4	M	15	72.1	1	3500	864.9	690.2	97.9	73.5
846447-052	70-72.5-4	898	MI-3	F	16	69.9	1	3050	799.0	630.5	101.3	61.8
846447-052	70-72.5-4	899	MI-3	M	16	71.6	1	3550	930.0	745.3	106.6	69.1
846447-052	70-72.5-4	817	MI-4	M	16	69.9	1	2700	728.3	578.4	84.2	61.5
846447-052	70-72.5-4	311	MI-4	M	16	71.4	1	2700	615.6	471.1	84.8	55.3

* Fillet tissue data for the 43-48 cm size group is the average of both fillets from the fish.
** Round weight refers to the unprocessed weight of the fish in the field.

Table 14. Percent lipid and mean ± one standard deviation of percent moisture measured in fat and skin tissues from Lake Superior lake trout (*Salvelinus namaycush namaycush*) fillets.

	FAT			SKIN		
Composite ID	Mean % moisture	STDEV	% Lipid	Mean % moisture	STDEV	% Lipid
SN43-48-1	72.8	0.153	9.04	62.0	1.44	10.7
SN43-48-2	71.2	0.265	10.6	56.5	0.666	15
SN43-48-3	73.5	0.200	9.12	60.9	0.436	8.62
SN43-48-4	65.9	0.569	17.1	58.0	0.917	11.8
SN52-54.5-1	65.7	0.153	19.6	58.3	0.656	11.1
SN52-54.5-2	65.4	0.611	18.2	56.0	0.600	12.9
SN52-54.5-3	66.1	1.83	16.6	62.4	1.10	8.65
SN52-54.5-4	66.4	1.22	17.8	59.3	0.493	11.4
SN61-63.5-1	60.4	2.58	22.3	58.0	0.265	12.1
SN61-63.5-2	61.9	0.666	21.7*	57.0	0.493	14.2
SN61-63.5-3	67.2	0.833	17.4	60.4	1.16	9.63*
SN61-63.5-4	71.1	0.351	11.9	60.8	0.503	11.2
SN70-72.5-1	58.6	0.929	25.1	61.1	0.700	12.2
SN70-72.5-2	66.3	0.666	16.6	59.4	0.321	11.7
SN70-72.5-3	63.3	0.907	19.1	57.8	0.755	13.1
SN70-72.5-4	64.3	1.87	17.6*	59.4	0.569	11.4*

* Value listed is the mean of duplicate samples.

Table 15. Individual Lake Superior lake trout (*Salvelinus namaycush namaycush*) composite chemical concentrations. Concentrations listed for skin-on trimmed fillets (SOT) and skin-on untrimmed fillets (SOUT) are estimated values based on the wet weight of tissues in the composites and percent lipid in those tissues. Values given for "Percent Moisture" and Percent Lipid" are percentages. All other data are wet weight concentrations in units of ug/kg. Significant figures are consistent with lab reported values.

Chemical Parameter	Method Detection Limit***	Estimated Quantitation Limit	Length Group*	Composite Number 1	Composite Number 2	Composite Number 3	Composite Number 4	Replicate** 1	Replicate** 2	Length Group Average	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Percent Moisture			43 to 48.0 cm	76.4	75.8	77.6	75.0			76.2	1.1	.	.	.	.
			52 to 54.5 cm	75.9	75.0	77.0	75.6	75.0	.	75.9	0.9	.	.	.	.
			61 to 63.5 cm	74.9	74.0	77.1	77.6	74.9	.	75.9	1.7	.	.	.	.
			70 to 72.5 cm	73.7	77.1	74.8	74.3			75.0	1.5	.	.	.	.
Percent Moisture Standard Deviation			43 to 48.0 cm	0.25	0.12	0.42	0.50			0.32	0.2	.	.	.	.
			52 to 54.5 cm	0.91	0.25	0.32	0.50	0.25	.	0.50	0.3	.	.	.	.
			61 to 63.5 cm	0.87	1.9	0.29	0.00	0.87	.	0.77	0.8	.	.	.	.
			70 to 72.5 cm	0.76	0.67	0.81	0.23			0.62	0.3	.	.	.	.
Percent Lipids			43 to 48.0 cm	3.25	3.42	2.78	5.57			3.76	1.24	.	.	.	.
			52 to 54.5 cm	4.66	5.91	4.30	5.78	6.05	5.77	5.16	0.80	.	.	.	.
			61 to 63.5 cm	6.08	6.03	4.04	3.25	6.50	5.66	4.85	1.43	.	.	.	.
			70 to 72.5 cm	6.81	4.22	5.98	5.26			5.57	1.10	.	.	.	.
2,4'-DDD	0.82	5.0	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
2,4'-DDE	1.2***	5.0	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	1.7	ND	ND	1.7	.	1.9	.	2.4	.
			61 to 63.5 cm	ND	1.4	1.6	2.2	ND	ND	1.7	0.42	2.1	0.62	2.7	0.71
			70 to 72.5 cm	2.7	2.2	5.1	ND			3.3	1.6	3.7	1.7	4.7	1.8
2,4'-DDT	1.1	5.0	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.

Table 15 continued…

Chemical Parameter	Method Detection Limit	Estimated Quantitation Limit	Length Group*	Composite Number 1	Composite Number 2	Composite Number 3	Composite Number 4	Replicate** 1	Replicate** 2	Length Group Average	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
4,4'-DDD	1.0	5.0	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	1.2	ND	1.3	1.7	ND	ND	1.4	0.26	1.6	0.28	2.1	0.32
			61 to 63.5 cm	1.6	1.2	ND	2.4	1.6	ND	1.7	0.61	2.1	0.86	2.7	1.0
			70 to 72.5 cm	1.8	3.2	7.1	5.8			4.5	2.4	5.0	2.7	6.3	3.0
4,4'-DDE	0.74	5.0	43 to 48.0 cm	12	8	12	39			18	14	22	15	26	19
			52 to 54.5 cm	20	19	35	47	22	16	30	13	34	15	44	19
			61 to 63.5 cm	29	34	35	61	33	24	40	15	47	20	61	25
			70 to 72.5 cm	66	58	130	170			110	53	120	58	150	68
4,4'-DDT	1.1	5.0	43 to 48.0 cm	1.3	1.3	1.2	3.8			1.9	1.3	2.3	1.3	2.8	1.7
			52 to 54.5 cm	1.8	2.9	2.8	3.7	1.9	3.8	2.8	0.78	3.2	0.85	4.0	1.0
			61 to 63.5 cm	2.7	4.7	5.4	6.2	2.2	3.2	4.8	1.5	5.6	2.0	7.3	2.5
			70 to 72.5 cm	7.4	6.0	13	14			10	4.0	11	4.3	14	4.8
Aldrin	0.42	2.5	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Alpha-BHC	0.86	2.5	43 to 48.0 cm	1.1	1.4	ND	2.0			1.5	0.46	1.9	0.44	2.3	0.59
			52 to 54.5 cm	1.4	2.5	1.4	2.0	2.8	2.1	1.8	0.51	2.1	0.58	2.6	0.66
			61 to 63.5 cm	2.7	2.3	ND	0.9	2.8	2.6	2.0	0.93	2.3	0.97	3.0	1.3
			70 to 72.5 cm	2.5	ND	2.6	ND			2.6	0.07	2.8	0.13	3.5	0.12
Alpha-Chlordane	0.42	2.5	43 to 48.0 cm		1.1	1.2	5.9			2.7	2.7	3.3	3.0	4.0	3.7
			52 to 54.5 cm	1.9	2.1	2.3	4.1	2.3	1.9	2.6	1.0	3.0	1.1	3.8	1.4
			61 to 63.5 cm	2.3	2.6	2.4	3.3	2.8	1.8	2.7	0.45	3.1	0.72	4.1	0.85
			70 to 72.5 cm	4.4	3.1	2.6	8.8			4.7	2.8	5.3	3.1	6.7	3.8
Aroclor 1016	12	50	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.

Table 15 continued…

Chemical Parameter	Method Detection Limit	Estimated Quantitation Limit	Length Group*	Composite Number 1	Composite Number 2	Composite Number 3	Composite Number 4	Replicate** 1	Replicate** 2	Length Group Average	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Aroclor 1221	12	50	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Aroclor 1232	12	50	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Aroclor 1242	12	50	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Aroclor 1248	12	50	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Aroclor 1254	12	50	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Aroclor 1260	12	50	43 to 48.0 cm	28	23	28	86			41	30	50	31	61	40
			52 to 54.5 cm	35	39	64	93	38	40	58	27	65	30	84	37
			61 to 63.5 cm	54	69	79	110	54	53	78	24	92	34	120	41
			70 to 72.5 cm	110	95	200	530			230	200	260	220	330	270
Beta-BHC	1.1	2.5	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.

Table 15 continued…

Chemical Parameter	Method Detection Limit	Estimated Quantitation Limit	Length Group*	Composite Number 1	Composite Number 2	Composite Number 3	Composite Number 4	Replicate** 1	Replicate** 2	Length Group Average	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Cis-nonachlor	1.0	5.0	43 to 48.0 cm	3.2	2.6	4.3	11			5.3	3.9	6.4	4.1	7.8	5.2
			52 to 54.5 cm	5.9	5.4	9.5	11	5.7	5.1	8.0	2.7	9.0	3.0	12	3.8
			61 to 63.5 cm	7.9	7.8	8.3	12	9.2	6.6	9.0	2.0	11	3.0	14	3.6
			70 to 72.5 cm	14	12	23	31			20	8.8	22	9.5	28	11
Delta-BHC	0.68	2.5	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Dieldrin	1.1	5.0	43 to 48.0 cm	5.0	4.9	4.2	13			6.8	4.2	8.4	4.3	10	5.5
			52 to 54.5 cm	6.8	7.5	6.6	11	7.2	7.7	8.0	2.1	9.1	2.3	12	2.8
			61 to 63.5 cm	8.6	9.9	6.7	6.5	8.8	8.4	7.9	1.6	9.2	1.6	12	2.4
			70 to 72.5 cm	15	9.8	11	13			12	2.3	14	2.1	17	3.2
Endosulfan I	0.43	2.5	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Endosulfan II	0.8	5.0	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	1.6	ND	1.4	ND	ND	1.5	0.14	1.8	0.05	2.4	0.17
			70 to 72.5 cm	2.3	ND	ND	ND			2.3	.	2.5	.	3.3	.
Endosulfan Sulfate	2.0	5.0	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Endrin	0.84	5.0	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.

Table 15 continued…

Chemical Parameter	Method Detection Limit	Estimated Quantitation Limit	Length Group*	Composite Number 1	2	3	4	Replicate** 1	2	Length Group Average	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Endrin Aldehyde	1.0***	5.0	43 to 48.0 cm	ND	ND	ND	5.6			5.6	.	6.4	.	7.9	.
			52 to 54.5 cm	ND	ND	2.8	4.9	ND	ND	3.9	1.5	4.3	1.7	5.6	2.0
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Endrin Ketone	0.9	5.0	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Gamma-BHC (Lindane)	0.48	2.5	43 to 48.0 cm	ND	ND	ND	0.50			0.5	.	0.6	.	0.7	.
			52 to 54.5 cm	ND	0.56	ND	ND	0.56	ND	0.6	.	0.6	.	0.8	.
			61 to 63.5 cm	0.74	ND	ND	ND	0.90	0.57	0.7	.	0.8	.	1.1	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Gamma-Chlordane	1.6	2.5	43 to 48.0 cm		ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	1.7	1.6			1.7	0.07	1.8	0.08	2.2	0.04
Heptachlor	0.72	2.5	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Heptachlor Epoxide	0.66	2.5	43 to 48.0 cm	1.3	1.1	1.1	2.9			1.6	0.9	2.0	0.9	2.4	1.1
			52 to 54.5 cm	1.7	1.8	1.6	2.4	1.8	1.7	1.9	0.4	2.1	0.4	2.7	0.5
			61 to 63.5 cm	2.1	2.3	1.5	1.3	2.2	2.0	1.8	0.5	2.1	0.5	2.7	0.7
			70 to 72.5 cm	3.1	1.9	1.8	2.4			2.3	0.6	2.6	0.6	3.3	0.9
Hexachlorobenzene	0.45	2.5	43 to 48.0 cm	1.2	1.3	1.2	2.5			1.6	0.6	1.9	0.6	2.3	0.8
			52 to 54.5 cm	1.6	2.2	1.9	2.3	2.2	2.1	2.0	0.3	2.3	0.3	2.9	0.3
			61 to 63.5 cm	2.5	2.6	2.3	2.3	2.5	2.4	2.4	0.1	2.8	0.2	3.7	0.2
			70 to 72.5 cm	3.7	2.9	3.7	3.6			3.5	0.4	3.9	0.3	5.0	0.3

Table 15 continued…

Chemical Parameter	Method Detection Limit	Estimated Quantitation Limit	Length Group*	Composite Number 1	2	3	4	Replicate** 1	2	Length Group Average	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Methoxychlor	2.8***	25	43 to 48.0 cm	3.6	ND	3.9	ND			3.8	0.2	4.7	0.1	5.7	0.4
			52 to 54.5 cm	4.2	3.3	ND	ND	3.3	ND	3.8	0.6	4.3	0.8	5.6	1.3
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Mirex	0.99***	5.0	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	ND	1.5	ND	ND	ND	1.5	1.5	.	1.7	.	2.1	.
			61 to 63.5 cm	2.9	ND	2.3	5.1	ND	2.9	3.4	1.5	4.1	2.0	5.3	2.5
			70 to 72.5 cm	3.9	3.5	7.4	8.6			5.9	2.5	6.5	2.7	8.2	3.1
Oxychlordane	0.72	5.0	43 to 48.0 cm	0.9	0.8	1.2	2.8			1.4	0.9	1.7	1.0	2.1	1.3
			52 to 54.5 cm	1.8	1.7	3.1	3.1	1.6	1.8	2.4	0.8	2.8	0.8	3.5	1.1
			61 to 63.5 cm	3.0	3.5	2.4	3.4	3.1	2.8	3.1	0.5	3.6	0.7	4.7	0.9
			70 to 72.5 cm	5.4	4.1	4.8	7.4			5.4	1.4	6.1	1.5	7.7	1.8
Pentachloroanisole	0.36	2.5	43 to 48.0 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			52 to 54.5 cm	0.71	0.79	ND	0.66	0.79	ND	0.72	0.07	0.83	0.08	1.1	0.09
			61 to 63.5 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			70 to 72.5 cm	ND	ND	ND	0.84			0.84	.	0.93	.	1.2	.
Total Chlordane	sum of - cis-chlordane, trans-chlordane, cis-nonachlor, trans nonachlor, oxychlordane		43 to 48.0 cm	11	9	12	39			18	14	21	15	26	19
			52 to 54.5 cm	17	18	27	36	18	18	25	8.9	28	10	36	12
			61 to 63.5 cm	25	28	27	40	26	23	30	6.9	35	10	46	12
			70 to 72.5 cm	48	39	76	100			66	28	74	30	92	35
Total DDT	sum of - 2,4'-DDD, 2,4'-DDE, 2,4'-DDT, 4,4'-DDD, 4,4'-DDE, 4,4'DDT		43 to 48.0 cm	13	9.3	13	43			20	16	24	17	29	21
			52 to 54.5 cm	23	22	39	54	24	20	35	15	39	17	50	21
			61 to 63.5 cm	32	41	42	72	37	27	47	17	55	24	72	30
			70 to 72.5 cm	78	69	160	190			120	60	140	65	170	75
Total Mercury****	1.30		43 to 48.0 cm	99.0	82.0	188	170			135	52	.	.	.	.
			52 to 54.5 cm	142	133	305	247	133	133	207	83	.	.	.	.
			61 to 63.5 cm	227	168	244	280	230	224	230	47	.	.	.	.
			70 to 72.5 cm	320	292	422	534			392	110	.	.	.	.

Table 15 continued…

Chemical Parameter	Method Detection Limit	Estimated Quantitation Limit	Length Group*	Composite Number 1	Composite Number 2	Composite Number 3	Composite Number 4	Replicate** 1	Replicate** 2	Length Group Average	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Total PCBs	12	50	43 to 48.0 cm	28	23	28	86			41	30	50	31	61	40
			52 to 54.5 cm	35	39	64	93	38	40	58	27	65	30	84	37
			61 to 63.5 cm	54	69	79	110	54	53	78	24	92	34	120	41
			70 to 72.5 cm	110	95	200	530			230	200	260	220	330	270
Toxaphene	46	250	43 to 48.0 cm	57	53	54	170			84	58	100	60	130	77
			52 to 54.5 cm	77	97	86	160	84	110	110	38	120	42	150	51
			61 to 63.5 cm	115	140	130	170	110	120	140	23	160	37	210	44
			70 to 72.5 cm	230	180	350	390			290	99	320	110	410	120
Trans-nonachlor	0.8	5.0	43 to 48.0 cm	5.3	4.2	5.6	19			8.5	7.0	10	7.5	13	9.5
			52 to 54.5 cm	7.7	8.6	12	18	8.2	9.0	12	4.7	13	5.1	17	6.5
			61 to 63.5 cm	12	14	14	21	11	12	15	4.1	18	6.0	23	7.2
			70 to 72.5 cm	24	20	44	54			36	16	40	18	50	20

ND = Not detected. "ND" values were treated as "0" and were not included in length group average calculations.
* Length groups in centimeters correspond to inches as follows: 43 to 48 cm = 17 to 19 inches; 52 to 54.5 cm = 20.5 to 21.5 inches; 61 to 63.5 cm = 24 to 25 inches; and 70 to 72.5 cm = 27.5 to 28.5 inches.
** For the 52 to 54.5 cm length group, the values for composite 2 represent the average of two replicates. For the 61 to 63.5 cm length group, the values for composite 1 represent the average of two replicates.
*** The method detection limit and estimated quantitation limit values vary for each compound depending on sample dilutions and the presence of interferences that affect how a compound is quantitated. The values displayed for these analytes are the lowest reported values from En Chem based on no dilutions or interferences.
**** Total mercury concentrations were not calculated for SOT and SOUT fillets because mercury binds to muscle tissue and concentrations is not reduced by trimming fillets.

Table 16. Average relative percent difference (RPD) between measured and predicted chemical concentrations in Lake Superior lake trout (*Salvelinus namaycush namaycush*) fat and skin tissues. Only chemicals with both a predicted and measured observation are included.

Tissue	Chemical Parameter	Observations*	RPD	Tissue	Chemical Parameter	Observations*	RPD
FAT	4,4'-DDD	1	116%	SKIN	4,4'-DDD	1	68.6%
FAT	4,4'-DDE	3	22.5%	SKIN	4,4'-DDE	3	-17.4%
FAT	4,4'-DDT	3	-4.14%	SKIN	4,4'-DDT	3	-9.84%
FAT	Aroclor 1260	3	11.1%	SKIN	Aroclor 1260	3	-28.9%
FAT	Dieldrin	3	1.80%	SKIN	Dieldrin	3	-21.3%
FAT	Endrin Aldehyde	1	-28.4%	SKIN	Endrin Aldehyde	1	-46.0%
FAT	Heptachlor Epoxide	3	2.82%	SKIN	Heptachlor Epoxide	3	-31.4%
FAT	Hexachlorobenzene	3	41.5%	SKIN	Hexachlorobenzene	3	-3.83%
FAT	Mirex	1	210%	SKIN	Mirex	2	134%
FAT	Oxychlordane	3	-1.01%	SKIN	Oxychlordane	3	-28.6%
FAT	Total Chlordane	3	-7.60%	SKIN	Total Chlordane	3	-37.1%
FAT	Total DDT	3	17.7%	SKIN	Total DDT	3	-17.2%
FAT	Total PCBs	3	-41.3%	SKIN	Total PCBs	3	-62.6%
FAT	Toxaphene	3	-26.0%	SKIN	Toxaphene	3	-48.2%
FAT	Trans-nonachlor	3	10.2%	SKIN	Trans-nonachlor	3	-25.9%
FAT	alpha-BHC	1	-5.54%	SKIN	alpha-BHC	1	-31.1%
FAT	alpha-Chlordane	3	6.81%	SKIN	alpha-Chlordane	3	-40.1%
FAT	cis-nonachlor	3	-21.1%	SKIN	cis-nonachlor	3	-45.3%
FAT	gamma-BHC (Lindane)	1	39.5%	SKIN	gamma-Chlordane	1	-50.5%
FAT	gamma-Chlordane	1	-37.7%			Mean	-18.0%
		Mean	15.3%			StDev	44.6%
		StDev	55.7%				

* Observations – Number of composites represented in the RPD calculation. A total of three composites each of fat and skin were analyzed.

Table 17. Lake Superior lake trout (*Salvelinus namaycush namaycush*) mean, standard deviation, and range of chemical concentrations (ug/kg) in muscle tissue, skin-on trimmed fillet (SOT) and skin-on, untrimmed fillet (SOUT) for each composite size group. Results for SOT and SOUT fillets are estimated values based on the wet weight of tissues in the composites and percent lipid in those tissues. United States Food and Drug Administration (FDA) action levels regulating the commercial sale of fish are given for each chemical or chemical group.

Chemical Parameter	Tissue*	Lake Trout Size Group (cm)	Mean Conc. (ug/kg)	St. Dev. (ug/kg)	Range** (ug/kg)	FDA Level (ug/kg)
Total Mercury	M	46	135	52	82-188	1000***
	M	54	207	83	133-305	
	M	62	230	47	168-280	
	M	71	392	110	292-534	
Total PCBs	M	46	41	30	23-86	2000
	M	54	58	27	35-93	
	M	62	78	24	54-110	
	M	71	230	200	95-530	
	SOT	46	50	31	34-98	
	SOT	54	65	30	41-100	
	SOT	62	92	34	59-140	
	SOT	71	260	220	110-590	
	SOUT	46	61	40	39-120	
	SOUT	54	84	37	54-130	
	SOUT	62	120	41	78-180	
	SOUT	71	330	270	150-730	
Total Chlordane	M	46	18	14	8.7-39	300
	M	54	25	8.9	17-36	
	M	62	30	6.9	25-40	
	M	71	66	28	39-100	
	SOT	46	21	15	13-44	
	SOT	54	28	10	20-41	
	SOT	62	35	10	27-50	
	SOT	71	74	30	47-110	
	SOUT	46	26	19	15-55	
	SOUT	54	36	12	25-51	
	SOUT	62	46	12	35-64	
	SOUT	71	92	35	61-140	
Total DDT	M	46	20	16	9.3-43	5000
	M	54	35	15	22-54	
	M	62	47	17	32-72	
	M	71	120	60	69-190	
	SOT	46	24	17	14-49	
	SOT	54	39	17	25-61	
	SOT	62	55	24	35-91	
	SOT	71	140	65	83-210	
	SOUT	46	29	21	16-61	
	SOUT	54	50	21	31-77	
	SOUT	62	72	30	46-110	
	SOUT	71	170	75	110-260	
Aldrin/Dieldrin	M	46	6.8	4.2	4.2-13	300
	M	54	8.0	2.1	6.6-11	
	M	62	7.9	1.6	6.5-9.9	
	M	71	12	2.3	9.8-15	
	SOT	46	8.4	4.3	5.2-15	
	SOT	54	9.1	2.3	7.4-12	
	SOT	62	9.2	1.6	7.7-11	
	SOT	71	14	2.1	12-16	
	SOUT	46	10	5.5	6.4-18	
	SOUT	54	12	2.8	9.7-16	
	SOUT	62	12	2.4	10-15	
	SOUT	71	17	3.2	15-22	

Table 17 Continued…

Chemical Parameter	Tissue*	Lake Trout Size Group (cm)	Mean Conc. (ug/kg)	St. Dev. (ug/kg)	Range** (ug/kg)	FDA Level (ug/kg)
Heptachlor/Heptachlor Epoxide	M	46	1.6	0.9	1.1-2.9	300
	M	54	1.9	0.4	1.6-2.4	
	M	62	1.8	0.5	1.3-2.3	
	M	71	2.3	0.6	1.8-3.1	
	SOT	46	2.0	0.9	1.4-3.3	
	SOT	54	2.1	0.4	1.8-2.7	
	SOT	62	2.1	0.5	1.6-2.6	
	SOT	71	2.6	0.6	2.0-3.4	
	SOUT	46	2.4	1.1	1.7-4.1	
	SOUT	54	2.7	0.5	2.4-3.4	
	SOUT	62	2.7	0.7	2.1-3.6	
	SOUT	71	3.3	0.9	2.4-4.5	
Mirex	M	46	ND	.	.	100
	M	54	1.5****	.	.	
	M	62	3.4	1.5	ND-5.1	
	M	71	5.9	2.5	3.5-8.6	
	SOT	46	ND	.	.	
	SOT	54	1.7****	.	.	
	SOT	62	4.1	2.0	ND-6.4	
	SOT	71	6.5	2.7	4.2-9.5	
	SOUT	46	ND	.	.	
	SOUT	54	2.1****	.	.	
	SOUT	62	5.3	2.5	ND-8.1	
	SOUT	71	8.2	3.1	5.5-12	

ND = Not Detected

* M = Muscle tissue (skin-off, trimmed fillet), SOT = Skin-on trimmed fillet, SOUT = Skin-on untrimmed fillet.

** The 54 and 62 cm size group ranges include the mean of duplicate samples, i.e. duplicates were not treated as separate samples for inclusion in the concentration ranges.

*** The FDA action level for mercury is for methylmercury. Generally >95% of mercury in top predator fish such as lake trout is methylmercury (GLIFWC data, unpublished).

**** Not a mean value because it was the only detected concentration in the group.

Table 18. Comparison of Lake Superior lake trout (*Salvelinus namaycush namaycush*) contaminant data collected by the Great Lakes Indian Fish and Wildlife Commission (GLIFWC) between 1999 and 2003. Lake trout composite size group, mean chemical concentration, and concentration range are given for three chemicals/chemical groups.

	2003 Data			**1999 Data**		
Chemical Parameter	**Lake Trout Size Group (cm)**	**Mean Conc.**	**Range**	**Lake Trout Size Group (cm)**	**Mean Conc.**	**Range**
Total Mercury	43-48	135	82-188			
	52-54.5*	207	133-305			
	61-63.5*	230	168-280	64	163	133-193
	70-72.5	392	292-534	70	355	227-484
Total PCBs	43-48	41	23-86			
	52-54.5*	58	35-93			
	61-63.5*	78	54-110	64	229	178-280
	70-72.5	230	95-530	70	391	274-509
Total Chlordane	43-48	18	8.7-39			
	52-54.5*	25	17-36			
	61-63.5*	30	25-40	64	58	43-72
	70-72.5	66	39-100	70	99	72-127

* These ranges include the mean of duplicate samples, i.e. duplicates were not treated as separate samples for inclusion in the concentration ranges.

FIGURES

Figure 1. Lake Superior lake trout (*Salvelinus namaycush namaycush*) management units in the 1842 treaty-ceded area from which lake trout samples were collected.

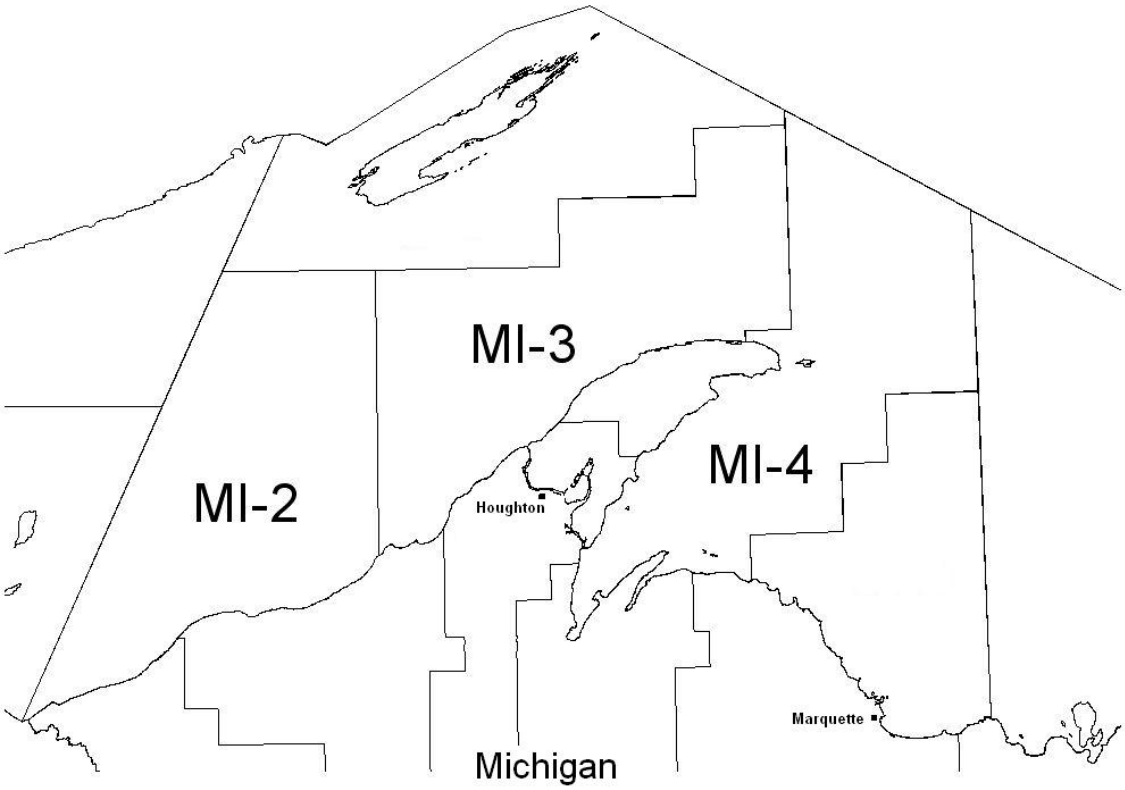

Figure 2. Great Lakes Indian Fish and Wildlife Commission (GLIFWC) lake trout (*Salvelinus namaycush namaycush*) monitoring data from Lake Superior lake trout management units MI-2, 3, and 4 from the years 1999-2003.

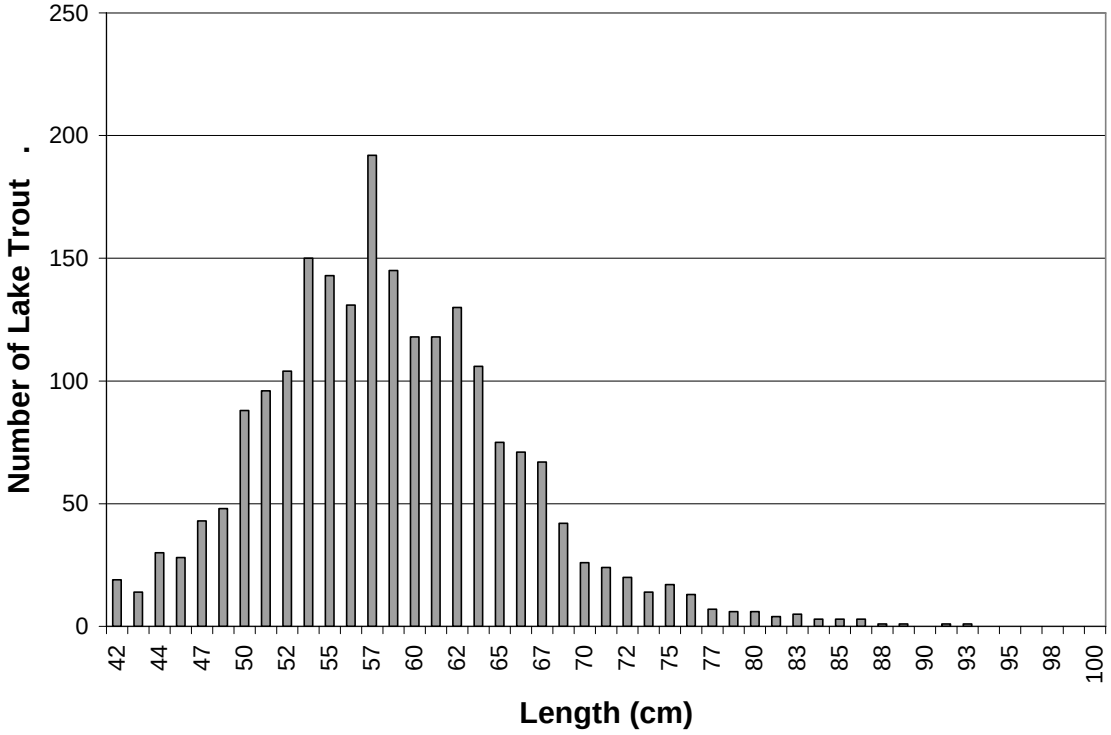

Figure 3. Mean ± one standard deviation of total mercury concentrations in Lake Superior lake trout (*Salvelinus namaycush namaycush*) muscle tissue (i.e. trimmed, skin-off fillet) composites.

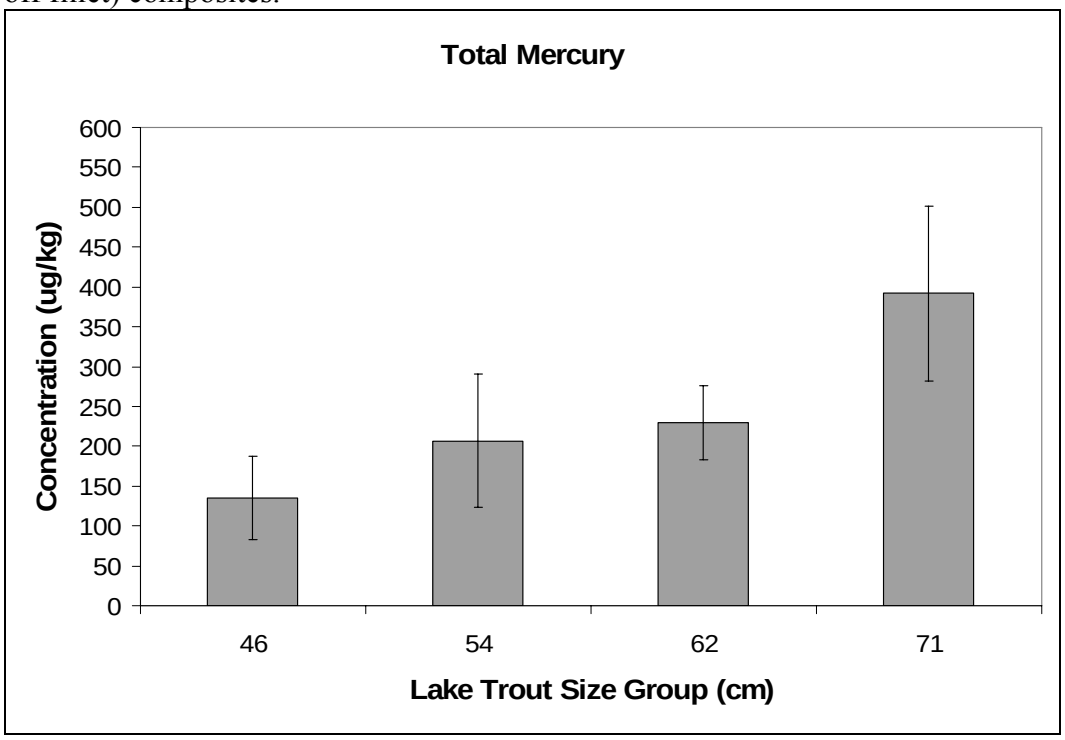

Figure 4. Mean ± one standard deviation of total PCB concentrations in Lake Superior lake trout (*Salvelinus namaycush namaycush*) muscle tissue (i.e. trimmed, skin-off fillet) composites.

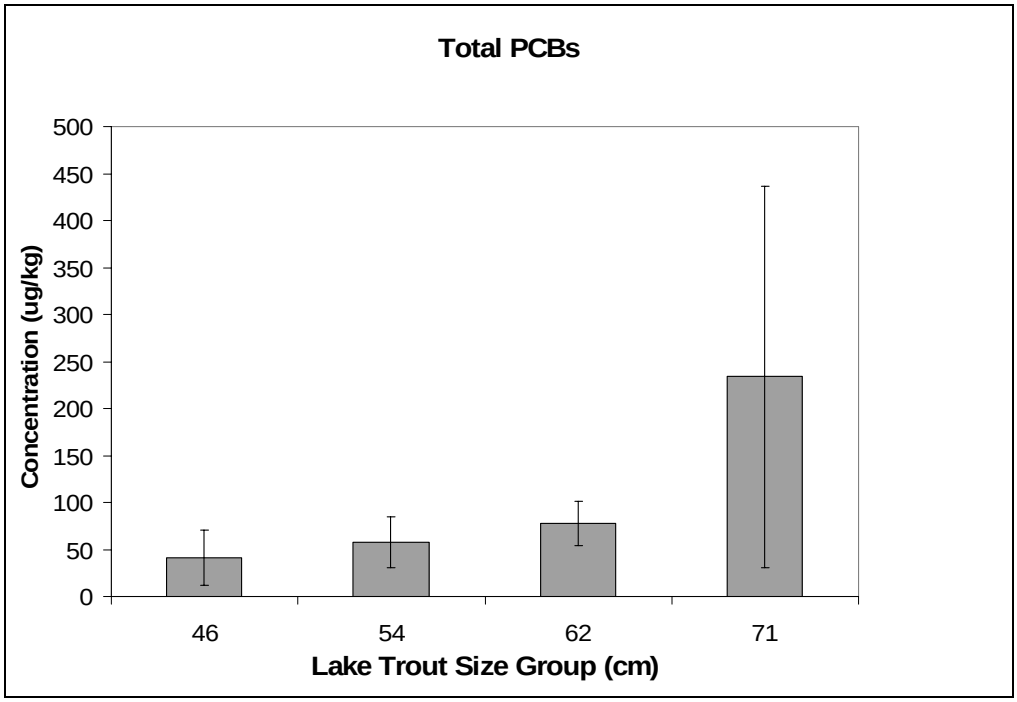

Figure 5. Mean ± one standard deviation of total chlordane concentrations in Lake Superior lake trout (*Salvelinus namaycush namaycush*) muscle tissue (i.e. trimmed, skin-off fillet) composites.

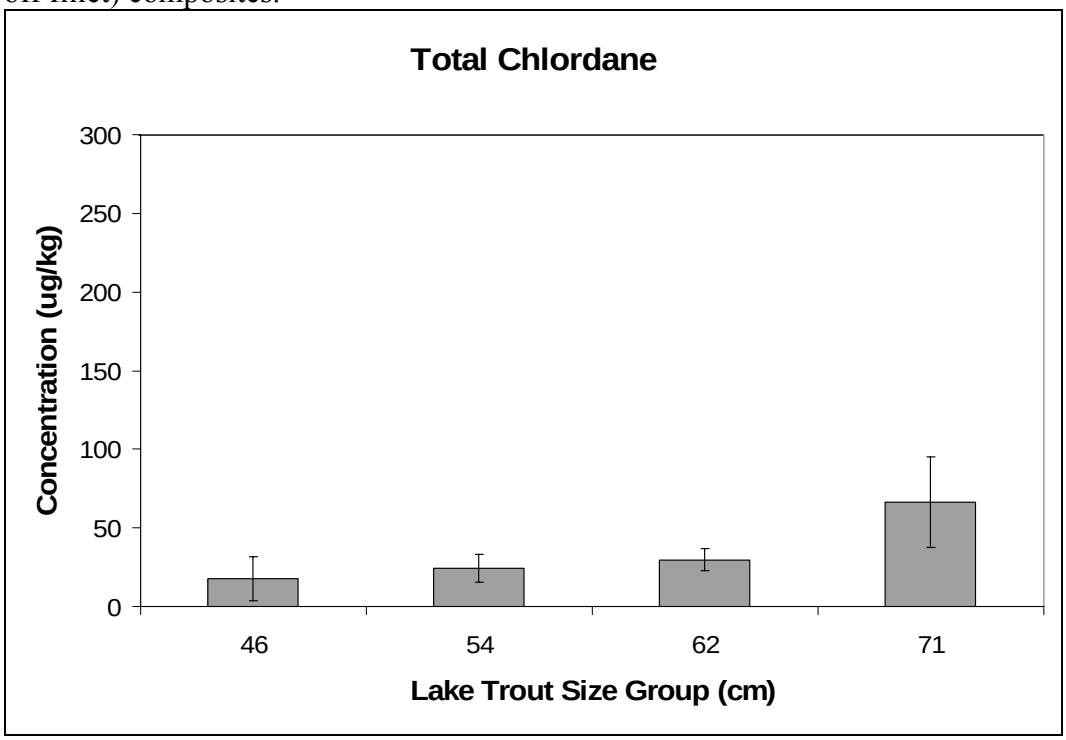

Figure 6. Mean ± one standard deviation of total DDT concentrations in Lake Superior lake trout (*Salvelinus namaycush namaycush*) muscle tissue (i.e. trimmed, skin-off fillet) composites.

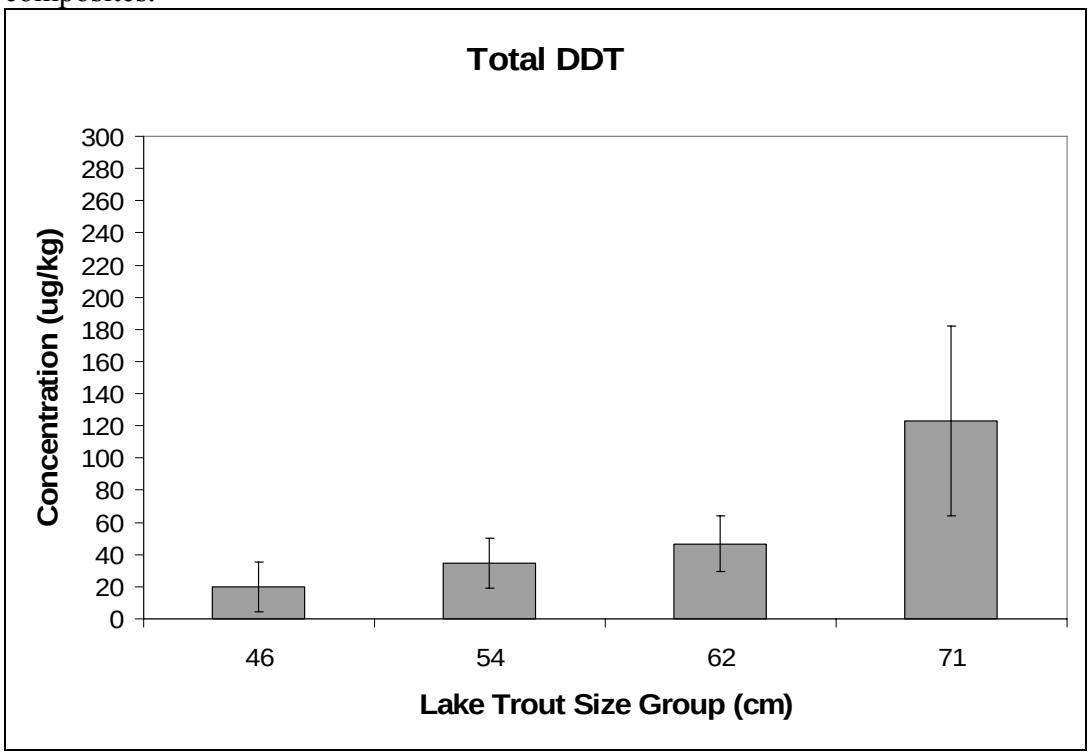

Figure 7. Mean ± one standard deviation of toxaphene concentrations in Lake Superior lake trout (*Salvelinus namaycush namaycush*) muscle tissue (i.e. trimmed, skin-off fillet) composites.

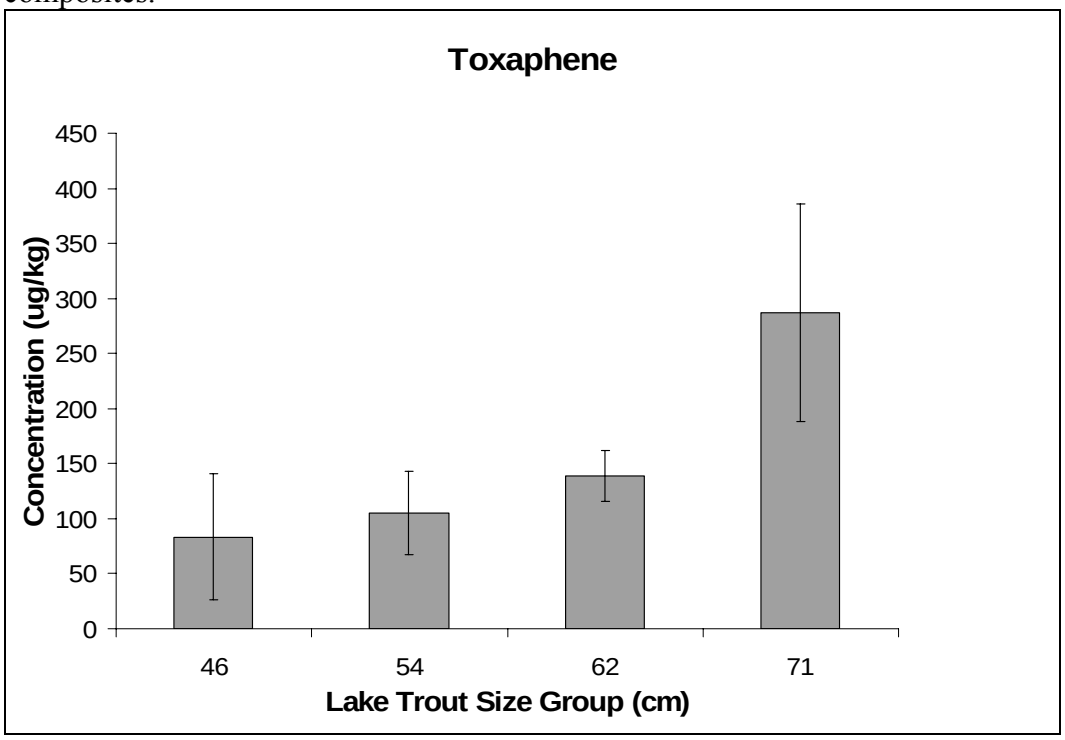

Figure 8. Mean ± one standard deviation of dieldrin concentrations in Lake Superior lake trout (*Salvelinus namaycush namaycush*) muscle tissue (i.e. trimmed, skin-off fillet) composites.

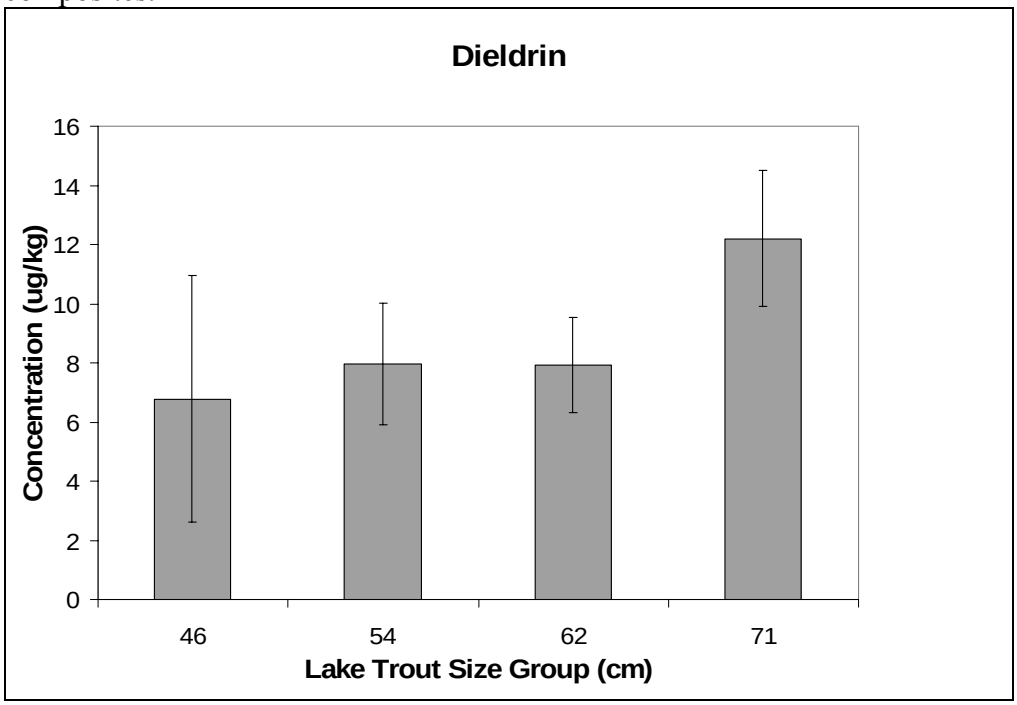

Figure 9. Mean ± one standard deviation of hexachlorobenzene concentrations in Lake Superior lake trout (*Salvelinus namaycush namaycush*) muscle tissue (i.e. trimmed, skin-off fillet) composites.

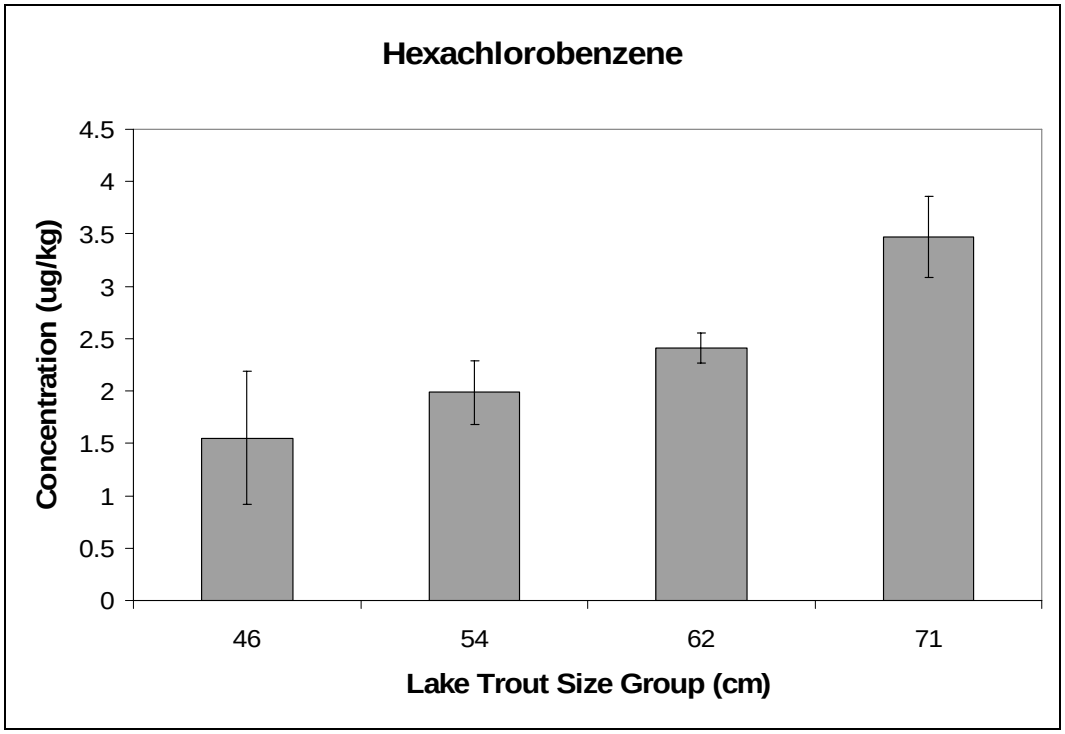

Figure 10. Mean ± one standard deviation of mirex concentrations in Lake Superior lake trout (*Salvelinus namaycush namaycush*) muscle tissue (i.e. trimmed, skin-off fillet) composites.

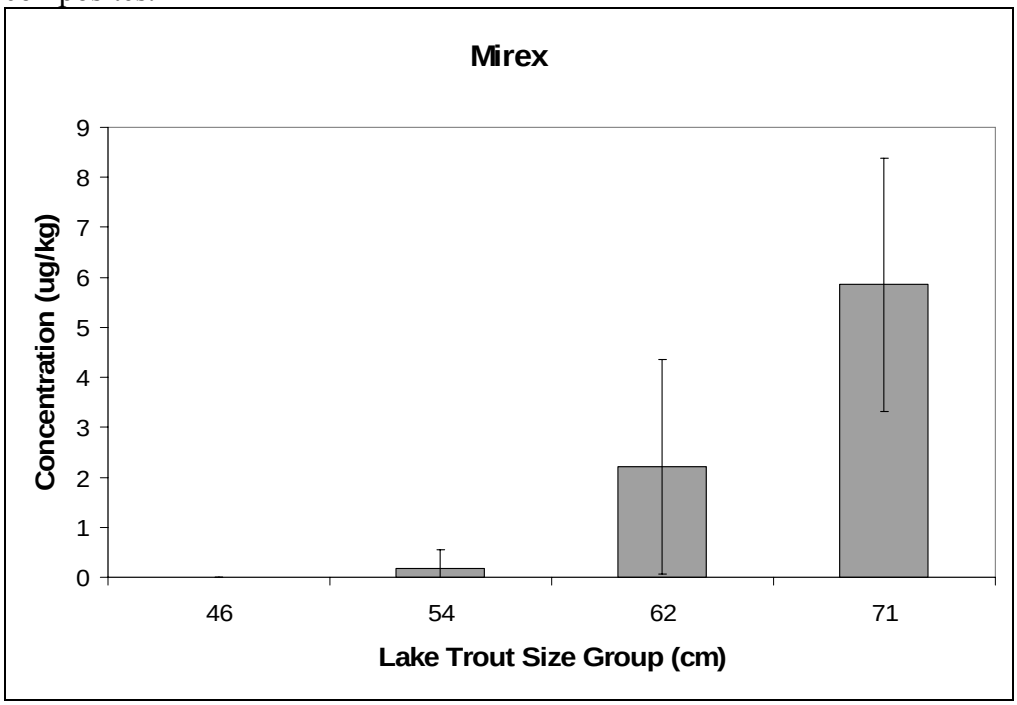

Figure 11. Mean ± one standard deviation of heptachlor epoxide concentrations in Lake Superior lake trout (*Salvelinus namaycush namaycush*) muscle tissue (i.e. trimmed, skin-off fillet) composites.

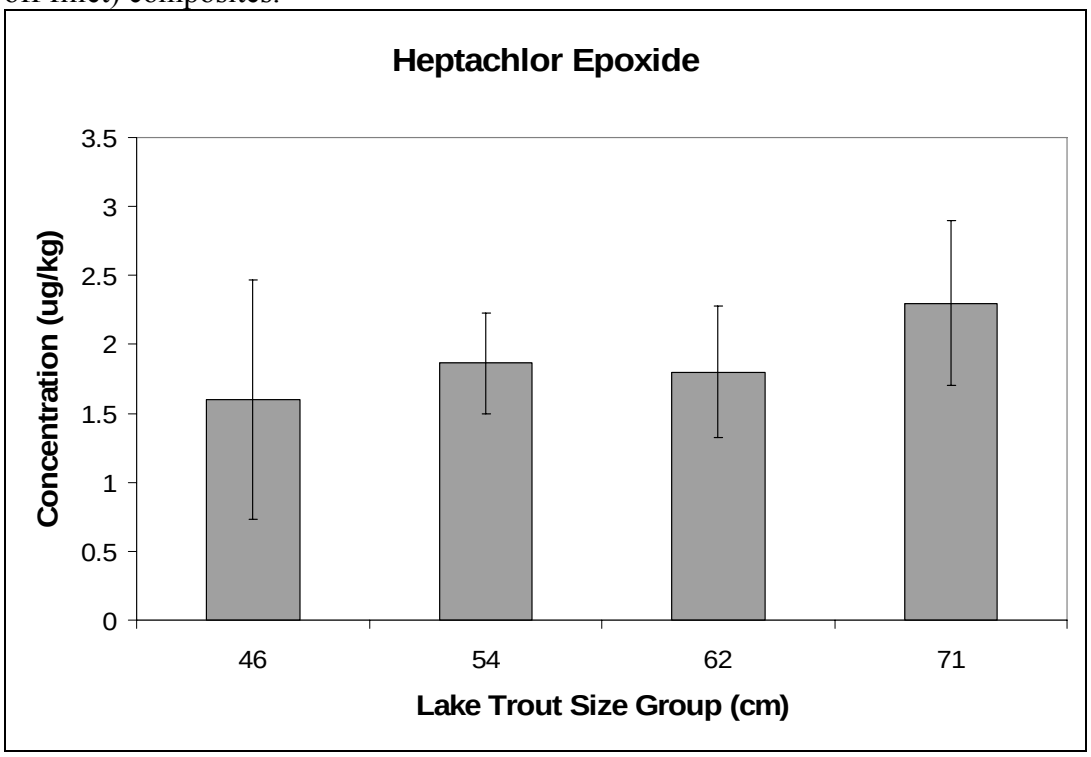

Figure 12. Plot of predicted versus measured organic chemical concentrations in three lake trout fat composite samples. Both the linear regression (solid line) and a line with a slope of one (dashed line) are given.

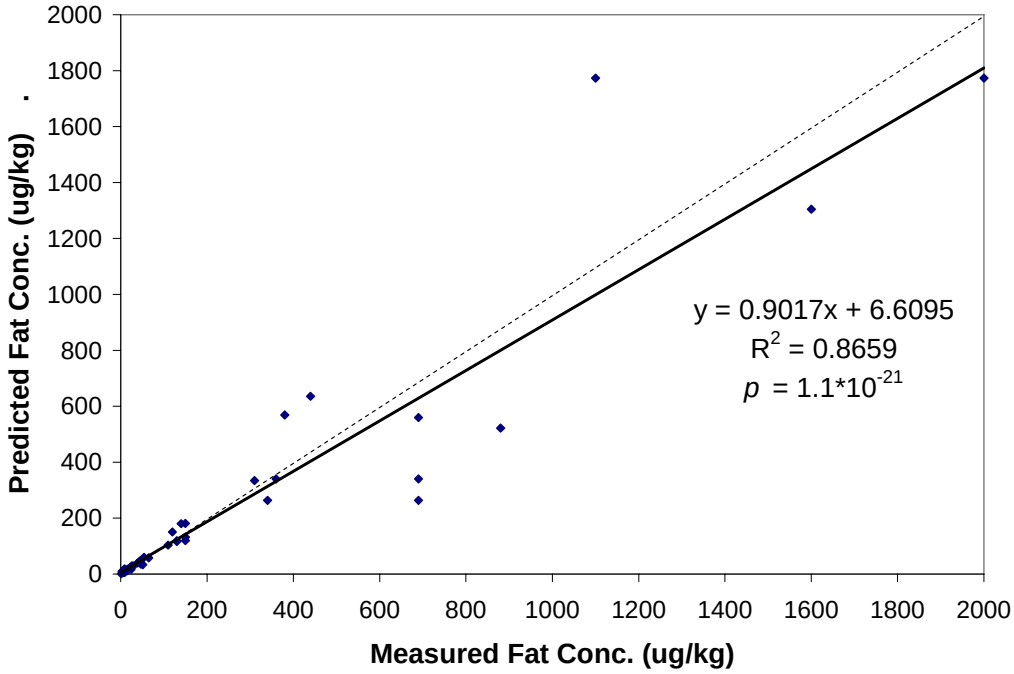

Figure 13. Plot of predicted versus measured organic chemical concentrations in three lake trout skin composite samples. Both the linear regression (solid line) and a line with a slope of one (dashed line) are given.

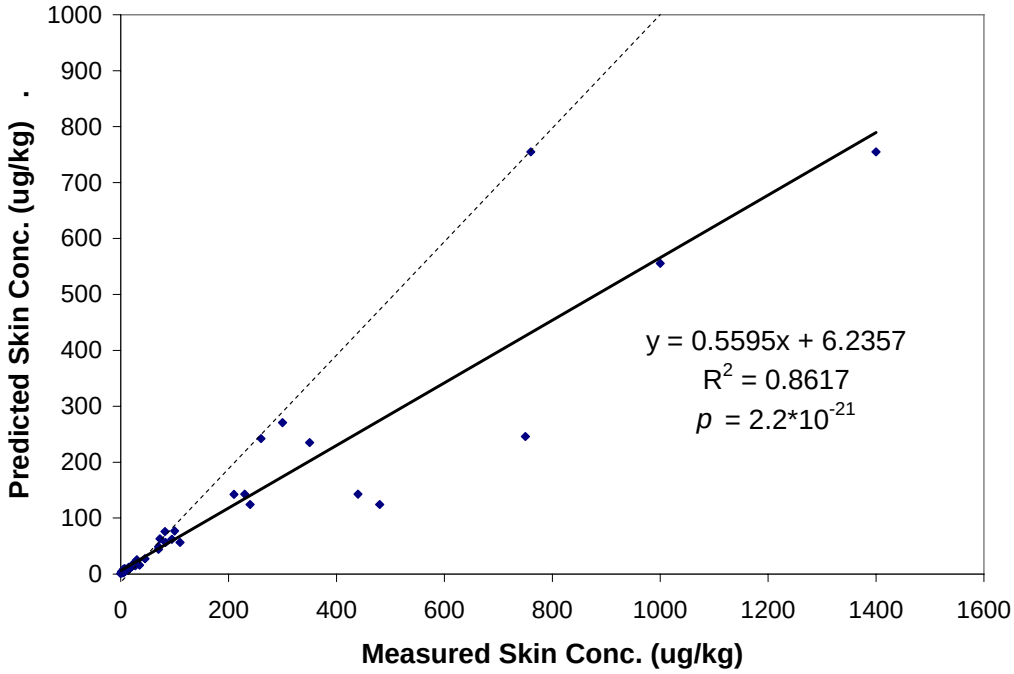

Exhibit 3

GREAT LAKES INDIAN FISH & WILDLIFE COMMISSION

P. O. Box 9 • Odanah, WI 54861 • 715/682-6619 • FAX 715/682-9294

• MEMBER TRIBES •

MICHIGAN
Bay Mills Community
Keweenaw Bay Community
Lac Vieux Desert Band

WISCONSIN
Bad River Band
Lac Courte Oreilles Band
Lac du Flambeau Band
Red Cliff Band
St. Croix Chippewa
Sokaogon Chippewa

MINNESOTA
Fond du Lac Band
Mille Lacs Band

To: Ann McCammon-Soltis, Policy Analyst

From: Matt Hudson, Environmental Biologist

Date: December 30, 2005

Re: Reporting Results for U.S. EPA Grant Number: EQ-98538501

Attached are results for U.S. EPA Grant Number: EQ-98538501. Also included are brief descriptions of the fish processing and analytical methods used to produce the data.

The objectives of this study as stated in the EPA-approved Quality Assurance Project Plan (QAPP) entitled "Lake Whitefish Collection, Compositing, and Environmental Chemical Contaminant Analysis Quality Assurance Project Plan" were to:

1. Determine the wet weight of each fillet's skin, lipid dense trimmings, and muscle tissue collected from lake whitefish captured in management unit MI-3.

2. Determine the concentration of chemicals listed in Table 1 in 16 composite muscle samples; lipid and moisture content in 16 composite muscle, 16 lipid-dense, and 16 skin samples; and archive these 48 composite samples from management unit MI-3.

3. Based on tissue wet weights and lipid and chemical content, mathematically estimate the chemical concentration in skin-on trimmed fillets and skin-on untrimmed fillets.

4. Compare the mean chemical composite values of the skin-off trimmed raw fillet, skin-on trimmed fillets and skin-on untrimmed fillets to the U.S. Food and Drug Administration's environmental chemical concentration limits for the sale of fish.

Exhibit 4

Other Study Objectives

Other study objectives in the project grant proposal that were addressed, are: 1) compare whitefish consumption advice used by each state (Michigan, Minnesota, and Wisconsin) for Lake Superior, 2) compare whitefish data collected in this study to that collected by Michigan, Minnesota, and Wisconsin for fish advisory purposes, and 3) compare GLIFWC whitefish data to advisory trigger levels used to set fish consumption advice by Michigan, Minnesota, and Wisconsin.

Methods

Whitefish Collection and Storage

Lake whitefish (*Coregonus clupeaformis*), hereafter referred to as whitefish, were collected on November 10, 2004 using gillnets at Eagle River shoal (47°25 N, 88°17 W) in Lake Superior lake trout fisheries management unit MI-3 (Figure 1). Four length ranges of whitefish were collected: 43-46, 48-51, 53-56, and 58-61 centimeters (cm). The length ranges selected span the length range of whitefish commonly harvested by tribal commercial fishermen (Figure 2). Samples were handled in a similar manner to commercially harvested fish and placed on ice within hours of collection. Samples were frozen intact within 24 hours of collection and remained frozen (at temperatures at or below -10°C) until processing at the analytical laboratory. The date, time, and conditions of collection and storage were documented on chain-of-custody forms.

Whitefish Processing into Composites

Total length, round weight, and aging material (scales) were collected from each fish prior to freezing. The Great Lakes Indian Fish and Wildlife Commission's (GLIFWC) Great Lakes Fisheries Section aged the fish to the nearest year. Fish were selected for each composite group based on length and age. Whitefish were processed into composites at the Lake Superior Research Institute (LSRI), University of Wisconsin-Superior in January and February of 2005 (Table 2).

Fish were thawed before processing. Laboratory personnel were trained by an experienced tribal fisherman during a previous GLIFWC study on the technique used to trim the fillets. Individual whitefish were filleted using a stainless steel knife. Fillets were segmented into skin, dorsal/ventral fatty tissue (fat), and muscle tissue. Each individual fillet component (i.e. skin, fat, muscle) was weighed separately, ground, and an equal weight of ground tissue used to form a composite. On each processing day, a can of commercial chunk light tuna (*Thunnus sp.*) was divided in half. One half was processed in the same manner as the whitefish composites and the other half was transferred directly to an amber sample jar. These samples were used as procedural blanks to check for contamination that may have been introduced during processing. All lab utensils and glassware were critically cleaned between each composite. Moisture analyses were conducted on the composites. Remaining composite tissues were

transferred to critically cleaned amber glass jars with Teflon lids and archived in a freezer at temperatures at or below -10°C.

Chemical Extraction and Analysis

Each of the 16 muscle tissue composite samples was analyzed for 37 chemicals (Table 1). Mercury was analyzed by LSRI according to LSRI SOP SA/13, *Cold Vapor Mercury Analysis in Biota*, based on EPA Method 245.6. Percent moisture was determined by LSRI using LSRI SOP NT/15 *Procedures for Determining Percent Moisture in Tissue Samples.*

Organic chemicals were analyzed by Pace Analytical, Inc. located in Kimberly, WI. Note that Pace was known as En Chem, Inc. at the beginning of this project. This name change resulted in the titles of the lab's standard operating procedures (SOPs) being changed, but the methods essentially remained the same as described in the project QAPP. The organic chemicals were extracted according to Pace SOP KM-O-001 (based on EPA SW846 Method 3540C). Percent lipid was determined by Pace SOP KM-L-003, based on Standard Methods for the Examination of Water and Wastewater # 5520, 1992. Lipids were removed from the sample extracts using gel permeation chromatography (Pace SOP KM-O-004, based on EPA SW846 Method 3640A). Following removal of lipids, the samples were filtered through a silica gel column to separate the chlorinated pesticides from the PCBs (Pace SOP KM-O-012, based on EPA SW846 Method 3630C). The final extracts were analyzed for PCBs according to Pace SOP KM-O-002 (based on EPA Method 8082) and chlorinated pesticides according to Pace SOP KM-O-014 (based on EPA Method 8081A).

A more complete description of the methods can be found in the QAPP for this project entitled "Lake Whitefish Collection, Compositing, and Environmental Chemical Contaminant Analysis Quality Assurance Project Plan".

Results

Quality Control

Results from quality control (QC) analyses used to monitor data quality for the organic chemical analyses can be found in Tables 3 - 7. QC results from the total mercury analyses can be found in Tables 8 - 11.

Objective #1 - Determine the wet weight of each fillet's skin, lipid dense trimmings, and muscle tissue collected from lake whitefish captured in management unit MI-3.

Table 12 lists descriptive data including tag number, sex, age, and length, along with the weight of muscle, skin, and fat tissues for the 64 whitefish that were sorted into composite samples. An equal weight of tissue from each fish was used to form a composite and this weight is not reported in Table 12.

Objective #2 - Determine the concentration of chemicals listed in Table 1 in 16 composite muscle samples; lipid and moisture content in 16 composite muscle, 16 lipid-dense, and 16 skin samples; and archive these 48 composite samples from management unit MI-3.

Objective #3 - Based on tissue wet weights and lipid and chemical content, mathematically estimate the chemical concentration in skin-on trimmed (SOT) fillets and skin-on untrimmed (SOUT) fillets.

Table 13 provides skin and fat tissue composite mean ± one standard deviation percent moisture and percent lipid measurements. Table 14 provides the whitefish data by composite and by chemical. Table 14 also includes mean ± one standard deviation of muscle composite chemical concentrations for each size group and estimated mean ± one standard deviation of chemical concentrations in SOT and SOUT fillets. These estimates were calculated using the assumption that organic, PBT contaminants partition primarily to the lipid tissue of organisms (Mackay 1982) and were based on tissue weights recorded during fish tissue processing, and percent lipid measured in each tissue. Regression statistics for five representative organic contaminants plotted against percent lipid in whitefish muscle tissue are provided as a test of the lipid assumptions used (Table 15).

All tissue composites have been archived at LSRI in critically cleaned amber glass jars with Teflon lids, frozen at temperatures at or below -10°C.

Objective #4 - Compare the mean chemical composite values of the skin-off trimmed raw fillet, skin-on trimmed fillets and skin-on untrimmed fillets to the U.S. Food and Drug Administration's environmental chemical concentration limits for the sale of fish.

The United States Food and Drug Administration (FDA) regulates the sale of fish based on concentrations of various chemicals measured in fish fillets that are to be sold commercially. Table 16 compares Lake Superior whitefish muscle tissue concentrations of chemicals and chemical groups to FDA concentration limits for those chemicals/groups. All whitefish muscle tissue concentrations, along with SOT and SOUT fillet estimated concentrations, were below current FDA fish tissue concentration limits.

GLIFWC conducted a study of PBT contaminants in Lake Superior fish (including whitefish) in 1999. Table 17 compares concentrations of three chemicals measured in whitefish muscle tissue composites in 1999 to those measured in the current study (2004).

Other Study Objectives Addressed

1) Compare whitefish consumption advice issued by each state (Michigan, Minnesota, and Wisconsin) for Lake Superior.

Table 18 provides current fish consumption advisory trigger level and "do not eat" concentrations used by jurisdictions around Lake Superior. Table 19 describes the chemicals currently driving whitefish consumption advice for Lake Superior, along with

the number and general location of whitefish samples collected for fish advisory purposes by each jurisdiction. Figures 3A and 3B show the current Lake Superior whitefish consumption advice issued by Michigan, Minnesota, and Wisconsin.

2) Compare whitefish data collected in this study to that collected by Michigan, Minnesota, and Wisconsin for fish advisory purposes.

Table 20 summarizes Lake Superior whitefish fillet data collected by Michigan, Minnesota, Wisconsin, and GLIFWC by year of data collection.

GLIFWC has also conducted similar studies to the current whitefish study described in this memo across common, tribally harvested size ranges of siscowet trout (*Salvelinus namaycush siscowet*, 1999) and lake trout (*Salvelinus namaycush namaycush*, 2003). Comparisons between siscowet trout, lake trout, and whitefish are shown for total mercury in Figure 4 and for total PCBs in Figure 5.

3) Compare GLIFWC whitefish data to advisory trigger levels used to set fish consumption advice by Michigan, Minnesota, and Wisconsin.

Figures 6-9 compare GLIFWC whitefish data to current fish advisory trigger and "do not eat" levels for total PCBs, mercury, total chlordane, and toxaphene that are used by Michigan, Minnesota, and Wisconsin to set fish consumption advice. The values are meant to be used as benchmarks for comparison and not to describe how a jurisdiction would interpret the data or set fish consumption advice based on these data.

References

Mackay, D. Correlation of bioconcentration factors. Environmental Science and Technology. 1982. 16: 274-278.

Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory. 1993. Great Lakes Sport Fish Advisory Task Force.

United States Food and Drug Administration. 2001. Fish and Fisheries Products Hazards and Control Guidance. Third Edition.

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TABLES

Table 1. Chemical and non-chemical analyses conducted on muscle tissue (e.g. trimmed, skin-off fillets) composite samples of Lake Superior whitefish (*Coregonus clupeaformis*).

No	Chemical Analyses	Lab Conducting Analysis	No	Chemical Analyses	Lab Conducting Analysis
1	**Total Chlordane**	Calculated by GLIFWC	22	Toxaphene	Pace
2	Cis-Chlordane	Pace	23	Aldrin	Pace
3	Trans-Chlordane	Pace	24	Dieldrin	Pace
4	Cis-nonachlor	Pace	25	Heptachlor	Pace
5	Trans-nonachlor	Pace	26	Heptachlor epoxide	Pace
6	Oxychlordane	Pace	27	Endrin Ketone	Pace
7	**Total PCBs**	Pace	28	Methoxychlor	Pace
8	1016	Pace	29	Hexachlorobenzene	Pace
9	1221	Pace	30	Mirex	Pace
10	1232	Pace	31	Pentachloroanisole	Pace
11	1242	Pace	32	Endosulfan	Pace
12	1248	Pace	33	Endrin	Pace
13	1254	Pace	34	Endosulfan sulfate	Pace
14	1260	Pace	35	Endrin aldehyde	Pace
15	**Total DDT**	Calculated by GLIFWC	36	α-benzene hexachloride	Pace
16	4,4'-DDT	Pace	37	β-benzene hexachloride	Pace
17	4,4'-DDE	Pace	38	δ-benzene hexachloride	Pace
18	4,4'-DDD	Pace	39	γ-benzene hexachloride	Pace
19	2,4'-DDT	Pace	40	Total mercury	LSRI
20	2,4'-DDE	Pace	41	Lipid Determination	Pace
21	2,4'-DDD	Pace	42	Moisture Determination	LSRI

Table 2. Mean length and age (± one standard deviation) for the four composites within each Lake Superior whitefish (*Coregonus clupeaformis*) size group.

Size Group (cm)	Mean Length (cm)	Mean Age
43-46	44.9 ± 0.6	7.4 ± 0.5
48-51	48.9 ± 0.5	8.0 ± 0.5
53-56	54.3 ± 0.7	9.3 ± 0.9
58-61	58.7 ± 0.4	10.4 ± 1.0

Table 3. Relative percent agreement (RPA*) of lipid concentration in duplicate Lake Superior whitefish (*Coregonus clupeaformis*) samples analyzed by Pace, Inc.

Date of Analysis	Composite No.	Sample 1	Sample 2	RPA	QC Limit RPA
3/23/2005	CC1718TF4	2.68	2.84	94.2	>65
3/23/2005	CC2122TF4	5.00	5.40	92.3	>65
3/28/2005	CC1920S4	17.0	16.7	98.2	>65
3/28/2005	CC2324S1	28.8	27.0	93.5	>65
3/28/2005	CC2122L4	30.2	27.4	90.3	>65
3/28/2005	CC2324L1	39.3	37.9	96.4	>65

*RPA is: 1 – (absolute value of the difference between the two samples/mean of the two samples)

Table 4. Relative percent agreement (RPA*) of PCB and pesticide concentrations in duplicate Lake Superior whitefish (*Coregonus clupeaformis*) samples analyzed by Pace, Inc.

Compound	CC1718 TF4	CC1718 TF4 DUP	RPA	CC2122 TF4	CC2122 TF4 DUP	RPA	QC Limit RPA**
Arochlor 1016	ND	ND	.	ND	ND	.	
Arochlor 1221	ND	ND	.	ND	ND	.	
Arochlor 1232	ND	ND	.	ND	ND	.	
Arochlor 1242	ND	ND	.	ND	ND	.	
Arochlor 1248	ND	ND	.	ND	ND	.	
Arochlor 1254	ND	ND	.	ND	ND	.	
Arochlor 1260	19	19	100	44	48	91.3	>65
Total PCBs	19	19	100	44	48	91.3	>65
2,4'-DDD	ND	ND	.	ND	ND	.	
2,4'-DDE	ND	ND	.	ND	ND	.	
2,4'-DDT	ND	ND	.	ND	ND	.	
4,4'-DDD	ND	ND	.	ND	ND	.	
4,4'-DDE	12	12	100	24	32	71.4	
4,4'-DDT	2.1	1.8	84.6	6.4	7.0	91.0	
Aldrin	ND	ND	.	ND	ND	.	
alpha-BHC	ND	ND	.	1.7	1.7	100	
alpha-Chlordane	0.89	0.93	95.6	3.1	3.4	90.8	
beta-BHC	ND	ND		ND	ND	.	
cis-nonachlor	5.2	5.4	96.2	13	14	92.6	
delta-BHC	ND	ND	.	ND	ND	.	
Dieldrin	5.7	6.3	90.0	12	17	65.5	
Endosulfan I	ND	ND	.	ND	ND	.	
Endosulfan II	ND	ND	.	ND	ND	.	
Endosulfan Sulfate	ND	ND	.	ND	ND	.	
Endrin	ND	ND	.	1.9	2.3	81.0	
Endrin Aldehyde	1.8	2.2	80.0	6.5	7.4	87.1	
Endrin Ketone	ND	ND	.	ND	ND	.	
gamma-BHC (Lindane)	ND	ND	.	ND	ND	.	
gamma-Chlordane	ND	ND	.	1.9	1.9	100	
Heptachlor	ND	ND	.	ND	ND	.	
Heptachlor Epoxide	2.3	2.6	87.8	5.9	7.0	82.9	
Hexachlorobenzene	1.9	1.7	88.9	3.3	4.6	67.1	
Methoxychlor	ND	ND	.	ND	ND	.	
Mirex	ND	ND	.	ND	ND	.	
Oxychlordane	1.5	1.6	93.5	3.3	3.5	94.1	
Pentachloroanisole	ND	ND	.	ND	ND	.	
Toxaphene	ND	ND	.	130	150	85.7	
Trans-nonachlor	6.3	6.6	95.3	16	18	88.2	

ND - Not Detectable - sample was below detection limit.
*RPA is: 1 – (absolute value of the difference between the two samples/mean of the two samples)
**QC limits were only available for PCB Aroclor analyses

Table 5. Spike recovery of PCBs and pesticides in two Lake Superior whitefish (*Coregonus clupeaformis*) samples analyzed by Pace, Inc.

Compound	Sample 1 CC1718TF4	Sample 2 CC2122TF4	QC Limits
Arochlor 1254	124	144*	43-130
alpha-BHC	105	102	69-123
beta-BHC	90	105	35-128
delta-BHC	80	100	57-126
gamma-BHC (Lindane)	95	110	52-126
Aldrin	90	95	52-122
Heptachlor	105	90	50-128
Heptachlor epoxide	94	100	51-130
Endosulfan I	70	90	45-140
Dieldrin	63	100	42-135
4,4'-DDE	108	105	46-152
Endrin	68	100	43-136
Endosulfan II	25*	100	46-147
4,4'-DDD	105	108	48-160
Endosulfan sulfate	18*	105	54-132
4,4'-DDT	120	116	49-148
Methoxychlor	5*	85	36-159
Endrin ketone	14*	105	61-139
Endrin aldehyde	8	46	6-96
alpha-Chlordane	110	105	52-139
gamma-Chlordane	85	86	55-136

* Spiked sample recovery not within control limits.

Table 6. Spike recovery of PCBs and pesticides in lab control spikes (LCS) and spike duplicates (LCS dup) analyzed by Pace, Inc.

Compound	BBLK096 LCS	BBLK096 LCS dup	RPD**	BBLK097 LCS	BBLK097 LCS dup	RPD	SVK1079-097 LCS	SVK1079-097 LCS dup	RPD	SVK1079-096F2MB LCS	SVK1079-096F2MB LCS dup	RPD	QC Limits % Recovery	QC Limits % RPD
Arochlor 1254							100	88	13	96	104	8	40-128	20
alpha-BHC	100	90	10	100	90	10							65-117	40
beta-BHC	85	60	34	100	75	28							58-115	40
delta-BHC	95	55*	53*	105	85	21							63-117	40
gamma-BHC (Lindane)	95	75	24	100	90	10							65-115	40
Aldrin	100	105	5	110	100	10							60-115	40
Heptachlor	85	95	11	95	90	5							58-118	40
Heptachlor epoxide	100	60*	50*	110	95	15							63-118	40
Endosulfan I	85	35*	83*	90	80	12							54-129	40
Dieldrin	95	32*	98*	98	88	11							63-117	40
4,4'-DDE	115	125	8	130	118	10							60-150	40
Endrin	92	30*	102*	95	88	8							55-116	40
Endosulfan II	82	8*	163*	90	80	12							57-120	40
4,4'-DDD	98	85	14	105	92	13							63-128	40
Endosulfan sulfate	78	0*	200*	92	80	14							61-123	40
4,4'-DDT	135*	62	73*	118	105	11							62-127	40
Methoxychlor	75	0*	200*	80	75	6							33-141	40
Endrin ketone	90	3*	186*	95	85	11							64-132	40
Endrin aldehyde	55	0*	200*	65	52	21							16-115	40
alpha-Chlordane	105	100	5	100	95	5							58-125	40
gamma-Chlordane	80	80	0	80	80	0							64-120	40
2,4'-DDD	130			132*									70-130	
2,4'-DDE	115			118									70-130	
2,4'-DDT	165*			122									70-130	
cis-Nonachlor	178*			182*									70-130	
trans-Nonachlor	122			122									70-130	
Oxychlordane	100			100									70-130	
Hexachlorobenzene	90			90									70-130	
Pentachloroanisole	100			100									70-130	
Mirex	128			142*									70-130	
Toxaphene	75			75									60-140	

* Spiked sample recovery not within control limits.

** RPD = Relative percent difference as calculated by Pace (absolute value of the difference between the two samples/mean of the two samples).

Table 7. Results of Standard Reference Material (SRM) analysis. SRM-1946 was the Certified Standard Reference Material used. SRM 096 and 097 refer to the SRM 1946 samples analyzed by Pace, Inc. Results are compared to Quality Control (QC) ranges issued for SRM 1946 and to Pace's QC ranges for the same analytes.

Compound Name	SRM 1946 Conc. µg/Kg	SRM 1946 Uncertainty	SRM QC Range (ug/kg)		SRM 096	SRM 097	Pace Lab Control Spike QC limits	Pace QC Range (ug/kg)		SRM 096	SRM 097
Alpha-BHC	5.72	±0.65	6.37	5.07	6.8*	7.0*	65-117	3.7	6.7	6.8*	7.0*
Gamma-BHC	1.14	±0.18	1.32	0.960	1.4*	1.4*	65-115	0.7	1.31	1.4*	1.4*
Heptachlor epoxide	5.50	±0.23	5.73	5.27	8.2*	7.4*	63-118	3.5	6.5	8.2*	7.4*
Dieldrin	32.5	±3.5	36.0	29.0	40*	38*	63-117	20.5	38.0	40*	38
4,4'-DDE	373	±48	421	325	380	380	60-150	223.8	559.5	380	380
4,4'-DDD	17.7	±2.8	20.5	14.9	13*	13*	60-150	10.6	26.6	13	13
4,4'-DDT	37.2	±3.5	40.7	33.7	46*	45*	62-127	23.1	47.2	46	45
Alpha-chlordane	32.5	±1.8	33.3	30.7	38*	36*	58-125	18.9	40.6	38	36
Gamma-chlordane	8.36	±0.91	9.27	7.45	10*	10*	55-136	4.6	11.4	10	10
2,4'-DDD	2.20	±0.25	2.45	1.95	0*	0*	60-150	1.3	3.3	0*	0*
2,4'-DDE	1.04	±0.29	1.33	0.75	14*	13*	40-160	0.4	1.7	14*	13*
2,4'-DDT	22.3	±3.2	25.5	19.1	15*	14*	40-160	8.9	35.7	15	14
Cis-nonachlor	59.1	±3.6	62.7	55.5	84*	87*	60-150	35.5	88.7	84	87
Trans-nonachlor	99.6	±7.6	107	92.0	130*	130*	60-150	59.8	149.4	130	130
Oxychlordane	18.9	±1.5	20.4	17.4	20	19	60-150	11.3	28.4	20	19
Hexachlorobenzene	7.25	±0.83	8.08	6.42	10*	9.7*	60-150	4.4	10.9	10	9.7
Mirex	6.47	±0.77	7.24	5.70	0*	0*	60-150	3.9	9.7	0*	0*
% Lipid	10.2	±0.48	10.7	9.72	10.5	10.7				10.5	10.7

* Analyte concentration was outside of given quality control (QC) range.

Table 8. Relative percent agreement (RPA*) of procedural blank samples [commercial tuna fish (*Thunnus sp.*) before and after grinding] for total mercury analysis by LSRI.

Date of Analysis	Grinding Date	Before Grinding	After Grinding	Mean	RPA	QC Limit RPA
3/17/2005	1/26/2005	0.086	0.093	0.090	92.2	>50
3/17/2005	2/10/2005	0.039	0.050	0.045	75.3	>50
3/17/2005	2/16/2005	0.035	0.030	0.033	84.6	>50
3/17/2005	2/18/2005	0.034	0.038	0.036	88.9	>50
3/17/2005	2/22/2005	0.042	0.037	0.040	87.3	>50
3/17/2005	2/23/2005	0.038	0.046	0.042	81.0	>50

*RPA is: 1 – (absolute value of the difference between the two samples/mean of the two samples)

Table 9. Mercury concentrations of dogfish tissue supplied by the National Research Council Canada (DORM-2) and analyzed by LSRI. The tissue has a certified mercury concentration of 4.64±0.26 μgHg/g tissue. The acceptable range of mercury concentration was 3.61-5.16 μgHg/g based upon DORM-2 analyses conducted from July 3, 2003 to August 12, 2003.

Date of Analysis	Sample 1	Sample 2	Mean	Std. Dev.	Percent of Expected
3/17/2005	4.49	5.15	4.82	0.47	104
3/17/2005	4.87	4.05	4.46	0.58	96.1

Table 10. Relative percent agreement (RPA*) between duplicate analysis for total mercury (wet weight) content in skinless fillet tissue of composited Lake Superior whitefish (*Coregonus clupeaformis*) analyzed by LSRI.

Date of Analysis	Sample ID	Sample 1	Sample 2	RPA	QC Limit RPA
3/17/2005	CC1920TF3	0.055	0.054	98.6	>83.7
3/17/2005	CC2324TF4	0.116	0.116	100	>83.7
3/17/2005	Tuna Before 2/23	0.043	0.033	73.7	>83.7

*RPA is: 1 – (absolute value of the difference between the two samples/mean of the two samples)

Table 11. Percent of total mercury Recovered from skinless fillet tissue of composited Lake Superior whitefish (*Coregonus clupeaformis*) spiked with a known quantity of mercury by LSRI.

Date of Analysis	Sample ID	Spike #1	Spike #2	Mean	Std. Dev.	QC Limits % Recovery
3/17/2005	CC1920TF3	99.0	98.0	98.5	0.68	54.4-114
3/17/2005	CC2324TF4	98.5	97.5	98.0	0.75	54.4-114
3/17/2005	Tuna Before 2/23	102.6	100.6	101.6	1.4	54.4-114

Table 12. Individual Lake Superior whitefish (*Coregonus clupeaformis*) descriptive data for fish contained in each composite. Tissue weights are wet weight values. These weights are not the weight of tissue used to form the composites.

Sample ID	Tag Num	Sex	Age	Length (in)	Length (cm)	Round Wt* (g)	Whole Fillet Wt (g)	Muscle Wt (g)	Fat Wt (g)	Skin Wt (g)
CC43-46-1	1902	M	7	17.4	44.2	700	193.5	171.3	4.3	15.1
CC43-46-1	1995	M	7	17.4	44.2	700	176.6	150.6	11.8	11.7
CC43-46-1	1984	M	7	17.4	44.2	700	208.5	174.8	14.7	15.8
CC43-46-1	1910	M	7	17.2	43.7	600	171	143.6	12.9	12.2
CC43-46-2	1983	M	7	17.6	44.7	800	195.5	172.6	6.3	12.1
CC43-46-2	1993	M	8	17.5	44.5	700	170	137.4	16.5	11.5
CC43-46-2	1904	M	7	17.6	44.7	700	192.6	165.5	11.4	12.3
CC43-46-2	1999	F	7	17.7	45.0	700	225.4	191.9	8.4	20.1
CC43-46-3	1994	M	8	17.8	45.2	700	203.7	174.3	11.6	13.6
CC43-46-3	1907	M	8	17.8	45.2	800	197.1	161.9	17.7	14.2
CC43-46-3	1921	M	8	17.8	45.2	700	203.8	158.2	24.9	16.5
CC43-46-3	1991	M	8	17.7	45.0	800	222.9	169.1	34.0	15.0
CC43-46-4	1901	M	7	18	45.7	900	249.4	214.8	11.6	18.7
CC43-46-4	1905	M	7	17.9	45.5	700	188.2	166.4	9.3	10.1
CC43-46-4	1982	M	8	17.9	45.5	800	195.2	170.5	7.3	15.6
CC43-46-4	2000	M	7	18	45.7	700	205.1	183.6	3.7	14.3
CC48-51-1	1848	F	8	19	48.3	900	222.1	194.8	7.3	19
CC48-51-1	1940	M	8	19.1	48.5	1000	273.4	231.4	17.8	22.9
CC48-51-1	1926	M	8	19	48.3	1000	266.3	222.6	21.7	17.3
CC48-51-1	1841	M	7	19.1	48.5	1000	270.4	224.5	21.9	21.0
CC48-51-2	1909	F	8	19.2	48.8	1000	211.2	178.0	13.8	15.5
CC48-51-2	1935	F	7	19.2	48.8	900	232.1	176.7	32.4	16.2
CC48-51-2	1914	M	8	19.2	48.8	1000	280.6	228.8	34.5	19.2
CC48-51-2	1913	M	8	19.2	48.8	1000	286.9	226.8	37.9	19.5
CC48-51-3	1985	M	9	19.3	49.0	1000	320.0	256.8	34.4	23.1
CC48-51-3	1988	M	8	19.4	49.3	1000	286.8	229.6	31.9	20.3
CC48-51-3	1918	F	8	19.3	49.0	1000	253.7	214.7	18.3	17.3
CC48-51-3	1850	M	8	19.2	48.8	900	247.4	217.0	14.2	14.0
CC48-51-4	1842	M	8	19.4	49.3	1000	302.1	263.1	16.4	18.7
CC48-51-4	1927	F	9	19.4	49.3	1000	245.8	203.1	15.0	20.3
CC48-51-4	1939	M	8	19.5	49.5	1000	293.4	240.2	20.5	24.9
CC48-51-4	1912	M	8	19.8	50.3	1000	315.0	255.6	31.6	22.3
CC53-56-1	1932	M	8	21	53.3	1200	338.4	290.8	23.7	19.9
CC53-56-1	1931	F	9	21.1	53.6	1300	413.5	333.2	47.1	25.3
CC53-56-1	1933	M	9	21.1	53.6	1500	392.2	320.6	39.2	27.5
CC53-56-1	1936	F	9	21.1	53.6	1200	308.6	260.2	18.3	26.1
CC53-56-2	1930	M	10	21.3	54.1	1500	287.1	233.7	26.1	22.7
CC53-56-2	1938	M	10	21.1	53.6	1400	402.0	328.8	45.9	23.4
CC53-56-2	1929	M	10	21.2	53.8	1400	381.8	328.3	25.0	23.4
CC53-56-2	1906	M	9	21.2	53.8	1500	414.9	355.5	24.8	28.1
CC53-56-3	1922	M	8	21.4	54.4	1500	454.7	356.8	59.1	27.3
CC53-56-3	1934	M	9	21.4	54.4	1400	398.7	314.1	44.9	29.1

Table 12 continued…

Sample ID	Tag Num	Sex	Age	Length (in)	Length (cm)	Round Wt* (g)	Whole Fillet Wt (g)	Muscle Wt (g)	Fat Wt (g)	Skin Wt (g)
CC53-56-3	1986	M	11	21.4	54.4	1400	383.4	320.4	28.6	26.7
CC53-56-3	1844	M	8	21.6	54.9	1400	368.0	293.6	47.5	21.9
CC53-56-4	1843	M	9	21.6	54.9	1300	347.2	291.6	27.5	23.2
CC53-56-4	1928	M	10	21.6	54.9	1300	351.5	290.2	34.5	22.4
CC53-56-4	1911	M	9	21.7	55.1	1500	409.3	347.8	29.5	27.6
CC53-56-4	1979	M	10	22	55.9	1400	400.9	335.9	35.0	23.8
CC58-61-1	1916	M	9	23	58.4	1500	468.5	362.7	36.2	39.0
CC58-61-1	1997	M	9	23.2	58.9	1900	511.2	407.6	41.0	50.1
CC58-61-1	1908	M	9	23.2	58.9	2000	603.9	483.4	37.4	45.8
CC58-61-1	1925	M	10	23	58.4	2000	518.3	435.6	40.3	35.4
CC58-61-2	1917	M	10	23.1	58.7	1800	519.2	418.4	48.4	39.8
CC58-61-2	1992	M	10	23.1	58.7	1700	472.8	380.8	45.2	36.8
CC58-61-2	1987	M	10	23	58.4	1700	489.2	406.3	36.0	35.5
CC58-61-2	1998	M	10	23.1	58.7	1600	511.1	408.4	47.4	40.4
CC58-61-3	1919	F	11	23	58.4	2000	457.1	346.5	69.5	34.1
CC58-61-3	1846	M	11	23	58.4	1800	481.3	401.1	39.1	31.5
CC58-61-3	1924	F	12	23	58.4	2000	436.1	347.5	49.2	33.1
CC58-61-3	1937	M	12	23	58.4	1800	466.3	391.9	30.2	35.1
CC58-61-4	1923	M	11	23.2	58.9	1800	510.3	425.0	42.3	33.2
CC58-61-4	1849	M	11	23.2	58.9	NA	595.8	483.3	68.9	33.7
CC58-61-4	1996	M	11	23.4	59.4	1800	495.8	399.8	50.9	36.0
CC58-61-4	1915	F	11	23.5	59.7	2000	469.7	377.0	49.7	35.1

* Round weight refers to the unprocessed weight of the fish in the field.
NA = Not Available

Table 13. Percent lipid and mean ± one standard deviation of percent moisture measured in fat and skin tissues from Lake Superior whitefish (*Coregonus clupeaformis*) fillets.

	Fat			Skin		
Sample ID	% Lipid	Mean % Moisture	STDEV	% Lipid	Mean % Moisture	STDEV
CC43-46-1	17.4	66.72	0.91	14.3	64.04	1.16
CC43-46-2	14.6	68.94	0.35	13.2	63.30	0.70
CC43-46-3	10.9	71.35	0.24	11.4	63.87	0.97
CC43-46-4	15.7	67.51	0.20	13.7	63.90	0.46
CC48-51-1	22.5	62.99	1.93	15.6	63.74	0.41
CC48-51-2	24.0	60.16	0.30	14.1	62.44	0.37
CC48-51-3	24.0	52.97	2.34	13.5	59.67	2.28
CC48-51-4	25.5	53.43	19.19	16.9*	60.01	0.05
CC53-56-1	24.7	59.80	0.83	12.1	65.16	0.61
CC53-56-2	26.7	55.04	0.85	14.8	64.13	0.96
CC53-56-3	17.8	65.50	0.46	16.0	62.10	0.20
CC53-56-4	28.8*	56.37	0.65	14.5	61.48	0.67
CC58-61-1	38.6*	42.18	2.55	27.9*	49.62	0.18
CC58-61-2	29.7	53.63	0.41	20.6	56.35	0.25
CC58-61-3	22.1	61.12	0.79	11.5	65.30	0.06
CC58-61-4	29.0	52.48	5.58	20.5	57.56	0.76

* Value listed is the mean of duplicate samples.

Table 14. Individual Lake Superior whitefish (*Coregonus clupeaformis*) muscle tissue composite chemical concentrations. Concentrations listed for skin-on trimmed fillets (SOT) and skin-on untrimmed fillets (SOUT) are estimated values based on the wet weight of tissues in the composites and percent lipid in those tissues. "Percent Moisture" data for each composite are the average of three replicates. Values given for "Percent Moisture" and Percent Lipid" are percentages. All other data are wet weight concentrations in units of ug/kg. Significant figures are consistent with lab reported values.

Chemical Parameter	Method Detection Limit	Estimated Quantitation Limit	Length Group*	Composite Number				Replicate**		Length Group Average***	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
				1	2	3	4	1	2						
Percent Moisture			43 to 46 cm	77.0	77.3	78.7	77.1	.	.	77.5	0.8	.	.	.	.
			48 to 51 cm	77.2	77.0	76.3	76.2			76.7	0.5	.	.	.	.
			53 to 56 cm	77.0	75.9	76.3	74.6	.	.	76.0	1.0	.	.	.	.
			58 to 61 cm	72.6	73.8	75.7	73.8			74.0	1.3	.	.	.	.
Percent Moisture Standard Deviation			43 to 46 cm	0.3	0.2	0.0	0.8	.	.	0.3	0.3	.	.	.	.
			48 to 51 cm	0.4	0.2	0.5	0.0			0.3	0.2	.	.	.	.
			53 to 56 cm	0.3	0.2	0.2	0.3	.	.	0.3	0.1	.	.	.	.
			58 to 61 cm	0.1	0.3	0.1	0.5			0.3	0.2	.	.	.	.
Percent Lipids			43 to 46 cm	2.42	2.92	2.52	2.76	2.68	2.84	2.66	0.23	.	.	.	.
			48 to 51 cm	3.74	2.89	3.89	4.16			3.67	0.55	.	.	.	.
			53 to 56 cm	3.50	4.57	4.01	5.20	5.00	5.40	4.32	0.73	.	.	.	.
			58 to 61 cm	7.76	6.24	4.70	6.31			6.25	1.25	.	.	.	.
2,4'-DDD	0.82	5.0	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
2,4'-DDE	1.2	5.0	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
2,4'-DDT	1.1	5.0	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	1.2	ND	1.6	ND			1.4	0.3	1.6	0.2	2.0	0.4

Table 14 continued…

Chemical Parameter	Method Detection Limit	Estimated Quantitation Limit	Length Group*	Composite Number 1	2	3	4	Replicate** 1	2	Length Group Average***	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
4,4'-DDD	1.0	5.0	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	1.1			1.1	.	1.4	.	1.7	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
4,4'-DDE	0.74	5.0	43 to 46 cm	11	11	11	12	12	12	11	1	15	1	17	1
			48 to 51 cm	15	13	20	16			16	3	20	3	27	4
			53 to 56 cm	28	30	35	28	24	32	30	3	36	5	47	5
			58 to 61 cm	36	44	35	26			35	7	42	9	52	11
4,4'-DDT	1.1	5.0	43 to 46 cm	2.1	2.1	2.3	2.0	2.1	1.8	2.1	0.1	2.8	0.2	3.3	0.4
			48 to 51 cm	3.2	2.6	4.3	3.8			3.5	0.7	4.3	0.8	5.9	0.8
			53 to 56 cm	5.8	5.7	5.4	6.7	6.4	7.0	5.9	0.6	6.9	0.4	9.2	0.8
			58 to 61 cm	9.9	11	6.8	4.5			8.1	3.0	9.6	3.8	12	4
Aldrin	0.42	2.5	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Alpha-BHC	0.86	2.5	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	0.89	ND	0.98	ND			0.94	0.06	1.1	0.0	1.5	0.1
			53 to 56 cm	1.2	1.3	1.0	1.7	1.7	1.7	1.3	0.3	1.5	0.3	2.0	0.4
			58 to 61 cm	3.6	1.8	1.2	2.3			2.2	1.0	2.7	1.3	3.3	1.5
Alpha-Chlordane	0.42	2.5	43 to 46 cm	1.5	1.3	1.1	0.91	0.89	0.93	1.2	0.3	1.6	0.4	1.9	0.5
			48 to 51 cm	2.1	2.2	2.4	1.9			2.2	0.2	2.7	0.2	3.7	0.7
			53 to 56 cm	2.9	2.2	1.9	3.3	3.1	3.4	2.6	0.6	3.0	0.7	4.0	1.0
			58 to 61 cm	4.3	4.8	6.0	2.9			4.5	1.3	5.3	1.4	6.6	1.8
Aroclor 1016	12	50	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.

Table 14 continued…

Chemical Parameter	Method Detection Limit	Estimated Quantitation Limit	Length Group*	Composite Number 1	2	3	4	Replicate** 1	2	Length Group Average***	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Aroclor 1221	12	50	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Aroclor 1232	12	50	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Aroclor 1242	12	50	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Aroclor 1248	12	50	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Aroclor 1254	12	50	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Aroclor 1260	12	50	43 to 46 cm	21	17	19	19	19	19	19	2	25	3	29	5
			48 to 51 cm	25	23	35	28			28	5	35	5	47	7
			53 to 56 cm	53	50	43	46	44	48	48	4	56	5	75	10
			58 to 61 cm	58	65	68	41			58	12	68	14	86	17
Beta-BHC	1.1	2.5	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.

Table 14 continued…

Chemical Parameter	Method Detection Limit	Estimated Quantitation Limit	Length Group*	Composite Number 1	2	3	4	Replicate** 1	2	Length Group Average***	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Cis-nonachlor	1.0	5.0	43 to 46 cm	6.0	5.6	5.5	5.3	5.2	5.4	5.6	0.3	7.3	0.7	8.7	1.1
			48 to 51 cm	8.4	7.2	10	8.5			8.5	1.1	11	1	14	1
			53 to 56 cm	13	12	12	14	13	14	13	1	15	1	20	2
			58 to 61 cm	18	21	16	13			17	3	20	4	25	5
Delta-BHC	0.68	2.5	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Dieldrin	1.1	5.0	43 to 46 cm	7.4	7.6	5.8	6.0	5.7	6.3	6.7	0.9	8.8	1.4	10	2
			48 to 51 cm	11	12	10	12			11	1	14	2	19	4
			53 to 56 cm	13	15	10	15	12	17	13	2	15	2	20	3
			58 to 61 cm	24	24	20	21			22	2	26	3	33	3
Endosulfan I	0.43	2.5	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Endosulfan II	0.80	5.0	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND		ND		ND	
			48 to 51 cm	0.89	0.88	0.86	ND			0.88	0.02	1.1	0.1	1.5	0.3
			53 to 56 cm	0.94	ND	ND	1.4	ND	1.4	1.2	0.3	1.3	0.3	1.8	0.3
			58 to 61 cm	2.0	1.9	4.0	1.6			2.4	1.1	2.8	1.2	3.5	1.6
Endosulfan Sulfate	2.0	5.0	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Endrin	0.84	5.0	43 to 46 cm	0.93	1.0	ND	ND	ND	ND	1.0	0.0	1.3	0.0	1.5	0.1
			48 to 51 cm	1.3	1.6	1.6	1.4			1.5	0.2	1.8	0.2	2.6	0.6
			53 to 56 cm	2.0	1.9	1.3	2.1	1.9	2.3	1.8	0.4	2.1	0.4	2.9	0.6
			58 to 61 cm	3.2	3.0	2.5	2.6			2.8	0.3	3.3	0.5	4.2	0.5

Table 14 continued…

Chemical Parameter	Method Detection Limit	Estimated Quantitation Limit	Length Group*	Composite Number 1	2	3	4	Replicate** 1	2	Length Group Average***	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Endrin Aldehyde	1.0	5.0	43 to 46 cm	3.2	3.1	3.0	2.0	1.8	2.2	2.8	0.6	3.7	0.8	4.4	1.1
			48 to 51 cm	3.5	3.6	5.0	4.6			4.2	0.7	5.2	0.7	7.1	1.1
			53 to 56 cm	6.3	6.3	5.0	7.0	6.5	7.4	6.1	0.8	7.2	0.7	9.6	1.3
			58 to 61 cm	8.9	10	8.3	6.6			8.5	1.4	10	2	12	2
Endrin Ketone	0.90	5.0	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Gamma-BHC (Lindane)	0.48	2.5	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	0.51	ND	ND	ND	ND	0.51	.	0.59	.	0.78	.
			58 to 61 cm	0.87	ND	ND	0.62			0.75	0.18	0.90	0.25	1.1	0.2
Gamma-Chlordane	1.6	2.5	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	1.8	2.3	2.1	1.9	1.9	1.9	2.0	0.2	2.4	0.3	3.2	0.3
			58 to 61 cm	5.2	5.7	2.7	1.7			3.8	1.9	4.6	2.4	5.6	2.8
Heptachlor	0.72	2.5	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Heptachlor Epoxide	0.66	2.5	43 to 46 cm	2.7	2.9	2.7	2.5	2.3	2.6	2.7	0.2	3.5	0.3	4.2	0.5
			48 to 51 cm	4.0	4.0	4.0	5.2			4.3	0.6	5.4	0.8	7.3	1.1
			53 to 56 cm	5.5	6.7	4.1	6.5	5.9	7.0	5.7	1.2	6.7	1.2	8.9	1.7
			58 to 61 cm	10	9.6	7.6	9.0			9.1	1.1	11	2	13	2
Hexachlorobenzene	0.45	2.5	43 to 46 cm	2.4	2.3	2.0	1.8	1.9	1.7	2.1	0.3	2.8	0.4	3.3	0.6
			48 to 51 cm	2.6	2.6	3.1	2.6			2.7	0.3	3.4	0.2	4.7	0.7
			53 to 56 cm	3.0	3.6	2.6	4.0	3.3	4.6	3.3	0.6	3.8	0.6	5.1	0.8
			58 to 61 cm	4.5	4.8	3.6	3.2			4.0	0.8	4.8	1.0	5.9	1.1

Table 14 continued…

Chemical Parameter	Method Detection Limit	Estimated Quantitation Limit	Length Group*	Composite Number 1	Composite Number 2	Composite Number 3	Composite Number 4	Replicate** 1	Replicate** 2	Length Group Average***	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Methoxychlor	2.8	25	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Mirex	0.99	5.0	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Oxychlordane	0.72	5.0	43 to 46 cm	1.4	1.6	1.7	1.6	1.5	1.6	1.6	0.1	2.0	0.1	2.4	0.2
			48 to 51 cm	2.0	1.4	2.1	2.3			2.0	0.4	2.4	0.4	3.3	0.3
			53 to 56 cm	3.6	3.6	3.4	3.4	3.3	3.5	3.5	0.1	4.1	0.2	5.5	0.4
			58 to 61 cm	4.9	5.9	4.3	4.8			5.0	0.7	5.9	0.9	7.4	1.0
Pentachloroanisole	0.36	2.5	43 to 46 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			48 to 51 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			53 to 56 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			58 to 61 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
Total Chlordane	sum of - cis-chlordane, trans-chlordane, cis-nonachlor, trans nonachlor, oxychlordane		43 to 46 cm	16	15	15	15	14	15	15	1	20	2	23	3
			48 to 51 cm	22	19	27	23			23	3	28	3	39	4
			53 to 56 cm	38	36	36	39	37	41	37	2	44	1	58	4
			58 to 61 cm	55	65	48	38			52	11	61	15	76	17
Total DDT	sum of - 2,4'-DDD, 2,4'-DDE, 2,4'-DDT, 4,4'-DDD, 4,4'-DDE, 4,4'DDT		43 to 46 cm	13	13	13	14	14	14	13	1	17	1	20	1
			48 to 51 cm	18	16	24	20			20	3	24	3	33	4
			53 to 56 cm	34	36	40	35	30	39	36	3	43	5	57	5
			58 to 61 cm	47	55	43	31			44	10	52	13	65	15
Total Mercury****	1.3		43 to 46 cm	50	60	56	58			56	4	.	.	.	.
			48 to 51 cm	59	60	55	70	55	54	61	7	.	.	.	.
			53 to 56 cm	85	98	99	76			90	11	.	.	.	.
			58 to 61 cm	82	92	100	120	120	120	98	14	.	.	.	.

Table 14 continued…

Chemical Parameter	Method Detection Limit	Estimated Quantitation Limit	Length Group*	Composite Number 1	2	3	4	Replicate** 1	2	Length Group Average***	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Total PCBs	12	50	43 to 46 cm	21	17	19	19	19	19	19	2	25	3	29	5
			48 to 51 cm	25	23	35	28			28	5	35	5	47	7
			53 to 56 cm	53	50	43	46	44	48	48	4	56	5	75	10
			58 to 61 cm	58	65	68	41			58	12	68	14	86	17
Toxaphene	46	250	43 to 46 cm	65	ND	49	ND	ND	ND	57	11	77	19	94	23
			48 to 51 cm	90	93	110	100			98	9	120	10	170	20
			53 to 56 cm	140	120	100	140	130	150	130	20	150	20	200	30
			58 to 61 cm	210	230	180	130			190	40	220	60	280	60
Trans-Nonachlor	0.80	5.0	43 to 46 cm	6.8	6.6	6.6	6.5	6.3	6.6	6.6	0.1	8.7	0.5	10	1
			48 to 51 cm	9.9	8.4	12	9.9			10	1	13	1	17	2
			53 to 56 cm	17	16	17	17	16	18	17	1	20	1	26	2
			58 to 61 cm	23	28	19	16			22	5	26	7	32	8

ND = Not detected
* Length groups in centimeters correspond to inches as follows: 43 to 46 cm = 17 to 18 inches; 48 to 51 cm = 19 to 20 inches; 53 to 56 cm = 21 to 22 inches; and 58 to 61 cm = 23 to 24 inches.
** For the 43 to 46 cm and 53 to 56 cm length groups, the values for composite 4 represent the average of two replicates.
*** "ND" values were treated as "0" and were not included in length group average calculations.
**** Duplicate measurements for total mercury analysis were run on composite 3 of the 48 to 51 cm length group and composite 4 of the 58 to 61 cm length group. Total mercury concentrations are listed as reported by the Lake Superior Research Institute. Total mercury concentrations were not calculated for SOT and SOUT fillets because mercury binds to muscle tissue and is not reduced by trimming fillets.

Table 15. Statistics for five representative organic contaminants regressed against percent lipid in muscle tissue to test lipid partitioning assumptions used in estimating chemical concentrations in SOT and SOUT fillets.

Chemical or Chemical group	**Number of samples**	**r-squared**	**p-value**	**slope**
Total PCBs	16	0.54	0.0011	8.3
Total Chlordane	16	0.73	<0.0001	8.6
Total DDT	16	0.65	0.0002	7.2
Toxaphene	14	0.69	0.0002	28
Dieldrin	16	0.85	<0.0001	3.6

Table 16. Lake Superior whitefish (*Coregonus clupeaformis*) mean, standard deviation, and range of chemical concentrations (ug/kg) in muscle tissue, skin-on trimmed fillets (SOT) and skin-on, untrimmed fillets (SOUT) for each composite size group. Results for SOT and SOUT fillets are estimated values based on the wet weight of tissues in the composites and percent lipid in those tissues. United States Food and Drug Administration (FDA) fish tissue concentration levels regulating the commercial sale of fish are given for each chemical or chemical group.

Chemical Parameter	Tissue***	Whitefish Size Group (cm)	Mean Conc. (ug/kg)	St. Dev. (ug/kg)	Range (ug/kg)	FDA Level (ug/kg)
Total Mercury**	M	43-46*	56	4	50-60	1000****
	M	48-51	61	6	55-70	
	M	53-56*	90	11	76-99	
	M	58-61	98	14	82-116	
Total PCBs	M	43-46*	19	2	17-21	2000
	M	48-51	28	5	23-35	
	M	53-56*	48	4	43-53	
	M	58-61	58	12	41-68	
	SOT	43-46*	25	3	22-29	
	SOT	48-51	35	5	30-42	
	SOT	53-56*	56	5	52-63	
	SOT	58-61	68	14	48-78	
	SOUT	43-46*	29	5	25-36	
	SOUT	48-51	47	7	39-56	
	SOUT	53-56*	75	10	67-89	
	SOUT	58-61	86	17	61-100	
Total Chlordane	M	43-46*	15	1	15-16	300
	M	48-51	23	3	19-27	
	M	53-56*	37	2	36-39	
	M	58-61	52	11	38-65	
	SOT	43-46*	20	2	19-22	
	SOT	48-51	28	3	25-32	
	SOT	53-56*	44	1	42-45	
	SOT	58-61	61	15	44-78	
	SOUT	43-46*	23	3	21-27	
	SOUT	48-51	39	4	35-44	
	SOUT	53-56*	58	4	55-64	
	SOUT	58-61	76	17	57-97	
Total DDT	M	43-46*	13	1	13-14	5000
	M	48-51	20	3	16-24	
	M	53-56*	36	3	34-40	
	M	58-61	44	10	31-55	
	SOT	43-46*	17	1	17-18	
	SOT	48-51	24	3	21-28	
	SOT	53-56*	43	5	39-49	
	SOT	58-61	52	13	36-66	
	SOUT	43-46*	20	1	19-22	
	SOUT	48-51	33	4	28-39	
	SOUT	53-56*	57	5	51-62	
	SOUT	58-61	65	15	46-82	
Aldrin/Dieldrin	M	43-46*	6.7	0.9	5.8-7.6	300
	M	48-51	11	1	10-12	
	M	53-56*	13	2	10-15	
	M	58-61	22	2	20-24	
	SOT	43-46*	8.8	1.4	7.5-10	
	SOT	48-51	14	2	12-16	
	SOT	53-56*	15	2	12-17	
	SOT	58-61	26	3	22-30	
	SOUT	43-46*	10	2	8.7-13	
	SOUT	48-51	19	4	16-25	
	SOUT	53-56*	20	3	16-23	
	SOUT	58-61	33	3	29-36	

Table 16 Continued…

Chemical Parameter	Tissue***	Whitefish Size Group (cm)	Mean Conc. (ug/kg)	St. Dev. (ug/kg)	Range (ug/kg)	FDA Level (ug/kg)
Heptachlor/Heptachlor Epoxide	M	43-46*	2.7	0.2	3.5-4.2	300
	M	48-51	4.3	0.6	4-5.2	
	M	53-56*	5.7	1.2	5.5-6.7	
	M	58-61	9.1	1.1	7.6-10	
	SOT	43-46*	3.5	0.3	3.2-3.7	
	SOT	48-51	5.4	0.8	5.1-6.5	
	SOT	53-56*	6.7	1.2	5.0-7.8	
	SOT	58-61	11	2	8.5-12	
	SOUT	43-46*	4.2	0.5	3.5-4.6	
	SOUT	48-51	7.3	1.1	6.3-8.5	
	SOUT	53-56*	8.9	1.7	6.4-10	
	SOUT	58-61	13	2	11-15	
Mirex	M	43-46*	ND	.	ND	100
	M	48-51	ND	.	ND	
	M	53-56*	ND	.	ND	
	M	58-61	ND	.	ND	
	SOT	43-46*	ND	.	ND	
	SOT	48-51	ND	.	ND	
	SOT	53-56*	ND	.	ND	
	SOT	58-61	ND	.	ND	
	SOUT	43-46*	ND	.	ND	
	SOUT	48-51	ND	.	ND	
	SOUT	53-56*	ND	.	ND	
	SOUT	58-61	ND	.	ND	

ND = Not Detected

* These ranges include the mean of duplicate samples, i.e. duplicates were not treated as separate samples for inclusion in the concentration ranges.

** Because mercury binds to muscle tissue, trimming the fillet will not reduce mercury concentrations. Therefore, mercury concentrations were not calculated for SOT and SOUT fillets.

*** M = trimmed, skin-off muscle tissue; SOT = skin-on, trimmed fillet; SOUT = skin-on, untrimmed fillet.

**** The FDA action level for mercury is for methylmercury. Generally >95% of mercury in top predator fish such as lake trout is methylmercury (GLIFWC data, unpublished).

Table 17. Comparison of Lake Superior whitefish (*Coregonus clupeaformis*) muscle tissue contaminant data collected by the Great Lakes Indian Fish and Wildlife Commission (GLIFWC) in 1999 and 2003. Whitefish composite size group (cm), mean chemical concentration (ug/kg), and concentration range (ug/kg) are given for three chemicals/chemical groups.

	2003 Data			**1999 Data**		
Chemical Parameter	**Whitefish Size Group**	**Mean Conc.**	**Range**	**Whitefish Size Group**	**Mean Conc.**	**Range**
Total Mercury	43-46*	56	50-60			
	48-51	61	55-70			
	53-56*	90	76-99			
	58-61	98	82-116	56-61	65	60-70
Total PCBs	43-46*	19	17-21			
	48-51	28	23-35			
	53-56*	48	43-53			
	58-61	58	41-68	56-61	32	20-45
Total Chlordane	43-46*	15	15-16			
	48-51	23	19-27			
	53-56*	37	36-39			
	58-61	52	38-65	56-61	14	11-17

* These ranges include the mean of duplicate samples, i.e. duplicates were not treated as separate samples for inclusion in the concentration ranges

Table 18. Current (as of 2005) trigger and "do not eat" (DNE) fish tissue concentrations (in ug/kg wet weight) used by jurisdictions on the United States side of Lake Superior to set sport fish consumption advisories. More specific advice (such as a concentration defining one meal per week or per month) for some contaminants are available, but are not listed here. The listed contaminants are responsible for the majority of advisories on the U.S. side of Lake Superior*. Concentrations are wet weight in micrograms of contaminant per kilogram of fish tissue (parts per billion) unless noted.

Jurisdiction	Mercury		Total PCBs*****		Toxaphene		Total Chlordane	
	Trigger	DNE	Trigger	DNE	Trigger	DNE	Trigger	DNE
Sensitive Populations**								
Wisconsin	50	>1000	50	>1900	-	-	-	>5620
Minnesota	50	>1000	50	>1900	-	-	-	-
Michigan****	500	>1500	50	>1900	5000	-	300	-
General Population***								
Wisconsin	160	-	50	>1900	-	-	-	-
Minnesota	160	>2800	50	>1900	-	-	-	-
Michigan****	500	>1500	2000	-	5000	-	300	-

* In Ontario, 65% of Lake Superior advisories based on their 2005 guidance are caused by dioxins/furans and dioxin-like PCBs.

** The sensitive population is defined as women of childbearing age and children under the age of 15.

*** The general population is defined as men above age 15 and women beyond childbearing years or above age 15 and not planning to have children.

**** The Michigan Department of Community Health sets fish consumption advice for most contaminants including: total PCBs for the general population, toxaphene, dioxin TEQs, and total chlordane, based on the percentage of measured fish tissue concentrations that exceed the trigger level.

***** Total PCB advice for Wisconsin, Minnesota, and for sensitive populations in Michigan, is based on the Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory, developed by the Great Lakes Sport Fish Advisory Task Force, September 1993.

Table 19. Comparison of some current methods and total fillet samples used by states around Lake Superior to set whitefish (*Coregonus clupeaformis*) consumption advice.

State	Chemical driving advice	Analytical Method	Total whitefish samples collected	Total whitefish samples used for setting advice**	Location of sample collections to date (lake trout mgmt unit)
Michigan	Total PCBs	Sum of individual congeners	46	46	MI-5
Wisconsin	Total PCBs	Sum of Aroclor mixtures	24	15	WI-2
Minnesota	Total PCBs	Sum of Aroclor mixtures	9*	15	MN-3

* Five of the Minnesota samples are fillets, two are composites of 5 fillets each, and two are fish tissue plugs rather than fillets.

** Wisconsin and Minnesota combine their data for setting Lake Superior whitefish consumption advice. The two states currently use data collected only within the past 10 years for setting the whitefish advisory. Michigan uses all whitefish data collected by looking for trends in the data over time to determine whether the advisory needs to be updated.

Table 20. Summary of Lake Superior whitefish total mercury and total PCB data collected by the Great Lakes Indian Fish & Wildlife Commission (GLIFWC), Minnesota Department of Natural Resources (MNDNR), Michigan Department of Environmental Quality (MI DEQ), and Wisconsin Department of Natural Resources (WDNR). Results from each jurisdiction are summarized by year. Only fillet data results are listed. Whole fish and other non-fillet data were not included in this summary. GLIFWC samples were composites while other samples were largely individual fish. Note that concentrations are listed in units of mg/kg or parts per million. Mean results are given along with ± one standard deviation.

Agency	Year	Mgmt Unit	No. Analyses/No. Fish**	Length Mean (cm)	Length Range (cm)	Mean total mercury (mg/kg wet wt)	Total mercury range (mg/kg wet wt)	Mean total PCBs (Aroclors, mg/kg wet wt)	Total PCB Range (mg/kg wet wt)
MNDNR	1987	MN-3	2/10	58.7±0.4	NA***	0.074±0.003	0.072-0.076	0.079±0.086	0.018-0.14
MNDNR	2000	MN-3	5/5	54.4±5.5	48.8-60.5	0.02±0.01	0.01-0.03	0.01±0	0.01-0.01
MI DEQ	1986	MI-5	10/10	52.5±2.1	48-55	<0.1	NA	0.108±0.016	0.083-0.134
MI DEQ	1992	MI-5	7/7	49.9±4.3	44-56	0.05±0.02	0.03-0.09	0.068±0.022	0.029-0.092
MI DEQ	1993	MI-5	5/5	53.6±5.9	47-62	0.04±0.01	0.03-0.06	0.062±0.040	0.026-0.125
MI DEQ	1996	MI-5	20/20	54.2±5.5	45.2-63.2	0.05±0.01	0.03-0.09	0.100±0.056	0.033-0.208
MI DEQ	2000	MI-5	15/15	54.7±5.3	48.4-62.3	0.06±0.02	0.04-0.1	0.049±0.026****	0.013-0.096
MI DEQ	2002	MI-5	11/11	58.4±10.4	46.6-75.8	0.08±0.02	0.05-0.13	0.060±0.037****	0.024±0.141
WDNR	1974	WI-2	2/2	32.4±15.3	21.6-43.2	NA	NA	0.2±0.1	0.1-0.3
WDNR	1976	WI-2	2/2	61.1±3.1	58.9-63.2	NA	NA	1.5±1.8	0.21-2.7
WDNR	1985	WI-2	2/2	44.6±0.9	43.9-45.2	NA	NA	0.2±0	0.20-0.20
WDNR	1986	WI-2	1/1	64.8	NA	NA	NA	0.21	NA
WDNR	1987	WI-2	3/3	65.7±3.8	63.0-70.1	NA	NA	0.45±0.42	0.20-0.93
WDNR	1988	WI-2	4/4	43.4±17.9	32.0-70.1	0.073±0.039	0.05-0.13	0.23±0.06	0.20-0.31
WDNR	2003	WI-2	10/10	47.4±2.2	45.0-52.1	0.051±0.015	0.028-0.083	0.27±0.17	0.11-0.52
GLIFWC	1999	MI-4	4/47	57.3±0.3	55.9-61.0	0.051±0.007	0.046-0.061	0.058±0.009	0.051-0.071
GLIFWC*	2004	MI-3	4/16	44.9±0.6	43.7-45.7	0.056±0.004	0.050-0.060	0.029±0.005	0.025-0.036
GLIFWC*	2004	MI-3	4/16	48.9±0.5	48.3-50.3	0.061±0.006	0.055-0.070	0.047±0.007	0.039-0.056
GLIFWC*	2004	MI-3	4/16	54.3±0.7	53.3-55.9	0.090±0.011	0.076-0.099	0.075±0.010	0.067-0.089
GLIFWC*	2004	MI-3	4/16	58.7±0.4	58.4-59.7	0.098±0.014	0.082-0.116	0.086±0.017	0.061-0.10

* GLIFWC segmented fillets into muscle, skin, and fat tissues. In 2004, chemical concentrations were only measured in trimmed, skin-off muscle tissue. PCB concentrations listed here are estimates for a skin-on, untrimmed fillet based on lipid normalized muscle concentrations and percent lipid in the skin and fat tissues. Total mercury concentrations for the GLIFWC 2004 samples are reported for muscle tissue only (i.e. the skin and fat have been removed unlike the other fillet samples listed in this table).

** No. Analyses/No. Fish = No. Analyses denotes the number of laboratory analyses the data represent. No. Fish denotes the number of fish represented in those analyses. When the two numbers are equal, individual fish were analyzed, when the numbers are not equal, composites were analyzed.

*** NA = Not Available

**** MI DEQ total PCB data from 2000 and 2002 are reported as the sum of individual PCB congeners as opposed to the sum of Aroclors.

FIGURES

Figure 1. Lake Superior lake trout (*Salvelinus namaycush namaycush*) management units (United States waters). Whitefish samples were collected from Eagle River Shoal (marked with an "X") in management unit MI-3.

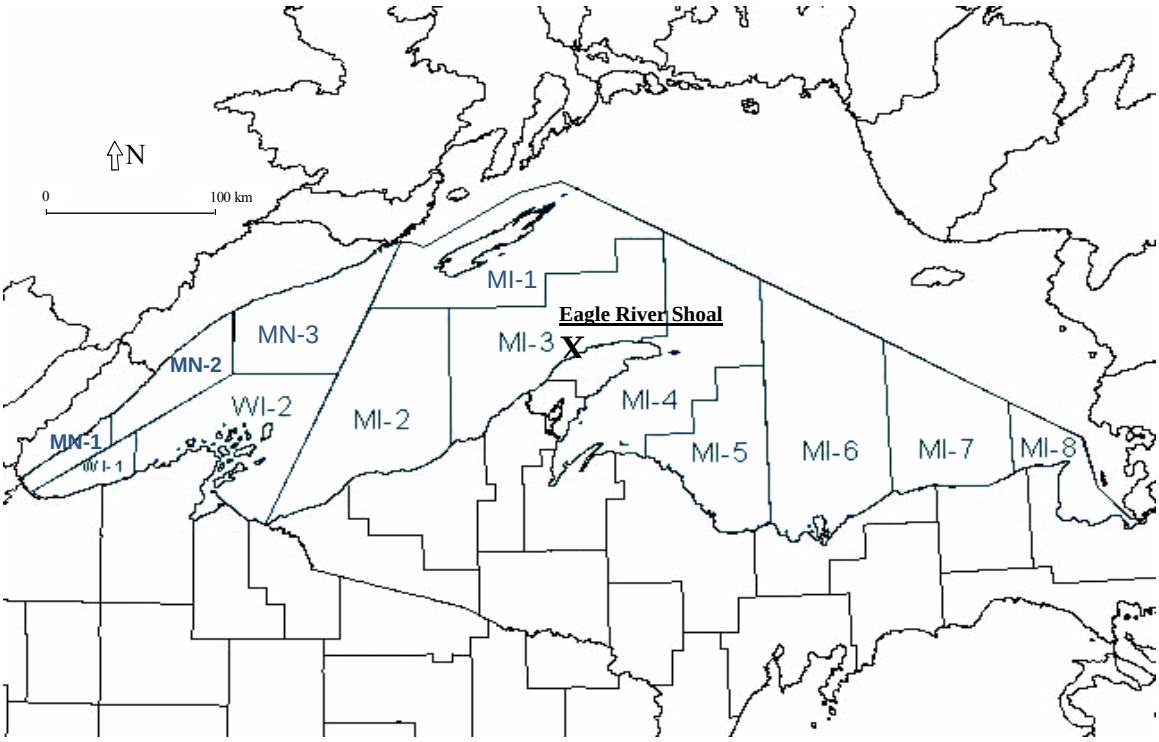
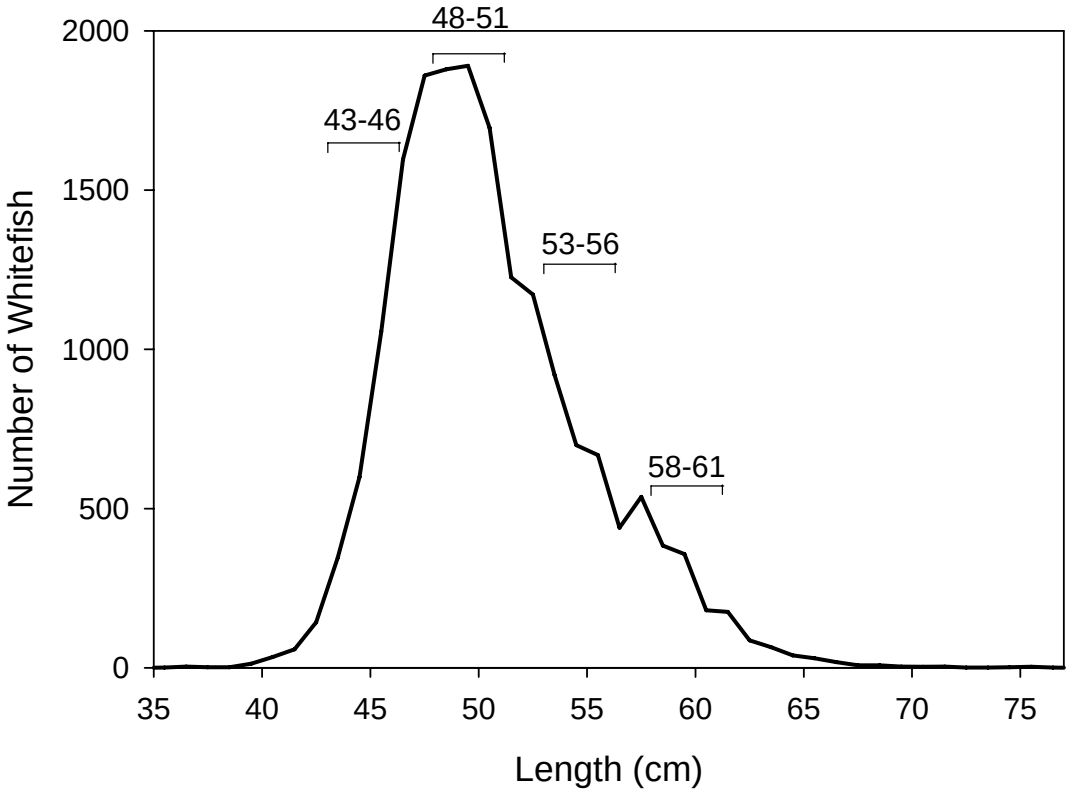


Figure 2. Great Lakes Indian Fish and Wildlife Commission (GLIFWC) whitefish (*Coregonus clupeaformis*) monitoring data from Lake Superior lake trout management unit MI-3 from the years 1985-2004. Numbered ranges indicate the size ranges of whitefish sampled.



Figures 3A and B. Comparison of Michigan, Minnesota and Wisconsin Lake Superior whitefish (*Coregonus clupeaformis*) consumption advice for sensitive populations (i.e. women of childbearing age and children under the age of 15, Figure A) and the general population (i.e. women beyond childbearing age and men above age 15, Figure B).

Figure 3A – Sensitive population

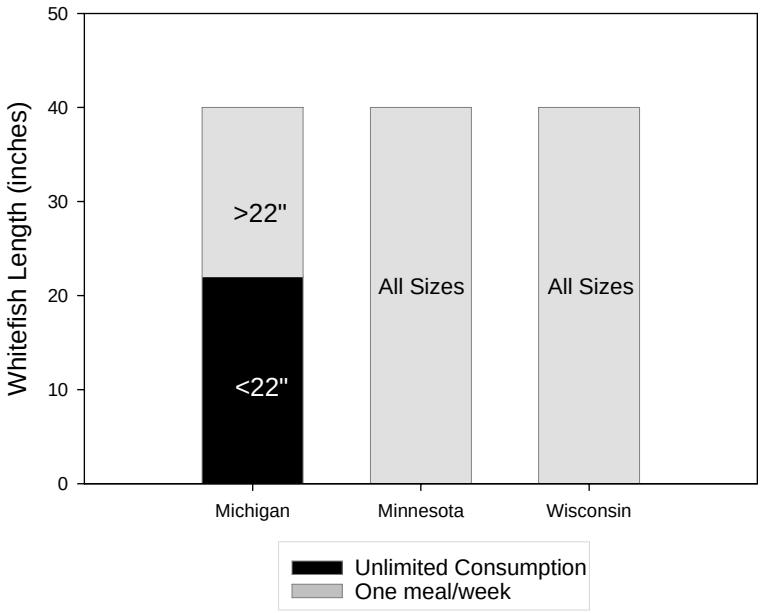


Figure 3B – General population

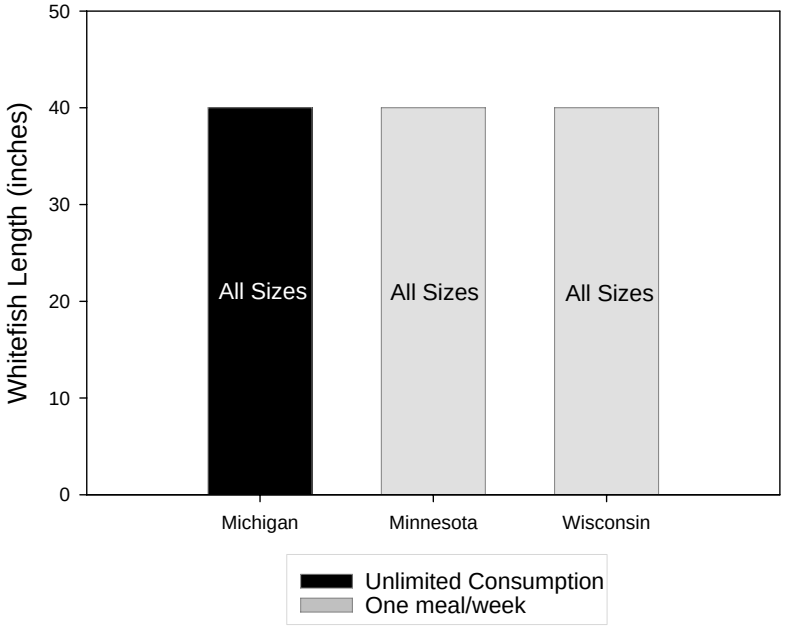


Figure 4. Total mercury concentrations (mean ± one standard deviation) for three species of Lake Superior fish. The sizes of fish span the length range of each species commonly harvested by tribal commercial fishermen. Data for siscowet trout (*Salvelinus namaycush siscowet*) and lake trout (*Salvelinus namaycush namaycush*) were previously reported by the Great Lakes Indian Fish and Wildlife Commission (GLIFWC).

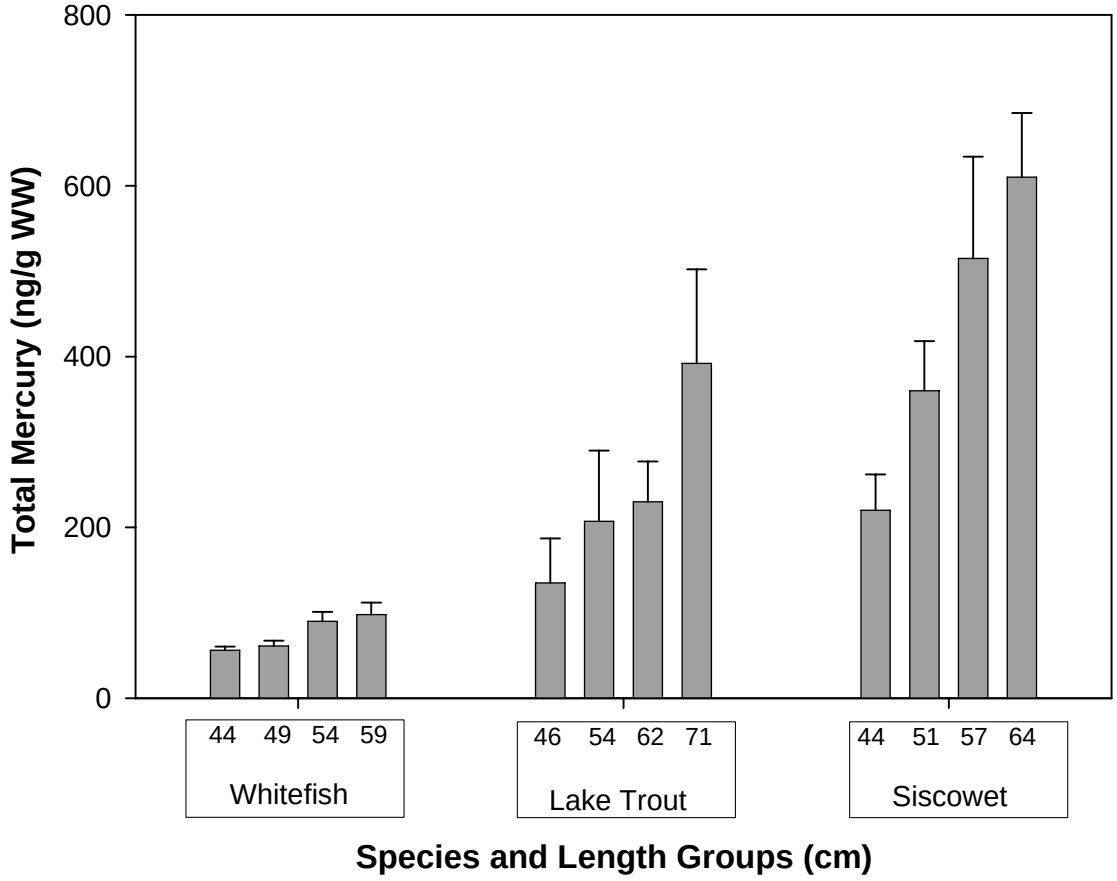
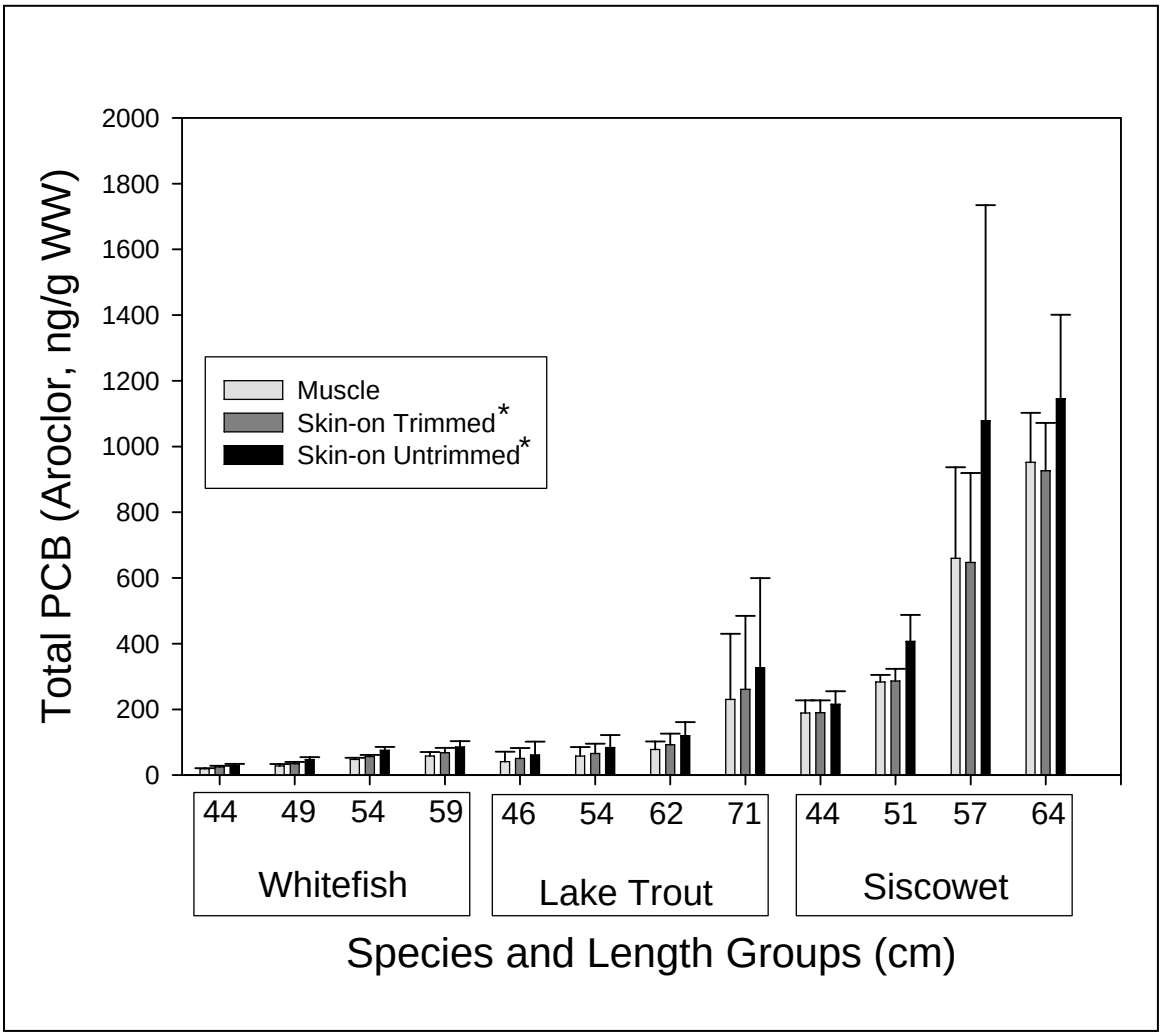


Figure 5. Total PCB concentrations (mean ± one standard deviation) for three species of Lake Superior fish. The sizes of fish span the length range of each species commonly harvested by tribal commercial fishermen. Data for siscowet trout (*Salvelinus namaycush siscowet*) and lake trout (*Salvelinus namaycush namaycush*) were previously reported by the Great Lakes Indian Fish and Wildlife Commission (GLIFWC).



* Concentrations in “skin-on trimmed” and “skin-on untrimmed" fillets were measured for siscowet trout and estimated for lake trout and whitefish based on lipid normalized muscle tissue concentrations and skin and fat tissue lipid content.

Figure 6. Total PCB concentrations (mean ± one standard deviation) in Lake Superior whitefish (*Coregonus clupeaformis*) muscle tissue composites. Concentrations in SOT and SOUT fillets are estimated based on muscle tissue concentrations and percent lipid in respective skin and fat tissues. SOT and SOUT refer to "skin on trimmed" and "skin on untrimmed" fillets. The trigger and "do not eat" fish tissue concentrations used by Michigan, Minnesota, and Wisconsin to set fish consumption advice are shown as lines. These states use values agreed upon in the "Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory" (Great Lakes Sport Fish Advisory Task Force, Sept. 1993).

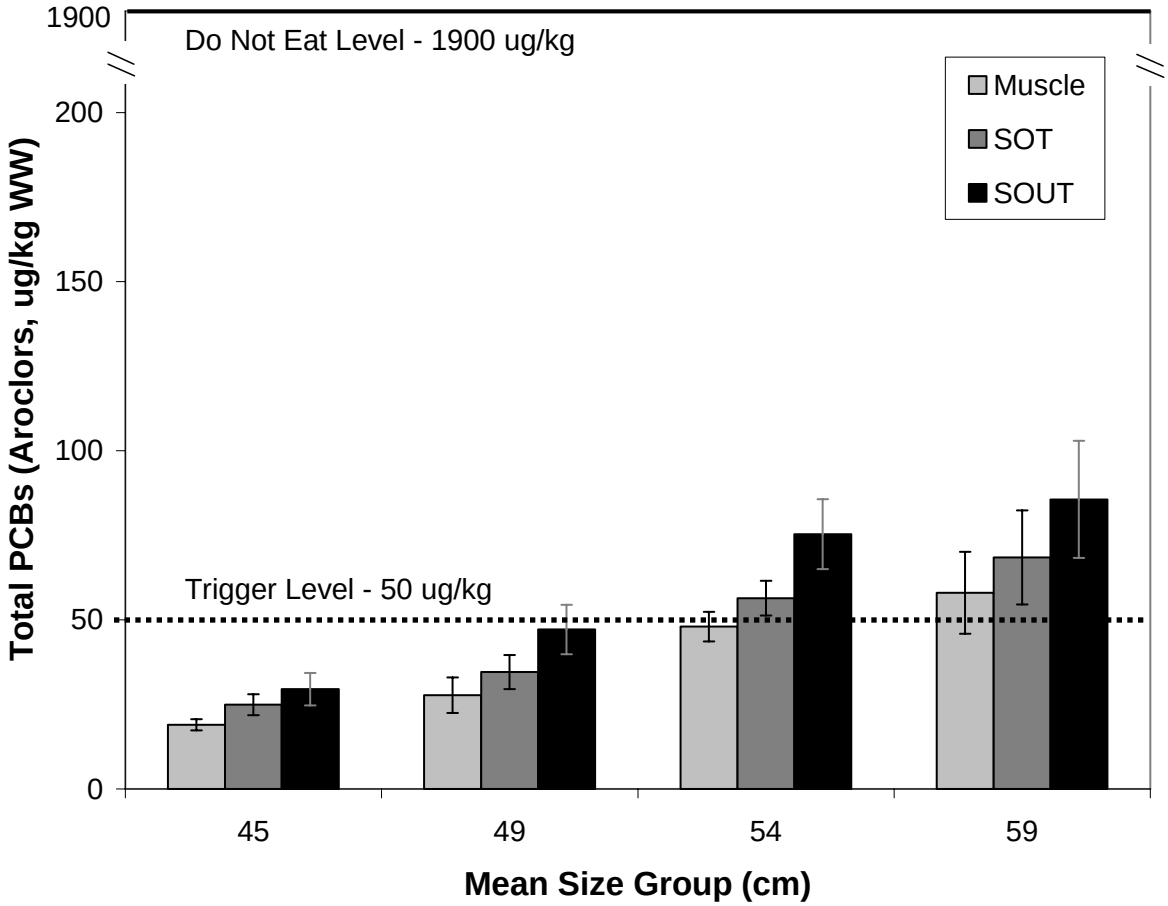


Figure 7. Total mercury concentrations (mean ± one standard deviation) in Lake Superior whitefish (*Coregonus clupeaformis*) muscle tissue (i.e. trimmed, skin-off fillet) composites. Estimates of mercury concentrations in skin on trimmed (SOT) and skin on untrimmed fillets (SOUT) were not calculated because mercury binds to muscle tissue and cannot be removed by trimming a fillet. The trigger and "do not eat" fish tissue concentrations used by Michigan, Minnesota, and Wisconsin to set fish consumption advice are shown as lines.

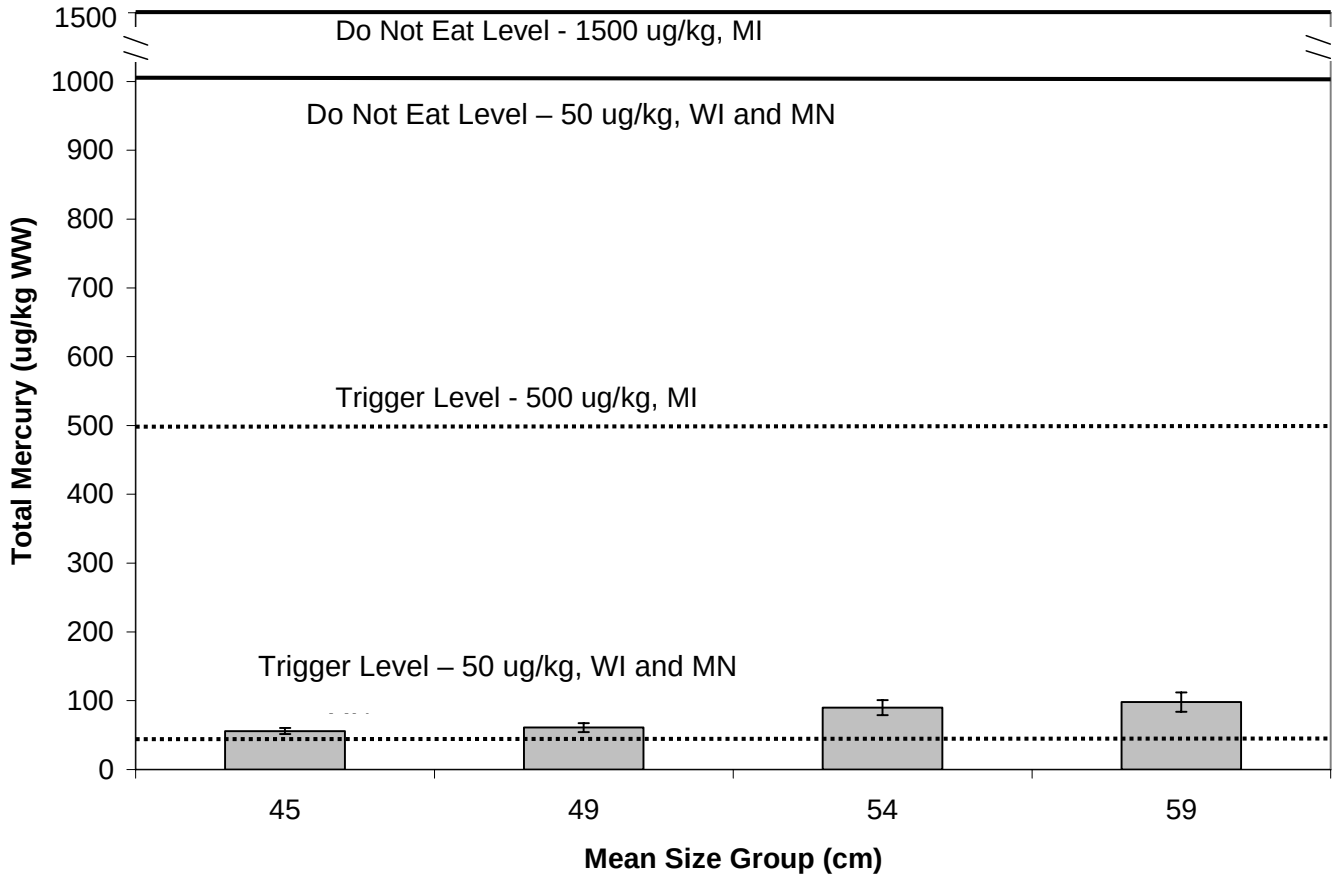


Figure 8. Total chlordane concentrations (mean ± one standard deviation) in Lake Superior whitefish (*Coregonus clupeaformis*) muscle tissue composites. Concentrations in SOT and SOUT fillets are estimated based on muscle tissue concentrations and percent lipid in respective skin and fat tissues. SOT and SOUT refer to "skin on trimmed" and "skin on untrimmed" fillets. The trigger and/or "do not eat" fish tissue concentrations used by Michigan and Wisconsin to set fish consumption advice are shown as lines.

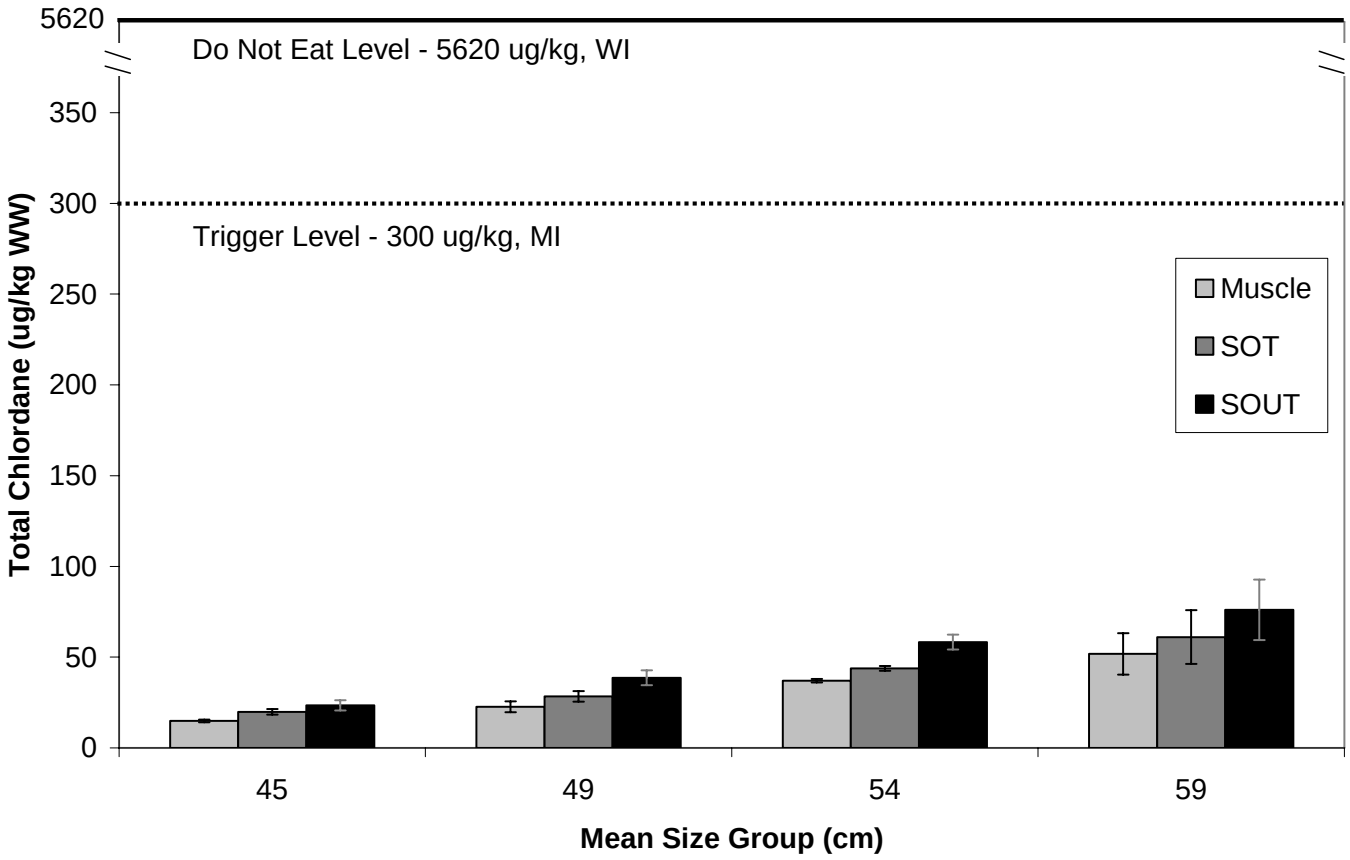


Figure 9. Toxaphene concentrations (mean ± one standard deviation) in Lake Superior whitefish (*Coregonus clupeaformis*) muscle tissue composites. Concentrations in SOT and SOUT fillets are estimated based on muscle tissue concentrations and percent lipid in respective skin and fat tissues. SOT and SOUT refer to "skin on trimmed" and "skin on untrimmed" fillets. The trigger fish tissue concentration used by Michigan to set fish consumption advice is shown as a line.

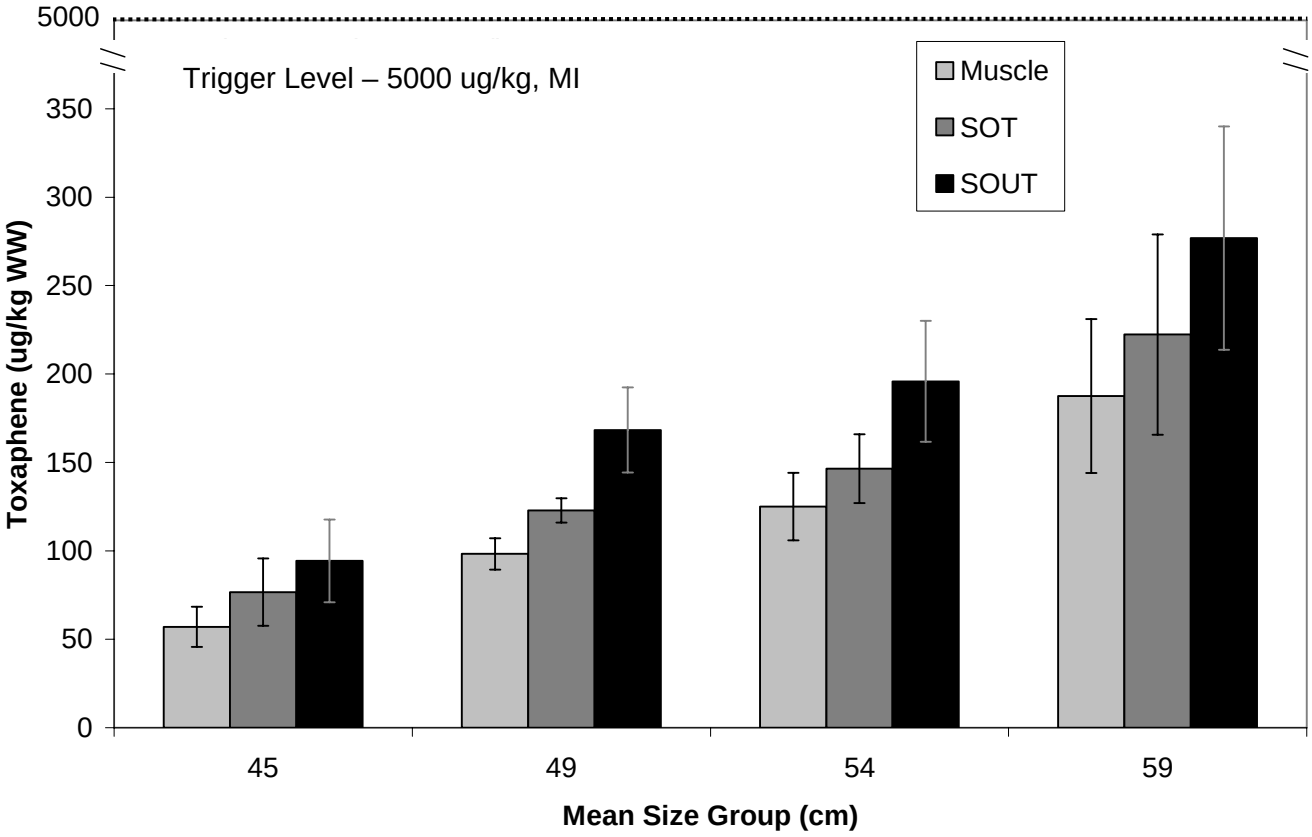


Exhibit 4

GREAT LAKES INDIAN FISH & WILDLIFE COMMISSION
P. O. Box 9 • Odanah, WI 54861 • 715/682-6619 • FAX 715/682-9294

• MEMBER TRIBES •

MICHIGAN
Bay Mills Community
Keweenaw Bay Community
Lac Vieux Desert Band

WISCONSIN
Bad River Band
Lac Courte Oreilles Band
Lac du Flambeau Band
Red Cliff Band
St. Croix Chippewa
Sokaogon Chippewa

MINNESOTA
Fond du Lac Band
Mille Lacs Band

To: Ann McCammon-Soltis, Director of Intergovernmental Affairs

From: Matt Hudson, Environmental Biologist

Date: September 30, 2007

Re: Reporting Results for Cisco Contaminant Testing Under U.S. EPA Grant Number GL00E06501:

Attached are results for cisco contaminant testing under U.S. EPA Grant Number: GL00E06501. Also included are brief descriptions of the fish processing and analytical methods used to produce the data. Please note that "lake herring" are now referred to as "cisco." The scientific name (*Coregonus artedii*) has not changed, but to be consistent with current nomenclature, the term "cisco" will be used to describe what had been referred to as "lake herring," except when describing documents that already exist for this project.

The objectives of this study as stated in the EPA-approved Quality Assurance Project Plan (QAPP) entitled "Lake Herring Collection, Compositing, and Environmental Chemical Contaminant Analysis Quality Assurance Project Plan" were to:

1. Determine the wet weight of each fillet's skin, lipid dense trimmings, and muscle tissue collected from cisco captured in management unit WI-2.

2. Determine the concentration of chemicals listed in Table 2 in 16 composite muscle samples; lipid and moisture content in 16 composite muscle, 16 lipid-dense, and 16 skin samples; and archive these 48 composite samples from management unit WI-2.

3. Based on tissue wet weights and lipid and chemical content, mathematically estimate the chemical concentration in skin-on trimmed fillets and skin-on untrimmed fillets.

4. Compare the mean chemical composite values of the skin-off trimmed fillet (i.e. muscle tissue), skin-on trimmed fillets and skin-on untrimmed fillets to the U.S. Food and Drug Administration's environmental chemical concentration limits for the sale of fish.

The project grant proposal and QAPP also state that results were to be compared to state guidelines for contaminant levels in fish tissue, other Lake Superior cisco data that are available and to GLIFWC's contaminant data on other Lake Superior fish species. These comparisons are included in this report.

Methods

Cisco Collection and Storage

Lake Superior cisco (*Coregonus artedii*), hereafter referred to as cisco, were collected on November 20, 2006 using gillnets near Chebomnicon Bay on the east side of Madeline Island (47° 026 N, 90° 43.016 W) in Lake Superior lake trout fisheries management unit WI-2 (Figure 1). Four length ranges of cisco were collected: 13.0-13.5 inches (in) (33-34 centimeters [cm]), 15.0-15.5 in (38-39 cm), 16.0-16.5 in (41-42 cm), and 17.5-18.5 in (45-47 cm). Cisco were measured in inches during field collection but were converted to centimeters for data analysis purposes. These length ranges differed slightly from original length ranges developed from commercial cisco harvest data in Michigan waters of Lake Superior. Data from Michigan waters were used to provide a best estimate for field sampling because cisco harvest from Wisconsin waters is not typically monitored for fish length. During field sampling, an insufficient number of large cisco were available, so adjustments to the length ranges were made to accommodate the length range of cisco being captured (Table 1). These changes are reflected in Section B of the approved project QAPP.

Samples were handled in a similar manner to commercially harvested fish and placed on ice as they were collected on the boat. Samples were frozen intact within 24 hours of collection and remained frozen (at temperatures at or below -10°C) until processing at the analytical laboratory. The date, time, and conditions of collection and storage were documented on chain-of-custody forms.

Cisco Processing into Composites

Total length and aging material (otoliths) were collected from each fish prior to freezing. The Great Lakes Indian Fish and Wildlife Commission's (GLIFWC) Great Lakes Fisheries Section aged the fish to the nearest year. Fish were selected for each composite group based on length and age. Cisco were processed into composites at the Lake Superior Research Institute (LSRI), University of Wisconsin-Superior in January and February of 2007.

Fish were thawed before processing. Individual cisco were filleted using a stainless steel knife. Fillets were segmented into skin, dorsal/ventral fatty tissue (fat), and muscle tissue. Each individual fillet component (i.e. skin, fat, muscle) was weighed separately, ground, and an equal weight of ground tissue used to form a composite. On the first, middle and final processing day, a can of commercial chunk light tuna (*Thunnus sp.*) was divided in half. One half was processed in the same manner as the cisco composites and the other half was transferred directly to an amber sample jar. These samples were used as procedural blanks to check for contamination that may have been introduced during

processing. They were analyzed for total mercury but not for the organic chemicals. All lab utensils and glassware were critically cleaned between each composite. Moisture analyses were conducted on the composites. Remaining composite tissues were transferred to critically cleaned amber glass jars with Teflon lids and archived in a freezer at temperatures at or below -10°C.

Chemical Extraction and Analysis

Each of the 16 muscle tissue composite samples was analyzed for 37 chemicals (Table 2). Mercury was analyzed by LSRI according to LSRI SOP SA/13, *Cold Vapor Mercury Analysis in Biota*, based on EPA Method 245.6. Percent moisture was determined by LSRI using LSRI SOP NT/15 *Procedures for Determining Percent Moisture in Tissue Samples.*

Organic chemicals were analyzed by Pace Analytical, Inc. located in Green Bay, WI. The organic chemicals were extracted according to Pace SOP KM-O-001 (based on EPA SW846 Method 3540C). Percent lipid was determined by Pace SOP KM-L-003, based on Standard Methods for the Examination of Water and Wastewater # 5520, 1992. Lipids were removed from the sample extracts using gel permeation chromatography (Pace SOP KM-O-004, based on EPA SW846 Method 3640A). Following removal of lipids, the samples were filtered through a silica gel column to separate the chlorinated pesticides from the PCBs (Pace SOP KM-O-012, based on EPA SW846 Method 3630C). The final extracts were analyzed for PCBs according to Pace SOP KM-O-002 (based on EPA Method 8082) and chlorinated pesticides according to Pace SOP KM-O-014 (based on EPA Method 8081A).

A more complete description of the methods can be found in the QAPP for this project entitled "Lake Herring Collection, Compositing, and Environmental Chemical Contaminant Analysis Quality Assurance Project Plan".

Results

Quality Control

Results from quality control (QC) analyses used to monitor data quality for the organic chemical analyses can be found in Tables 3 - 7. QC results from the total mercury analyses can be found in Tables 8 - 11. A Laboratory Data Review Checklist (GLIFWC SOP AD.006) was used to help complete the data review process. Overall, the sample data were in good agreement with the quality assurance parameters, so the data were determined to be precise and accurate (Appendix A).

Objective #1 - Determine the wet weight of each fillet's skin, lipid dense trimmings, and muscle tissue collected from cisco captured in management unit WI-2.

Table 12 lists descriptive data including tag number, sex, age, and length, along with the weight of the whole fillet, muscle, skin, and fat tissues for the 64 cisco that were sorted

into composite samples. An equal weight of tissue from each fish was used to form each composite. These data were recorded but are not reported in this memo.

Objective #2 - Determine the concentration of chemicals listed in Table 2 in 16 composite muscle samples; lipid and moisture content in 16 composite muscle, 16 lipid-dense, and 16 skin samples; and archive these 48 composite samples from management unit WI-2.

Objective #3 - Based on tissue wet weights and lipid and chemical content, mathematically estimate the chemical concentration in skin-on trimmed (SOT) fillets and skin-on untrimmed (SOUT) fillets.

Table 13 provides skin and fat tissue composite mean ± one standard deviation percent moisture and percent lipid measurements. Table 14 provides the cisco data by composite and by chemical. Table 14 also includes mean ± one standard deviation of muscle composite chemical concentrations for each size group and estimated mean ± one standard deviation of chemical concentrations in SOT and SOUT fillets. These estimates were calculated using the assumption that organic, PBT contaminants partition primarily to the lipid tissue of organisms (Mackay 1982) and were based on tissue weights recorded during fish tissue processing, and percent lipid measured in each tissue. Regression statistics for six of the most frequently detected organic contaminants plotted against percent lipid in cisco muscle tissue are provided as a test of the lipid assumptions used (Table 15).

All tissue composites were archived at LSRI in critically cleaned amber glass jars with Teflon lids, frozen at temperatures at or below -10°C.

Objective #4 - Compare the mean chemical composite values of the skin-off trimmed raw fillet, skin-on trimmed fillets (SOT) and skin-on untrimmed (SOUT) fillets to the U.S. Food and Drug Administration's environmental chemical concentration limits for the sale of fish.

The United States Food and Drug Administration (FDA) regulates the sale of fish based on concentrations of various chemicals measured in fish fillets that are to be sold commercially. Table 16 compares Lake Superior cisco muscle tissue concentrations of chemicals and chemical groups to FDA concentration limits for those chemicals/groups. All cisco muscle tissue concentrations, along with SOT and SOUT fillet estimated concentrations were below current FDA fish tissue concentration limits.

GLIFWC conducted a study of PBT contaminants in Lake Superior fish (including cisco) in 1999. Table 17 compares concentrations of three chemicals measured in cisco muscle tissue composites in 1999 to those measured in the current study (2006).

Other Study Objectives Addressed

1) Compare cisco consumption advice issued by each state (Michigan, Minnesota, and Wisconsin) for Lake Superior.

Table 18 provides current fish consumption advisory trigger level and "do not eat" concentrations used by jurisdictions around Lake Superior. Figures 2A and 2B show the current Lake Superior cisco consumption advice issued by Michigan, Minnesota, and Wisconsin.

2) Compare GLIFWC cisco data to advisory trigger levels used to set fish consumption advice by Michigan, Minnesota, and Wisconsin.

Figures 3-5 compare GLIFWC cisco data to current fish advisory trigger and "do not eat" levels for total PCBs, mercury and total chlordane that are used by Michigan, Minnesota, and Wisconsin to set fish consumption advice. The values are meant to be used as benchmarks for comparison and not to describe how a jurisdiction would interpret the data or set fish consumption advice based on these data.

3) Compare cisco data collected in this study to that collected by Michigan, Minnesota, and Wisconsin for fish advisory purposes.

Table 19 summarizes Lake Superior cisco fillet data collected by Michigan, Minnesota, Wisconsin, and GLIFWC over the past ten years (1996-2006). Results are combined for each jurisdiction from this time period and are intended to give a broad indication of whether mercury and PCB data from cisco collected by different jurisdictions were being detected at similar concentrations across Lake Superior.

GLIFWC has conducted similar studies to the current cisco study across common, tribally harvested size ranges of siscowet trout (*Salvelinus namaycush siscowet*, 1999), lake trout (*Salvelinus namaycush namaycush*, 2003) and lake whitefish (*Coregonus clupeaformis,* 2004). Comparisons between siscowet trout, lake trout, lake whitefish and cisco are shown for total mercury in Figure 6 and for total PCBs in Figure 7.

References

Mackay, D. Correlation of bioconcentration factors. Environmental Science and Technology. 1982. 16: 274-278.

Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory. 1993. Great Lakes Sport Fish Advisory Task Force.

United States Food and Drug Administration. 2001. Fish and Fisheries Products Hazards and Control Guidance. Third Edition.

cc Neil Kmiecik, Biological Services Director
John Coleman, Environmental Section Leader
James Thannum, Planning Director

TABLES

Table 1. Original and field-modified target length ranges and mean length and age (± one standard deviation) for the four composites within each Lake Superior cisco (*Coregonus artedii*) size group.

Common Name	Genus Species	Target Length Range, Planned (in)	Target Length Range, Actual (in)	Target Length Range, Actual (cm)	Mean Length (cm)	Mean age (yr)
Cisco	*Coregonus artedii*	13.5 to 14.5	13.0 to 13.5	33 to 34	33.8 ± 0.5	5.6 ± 2.7
Cisco	*Coregonus artedii*	15.5 to 16.5	15.0 to 15.5	38 to 39	39.2 ± 0.4	6.8 ± 1.7
Cisco	*Coregonus artedii*	17.5 to 18.5	16.0 to 16.5	41 to 42	41.1 ± 0.4	7.9 ± 1.3
Cisco	*Coregonus artedii*	19.5 to 20.5	17.5 to 18.5	45 to 47	45.5 ± 1.1	10.9 ± 3.2

Table 2. Chemical and non-chemical analyses conducted on muscle tissue (e.g. trimmed, skin-off fillets) composite samples of Lake Superior cisco (*Coregonus artedii*).

No	Chemical Analyses	Lab Conducting Analysis	No	Chemical Analyses	Lab Conducting Analysis
1	**Total Chlordane**	Calculated by GLIFWC	22	Toxaphene	Pace
2	Cis-Chlordane	Pace	23	Aldrin	Pace
3	Trans-Chlordane	Pace	24	Dieldrin	Pace
4	Cis-nonachlor	Pace	25	Heptachlor	Pace
5	Trans-nonachlor	Pace	26	Heptachlor epoxide	Pace
6	Oxychlordane	Pace	27	Endrin Ketone	Pace
7	**Total PCBs**	Pace	28	Methoxychlor	Pace
8	1016	Pace	29	Hexachlorobenzene	Pace
9	1221	Pace	30	Mirex	Pace
10	1232	Pace	31	Pentachloroanisole	Pace
11	1242	Pace	32	Endosulfan	Pace
12	1248	Pace	33	Endrin	Pace
13	1254	Pace	34	Endosulfan sulfate	Pace
14	1260	Pace	35	Endrin aldehyde	Pace
15	**Total DDT**	Calculated by GLIFWC	36	α-benzene hexachloride	Pace
16	4,4'-DDT	Pace	37	β-benzene hexachloride	Pace
17	4,4'-DDE	Pace	38	δ-benzene hexachloride	Pace
18	4,4'-DDD	Pace	39	γ-benzene hexachloride	Pace
19	2,4'-DDT	Pace	40	Total mercury	LSRI
20	2,4'-DDE	Pace	41	Lipid Determination	Pace
21	2,4'-DDD	Pace	42	Moisture Determination	LSRI

Table 3. Relative percent agreement (RPA*) of PCB and pesticide concentrations in duplicate Lake Superior cisco (*Coregonus artedii*) samples analyzed by Pace, Inc.

Compound	CA33-34TF1	CA33-34TF1 DUP	RPA	CA45-47TF4	CA45-47TF4 DUP	RPA	QC Limits RPA
Arochlor 1016	ND	ND	.	ND	ND	.	60
Arochlor 1221	ND	ND	.	ND	ND	.	60
Arochlor 1232	ND	ND	.	ND	ND	.	60
Arochlor 1242	ND	ND	.	ND	ND	.	60
Arochlor 1248	ND	ND	.	ND	ND	.	60
Arochlor 1254	ND	ND	.	ND	ND	.	60
Arochlor 1260	ND	ND	.	21	19	91.3	60
Total PCBs	ND	ND	.	21	19	91.3	60
2,4'-DDD	ND	ND	.	ND	ND	.	60
2,4'-DDE	ND	ND	.	ND	ND	.	60
2,4'-DDT	ND	ND	.	ND	ND	.	60
4,4'-DDD	ND	ND	.	ND	ND	.	60
4,4'-DDE	ND	3.0	.	6.9	6.1	87.7	60
4,4'-DDT	ND	ND	.	ND	ND	.	60
Aldrin	ND	ND	.	ND	ND	.	60
alpha-BHC	ND	ND	.	ND	ND	.	60
alpha-Chlordane	ND	ND	.	1.5	1.4	93.1	60
beta-BHC	ND	ND	.	ND	ND	.	60
cis-nonachlor	0.88	1.2	73.3	2.9	2.5	85.2	60
delta-BHC	ND	ND	.	ND	ND	.	60
Dieldrin	2.3	3.8	60.5	2.0	1.9	94.9	60
Endosulfan I	ND	ND	.	ND	ND	.	60
Endosulfan II	ND	ND	.	ND	ND	.	60
Endosulfan Sulfate	ND	ND	.	ND	ND	.	60
Endrin	ND	ND	.	ND	ND	.	60
Endrin Aldehyde	ND	ND	.	ND	ND	.	60
Endrin Ketone	ND	ND	.	ND	ND	.	60
gamma-BHC (Lindane)	ND	ND	.	ND	ND	.	60
gamma-Chlordane	ND	ND	.	ND	ND	.	60
Heptachlor	ND	ND	.	ND	ND	.	60
Heptachlor Epoxide	ND	ND	.	ND	ND	.	60
Hexachlorobenzene	ND	ND	.	ND	ND	.	60
Methoxychlor	ND	ND	.	ND	ND	.	60
Mirex	ND	ND	.	ND	ND	.	60
Oxychlordane	ND	ND	.	ND	ND	.	60
Pentachloroanisole	ND	ND	.	ND	ND	.	60
Toxaphene	ND	ND	.	78	ND	.	60
Trans-nonachlor	1.6	1.5	93.3	3.3	2.6	76.3	60

ND - Not Detectable - sample was below detection limit.
*RPA is: 1 – (absolute value of the difference between the two samples/mean of the two samples)

Table 4. Relative percent agreement (RPA*) of lipid concentration in duplicate Lake Superior cisco (*Coregonus artedii*) samples analyzed by Pace, Inc.

Date of Analysis	Composite No.	Sample 1	Sample 2	RPA*	QC Limit RPA
3/8/2007	CA3334TF1	2.04	2.17	93.8	>65
3/8/2007	CA4547TF4	2.17	2.10	96.7	>65
3/28/2007	CA3334L1	11.9	12.0	99.2	>65
3/28/2007	CA3334S1	15.0	14.6	97.3	>65

*RPA is: 1 – (absolute value of the difference between the two samples/mean of the two samples)

Table 5. Percent spike recovery of PCBs and pesticides in two Lake Superior cisco (*Coregonus artedii*) samples analyzed by Pace, Inc.

Compound	Sample 1 CA38-39TF2	Sample 2 CA38-39TF2DUP	QC Limits Recovery	RPA*	QC Limits RPA
Aroclor 1254	91	91	43-130	99.8	44
4,4'-DDD	95	86	48-160	90.2	62
4,4'-DDE	93	96	46-152	96.9	60
4,4'-DDT	99	86	49-148	85.4	68
Aldrin	100	99	52-122	99.2	62
alpha-BHC	88	89	69-123	98.9	89
alpha-Chlordane	102	96	52-139	94.8	62
beta-BHC	86	94	35-128	90.9	64
delta-BHC	91	89	57-126	97.3	77
Dieldrin	81	77	42-135	94.6	56
Endosulfan I	77	70	45-140	90.5	70
Endosulfan II	98	93	46-147	94.1	55
Endosulfan Sulfate	95	92	54-132	97.4	78
Endrin	87	80	43-136	91.5	61
Endrin Aldehyde	40	27	6-96	64.1	50
Endrin Ketone	91	87	61-139	96.0	74
gamma-BHC (Lindane)	84	85	52-126	99.1	65
gamma-Chlordane	85	83	55-136	97.1	67
Heptachlor	68	69	50-128	98.9	65
Heptachlor Epoxide	100	93	51-130	92.8	50
Methoxychlor	74	72	36-159	96.5	50

*RPA is: 1 – (absolute value of the difference between the two samples/mean of the two samples)

Table 6. Percent spike recovery of PCBs and pesticides in lab control spikes (LCS) and spike duplicates (LCS dup) analyzed by Pace, Inc.

	QC Batch Number: 18613			QC Batch Number: 19235				
Compound	LCS Recovery	LCS dup Recovery	LCS/ LCS dup RPA**	LCS Recovery	LCS dup Recovery	LCS/ LCS dup RPA	QC Limits Recovery	QC Limits RPD
Aroclor 1254	101	105	95.5	92	95	97	40-128	60
2,4'-DDD	135*	150*	89.5	.	.	.	70-130	60
2,4'-DDE	38*	31*	79.7	.	.	.	70-130	60
2,4'-DDT	120	110	91.3	.	.	.	70-130	60
4,4'-DDD	99	100	99.1	95	85	88.3	63-128	60
4,4'-DDE	111	114	97.4	115	116	98.8	60-150	60
4,4'-DDT	98	97	99.8	94	81	84.5	62-127	60
Aldrin	107	109	98.0	115*	101	87.0	60-110	60
alpha-BHC	93	99	93.6	94	82	86.1	65-117	60
alpha-Chlordane	96	102	94.1	96	82	83.7	58-125	60
beta-BHC	92	94	98.0	94	80	83.5	58-109	60
cis-nonachlor	210*	220*	95.3	.	.	.	70-130	60
delta-BHC	103	100	96.9	106	85	78.2	63-117	60
Dieldrin	90	87	97.3	92	78	83.3	63-117	60
Endosulfan I	83	83	99.2	86	74	84.4	54-129	60
Endosulfan II	105	100	95.2	109	90	80.2	57-120	60
Endosulfan Sulfate	101	99	97.4	108	85	76.6	61-123	60
Endrin	95	89	93.4	95	77	79.1	55-116	60
Endrin Aldehyde	53	45	83.6	48	30	52.7*	16-75	60
Endrin Ketone	94	91	97.2	98	79	77.9	64-132	60
gamma-BHC (Lindane)	91	94	97.6	92	77	81.9	65-115	60
gamma-Chlordane	86	92	93.9	80	70	86.5	64-120	60
Heptachlor	78	80	97.7	82	76	93.4	58-118	60
Heptachlor Epoxide	102	103	98.4	100	86	84.6	63-118	60
Hexachlorobenzene	90	90	100	.	.	.	60-140	60
Methoxychlor	75	75	99.4	86	71	80.9	33-141	60
Mirex	110	110	100	.	.	.	60-140	60
Oxychlordane	110	120	91.3	.	.	.	70-130	60
Pentachloroanisole	50*	37*	70.1	.	.	.	70-130	60
Toxaphene	105	110	95.3	.	.	.	60-140	60
trans-Nonachlor	120	125	95.9	.	.	.	70-130	60

* Spiked sample recovery not within control limits.
** RPA is: 1 – (absolute value of the difference between the two samples/mean of the two samples)

Table 7. Results of Standard Reference Material (SRM) analysis. SRM-1946 was the Certified Standard Reference Material used. SRM 1 and 2 refer to the SRM 1946 samples analyzed by Pace, Inc. Results are compared to Quality Control (QC) ranges issued for SRM 1946 and to Pace's QC ranges for the same analytes.

Compound Name	SRM 1946 Conc. µg/Kg	SRM 1946 Uncertainty	SRM QC Range (ug/kg)		SRM 1	SRM 2	En Chem Matrix spike QC limits	En Chem QC Range (ug/kg)		SRM 1	SRM 2
Alpha-BHC	5.72	±0.65	6.37	5.07	5.2	7.7*	69-123	3.7	6.7	5.2	7.7*
Gamma-BHC	1.14	±0.18	1.32	0.96	1	1.1	57-126	0.7	1.3	1	1.1
Heptachlor epoxide	5.50	±0.23	5.73	5.27	6.7*	7.7*	51-130	3.5	6.5	6.7*	7.7*
Dieldrin	32.5	±3.5	36.0	29.0	32	36	42-135	20	38	32	36
4,4'-DDE	373	±48	421	325	330	360	46-152	224	560	330	360
4,4'-DDD	17.7	±2.8	20.5	14.9	8.6*	10*	48-160	11	27	8.6*	10*
4,4'-DDT	37.2	±3.5	40.7	33.7	45*	60*	49-148	23	47	45	60*
Alpha-chlordane	32.5	±1.8	33.3	30.7	29*	34*	52-139	19	41	29	34
Gamma-chlordane	8.36	±0.91	9.27	7.45	11*	12*	55-136	4.6	11	11	12*
2,4'-DDD	2.20	±0.25	2.45	1.95	0*	0*	70-130	1.5	2.9	0*	0*
Cis-nonachlor	59.1	±3.6	62.7	55.5	70*	78*	70-130	41	77	70	78*
Trans-nonachlor	99.6	±7.6	107	92.0	68*	82*	70-130	70	129	68	82
Oxychlordane	18.9	±1.5	20.4	17.4	16*	17	70-130	13	25	16	17
Hexachlorobenzene	7.25	±0.83	8.08	6.42	8.4*	10*	70-130	5.1	9.4	8.4	10*
Mirex	6.47	±0.77	7.24	5.70	5.4*	5.6*	70-130	4.5	8.4	5.4	5.6

* Analyte concentration was outside of given quality control (QC) range.

Table 8. Relative percent agreement (RPA*) of total mercury concentrations in procedural blank samples (commercial tuna fish [*Thunnus sp.*]) before and after grinding or grinding and blending by LSRI.

Analysis Date	Grinding Date	Before Grinding (µg Hg/g)	After Grinding (µg Hg/g)	After Grinding/ Blending (µg Hg/g)	Mean (µg Hg/g)	Relative Percent Agreement
4/3/2007	1/24/2007	0.096	0.096		0.096	100.0
4/3/2007	1/24/2007	0.096		0.109	0.103	87.4
4/3/2007	2/1/2007	0.024	0.024		0.024	100.0
4/3/2007	2/1/2007	0.024		0.026	0.025	92.0
4/3/2007	2/22/2007	0.028	0.028		0.028	100.0
4/3/2007	2/22/2007	0.028		0.030	0.029	93.1

*RPA is: 1 – (absolute value of the difference between the two samples/mean of the two samples)

Table 9. Mercury concentrations of dogfish tissue supplied by the National Research Council Canada (DORM-2) and analyzed by LSRI. The tissue has a certified mercury concentration of 4.64±0.26 µgHg/g tissue. The acceptable range of mercury concentration was 3.40-5.24 µg Hg/g based upon LSRI DORM-2 analyses conducted from 2003 through 2005.

Sample 1 (µg Hg/g)	Sample 2 (µg Hg/g)	Mean	Std. Dev.	Percent of Expected
4.63	4.58	4.60	0.04	99.1
4.60	4.42	4.51	0.13	97.2

Table 10. Relative percent agreement (RPA*) between duplicate analysis for total mercury (wet weight) content in skinless fillet tissue of composited Lake Superior cisco (*Coregonus artedii*) analyzed by LSRI.

Date of Analysis	Sample ID	Sample 1 (µg Hg/g)	Sample 2 (µg Hg/g)	Relative Percent Agreement
4/3/2007	CA33-34TF2	0.041	0.039	95.0
4/3/2007	CA45-47TF3	0.093	0.085	91.0

*RPA is: 1 – (absolute value of the difference between the two samples/mean of the two samples)

Table 11. Percent of total mercury recovered from skinless fillet tissue of composited Lake Superior cisco (*Coregonus artedii*) spiked with a known quantity of mercury by LSRI.

Date of Analysis	Sample ID	Spike #1	Spike #2	Mean	Std. Dev.
4/3/2007	CA33-34TF2	101	101	101	0.00
4/3/2007	CA45-47TF3	109	108	109	0.71

Table 12. Individual Lake Superior cisco (*Coregonus artedii*) descriptive data for fish contained in each composite. Tissue weights are wet weight values. These weights are not the weight of tissue used to form the composites.

Sample ID	Tag Num	Sex	Age (yr)	Length (in)	Length (cm)	Whole Fillet Wt (g)	Muscle Wt (g)	Fat Wt (g)	Skin Wt (g)
CA33-34-1	6553	F	2	13.0	33.0	165.8	122.8	20.1	18.8
CA33-34-1	1886	F	3	13.3	33.8	170.8	121.2	25.7	19.8
CA33-34-1	9296	M	3	13.0	33.0	177.1	133.4	17.0	24.1
CA33-34-1	7600	M	3	13.0	33.0	166.6	122.0	23.2	18.4
CA33-34-2	9295	F	3	13.5	34.3	200.0	144.7	29.0	21.3
CA33-34-2	6552	M	3	13.5	34.3	195.5	159.1	18.2	13.4
CA33-34-2	2080	M	4	13.4	34.0	159.0	124.0	11.1	26.2
CA33-34-2	9181	M	4	13.5	34.3	218.6	175.5	17.4	19.2
CA33-34-3	2087	F	6	13.4	34.0	222.7	175.4	21.0	21.8
CA33-34-3	9180	F	7	13.5	34.3	203.9	165.6	16.5	18.9
CA33-34-3	1884	F	8	13.2	33.5	181.3	149.1	11.3	16.1
CA33-34-3	9297	M	8	13.0	33.0	164.9	133.4	11.0	16.6
CA33-34-4	7598	M	8	13.5	34.3	230.6	180.3	19.9	25.4
CA33-34-4	6551	M	8	13.5	34.3	218.9	174.1	20.2	22.5
CA33-34-4	7599	M	9	13.5	34.3	220.5	179.6	20.6	16.9
CA33-34-4	2078	M	10	13.4	34.0	209.3	169.8	15.3	22.1
CA38-39-1	6587	M	3	15.5	39.4	359.0	303.4	20.9	28.8
CA38-39-1	1885	M	5	15.2	38.6	332.3	273.3	21.8	30.6
CA38-39-1	6593	F	5	15.5	39.4	355.7	282.3	27.0	39.5
CA38-39-1	6627	F	5	15.5	39.4	323.3	250.1	28.1	35.6
CA38-39-2	2063	M	6	15.4	39.1	365.0	292.5	26.9	40.6
CA38-39-2	2061	M	7	15.4	39.1	298.7	241.4	22.7	28.7
CA38-39-2	2077	M	7	15.4	39.1	278.8	224.0	20.2	29.2
CA38-39-2	6589	M	7	15.5	39.4	330.2	256.0	32.8	33.6
CA38-39-3	6591	F	7	15.5	39.4	297.8	230.0	33.2	26.0
CA38-39-3	6626	M	7	15.0	38.1	302.1	240.6	25.5	31.0
CA38-39-3	9179	F	7	15.3	38.9	268.6	204.0	28.5	26.1
CA38-39-3	2069	M	8	15.5	39.4	363.5	297.0	28.0	32.1
CA38-39-4	2071	F	8	15.5	39.4	274.1	212.8	30.5	26.8
CA38-39-4	2088	M	8	15.5	39.4	351.1	259.3	56.3	26.9
CA38-39-4	6628	M	8	15.5	39.4	325.7	251.0	38.4	29.9
CA38-39-4	6595	M	10	15.5	39.4	323.7	246.9	40.6	29.3
CA41-42-1	2034	F	6	16.0	40.6	322.9	255.5	28.6	32.0
CA41-42-1	6632	M	6	16.2	41.1	360.4	288.1	25.6	39.7
CA41-42-1	6634	F	6	16.1	40.9	354.3	295.0	19.3	38.0
CA41-42-1	2037	M	7	16.0	40.6	396.2	317.5	29.9	41.0
CA41-42-2	6625	F	7	16.1	40.9	329.7	266.5	24.4	31.8
CA41-42-2	2035	M	8	16.0	40.6	406.3	336.6	30.9	32.9
CA41-42-2	6629	F	8	16.2	41.1	405.0	321.3	42.5	34.7
CA41-42-2	2083	F	8	16.0	40.6	318.9	254.3	27.8	29.7
CA41-42-3	2036	F	8	16.5	41.9	368.0	276.9	37.2	45.2
CA41-42-3	6633	M	8	16.5	41.9	408.0	349.0	24.2	29.5
CA41-42-3	6635	F	8	16.3	41.4	473.3	395.0	43.0	29.4
CA41-42-3	6636	M	8	16.2	41.1	376.8	304.4	31.2	35.3
CA41-42-4	2033	M	9	16.2	41.1	382.7	308.3	33.5	32.2
CA41-42-4	6630	M	9	16.3	41.4	371.8	292.6	35.0	36.6

Table 12 Continued…

Sample ID	Tag Num	Sex	Age (yr)	Length (in)	Length (cm)	Whole Fillet Wt (g)	Muscle Wt (g)	Fat Wt (g)	Skin Wt (g)
CA41-42-4	2038	F	10	16.0	40.6	385.3	294.0	40.6	38.7
CA41-42-4	6631	M	10	16.0	40.6	356.6	286.0	33.1	36.9
CA45-47-1	6594	F	8	17.4	44.2	461.4	376.4	29.3	43.2
CA45-47-1	6586	F	9	17.4	44.2	453.8	376.3	30.3	39.1
CA45-47-1	2081	F	8	17.7	45.0	528.1	430.6	38.6	47.1
CA45-47-1	2041	F	7	17.6	44.7	437.9	366.6	28.3	37.9
CA45-47-2	2040	M	10	17.4	44.2	484.4	395.4	44.0	36.9
CA45-47-2	2074	M	10	18.1	46.0	572.3	457.3	52.4	50.8
CA45-47-2	6584	F	10	17.7	45.0	474.6	366.0	58.2	43.2
CA45-47-2	2073	F	11	17.7	45.0	458.8	370.2	NA	38.8
CA45-47-3	2039	M	8	18.5	47.0	583.6	473.6	52.5	49.8
CA45-47-3	6585	F	9	18.5	47.0	530.7	425.9	48.5	46.4
CA45-47-3	2076	M	10	18.5	47.0	505.6	410.5	40.8	44.5
CA45-47-3	6598	M	11	18.2	46.2	555.6	458.0	42.1	47.0
CA45-47-4	2075	F	14	18.4	46.7	513.0	423.6	32.8	45.6
CA45-47-4	2090	F	18	18.5	47.0	550.4	446.1	47.8	48.1
CA45-47-4	2042	M	15	17.9	45.5	500.8	399.9	48.1	43.8
CA45-47-4	6596	M	16	17.4	44.2	490.6	400.7	39.6	43.0

NA = Not Available

Table 13. Percent lipid and mean ± one standard deviation of percent moisture measured in fat and skin tissues from Lake Superior cisco (*Coregonus artedii*) composites.

	Fat			Skin		
Sample ID	% Lipid	Mean % Moisture	STDEV	% Lipid	Mean % Moisture	STDEV
CA33-34-1	12.0*	67.8	0.2	14.8*	61.8	0.5
CA33-34-2	16.1	62.3	0.5	16.0	60.3	0.5
CA33-34-3	18.4	61.4	0.8	15.6	59.8	0.6
CA33-34-4	17.6	62.0	0.4	13.4	62.9	1.5
CA38-39-1	25.2	53.9	0.6	19.9	53.1	1.5
CA38-39-2	23.0	55.5	0.8	18.8	57.2	0.2
CA38-39-3	19.0	60.7	1.4	17.6	58.3	0.7
CA38-39-4	19.2	61.3	1.2	17.0	57.6	0.9
CA41-42-1	25.1	54.1	0.9	21.2	53.6	1.0
CA41-42-2	17.8	63.4	0.7	15.0	62.3	0.6
CA41-42-3	19.5	60.0	0.5	16.6	60.1	0.5
CA41-42-4	21.9	57.3	0.5	17.4	60.0	0.8
CA45-47-1	24.6	53.0	0.3	19.6	57.4	2.6
CA45-47-2	23.2	61.7	1.1	16.5	59.6	0.2
CA45-47-3	23.7	57.1	1.2	17.7	58.6	0.1
CA45-47-4	14.2*	66.2	0.8	8.85*	67.9	0.2

* Value listed is the mean of duplicate samples.

Table 14. Individual Lake Superior cisco (*Coregonus artedii*) muscle tissue composite chemical concentrations. Concentrations listed for skin-on trimmed fillets (SOT) and skin-on untrimmed fillets (SOUT) are estimated values based on the wet weight of tissues in the composites and percent lipid in those tissues. Mean and standard deviation concentrations for each length group do not include "not-detected (ND) results. "Percent Moisture" data for each composite are the average of three replicates. Values given for "Percent Moisture" and Percent Lipid" are percentages. All other data are wet weight concentrations in units of µg/kg. Significant figures are consistent with lab reported values.

Chemical Parameter	Limit Of Detection	Limit Of Quantitation	Length Group*	Composite Number 1	2	3	4	Replicate** 1	2	Length Group Average***	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Percent Moisture			33 to 34 cm	75.7	75.2	75.0	76.2			75.5	0.5	.	.	.	.
			38 to 39 cm	74.0	75.4	75.4	74.4			74.8	0.7	.	.	.	.
			41 to 42 cm	73.9	74.6	75.8	75.7			75.0	0.9	.	.	.	.
			45 to 47 cm	74.6	74.2	74.0	75.4			74.6	0.6	.	.	.	.
Percent Moisture Standard Deviation			33 to 34 cm	0.1	0.2	0.3	0.3			0.2	.	.	.	.	.
			38 to 39 cm	0.2	0.1	0.1	0.4			0.2	.	.	.	.	.
			41 to 42 cm	0.2	0.2	0.2	0.2			0.2	.	.	.	.	.
			45 to 47 cm	0.2	0.3	0.1	0.1			0.2	.	.	.	.	.
Percent Lipids			33 to 34 cm	2.11	2.84	2.61	2.42	2.04	2.17	2.49	0.31	3.94	0.33	4.98	0.34
			38 to 39 cm	1.80	3.09	2.80	3.05			2.69	0.60	4.38	0.47	5.86	0.53
			41 to 42 cm	4.13	3.67	3.15	3.17			3.53	0.47	5.01	0.74	6.27	0.78
			45 to 47 cm	4.68	3.62	3.29	2.14	2.17	2.10	3.43	1.05	4.63	1.36	5.97	1.55
2,4'-DDD	0.63	2.1	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			38 to 39 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			41 to 42 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
2,4'-DDE	0.83	2.8	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			38 to 39 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			41 to 42 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
2,4'-DDT	0.73	2.4	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.
			38 to 39 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			41 to 42 cm	ND	ND	ND	ND			ND	.	ND	.	ND	.
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	.	ND	.	ND	.

Table 14 continued…

Chemical Parameter	Limit Of Detection	Limit Of Quantitation	Length Group*	Composite Number 1	2	3	4	Replicate** 1	2	Length Group Average***	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
4,4'-DDD	1.5	5.0	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
4,4'-DDE	2.1	7.0	33 to 34 cm	3.0	ND	ND	3.1	ND	3.0	3.1	0.1	4.6	·	6.1	·
			38 to 39 cm	ND	3.0	2.7	5.8			3.8	1.7	5.8	2.4	7.8	3.6
			41 to 42 cm	ND	5.2	4.5	3.7			4.5	0.8	6.2	0.6	7.9	0.5
			45 to 47 cm	5.3	5.2	4.4	6.5	6.9	6.1	5.4	0.9	7.3	1.2	9.5	1.7
4,4'-DDT	1.8	5.9	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	2.5	ND	ND			2.5	·	3.3	·	4.0	·
			45 to 47 cm	ND	2.0	ND	ND	ND	ND	2.0	·	2.7	·	3.7	·
Aldrin	1.0	3.3	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Alpha-BHC	1.3	4.2	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
alpha-Chlordane	0.97	3.2	33 to 34 cm	1.0	1.0	ND	1.4	ND	1.0	1.1	0.2	1.8	0.4	2.3	0.6
			38 to 39 cm	ND	1.4	1.3	2.1			1.6	0.4	2.5	0.6	3.3	0.9
			41 to 42 cm	ND	2.2	1.5	2.1			1.9	0.4	2.7	0.5	3.4	0.7
			45 to 47 cm	2.1	1.7	1.6	1.5	1.5	1.4	1.7	0.3	2.3	0.3	3.0	0.3
Aroclor 1016	19	63	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·

Table 14 continued…

Chemical Parameter	Limit Of Detection	Limit Of Quantitation	Length Group*	Composite Number 1	2	3	4	Replicate** 1	2	Length Group Average***	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Aroclor 1221	19	63	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Aroclor 1232	19	63	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Aroclor 1242	19	63	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Aroclor 1248	19	63	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Aroclor 1254	19	63	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Aroclor 1260	19	63	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	20	21	19	20	·	27	·	36	·
Beta-BHC	1.9	6.3	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·

Table 14 continued…

Chemical Parameter	Limit Of Detection	Limit Of Quantitation	Length Group*	Composite Number 1	2	3	4	Replicate** 1	2	Length Group Average***	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
cis-Nonachlor	0.72	2.4	33 to 34 cm	1.0	1.1	0.9	1.7	0.88	1.2	1.2	0.4	1.8	0.5	2.3	0.7
			38 to 39 cm	ND	1.6	1.3	2.6			1.8	0.7	2.8	0.9	3.8	1.5
			41 to 42 cm	1.2	4.4	2.9	2.9			2.9	1.3	4.0	1.6	5.0	2.1
			45 to 47 cm	3.8	3.5	3.4	2.7	2.9	2.5	3.4	0.5	4.6	0.5	5.9	0.7
Delta-BHC	0.91	3.0	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Dieldrin	1.7	5.7	33 to 34 cm	3.05	2.7	2.3	3.2	2.3	3.8	2.8	0.4	4.2	0.5	5.3	0.8
			38 to 39 cm	ND	2.6	2.5	3.0			2.7	0.3	4.2	0.3	5.5	0.6
			41 to 42 cm	3.3	3.7	2.8	3.1			3.2	0.4	4.6	0.4	5.7	0.5
			45 to 47 cm	4.2	3.5	2.8	2.0	2.0	1.9	3.1	1.0	4.2	1.2	5.4	1.4
Endosulfan I	1.0	3.5	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Endosulfan II	1.5	4.9	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Endosulfan Sulfate	2.0	6.7	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Endrin	2.1	6.9	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·

Table 14 continued…

Chemical Parameter	Limit Of Detection	Limit Of Quantitation	Length Group*	Composite Number 1	2	3	4	Replicate** 1	2	Length Group Average***	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Endrin Aldehyde	1.2	4.0	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	1.9			1.9	·	2.8	·	3.8	·
			45 to 47 cm	2.0	1.9	1.8	ND	ND	ND	1.9	0.1	2.6	0.0	3.3	0.2
Endrin Ketone	3.1	10	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
gamma-BHC (Lindane)	0.72	2.4	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
gamma-Chlordane	1.6	5.2	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Heptachlor	1.0	3.4	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Heptachlor Epoxide	1.3	4.3	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Hexachlorobenzene	2.2	7.2	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·

Table 14 continued…

Chemical Parameter	Limit Of Detection	Limit Of Quantitation	Length Group*	Composite Number 1	2	3	4	Replicate** 1	2	Length Group Average***	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Methoxychlor	8.0	27	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Mirex	1.2	4.1	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Oxychlordane	0.95	3.2	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Pentachloroanisole	0.83	2.8	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
Total Chlordane	sum of - alpha-Chlordane, gamma-Chlordane, cis-Nonachlor, trans-Nonachlor, Oxychlordane		33 to 34 cm	3.1	3.8	2.2	5.7	2.5	3.7	3.7	1.5	5.6	2.2	7.1	3.0
			38 to 39 cm	0.87	5.3	4.9	8.4			4.9	3.1	7.6	4.4	10	6.1
			41 to 42 cm	3.7	11	7.5	7.7			7.5	3.0	10	3.7	13	4.7
			45 to 47 cm	9.0	7.8	8.4	7.1	7.7	6.5	8.1	0.8	11	0.9	14	1.1
Total DDT	sum of - 2,4'-DDD, 2,4'-DDE, 2,4'-DDT, 4,4'-DDD, 4,4'-DDE, 4,4'DDT		33 to 34 cm	3.0	ND	ND	3.1	ND	3.0	3.1	0.1	5.1	0.6	6.5	0.5
			38 to 39 cm	ND	3.0	2.7	5.8			2.9	1.7	5.8	2.4	7.8	3.6
			41 to 42 cm	ND	7.7	4.5	3.7			5.3	2.1	7.3	2.4	9.2	2.6
			45 to 47 cm	5.3	7.2	4.4	6.5	6.9	6.1	5.9	1.2	8.0	1.6	10	2.6
Total Mercury****	4.2	14	33 to 34 cm	37	32	32	46			37	6.6	·	·	·	·
			38 to 39 cm	36	40	56	69	41	39	50	15	·	·	·	·
			41 to 42 cm	38	72	60	61			58	14	·	·	·	·
			45 to 47 cm	71	87	89	130	93	85	94	25	·	·	·	·

Table 14 continued…

Chemical Parameter	Limit Of Detection	Limit Of Quantitation	Length Group*	Composite Number 1	2	3	4	Replicate** 1	2	Length Group Average***	Length Group STDEV	Skin-on Trimmed (SOT) Fillet Average	Skin-on Trimmed (SOT) Fillet STDEV	Skin-on Untrimmed (SOUT) Fillet Average	Skin-on Untrimmed (SOUT) Fillet STDEV
Total PCBs	19	63	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			45 to 47 cm	ND	ND	ND	20	21	19	20	·	27	·	36	·
Toxaphene	64	210	33 to 34 cm	ND	ND	ND	ND	ND	ND	ND	·	ND	·	ND	·
			38 to 39 cm	ND	ND	ND	ND			ND	·	ND	·	ND	·
			41 to 42 cm	ND	120	ND	ND			120	.	160	.	190	.
			45 to 47 cm	100	ND	ND	78	78	ND	89	16	120	21	150	15
trans-Nonachlor	0.67	2.2	33 to 34 cm	1.6	1.7	1.3	2.6	1.6	1.5	1.8	0.6	2.9	0.8	3.6	1.1
			38 to 39 cm	0.87	2.3	2.3	3.7			2.3	1.2	3.6	1.5	4.9	2.1
			41 to 42 cm	2.5	3.9	3.1	2.7			3.1	0.6	4.3	0.6	5.4	0.7
			45 to 47 cm	3.1	2.6	3.4	3.0	3.3	2.6	3.0	0.3	4.2	0.6	5.4	0.8

ND = Not detected

* Length groups in centimeters correspond approximately to inches as follows: 33 to 34 cm = 13.0 to 13.5 inches; 38 to 39 cm = 15.0 to 15.5 inches; 41 to 42 cm = 16.0 to 16.5 inches; and 45 to 47 cm = 17.5 to 18.5 inches.

** For the 33 to 34 cm length group, the values for composite 1, and for the 45 to 47 cm length groups, the values for composite 4, represent the average of two replicates.

*** "ND" values were treated as "0" and were not included in length group average calculations.

**** Duplicate measurements for total mercury analysis were run on composite 2 of the 38 to 39 cm length group and composite 3 of the 45 to 47 cm length group. Total mercury concentrations were not calculated for SOT and SOUT fillets because mercury binds to muscle tissue and is not reduced by trimming fillets.

Table 15. Statistics for the six most detected organic contaminants in Lake Superior cisco (*Coregonus artedii*) muscle tissue regressed against percent lipid in muscle tissue to test lipid partitioning assumptions used in estimating chemical concentrations in SOT and SOUT fillets.

Chemical or Chemical group	Number of Samples >LOD	r-squared	p-value	slope
Total Chlordane*	16	0.33	0.02	2.1
alpha-Chlordane	13	0.46	0.01	0.41
cis-Nonachlor	15	0.27	0.05	0.85
trans-Nonachlor	16	0.31	0.02	0.63
Total DDT	12	0.16	0.2	1.0
Dieldrin	15	0.57	0.001	0.61

* Total Chlordane is the sum of alpha-Chlordane, gamma-Chlordane, cis-Nonachlor, trans-Nonachlor, and Oxychlordane

Table 16. Lake Superior cisco (*Coregonus artedii*) mean, standard deviation, and range of chemical concentrations (µg/kg) in muscle tissue, skin-on trimmed fillets (SOT) and skin-on, untrimmed fillets (SOUT) for each composite length group. Results for SOT and SOUT fillets are estimated values based on the wet weight of tissues in the composites and percent lipid in those tissues. United States Food and Drug Administration (FDA) fish tissue concentration levels regulating the commercial sale of fish are given for each chemical or chemical group. Mean and standard deviations in bold refer to one or more composites within that length group were not included in calculations because of "not-detected" (ND) results.

Chemical Parameter	Tissue***	Cisco Length Group (cm)	Mean Conc. ****	St. Dev.	Range	FDA Level (µg/kg)
Total Mercury**	M	33-34	37	6.6	32-46	1000*****
	M	38-39*	50	15	36-69	
	M	41-42	58	14	38-72	
	M	45-47*	94	25	71-130	
Total PCBs	M	33-34*	ND	.	ND	2000
	M	38-39	ND	.	ND	
	M	41-42	ND	.	ND	
	M	45-47*	**20**	.	ND-20	
	SOT	33-34*	ND	.	ND	
	SOT	38-39	ND	.	ND	
	SOT	41-42	ND	.	ND	
	SOT	45-47*	**27**	.	ND-27	
	SOUT	33-34*	ND	.	ND	
	SOUT	38-39	ND	.	ND	
	SOUT	41-42	ND	.	ND	
	SOUT	45-47*	**36**	.	ND-36	
Total Chlordane	M	33-34*	3.7	1.5	2.2-5.7	300
	M	38-39	4.9	3.1	0.87-8.4	
	M	41-42	7.5	3.0	3.7-11	
	M	45-47*	8.1	0.8	7.1-9.0	
	SOT	33-34*	5.6	2.2	3.4-8.5	
	SOT	38-39	7.6	4.4	1.8-12	
	SOT	41-42	10	3.7	5.5-14	
	SOT	45-47*	11	0.9	9.3-12	
	SOUT	33-34*	7.1	3.0	4.2-11	
	SOUT	38-39	10	6.1	2.5-17	
	SOUT	41-42	13	4.7	6.6-17	
	SOUT	45-47*	14	1.1	12-16	
Total DDT	M	33-34*	**3.1**	**0.1**	ND-3.1	5000
	M	38-39	**2.9**	**1.7**	ND -5.8	
	M	41-42	**5.3**	**2.1**	ND -7.7	
	M	45-47*	5.9	1.2	4.4-7.2	
	SOT	33-34*	**5.1**	**0.6**	ND -5.5	
	SOT	38-39	**5.8**	**2.4**	ND -8.6	
	SOT	41-42	**7.3**	**2.4**	ND -10	
	SOT	45-47*	8.0	1.6	7.0-9.7	
	SOUT	33-34*	**6.5**	**0.5**	ND -6.9	
	SOUT	38-39	**7.8**	**3.6**	ND -12	
	SOUT	41-42	**9.2**	**2.6**	ND -12	
	SOUT	45-47*	10	2.6	8.2-13	
Aldrin/Dieldrin	M	33-34*	2.8	0.4	2.3-3.2	300
	M	38-39	**2.7**	**0.3**	ND-3.0	
	M	41-42	3.2	0.4	2.8-3.7	
	M	45-47*	3.1	1.0	2.0-4.2	
	SOT	33-34*	4.2	0.5	3.5-7.0	
	SOT	38-39	**4.2**	**0.3**	ND-4.4	
	SOT	41-42	4.6	0.4	3.9-4.9	
	SOT	45-47*	4.2	1.2	2.5-5.5	
	SOUT	33-34*	5.3	0.8	4.4-8.7	
	SOUT	38-39	**5.5**	**0.6**	ND-6.2	
	SOUT	41-42	5.7	0.5	5.0-6.1	
	SOUT	45-47*	5.4	1.4	3.4-6.5	

Table 16 Continued…

Chemical Parameter	Tissue***	Cisco Size Group (cm)	Mean Conc. ****	St. Dev.	Range	FDA Level (µg/kg)
Heptachlor/Heptachlor Epoxide	M	33-34*	ND	.	ND	300
	M	38-39	ND	.	ND	
	M	41-42	ND	.	ND	
	M	45-47*	ND	.	ND	
	SOT	33-34*	ND	.	ND	
	SOT	38-39	ND	.	ND	
	SOT	41-42	ND	.	ND	
	SOT	45-47*	ND	.	ND	
	SOUT	33-34*	ND	.	ND	
	SOUT	38-39	ND	.	ND	
	SOUT	41-42	ND	.	ND	
	SOUT	45-47*	ND	.	ND	
Mirex	M	33-34*	ND	.	ND	100
	M	38-39	ND	.	ND	
	M	41-42	ND	.	ND	
	M	45-47*	ND	.	ND	
	SOT	33-34*	ND	.	ND	
	SOT	38-39	ND	.	ND	
	SOT	41-42	ND	.	ND	
	SOT	45-47*	ND	.	ND	
	SOUT	33-34*	ND	.	ND	
	SOUT	38-39	ND	.	ND	
	SOUT	41-42	ND	.	ND	
	SOUT	45-47*	ND	.	ND	

ND = Not Detected

* These ranges include the mean of duplicate samples, i.e. duplicates were not treated as separate samples for inclusion in the concentration ranges.

** Because mercury binds to muscle tissue, trimming the fillet will not reduce mercury concentrations. Therefore, mercury concentrations were not calculated for SOT and SOUT fillets.

*** M = trimmed, skin-off muscle tissue; SOT = skin-on, trimmed fillet; SOUT = skin-on, untrimmed fillet.

**** Only samples above the limit of detection were used to calculate mean concentrations.

***** The FDA action level for mercury is for methylmercury. Generally >95% of mercury in top predator fish such as lake trout is methylmercury (GLIFWC data, unpublished).

Table 17. Comparison of Lake Superior cisco (*Coregonus artedii*) contaminant data collected by the Great Lakes Indian Fish and Wildlife Commission (GLIFWC) in 1999 and 2006. Data from 1999 were only collected from skin-on untrimmed fillets (SOUT) and the cisco were collected from lake trout management unit MI-4 (2006 data were collected from management unit WI-2). Thus, except for total mercury, 2006 estimates for SOUT fillets are used for comparison. Cisco composite size group (cm), mean chemical concentration (ug/kg), and concentration range (µg/kg) are given for three chemicals/chemical groups.

	2006 Data (SOUT Estimate)			**1999 Data (SOUT)**		
Chemical Parameter	**Cisco Size Group**	**Mean Conc.**	**Range**	**Cisco Size Group**	**Mean Conc.**	**Range**
Total Mercury* **	33-34	37	32-46			
	38-39*	50	36-69			
	41-42	58	38-72			
	45-47*	94	71-130	38-43	107	65-149
Total PCBs	33-34*	ND	ND			
	38-39	ND	ND			
	41-42	ND	ND			
	45-47*	36**	ND-36	38-43	68	61-75
Total Chlordane	33-34*	7.1	4.2-11			
	38-39	10	2.5-17			
	41-42	13	6.6-17			
	45-47*	14	12-16	38-43	22	21-23

* These ranges include the mean of duplicate samples, i.e. duplicates were not treated as separate samples for inclusion in the concentration ranges.

** "Mean" concentration for this length group is the result for one sample because all others were below the limit of detection.

*** Because mercury binds to muscle tissue, SOUT concentration estimates were not made for total mercury with the 2006 data. Results displayed for total mercury in 2006 are for muscle tissue.

Table 18. Current (as of 2007) trigger and "do not eat" (DNE) fish tissue concentrations (in µg/kg [parts per billion] wet weight) used by jurisdictions on the United States side of Lake Superior to set sport fish consumption advisories. More specific advice (such as a concentration defining one meal per week or per month) for some contaminants are available, but are not listed here. The listed contaminants are responsible for the majority of advisories on the U.S. side of Lake Superior*.

Jurisdiction	Mercury		Total PCBs*****		Toxaphene		Total Chlordane	
	Trigger	DNE	Trigger	DNE	Trigger	DNE	Trigger	DNE
Sensitive Populations**								
Wisconsin	50	>950	50	>1900	-	-	-	>5620
Minnesota	50	>950	50	>1900	-	-	-	-
Michigan****	500	>1500	50	>1900	5000	-	300	-
General Population***								
Wisconsin	160	-	50	>1900	-	-	-	-
Minnesota	160	>2800	50	>1900	-	-	-	-
Michigan****	500	>1500	2000	-	5000	-	300	-

* In Ontario, 91% of Lake Superior advisories based on their 2007-08 guidance are caused by dioxins/furans and dioxin-like PCBs (Guide to Eating Ontario Sportfish 2007-2008 edition).

** The sensitive population is defined as women of childbearing age and children under the age of 15.

*** The general population is defined as men above age 15 and women beyond childbearing years or above age 15 and not planning to have children.

**** The Michigan Department of Community Health sets fish consumption advice for most contaminants including: total PCBs for the general population, toxaphene, dioxin TEQs, and total chlordane, based on the percentage of measured fish tissue concentrations that exceed the trigger level.

***** Total PCB advice for Wisconsin, Minnesota, and for sensitive populations in Michigan, is based on the Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory, developed by the Great Lakes Sport Fish Advisory Task Force, September 1993.

Table 19. Summary of Lake Superior cisco total mercury and total PCB data collected by the Great Lakes Indian Fish & Wildlife Commission (GLIFWC), Minnesota Department of Natural Resources (MNDNR), Michigan Department of Environmental Quality (MI DEQ), and Wisconsin Department of Natural Resources (WDNR) between 1996 and 2006. Results are combined for each jurisdiction from this time period and are intended to give a broad indication of whether mercury and PCB data from cisco collected by different jurisdictions were being detected at similar concentrations across Lake Superior. Only fillet data results collected for fish advisory purposes are listed. Whole fish and other non-fillet data were not included in this summary. Results are a mix of composite samples and individual cisco. Concentrations are wet weight, listed in units of mg/kg or parts per million. Mean results are given along with ± one standard deviation. Results below detection limits were not included in mean and standard deviation calculations.

Agency	Years of Data Collection	No. Analyses/ No. Fish**	Length Mean (cm)	Length Range (cm)	Mean total mercury	Total mercury range	Mean total PCBs (Aroclors)	Total PCB Range	Number of PCB Analyses Below Detection Limit
MNDNR	2000,2002, 2003,2005	26/43	37.7±2.9	34.0-45.2	0.09±0.03	0.03-0.137	0.03±0.01	0.01-0.06	2
WDNR	2001,2003, 2005	17/23	31.5±6.9	18.8-39.1	0.076±0.044	0.023-0.19	0.084±0.036	ND-0.14	7
GLIFWC*	1999,2006	20/112	40.2±3.9	33.3-46.7	0.069±0.035	0.032-0.168	0.062±0.015	ND-0.078	15
MIDEQ	No Data over this time period								

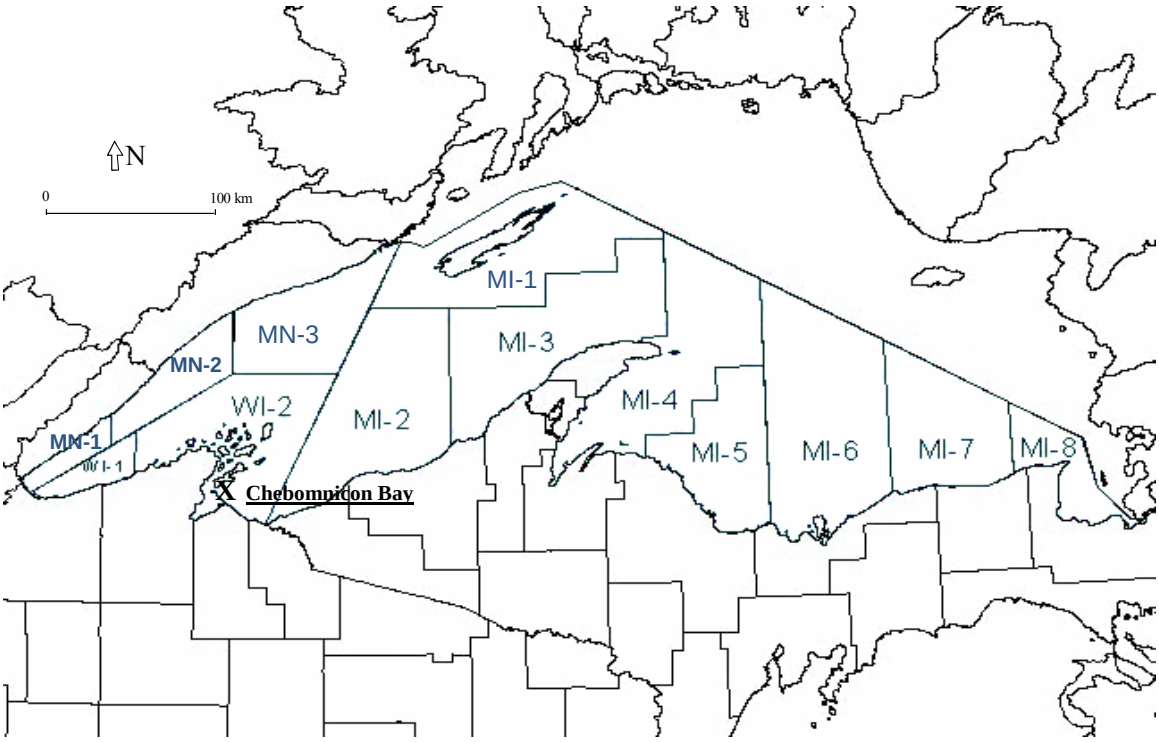
* GLIFWC segmented fillets into muscle, skin, and fat tissues. In 2006, chemical concentrations were only measured in trimmed, skin-off muscle tissue. PCB concentrations listed here are estimates for a skin-on, untrimmed fillet based on lipid normalized muscle concentrations and percent lipid in the skin and fat tissues. Total mercury concentrations for the GLIFWC 2006 samples are reported for muscle tissue only (i.e. the skin and fat have been removed unlike the other fillet samples listed in this table).

** No. Analyses/No. Fish = No. Analyses denotes the number of laboratory analyses the data represent. No. Fish denotes the number of fish represented in those analyses. When the two numbers are equal, individual fish were analyzed, when the numbers are not equal, composites were analyzed.

*** ND = Not Detected

FIGURES

Figure 1. Lake Superior lake trout management units (United States waters). Cisco samples were collected near Chebomnicon Bay on the southeast side of Madeline Island in lake trout management unit WI-2 (marked with an "X").



Figures 2A and B. Comparison of Michigan, Minnesota and Wisconsin Lake Superior cisco (*Coregonus artedii*) consumption advice for sensitive populations (i.e. women of childbearing age and children under the age of 15, Figure A) and the general population (i.e. women beyond childbearing age and men above age 15, Figure B).

Figure 2A – Sensitive population

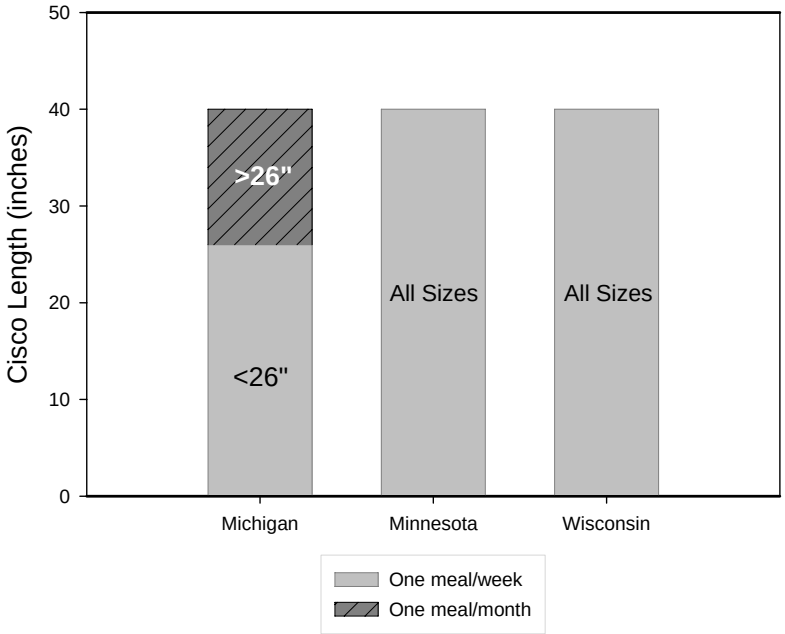


Figure 2B – General population

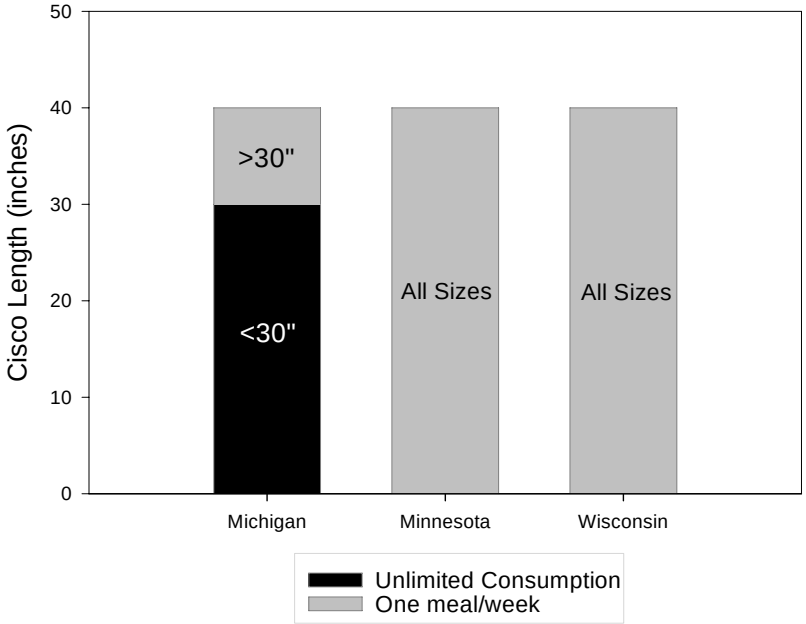


Figure 3. Total PCB concentrations (mean ± one standard deviation) in Lake Superior cisco (*Coregonus artedii*) muscle tissue composites. Only one of the 16 composites (in the largest length group) had a detectable PCB concentration ("ND" means "Not Detected"). Concentrations in SOT and SOUT fillets are estimated based on muscle tissue concentrations and percent lipid in respective skin and fat tissues. SOT and SOUT refer to "skin on trimmed" and "skin on untrimmed" fillets. The trigger and "do not eat" fish tissue concentrations used by Michigan, Minnesota, and Wisconsin to set fish consumption advice are shown as lines. These states use values agreed upon in the "Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory" (Great Lakes Sport Fish Advisory Task Force, Sept. 1993).

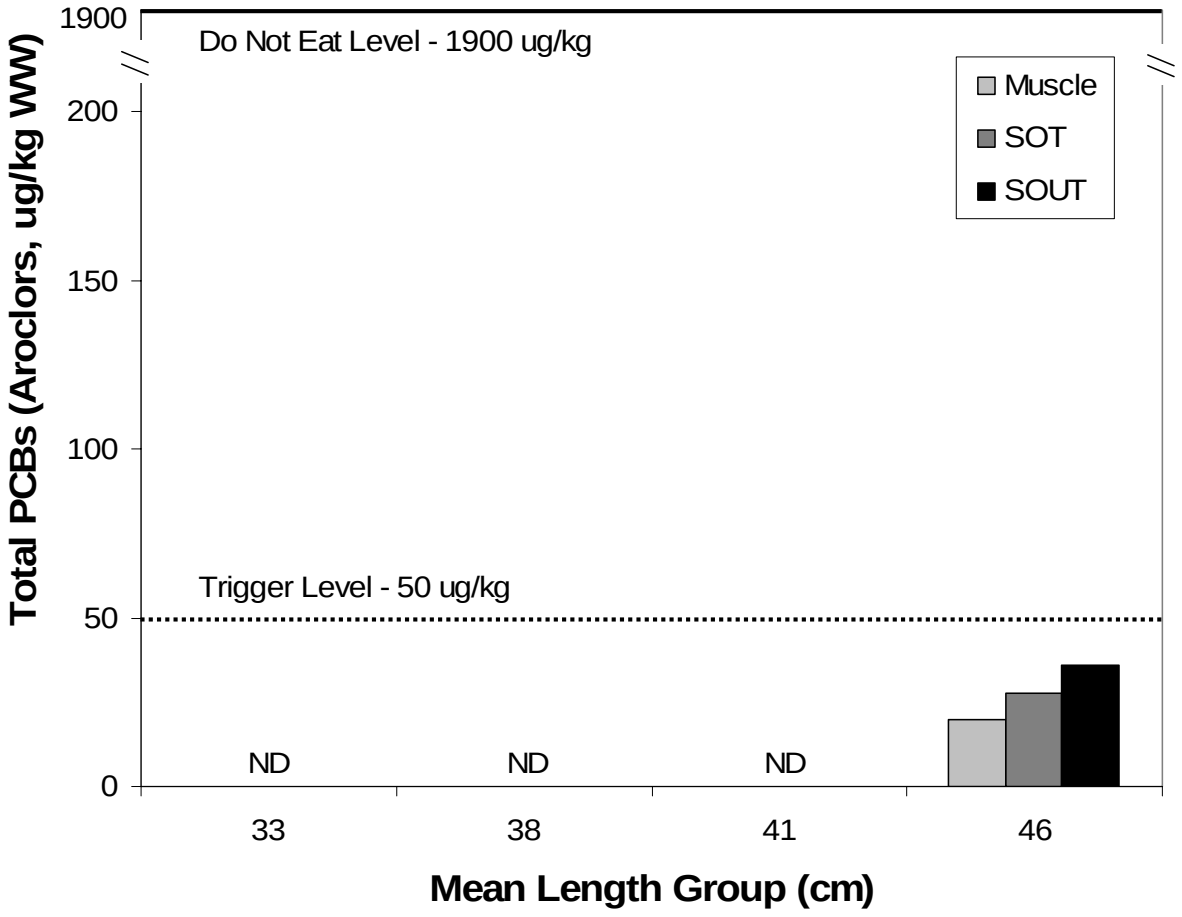


Figure 4. Total mercury concentrations (mean ± one standard deviation) in Lake Superior cisco (*Coregonus artedii*) muscle tissue (i.e. trimmed, skin-off fillet) composites. Estimates of mercury concentrations in skin on trimmed (SOT) and skin on untrimmed fillets (SOUT) were not calculated because mercury binds to muscle tissue and cannot be removed by trimming a fillet. The trigger and "do not eat" fish tissue concentrations used by Michigan, Minnesota, and Wisconsin to set fish consumption advice are shown as lines.

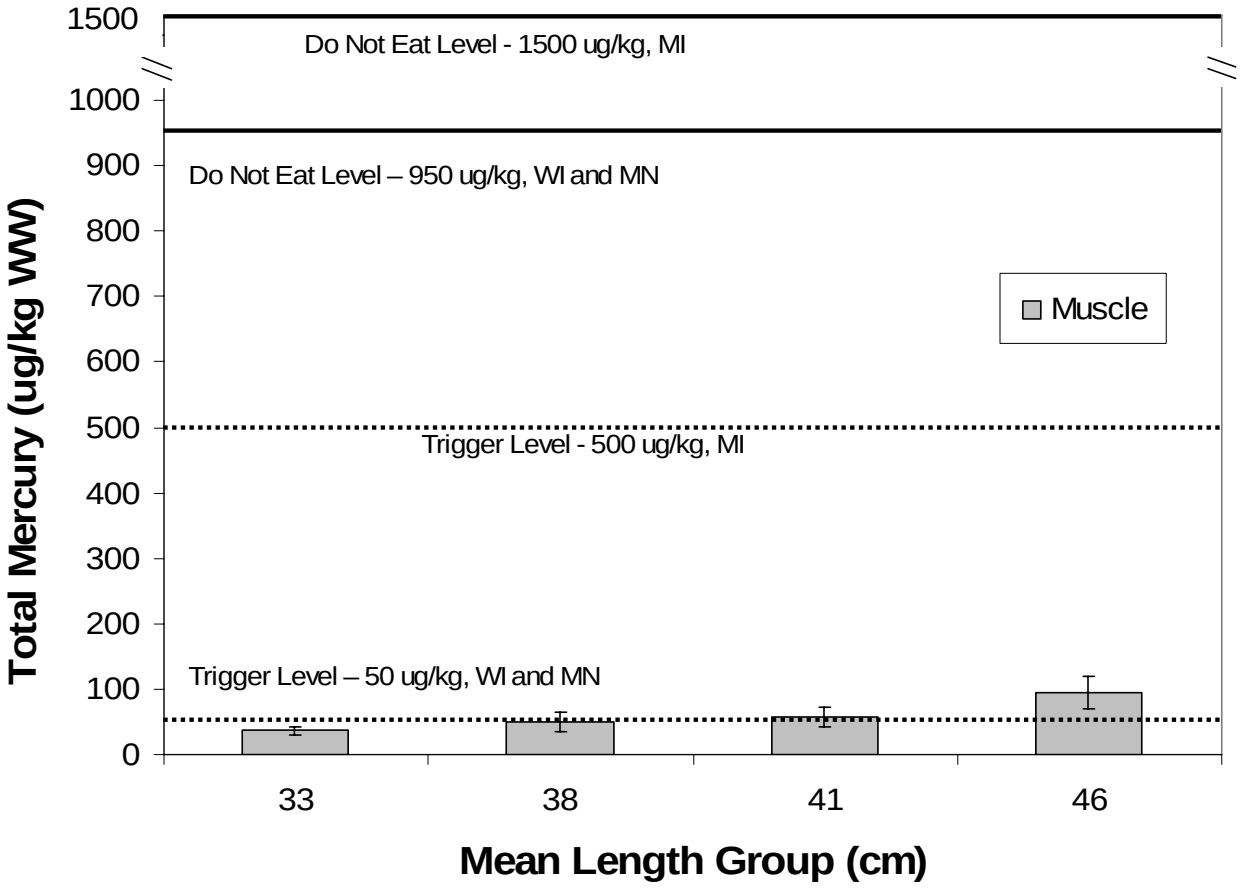


Figure 5. Total chlordane concentrations (mean ± one standard deviation) in Lake Superior cisco (*Coregonus artedii*) muscle tissue composites. Concentrations in SOT and SOUT fillets are estimated based on muscle tissue concentrations and percent lipid in respective skin and fat tissues. SOT and SOUT refer to "skin on trimmed" and "skin on untrimmed" fillets. The trigger and/or "do not eat" fish tissue concentrations used by Michigan and Wisconsin to set fish consumption advice are shown as lines.

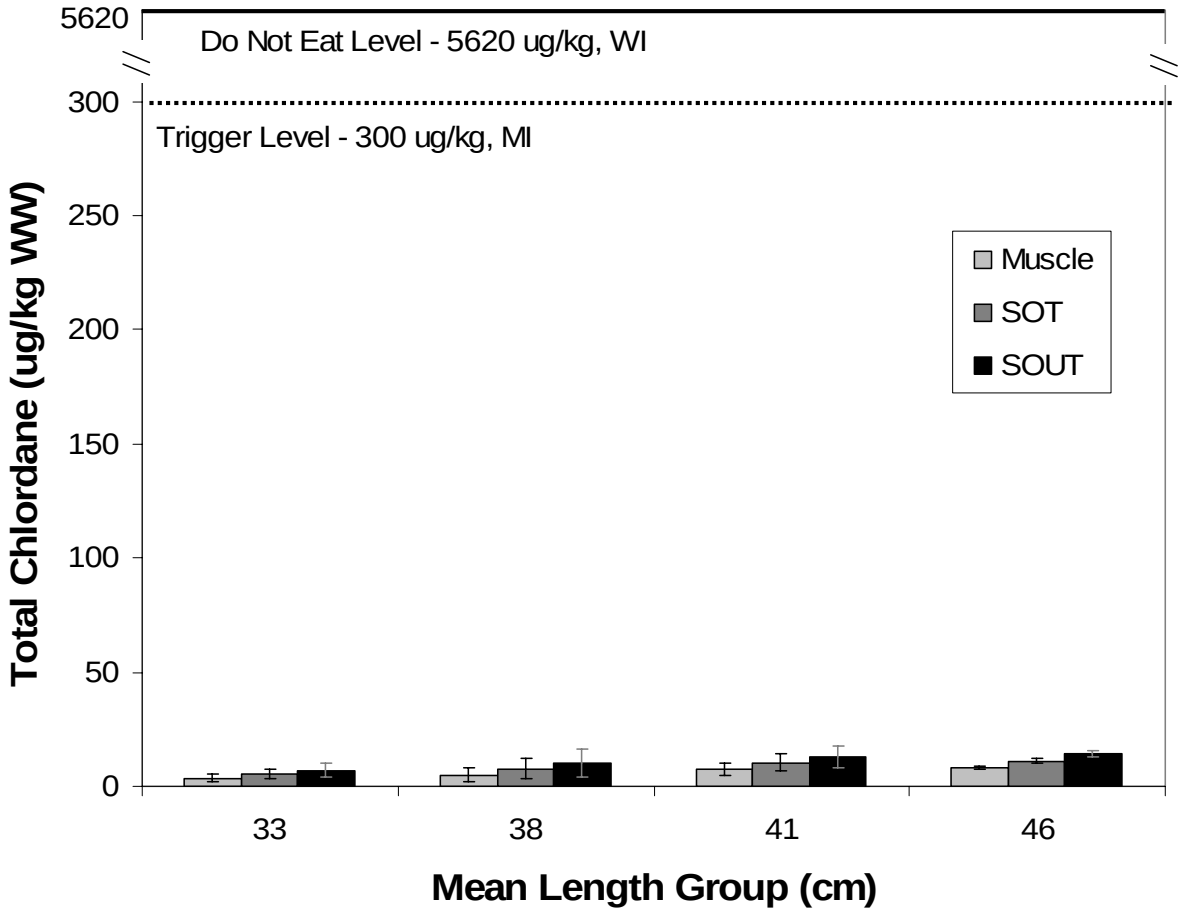


Figure 6. Total mercury concentrations (mean ± one standard deviation) for four species of Lake Superior fish. The sizes of fish span the length range of each species commonly harvested by tribal commercial fishermen. Data for siscowet trout (*Salvelinus namaycush siscowet*), lake trout (*Salvelinus namaycush namaycush*) and whitefish (*Coregonus clupeaformis*) were previously reported by the Great Lakes Indian Fish and Wildlife Commission (GLIFWC).

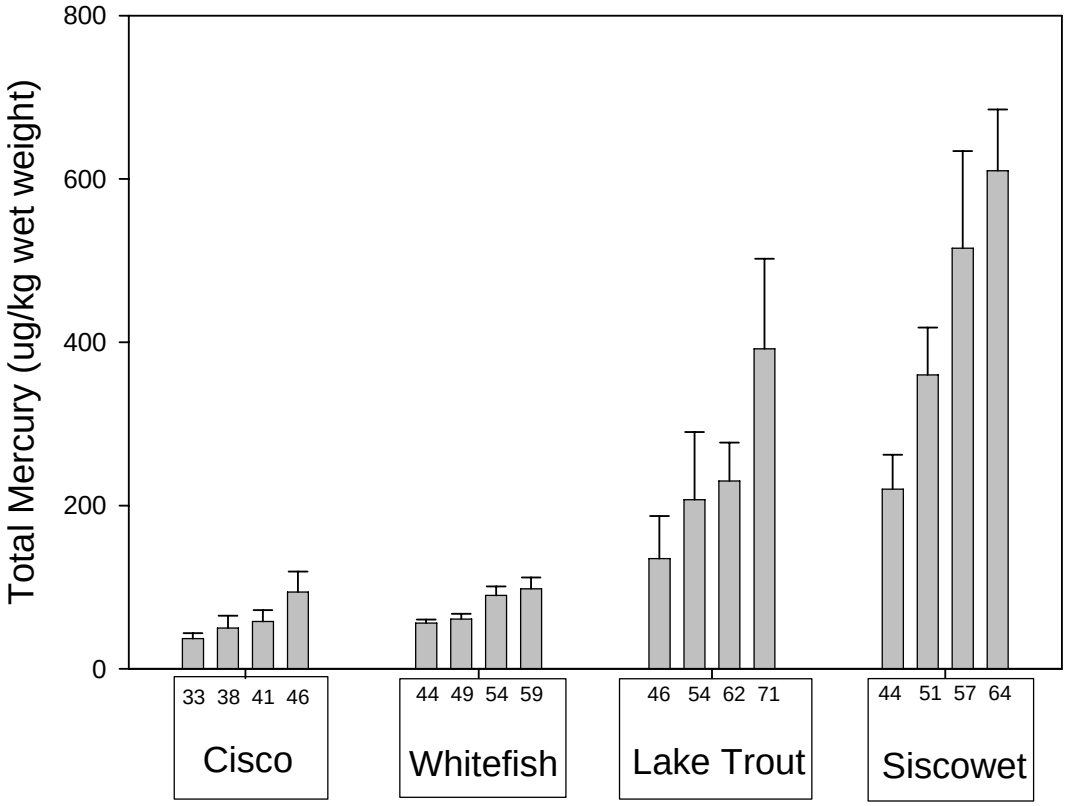
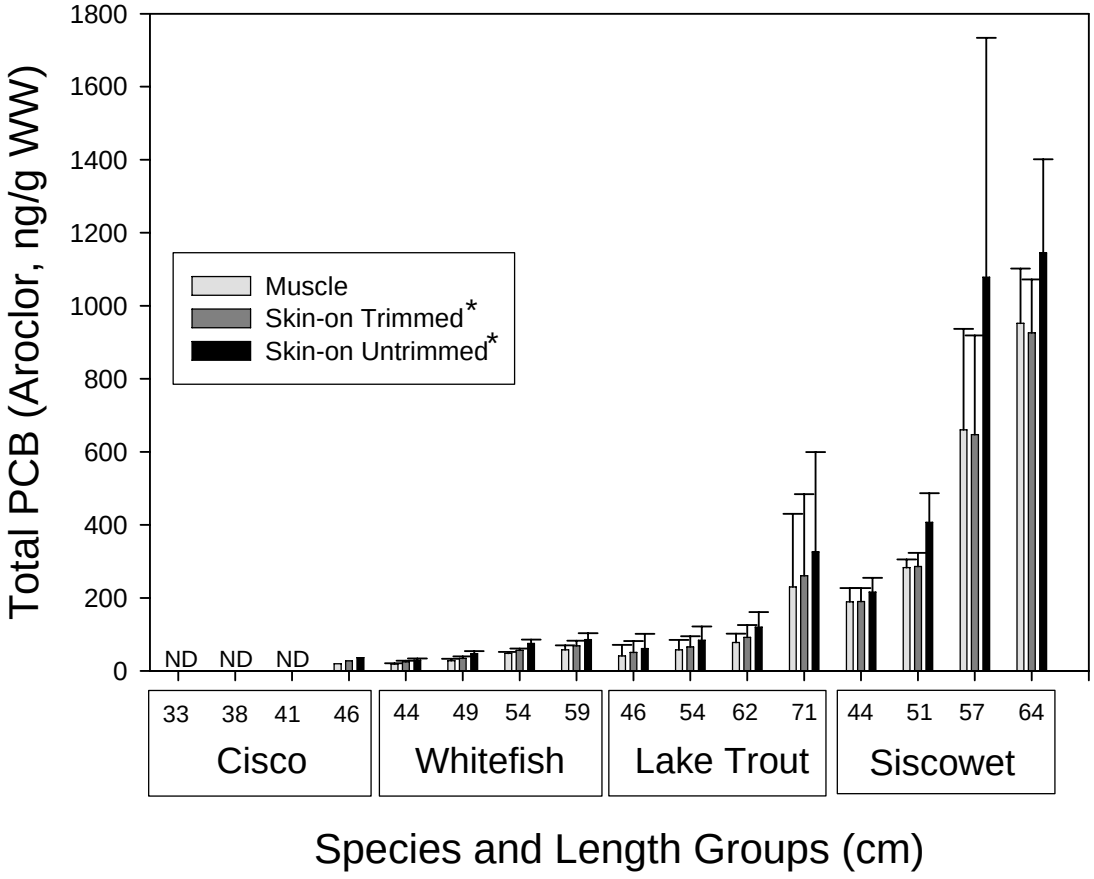


Figure 7. Total PCB concentrations (mean ± one standard deviation) for four species of Lake Superior fish. The sizes of fish span the length range of each species commonly harvested by tribal commercial fishermen. Data for siscowet trout (*Salvelinus namaycush siscowet*), lake trout (*Salvelinus namaycush namaycush*) and whitefish (*Coregonus clupeaformis*) were previously reported by the Great Lakes Indian Fish and Wildlife Commission (GLIFWC). "ND" means "Not Detected."



* Concentrations in "skin-on trimmed" and "skin-on untrimmed" fillets were measured for siscowet trout and estimated for lake trout, whitefish and cisco based on lipid normalized muscle tissue concentrations and skin and fat tissue lipid content.

APPENDICES

Appendix 1

Laboratory Data Review Checklist for
U.S. EPA Grant Number GL00E06501

Title: Laboratory Data Review Checklist

Introduction:

This procedure describes the data quality review process for evaluating chemical contaminant data received from contract laboratories.

Equipment:

Laboratory data review checklist (see attachment)
Black indelible ink pen

Procedure:

The GLIFWC project director or an appointed and properly trained GLIFWC staff member not involved in the project will perform this review.

Sampling Project: Lake Herring Contaminant Analysis

Date of Sampling: 11/2/06

Analytical Laboratory: Pace Analytical, Inc.

Mark each topic "Y," "N," or "NA" (not applicable), and comment as appropriate.

Y Final data package includes chain-of-custody forms.
Comment:

Y Chain-of-custody forms were properly completed and signed by everyone involved in transporting the samples.
Comment:

NA Laboratory records indicate sample custody seals were intact upon receipt.
Comment:

NA Samples arrived at the laboratory at the proper temperature.
Comment: Cooler on ice was documented & is appropriate - Note was made that samples were not frozen

Y All requested analyses were performed and were documented in the analytical report.
Comment: ~~8081A~~ ~~8082~~ 2 SRM 2 LCS/LCSD 2 Method Blank
~~3510C~~ ~~GPC~~ 2 Dup 1 MS/MSD

Y Analyses were performed according to the methods specified in the approved QA Project Plan.
Comment: KM-L-003
3510C
8081A
8082
GPC

Y Holding times for extraction and analysis were not exceeded.
Comment: According to case narrative

Y Method detection and/or quantitation limits were included in the report.
Comment:

Y A Narrative summarizing the analyses and describing any analysis problems was included in the final report.
Comment:

Y Data qualifiers and flags were explained in the analytical report.
Comment:

Y Method (laboratory) blank results were included for all analyses, at the appropriate frequency, and showed no laboratory contamination.
Comment: Note - 4,4'DDT was detected @ low level in one method blank - no action taken because 4,4'DDT was not found in the sample associated w/ this method blank.

NA Initial calibration data (if requested from the laboratory) were within QAPP, method, or laboratory SOP defined acceptance criteria for all analyses.
Comment: Wasn't requested but met criteria according to case narrative

NA Continuing calibration data (if requested from the laboratory) were within QAPP, method, or laboratory SOP defined acceptance criteria for all analyses.
Comment:

Y Matrix spike data were included for all pertinent analyses for every 20 samples.
Comment:

Y Laboratory Control Sample data were included for all analyses for every 20 samples.
Comment:

Y Laboratory Duplicate data were included for all analyses for every 20 samples.
Comment:

NA Field blanks do not contain analytes of interest or interfering compounds and are included for all pertinent analyses for every 20 samples.
Comment:

Y Field Duplicates are within QAPP-defined acceptance criteria and are included for all analyses for every 10 samples.
Comment:

Y Matrix spike results were listed and within QAPP or laboratory defined acceptance criteria.
Comment:

Y Matrix interferences were definitively identified either through a second analysis or use of Laboratory Control Sample Results.
Comment: Potential bias of toxaphene in LCS was explained

Y Laboratory Control Sample results were within QAPP or laboratory defined acceptance criteria.
Comment: LCS samples fortified w/ C Mix + Toxaphene had 8 QC limit exceedences - this was partially expected because of some compounds co-elute w/ Toxaphene (cis-nonachlor) Other exceedences were not compounds detected in the actual samples. The LCS fortified with the A/B Mix (no toxaphene) performed very well except for Aldrin (not detected in samples). Both the lake trout and whitefish studies had similar LCS results when spiked w/ toxaphene. It's possible the presence of toxaphene in the samples may bias some sample results, but this would be difficult to quantify.

Y Laboratory Duplicate results were within QAPP or laboratory defined acceptance criteria.
Comment: Not many analytes detected in samples - those detected were within 40% RPD in QA11

Y Reported results were within method detection or quantitation limits.
Comment:

Reviewer's Name (print): Matt Hudson

Reviewer's Signature: Matt Hudson

Reviewer's Title: Environmental Biologist

Address, Phone Number, and Email:
P.O. Box 9 Odanah WI 54861 715-682-6619
Mhudson@glifwc.org

Date of Data Review: 8/1/07
completion

*Note – This SOP is based on the model data review checklist found in EPA's CD-ROM Quality Assurance Project Plan Development Tool.

"Tribal Commodity Food Program Document"

2018

Tribal Commodity Food Program Document

Background

The Food Distribution Program on Indian Reservations (FDPIR) program, commonly referred to as Tribal Commodity Food program, is administered by the United States Department of Agriculture's (USDA) Food and Nutrition Services agency. According to their website, FDPIR is "a Federal program that provides USDA foods to low-income households, including the elderly, living on Indian reservations, and to Native American families residing in designated areas near reservations and in the State of Oklahoma" [1].

At the local level, Indian Tribal Organizations (ITO) or an agency of the State government administers FDPIR. During the 2017 fiscal year, 276 tribes received commodities through 102 Indian Tribal Organizations and 3 State agencies providing foods to 90,083 individual participants per month on average [2]. During this same year, the federal share of $47.69 million was provided to the local level for administration of the program and $103.31 million was used for food purchasing costs, totaling $151.0 million in appropriation [2].

2018 Farm Bill Section 4003(b) - FDPIR 638 Demonstration Program

The most recent Farm Bill provides many updates for the FDPIR program and its use of funds. See Appendix 1 for more information. The most relevant to this report is Section 4003 (b), which authorizes $5 million to be set aside for a pilot program which will allow a small number of ITOs to enter into 638 self-determination contracts with USDA in order to procure foods for their FDPIR package [3]. According to the Indigenous Food and Agriculture Initiative, "the demonstration will be used to determine the feasibility and effectiveness of transferring control as well as troubleshoot for any issues that may arise". It is possible that the demonstration could allow for more flexibility, regional purchasing, and purchasing of traditional food on a smaller scale, however, the program has yet to be developed.

At the time of publication of this report, the funds to be set aside await the conclusion of Federal appropriations and the development of the program by USDA and FNS. Tribal leadership is

encouraged to participate in the rule-making process to assist in developing a comprehensive pilot program.

USDA Purchasing

FDPIR only provides foods from a USDA program called USDA Foods. This program is a coordinated procurement and delivery system involving several USDA agencies. USDA Foods provides foods for several other Food and Nutrition Services programs including the National School Lunch Program and The Emergency Food Assistance Program. Each of these programs submit food requests to FNS with specifications and desired amounts. FNS then coordinates with USDA's Agricultural Marketing Service (AMS) to develop purchase plans and schedules. AMS then develops and announces detailed solicitation for each product, grants purchase awards to bidding vendors, and manages contracts in accordance with federal regulation and USDA policy [4].

"USDA's Agricultural Marketing Service (AMS) purchases a variety of domestically produced and processed commodity food products, through a competitive process among approved vendors. These purchases made by the AMS Commodity Procurement Program (CP) support American agriculture by encouraging the consumption of domestic foods. AMS-CP manages the Web-Based Supply Chain Management (WBSCM), the fully integrated, web-based ordering and procurement system used for the purchase of USDA Foods" [4].

Only approved vendors can submit a bid to supply the food product requested in the solicitation and bids can only be submitted through the Web-Based Supply Chain Management System. Approved vendors submit bids that outline the volume of product they can provide at a specific cost. Solicitations are awarded through a competitive process. Approved vendors **are allowed** to bid on a portion of the product volume requested through the solicitation or on the whole.

For example, in 2017 a solicitation for wild rice was announced by AMS for the FDPIR program. With technical assistance provide by the Intertribal Agriculture Council, both the White Earth Band and Leech Lake Band were able to successfully complete the vendor approval process. Each Band submitted a bid for a portion of the total requested amount of 150,000 pounds, and successfully received the award for their bids [5].

Standard Vendor Approval Process

Only approved vendors can submit bids to AMS solicitations. The standard approval process consists of five major steps which are outlined in Appendix 2 "Become a USDA Foods Vendor" along with the USDA's "Qualification Requirements for Prospective Contractors Selling Commodities to the USDA Agricultural Marketing Service" in Appendix 3 and the AMS "Qualification Requirements Checklist" in Appendix 4. Below is a summary of Qualification Requirements for Prospective Contractors:

A. Administrative Responsibilities

- Must complete the following prior to application package submission:
    - Register with System for Award Management (online system). See Appendix 5 for sample of information required.
    - Register with FDA and receive Food Facility Registration Number
        - Must be renewed every even numbered year between October 1 and December 31st (i.e. 2012, 2014, 2016, 2018, etc.) [6].
    - Small Business Certifications (if applicable)
    - Veteran's Administration Certification (if applicable)
    - Complete the Web-Based Supply Chain Management (WBSCM) registration form. See Appendix 6 for a sample of the registration form.

B. Responsible Prospective Contractor's Documentation

- Submit a written capabilities statement on company letterhead, to include:
    - A description of historical business experience
    - A list of products interested in providing as a contractor
- Submit three (3) letters of reference from customers, on customer's company letterhead, and signed by a company representative demonstrating the prospective contractors is responsible.

C. Financial Responsibility

- Submit a balance sheet, profit and loss statement, statement of cash flows, statement of retained earnings and notes to the financial statement.
    - These documents must be audited or reviewed by an independent certified public accountant.
    - These documents must be updated annually to maintain approval status

D. Food Safety and Sanitation Requirements

- A food defense plan encompassing pre-production raw materials, other ingredients and post-production finished products including storage and transportation must be documented and operational.
    - The plan will be audited by an AMS representative.
- Pre-Award plant surveys will be conducted by the applicable AMS Program Specialist or applicable USDA area to verify that AMS qualification requirements are met.
    - The survey will evaluate the technical, production, and transportation capabilities, and quality assurance and production control procedures of the prospective contractor.

<u>Constraints to Tribal Businesses</u>

1) Responsible Prospective Contractor's Documentation – Historical Business Experience

Newly formed tribal food entrepreneurs or entrepreneurs that have participated exclusively in a second economy, may not have the required historical business experience. Additionally, entrepreneurs may not have experience selling to other businesses or organizations, therefore, may not be able to provide letters of reference.

2) Food Safety and Sanitation Requirements – Food Defense Plans

Tribal food entrepreneurs may not have the training or skills to develop a food defense plan.

3) Food Safety and Sanitation Requirements –Inspections

Tribal food entrepreneurs may be found to fall short of the requirements during inspection.

Options for Tribal Businesses

1) U.S. Small Business Administration

Businesses who qualify can work with one or more of the many programs the U.S. Small Business Administration (SBA) offers to assist small business owners with government contracts and other small business needs. Small businesses, emerging, and other socio-economically diverse businesses who do not meet minimum qualifications are encouraged to work with SBA for a possible issuance of a Certificate of Competency. SBA's Certificate of Competency "certifies that the named business or businesses possess the responsibility to perform a specific Government procurement (or sale) contract, including any contract deriving from a reverse auction" [8]. The SBA is independent federal agency that offers business counseling, technical assistance, mentorship programs and other resources for the following business statuses [7]:

- Small (less than 500 employees or average annual receipts under $7.5 million)
- Women-Owned
- Veteran-Owned
- Service-Disabled Veteran Owned
- HUB Zone business (includes tribally owed)
- Socially and Economically Disadvantaged Individual Owned

2) Intertribal Agriculture Council – Technical Support

Founded in 1987, the Intertribal Agriculture Council (IAC) has been advocating for and assisting individual tribal producers and enterprises with agricultural policies and programs. The IAC works with the USDA's Office of Tribal Relations to provide free technical support to individual tribal producers and enterprises to assist in with the vendor approval process, bidding, and fulfilling successful awards [9].

Bidding - Commodity Requirements

After a food processor becomes an approved vendor they are eligible to submit bids for solicitations. Each solicitation invitation includes additional documents that detail the terms of the contract and product description. These terms are found in the attached bid certification questions document, master solicitation for commodity procurements-domestic programs document, product commodity requirements document, and product text. These documents describe in detail the requirements related to the product specifications, processing, inspection, warranty, packaging, materials, shipping, and unitization. See Appendix 7 for a sample solicitation and accompanying documents.

Each product will be inspected by the relevant agency to ensure the product meets requirements. The inspection costs are the responsibility of the vendor and vary depending on the agency. The following is an excerpt from the AMS "How the Process Works" webpage:

> *"Awarded contractors must perform according to the contract terms. To further ensure the quality and integrity of USDA Foods, audits and inspections for contract compliance are performed by AMS agents at the cost of the contractor. Waivers granted for deviations from contract requirements are uncommon, limited to minor infractions not affecting product safety, quality or shelf life. Any issues that arise during performance of a contract are addressed through communication and negotiation between the contractor and the AMS Contracting Officer."*

<u>Constraints to Tribal Businesses</u>

1) Competitive Bidding - Marketability

Even though there are funds set aside, as well as agencies and organizations that can assist small and tribal businesses with becoming an approved vendor, the bidding process will put these small businesses in competition with large companies for the same solicitations. Larger companies may have more business experience in the commercial market place and/or a history of successful government contracts, both making the larger company a more competitive bidder as they have an established record of responsibility. It will likely take a small business a year or more to successfully win an award [10].

2) Competitive Bidding – Profit loss

The private market often offers a better price for the commodity being solicited. Tribal businesses may need to offer their product at a price below the market value in order to win a government contract award. This can cause profit losses to the business, which could be unsustainable.

3) Inspections

Inspections fees range depending on the agency and the length of inspection. Additionally, products that do not meet requirements may undergo a second inspection at the request of the contractor. All inspections and associated fees are at the cost of the contractor. Inspection fees add to the overall production cost that reduces the profit margin.

<u>Options for Tribal Businesses</u>

1) Set-aside Contracts

The federal government aims to award 23% of all contract dollars to small businesses. One way they meet this goal is through two types of set-aside contracts that are only available to small businesses[7]. This can even the playing field by reducing the number of bidders and allowing for only small business bidders.

- The first is a competitive set-aside contract. Nearly all government contracts under $150,000 are competitive set-aside, where at a minimum of two small businesses are able to bid and compete for a government contract award.
- The second is a sole-source contract. This is a noncompetitive process which usually occurs when only one company is able fulfill the requirements of a contract.

2) Subcontracting

Small businesses can begin to build a working history with government contracts by subcontracting with larger companies that were successfully awarded. Often large companies will subcontract out portions of a government contract award. Working with these companies provides small businesses an opportunity to network and learn from the larger companies how to successfully fulfill a government contract and begins to build a reputation of responsibility and competency with government contracts [10].

3) Private Market

The private market may be a more advantageous market for the some tribal businesses. Private markets may be able to purchase items at a higher cost per unit (i.e. price per pound) than USDA Foods and often have lower barriers of entry. It is important for tribal businesses to understand the true market value of their goods and services before submitting a bid [5].

4) Loans

SBA can assist small businesses by connecting them to lending partners, lowering risks to lenders, thereby making it easier for small business to access capital for launching or growing their business. These funds can be used to help businesses meet requirements and pay for necessary accounting assistance through auditors or certified personal accounts or for required pre-award inspection services [7].

References

[1] USDA, “FDPIR Home Page 4.” [Online]. Available: https://www.fns.usda.gov/fdpir/food-distribution-program-indian-reservations-fdpir.

[2] USDA, “Food Distribution Program on Indian Reservations - Fact Sheet,” 2018.

[3] I. F. and A. Initiative, “The 2018 Farm Bill - One Pagers,” 2019.

[4] U. A. M. Service, “Selling Food to USDA.” [Online]. Available: https://www.ams.usda.gov/selling-food.

[5] “Personal Communication - Erin Shirl J.D. - Indigenous Food and Agriculture Initiative.” Conference Call.

[6] Food and Drug Administration, “Biennial Renewal of Food Facility Registration : Information for Startups and Small Entities,” 2018. [Online]. Available: https://www.fda.gov/food/registration-food-facilities/biennial-renewal-food-facility-registration-information-startups-and-small-entities.

[7] U. S. S. B. Administration, “U.S. Small Business Administration- Basic Requirements.” [Online]. Available: https://www.sba.gov/federal-contracting/contracting-guide/basic-requirements.

[8] U. S. Government, *What is the Certificate of Competency Program?* United States: Code of Federal Regulations, 2019.

[9] I. A. Council, “Intertribal Agriculture Council - Homepage.” [Online]. Available: https://www.indianag.org/.

[10] “Personal Communication - Small Business Administration - K. Sharma.” Telephone.

Farm Bill Improvements for FDPIR: [1]

1. Authorizes 2-year carryover funding. This will help FDPIR sites with daily administrative expenses of running the program.
2. Requires USDA to pay 80 percent of administrative costs FDPIR, with a 20 percent Tribal match. This is a slight reduction in the previous 25% match required in prior Farm Bills. Further, the 2018 legislation requires the match be waived without any corresponding limitation on administrative funding for that site where a tribe is financially unable or substantially burdened by the match requirement.
3. Provides that Tribes may use other federal funding sources to meet the match requirement.
4. Expands local food procurement to include "regionally-grown" foods and requires purchase of cost-effective traditional foods where practical.

FDPIR 638 Demonstration [2]

Public Law 93-638, often referred to as 638 authority, gives Tribes the ability to manage certain programs that are typically administered through federal departments.

The new Farm Bill has authorized $5 million for demonstration projects for Tribal organizations to enter into 638 self-determination and oversee FDPIR programs themselves. The demonstration will be used to determine the feasibility and effectiveness of transferring control as well as troubleshoot for any issues that may arise.

If this test run is successful, more Tribes may have the opportunity to have increased control over the way that their FDPIR program is administered. This could allow for increased additions of traditional foods in the FDPIR package and more Tribally produced foods. This provision opens the doors to expanding Tribal self-governance and food sovereignty.

Traditional Foods in Public Facilities

State, county, and local education programs are now eligible for the donation of traditional foods. [3]

Who can benefit from this provision? [4]

Native Gardens Project of the Standing Rock Sioux Tribe is an example of an educational organization working on expanding Farm-to-School policies in local school districts to encourage consumption of traditional, healthy foods in youth.

Become a USDA Foods Vendor

Below are six recommended steps for becoming a USDA approved vendor. We strongly recommend that prospective vendors explore the resources and documents below prior to submitting an application package.

Tools to Become a USDA Foods Vendor

- Webinar - How to Become a Certified USDA Vendor
- How to Become a Certified USDA Vendor Webinar Notes and Slides (pdf)
- New Vendor Qualification Checklist (pdf)

If you have any questions or concerns about the lists, please email NewVendor@ams.usda.gov

Step 1: Stay informed by subscribing & registering.

1. Subscribe to the AMS CP News to receive email notification of solicitations and awards (Note: receiving solicitations via AMS CP News does not make a vendor qualified to submit an offer.) Subscription is voluntary and you may unsubscribe at any time.

Step 2: Understand the Master Solicitations.

Review the Master Solicitation for Commodity Procurement (pdf) to understand the federal regulations, clauses, and provisions that affect USDA commodity contracts.

Step 3: Review the current purchase schedule & understand the purchase process.

Read through the list of current and past solicitations and award information. Also, read How the Process Works.

- Current Purchase Schedule for Fruits, Vegetables, Poultry, Eggs, Red Meat and Fish
- Current Purchase Schedule for Dairy, Bakery, Pasta, Grains, Cereals, Peanut and Vegetable Oil Products

Step 4: Review USDA commodity specifications and technical requirements.

These specifications and supplemental documents explain the production and processing requirements for USDA Foods.

Many AMS purchase programs require that suppliers and subcontractors undergo a technical approval process before they can supply raw materials or finished products under USDA contracts. This process may involve submission of production plans and/or technical proposals, product samples for evaluation, and on-site assessments of facilities and procedures. Information regarding the supplier eligibility process is contained in Supplements to the Master Solicitation, which accompany the product specifications:

- Product Specifications & Technical Requirements

Step 5: Learn the qualification requirements for being a vendor of:

1. New Vendor Qualification Requirements (pdf)

Step 6: Submit a Vendor Application Package

Each application package must include the following information (as detailed by the documents in Step 5 above):

1. System for Award Management (SAM) registration
2. Business Status (as indicated in SAM)
3. Completed WBSCM Vendor Registration Form
4. Company Letter (certifying ability to perform)
5. Three (3) Letters of Reference (from customers your company provided similar products to)
6. Business Type (and similar details)
7. Most Recent Audited Financial Statements

Completed application packages should be submitted via email.

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0273. The time required to complete this information collection is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Vendor Approval

The AMS Contracting Officer evaluates the Vendor Application Package and approves the applicant. If approved, the new vendor will be provided a WBSCM Corporate Vendor Administrator role and a Vendor Offer role. If denied, the reason(s) for denial shall be provided and the applicant must correct the issues if he/she wishes to re-apply.

Please Note: *As described in Step 4 above, many purchase programs require that suppliers undergo a technical approval process before they can participate. The technical approval process is separate from—and in addition to—the Qualification Requirements and application process described in Steps 5 and 6 above.*

Additional Resources

Qualified Bidders List

- USDA Vegetables, Fruit, & Tree Nuts (pdf)
- USDA Dairy, Grain, & Oilseeds (pdf)
- USDA Livestock, Poultry, and Fish (xls)
- Eligible Contractors and Suppliers List (pdf)

Have Questions?

At any time during the process, questions may be directed to:

Andrea Lang
New Vendor/Small Business Coordinator
USDA, AMS Commodity Procurement Staff
NewVendor@ams.usda.gov
202-720-4237

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News & Announcements

- 04/08 USDA Section 32 Dried Plums Purchase Program Announced
- 04/08 USDA Section 32 Fresh Pear Purchase Program Announced
- 04/03 USDA Fruit Purchase Program Announced

United States Department of Agriculture

Effective Date: March 1, 2017

Qualification Requirements for Prospective Contractors Selling Commodities to the USDA Agricultural Marketing Service

I. Introduction

The USDA's Agricultural Marketing Service (AMS), Commodity Procurement Staff (CPS), procures U.S. origin agricultural commodities and products (USDA Foods) for use in domestic food distribution programs. USDA Foods procured are delivered to schools, food banks, and Indian Reservations, and at times are used in disaster relief. These procurements also support American agriculture by encouraging domestic consumption when prices are advantageous.

These qualification requirements, as authorized under the Federal Acquisition Regulation (FAR), Subpart 9.2, Qualifications Requirements, are necessary for AMS to carry out its mission. A prospective contractor must be determined to be qualified by the Contracting Officer prior to submitting offers for AMS solicitations.

An interested prospective contractor may submit a qualification package at any time. Small businesses determined not to meet this qualification requirement, i.e., determined nonresponsible, will be referred to the Small Business Administration (SBA) for possible issuance of a Certificate of Competency (COC), in accordance with FAR subpart 19.6.

Prospective contractors shall complete and provide all materials requested herein. The Contracting Officer will review the package, determine if a prospective contractor is qualified, and add approved vendors to the Qualified Bidders List (QBL). A prospective contractor will be notified whether requirements have been satisfied and when the qualification package has been approved. Offers will not be accepted from a prospective contractor that has failed to comply with these requirements. Access to the Web-Based Supply Chain Management (WBSCM) system for submission of offers shall be granted only to Qualified Bidders after the qualification process has been completed and approved by the Contracting Officer.

Procurement information, including the AMS Master Solicitation for Commodity Procurements, commodity specifications, procurement schedules, information on WBSCM, current solicitations, and historical contract award information, is located on the AMS website at: https://www.ams.usda.gov/selling-food.

II. Qualification Requirements

The following are required of each prospective contractor to complete the qualification requirements process:

A. Administrative Requirements

1. System for Award Management (SAM).
   In accordance with FAR Part 4.1102, prospective contractors shall be registered in System for Award Management website. The contractor is responsible for the accuracy and completeness of the data within the SAM database, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. To remain active in SAM, after the initial registration, the contractor is required to review and update their company information on an annual basis, from the date of initial registration or subsequent updates. Annually, companies need to assure that all information in the SAM database is current, accurate and complete. The SAM website is located at: https://www.sam.gov/portal/public/SAM/. There is no fee to register in SAM.

2. FDA, Food Facility Registration Number.
   In accordance with the Food Safety Modernization Act of 2011 (FSMA), domestic facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States are required to register with the FDA and renew such registrations. If applicable, provide your FDA food facility registration number. FDA guidance is available at: http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm

3. SBA Certifications (if applicable).
   Submit a copy of the applicable SBA certificate if the firm is a certified 8(a), HUBZone, etc.

4. Veteran's Administration (VA) Certification (if applicable).
   If required by the contracting officer, submit a copy of the applicable certification as a Service-Disabled Veteran-Owned Small Business (SDVOSB).

5. Web-Based Supply Chain Management (WBSCM) Registration Form.
   USDA-AMS commodity procurements are conducted electronically through WBSCM computer system. Prospective contractor's must complete the WBSCM Vendor Registration Form available at: https://www.ams.usda.gov/resources/wscm-vendor-registration-form

B. Responsible Prospective Contractor's Documentation (FAR 9.104-1 and 9.104-3)

1. Prospective contractors shall provide a written capabilities statement on company letterhead with a signature, providing the firm's exact legal name, and include the following:

   - A description of historical business experiences including the number of years it has sold these or similar products in the commercial marketplace or to governmental entities.

   - A list of products that it is interested in providing (a copy of the WBSCM vendor registration form may be used).

   - Any additional pertinent information regarding a prospective contractor's capabilities, such as, but not limited to, news articles, company websites, brochures, etc., and evidence of a satisfactory record of integrity and business ethics, and verification that it is otherwise qualified and eligible to receive an award under applicable laws and regulations.

2. Three reference letters from customers that demonstrate the prospective contractor is responsible. These letters must be from the customer, on company letterhead and signed by the customer's representative.

3. For Non-manufacturers only.
   To demonstrate its capability to supply the products it wishes to bid on, non-manufacturers must provide a copy of the written agreement in effect between itself and an approved supplier. The agreement must be on company letterhead and must be signed by both parties. If the non-manufacturer has to change its supplier, a new written agreement between itself and the new supplier must be submitted for approval. Non-manufacturers must also submit a complaint and dispute resolution proposal which details how the non-manufacturer will resolve any potential complaints or hindrances that may arise.

   If a non-manufacturer represents itself as a small business concern, it must comply with 13 CFR 121.406(b):

   (b) Non-manufacturers. *(1) A firm may qualify as a small business concern for a requirement to provide manufactured products or other supply items as a non-manufacturer if it:*

   (i) Does not exceed 500 employees;
   (ii) Is primarily engaged in the retail or wholesale trade and normally sells the type of item being supplied;
   (iii) Takes ownership or possession of the item(s) with its personnel, equipment or facilities in a manner consistent with industry practice; and
   (iv) Will supply the end item of a small business manufacturer, processor or producer made in the United States, or obtains a waiver of such requirement pursuant to paragraph (b)(5) of this section.

C. Financial Responsibility (FAR 9.104-1(a) and 9.104-3(a))

A prospective contractor shall demonstrate that it has adequate financial resources to perform the contract, or the ability to obtain them, including the availability of necessary working capital and satisfactory credit.

The prospective contractor must provide its most current, complete comparative financial statement. The financial statement must be prepared in accordance with Generally Accepted Accounting Principles (GAAP) and be audited or reviewed by an independent certified public accountant in accordance with standards established by the American Institute of Certified Public Accountants. At a minimum, the statement should include a balance sheet, profit and loss statement, statement of cash flows, statement of retained earnings and any notes to the financial statement. For partnerships, the last fiscal year end or current financial statement of the partnership and the personal financial statement of each partner will be required. For individuals, financial statements that include all of his/her personal and business assets and liabilities will be required.

Annual review of Financial Responsibility:

Approved vendors added to AMS' Qualified Bidders List(s) that wish to remain on that list, and otherwise continue to meet qualification requirements, will be requested to submit an updated financial statement to AMS-CPS within 120 days of its fiscal year close to demonstrate current financial responsibility.

D. Food Safety and Sanitation Requirements.

1. Food Defense Requirements

All qualified contractors and subcontractors must have a documented and operational food defense plan that provides for the security of a plant's production processes and includes the storage and transportation of pre-production raw materials, other ingredients and post-production finished products. The plan shall address the following areas, where applicable: (1) food defense plan management; (2) outside and inside security of the production and storage facilities; (3) slaughter and processing, including all raw material sources; (4) controlled access to production and storage areas; (5) storage; (6) water and ice supply; (7) mail handling; (8) personnel security; and (9) transportation, shipping, and receiving (includes the sealing of any transport conveyance for truck lot and less-than-truck lot quantities of finished product).

The food defense plan must be audited by an AMS representative. Any nonconformance identified must be addressed in writing to both the Contracting Officer and Auditor. Contact the appropriate AMS Audit and Accreditation Program for information on food defense audit services. Contacts for each commodity area are found below and are also available on the AMS website at https://www.ams.usda.gov/services/auditing/apply.

Fruits, Vegetables & Specialty Crops
To apply for fruit and vegetable auditing services, contact the SCI division, Audit Services Branch at:
Telephone: (202) 720-5021
Fax: (202) 260-8927
Email: FVAudits@ams.usda.gov

Livestock, Poultry and Seed
To apply for Auditing Services, complete the Application for Service - LPS-109 form. View our Quality Systems Verification Programs Regulation. The completed LPS Form 109 must be sent to the Quality Assessment Division along with the cover letter requesting service and a complete copy of the client's program documentation. These documents can be sent via email to QAD.BusinessOps@ams.usda.gov or to the address below.

USDA, AMS, LPS, QAD
Business Operations Branch
10809 Executive Center Drive
Suite 318
Little Rock, AR 72211
Phone: (501) 312-2962
Fax: (501) 312-2968
Email: QAD.BusinessOps@ams.usda.gov

Dairy Plant Survey Program: For information on the Dairy Plant Survey Program, please visit this AMS website: https://www.ams.usda.gov/services/auditing/dairy-plant-survey-program

For meat, fish, poultry, and egg products, reference the Food Safety and Inspection Service (FSIS) "Security Guidelines for Food Processors" at the following website: http://www.fsis.usda.gov/OA/topics/SecurityGuide.pdf. Information for the transportation and distribution of meat, poultry, and egg products is found at the following website http://www.fsis.usda.gov/oa/topics/transportguide.htm.

For fruits, vegetables, shell eggs, and other food products regulated by the Food and Drug Administration (FDA), reference FDA's "Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance" dated October, 2007 at the following website: http://www.fda.gov/Food/FoodDefense/FoodSecurity/default.htm.

For dairy, grain, and oilseed products see quality assurance requirements in commodity requirements documents at the following website: https://www.ams.usda.gov/selling-food/product-specs.

2. Pre-Award Plant Surveys

After receiving the qualification information, a pre-award plant survey or capability assessment will be conducted to verify that a prospective contractor meets AMS qualification requirements. The pre-award survey/assessment will be conducted by the applicable USDA area, e.g., AMS Program Areas—Specialty Crop, Poultry, Livestock and Seed, Dairy or USDA's Federal Grain Inspection Service (FGIS)—to evaluate technical, production, and transportation capabilities, and quality assurance and production control procedures of the contractor.

Specific pre-award plant survey/assessment requirements are referenced in the Supplement and/or Commodity Specification(s) applicable to the commodities the prospective contractor is interested in supplying. These documents can be found on the Commodity Purchasing website at www.ams.usda.gov/commoditypurchasing. For more information, contact the Commodity Procurement Staff at 202-720-4517.

E. Submitting a Vendor Qualification Package

A prospective contractor is encouraged to submit the qualification package as soon as possible to allow ample time for the processes and approval, and subsequent WBSCM registration prior to the closing date of the targeted solicitation. A checklist (Exhibit 1) is provided to assist the applicant with submission of a complete package.
Submit the qualification packages to:

Ms. Andrea Lang
Small Business Coordinator
Email address: andrea.lang@ams.usda.gov.
Telephone No.: 202-720-4237

NOTICE
Except as provided in FAR Part 24.2 (the "Freedom of Information Act"), qualification information, including the pre-award survey reports, accumulated for purposes of determining the responsibility of a prospective contractor, shall not be released or disclosed outside the government. All information provided will be kept confidential to the extent permitted by law.

Under penalty of perjury, each qualification package must be submitted and signed by an individual who has the legal authority to contractually bind a prospective contractor on whose behalf that information package is submitted. If any information provided by a prospective contractor becomes inaccurate, a prospective contractor must immediately notify the Contracting Officer and provide updated and accurate information in writing. AMS reserves the right to waive minor irregularities and omissions in the information obtained in the qualification package submitted.

QUALIFICATION REQUIREMENTS August 2018

Print the following checklist and submit along with the completed qualification package.

Questions regarding qualifications and approval should be directed to Ms. Andrea Lang at 202-720-4237 or NewVendor@ams.usda.gov

• System for Award Management (SAM) www.sam.gov	
• **Business Status.** As indicated in SAM, business status is one of the following:	
○ Large Business	
○ Small Business	
○ Small Disadvantaged Business	
○ Women-Owned Business	
○ Veteran-Owned Business	
○ Service-Disabled Veteran-Owned Small Business	
○ HUBZone Business	
○ 8(a) Small Business Development Concern	
• **Completed WBSCM Vendor Registration Form**	
• **Company Letter**- certifying capability to perform	
• **Three (3) Letters of Reference** from customers your company sold the same or similar products to	
• **Business Type.** Check one: ☐ Manufacturer ☐ Non-manufacturer	
• **Check one or more as applicable.** ☐ Grower ☐ Grower/Packer/Shipper ☐ Processor ☐ Distributor/Wholesaler ☐ Broker	
• **Non-manufacturer.** The following requirements apply:	
○ Letter from manufacturer/supplier certifying its willingness to provide product that meets the USDA commodity specifications	
○ Complaint and Dispute Resolution Proposal	
• **Most Recent Audited Financial Statements**	

Please note that in order to be added to our Qualified Bidders List and eligible to begin bidding on products, you must complete the necessary inspections and be set up in the Web Based Supply Chain Management System.

View assistance for Overview~Registration Overview

Technician, you will be contacted by CAGE, if necessary, for any additional information.

Register Entity

- Overview
  - Registration Overview
- Purpose of Registration
- Core Data
- Representations and Certifications
- Points of Contact
- Submit Registration

BACK TO USER DASHBOARD

Overview

Registration Overview

SAM Entity Management registrants are required to submit detailed information on their entity in the following categories, depending on the purpose of the registration:

Core Data

Mandatory for all registration types. Includes, but is not limited to, an entity's DUNS and/or DoDAAC, name, address, CAGE or NCAGE, code, TIN or EIN number, general information, financial information, and details about any proceedings in which the entity may currently be involved.

Assertions

Documents self-assertions from each entity. Includes, but is not limited to, data about the types of goods and services the entity provides, the entity size, optional Electronic Data Interchange (EDI), and disaster relief data.

Representations & Certifications

Documents an entity's representations and certifications related to their small business status, responses to commonly used Federal Acquisition Regulation (FAR) and Defense Federal Acquisition Regulation Supplement (DFARS) provisions/clauses, and Architect-Engineer Responses (SF330 Part II).

Points of Contact

Mandatory for all registration types. The entity will be asked to provide contact information for any mandatory POC based on the information they provided during the registration process. Includes, but is not limited to, accounts receivable, electronic business, and government business.

Notes:

An entity within the SAM system includes prime contractors, organizations or individuals applying for assistance awards, those receiving loans, sole proprietors, corporations, partnerships, and any Federal government agencies desiring to do business with the government.

Entity Administrators and/or Entity Registration Representatives are responsible for ensuring the accuracy of an entity registration in SAM. An entity registration must be renewed every 365 days in order to remain active and will expire if it is not updated in a timely manner. An expired registration may affect the ability to do business with the Federal government.

START REGISTRATION

Welcome to Supplier Self-registration

If you would like to do business with USDA, please complete and submit the following form.
* - Required Field.

Company Details

Type of Vendor	◉ Central Vendor	○ International Freight Vendor
Are you a US-based Vendor?	◉ Yes	○ No
Are you registered with System for Award Management?	◉ Yes	○ No

Enter DUNS Number *

Name of the Company *

Address Data

First Name *		Last Name *	
E-Mail Address *			
Telephone *		Extension	
Fax *		Extension	
Street Address *			
Building		Suite No.	
Floor		City/Location *	
Zip Code *			
State/Region *		Country *	USA
PO Box		PO Box Zip code	
PO Box City			
PO Box State		PO Box Country	USA

Which Product/Service Categories do you Offer?

☐	BAGS-EMPTY	☐	BAKED PRODUCTS-PKGD	☐	BARLEY-PKGD
☐	BEANS, DRY	☐	BEANS, DRY-PKGD	☐	BEEF, CANNED
☐	BEEF, COOKED	☐	BEEF, FRESH	☐	BEEF, FROZEN
☐	BEEF, GROUND	☐	BEEF, ROAST	☐	BEEF, SPECIAL TRIM
☐	BISON PRODUCTS	☐	BUCKWHEAT-PKGD	☐	BULGUR-PKGD
☐	BUTTER	☐	CEREAL, FORTIFIED	☐	CEREAL, INSTANT
☐	CEREAL, PROCESSED	☐	CHEESE PROC, KOSHER	☐	CHEESE, MOZZARELLA
☐	CHEESE, NATURAL AMER	☐	CHEESE, PROCESSED	☐	CHICKEN, BULK
☐	CHICKEN, CANNED	☐	CHICKEN, COOKED	☐	CHICKEN, FROZEN
☐	COMMODITIES F&V	☐	CORN PRODUCTS	☐	CORN-SOY BLEND-PKGD
☐	CORN-SOY MILK-PKGD	☐	CORNMEAL-PKGD	☐	CRACKER PROD, PROC
☐	DEHYDRATED POTATO	☐	EGG PRODUCTS	☐	EMERGENCY PRODS-PKGD
☐	FISH, CANNED	☐	FISH, FROZEN	☐	FLOUR, BAKERY
☐	FLOUR, BAKERY KOSHER	☐	FLOUR, BAKERY MIX	☐	FLOUR, MASA
☐	FLOUR, WHEAT	☐	FLOUR, WHEAT-PKGD	☐	FREIGHT-DOMESTIC
☐	FREIGHT-OCEAN	☐	FRUIT, CANNED	☐	FRUIT, DRIED
☒	FRUIT, FRESH	☐	FRUIT, FROZEN	☐	FRUIT, JUICE
☐	GOOSE, FROZEN	☐	GRAIN PRODUCTS-BULK	☐	GRAIN PRODUCTS-PKGD
☐	GRITS, GRAIN	☐	HAM, FULLY COOKED	☐	INFANT FORMULA
☐	LAMB PRODUCTS	☐	MEAT PRODUCTS	☐	MILK, EVAPORATED
☐	MILK, FRESH-FLUID	☐	MILK, INSTANT	☐	MILK, NON-FAT DRY
☐	MILK, UHT	☐	MILK,NONFAT,DRY-PKGD	☐	N/A (CHES PROC KOSH)
☐	N/A (FLOUR,BAK KOSH)	☐	N/A (PENUT PROD,KOS)	☐	N/A (RICE,GRAIN KOS)
☐	N/A (SEED BUTR, KOS)	☐	N/A (VEG OIL KOSHER)	☐	NON-STANDARD
☐	NUTS	☐	OIL PRODS, RFND-BULK	☐	OIL PRODS,CRUDE-BULK
☐	OIL PRODUCTS-PKGD	☐	OIL, BULK	☐	OIL, CORN
☐	OIL, SUNFLOWER	☐	PANCAKES	☐	PASTA, MAC & CHEESE
☐	PASTA, MACARONI	☐	PASTA, OTHER	☐	PEANUT PROD, KOSHER
☐	PEANUT PRODUCTS	☐	PEANUT PRODUCTS-PKGD	☐	PEANUTS RAW SHELLED
☐	PEAS, DRY	☐	PEAS/LENTILS-PKGD	☐	PORK, CANNED
☐	PORK, COOKED	☐	PORK, FRESH	☐	PORK, FROZEN
☐	POTATO PRODUCTS-PKGD	☐	POULTRY PRODS-PKGD	☐	PRICE SUPPORT BUTTER
☐	PRICE SUPPORT CHEESE	☐	PRICE SUPPORT MILK	☐	PUDDING

☐	RAISINS-PKGD	☐	RICE, GRAIN	☐	RICE, GRAIN KOSHER
☐	RICE, MILLED-PKGD	☐	RICE, WILD	☐	SALMON-PKGD
☐	SEED BUTTER	☐	SEED BUTTER, KOSHER	☐	SERVICE AMS FV
☐	SERVICE AMS LS	☐	SERVICE AMS PY	☐	SERVICE DOM FREIGHT
☐	SERVICE DOM NATLWHSE	☐	SERVICE DOM SAMPLING	☐	SERVICE DOMESTIC
☐	SERVICE INT ADMIN	☐	SERVICE INT INSPECT	☐	SERVICE INT SURVEYS
☐	SERVICE INT VLO	☐	SERVICE PS STORAGE	☐	SHELL EGG
☐	SORGHUM GRITS-PKGD	☐	SOUP MIX-PKGD	☐	SOY PRODUCTS-PKGD
☐	SYRUP	☐	TALLOW-BULK	☐	TORTILLAS
☐	TURKEY, BULK	☐	TURKEY, CANNED	☐	TURKEY, COOKED
☐	TURKEY, FROZEN	☐	VEG OIL PROD DOM	☐	VEG OIL PROD, KOSHER
☐	VEGETABLE, CANNED	☐	VEGETABLE, DRIED	☐	VEGETABLE, FRESH
☐	VEGETABLE, FROZEN	☐	VEGETABLE, JUICE	☐	VEGETABLE, SOUP
☐	WHEAT-SOY BLEND-PKGD	☐	YOGURT	☐	

Organization Type

Select an Organization Type: Corporate Entity, Not Federal Tax Ex

Enter Text if you choose 'Others':

Data Privacy Statement

USDA Data Privacy Statement

The following statement is made in accordance with the Privacy Act of 1974 (5 USC 552a - as amended). The authority for requesting the information identified on this Website is 7 CFR Part 1400. The information will be used to evaluate bids to purchase commodities and provide services. The information collected may be disclosed to other Federal, State, Local government agencies, Tribal agencies, and nongovernmental entities that have been authorized access to the information by statute or regulation and/or as described in applicable Routine Uses identified in the System of Records Notice for USDA/FSA-2, Farm Records File (Automated). Providing the requested information is voluntary. However, failure to furnish the requested information will result in non-consideration. The provisions of appropriate criminal and civil fraud, privacy, and other statutes may be applicable to the information provided.

USDA WBSCM Team

Phone: 1-877-WBSCM-4U

Email: wbscm.servicedesk@caci.com

☐ Yes, I have read the data privacy statement and accept the terms.

Clear **Check**

Note :
* Check whether the form is completely filled using the Check button
* Once completed save and mail it to the Email address provided in the Form.

SOLICITATION
Domestic Commodity Invitation

Information
Description: **12-3J14-19-B-0364**
Bid invitation number: **2000006096**

Certification Questions :
Please answer all certification questions.

See attached documents:

1 . Bid Certification Questions
2 . Master Solicitation for Commodity Procurements-Domestic Programs
3 . RICE Products Commodity Requirements Document
4 . RICE Products TENDERING TEXT July-August 2019 SPECIAL

Attributes :

1. DUNS and Business Size Standard
2. System for Award Management (SAM).
2a. System for Award Management (SAM) - changes to this Solicitation.
3. Amendment to Solicitation.
4. All USDA contracts with the Offeror that have a Not-Later-Than date prior to the solicitation opening:

Permitted values:
- HAVE BEEN DELIVERED
- HAVE NOT BEEN DELIVERED
- NO PREVIOUS CONTRACTS

5. Brand name and pack size
6. Plant locations for all items has been verified pursuant to the Place of Performance-Sealed Bidding?
7. Supplier Agreements:

Permitted values:
- YES
- NO
- N/A

7a. Supplier Agreement-Capability Requirements

Permitted values:
- YES
- NO
- NOT APPLICABLE

8. Commodity Specifications
9. Offeror Contact information
9a. Emergency Point of Contact

Bid invitation Item details

Item	Material	Description	Required by	ZipCode	Quantity

SOLICITATION
Domestic Commodity Invitation

Information
Description: **12-3J14-19-B-0364**
Bid invitation number: **2000006096**

Item	Material	Description	Required by	ZipCode	Quantity	
10		*RICE, GRAIN*				
20		*RICE BRN US#1 LONG PARBOILED BAG-25 LB*				
30		*LOT: 553969868 CLEARFIELD UT / OGDEN ...*				
		Tendering text - Item : LOT: 553969868 CLEARFIELD UT / OGDEN UT /				
40	101031	RICE BRN US#1 LONG PARBOILED BAG-25 LB	07/16/2019-07/31/2019	84016	28,250.000	LB
50	101031	RICE BRN US#1 LONG PARBOILED BAG-25 LB	07/16/2019-07/31/2019	84404	13,750.000	LB
		Total Quantity for RICE BRN US#1 LONG PARBOILED BAG-25 LB			42,000.000	LB
60		*RICE BRN US#1 LONG PARBOILED PKG-24/2 LB*				
70		*LOT: 429866732 CLEARWATER FL / TAMPA ...*				
		Tendering text - Item : LOT: 429866732 CLEARWATER FL / TAMPA FL /				
80	100500	RICE BRN US#1 LONG PARBOILED PKG-24/2 LB	08/16/2019-08/31/2019	33756	10,512.000	LB
90	100500	RICE BRN US#1 LONG PARBOILED PKG-24/2 LB	08/16/2019-08/31/2019	33605	31,488.000	LB
		Total Quantity for RICE BRN US#1 LONG PARBOILED PKG-24/2 LB			42,000.000	LB
100		*RICE BRN US#1 LONG PARBOILED PKG-30/2 LB*				
110		*TUCSON AZ*				
120	100501	RICE BRN US#1 LONG PARBOILED PKG-30/2 LB	08/01/2019-08/15/2019	85713	42,000.000	LB
130	100501	RICE BRN US#1 LONG PARBOILED PKG-30/2 LB	08/16/2019-08/31/2019	85713	42,000.000	LB
		Total Quantity for RICE BRN US#1 LONG PARBOILED PKG-30/2 LB			84,000.000	LB
		Total Quantity for Invitation			168,000.000	LB

Jeffrey Jackson
Contracting Officer
United States Department of Agriculture

AMS Master Solicitation for Commodity Procurements
– Domestic Programs (MSCP-D)

for Domestic Food Distribution Program Purchases

Commercial Item, Sealed Bidding

Effective: March 25, 2019

USDA, Agricultural Marketing Service
Commodity Procurement Program
1400 Independence Ave., SW, Room 3522-S, STOP 0239
Washington, DC 20250-0239

MSCP-D Updates included in this version, (i.e., changes from the April 12, 2017, version)

General Updates		
Page	**Text**	**Change**
Title	"AMS Master Solicitation for Commodity Procurements" "Commodity Procurement **Staff**"	Add "Domestic Programs (MSCP-D)" to differentiate this Master Solicitation from the AMS Master Solicitation for *International* Food Aid Programs. Update to new organization name "Commodity Procurement **Program**"
8	"This version of the Master Solicitation…"	Updated from FAC 2005-95 to **FAC 2005-101**

Contract Clauses Updated		
Clause Number	**Clause Name**	**Change**
4A52.201-1	Contracting Officer Representative	Clarified language to indicate contracting officers **may** designate a COR(s) to assist with the contract.
52.204-13	System for Award Management Maintenance	New clause to replace the paragraph FAR removed from 52.212-4
4A52.211-1	Compensation for Delays in Delivery	Duplicate clause number, this clause has been updated to be 4A52.211-2
4A52.211-3	Regulatory Requirements for Commodities and Packaging	Add relevant regulations **cited to include** "applicable Food Safety Modernization Act regulations (FSMA), and sections in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act)"
4A52.211-4	Commodity/Packaging Labeling Requirements	New local clause added
52.212-4	Contract Terms and Conditions	Updated the clause to the latest provided by FAR dated Oct 2018
52.212-4	Contract Terms and Conditions	In paragraph (a)(2)(A)(ii), removed "and/or" at the end of the paragraph, as the introductory language of 52.212-4(a)(2)(A) already states the requirement is to submit "<u>one</u> of the following"
52.212-4	Contract Terms and Conditions	In paragraph (a)(2)(A)(iv),clarified by adding language in bold: "Report evidencing delivery of product (e.g., **Goods Receipt in WBSCM**, or Goods Receipt Detail Report **attached to invoice**);"
52.212-4	Contract Terms and Conditions	Delete paragraph numbering (vi) from the text in quotations within (a)(2)(A)(v), since that language is actually part of paragraph (v).
52.212-4	Contract Terms and Conditions	Delete addendum to paragraph (i) Payment. Additional prompt payment information for commodities has been moved to 4A52.232-2.
52.212-5	Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items	Updated the clause to the latest provided by FAR dated Oct 2018

AMS Master Solicitation for Commodity Procurements – Domestic Programs (MSCP-D)
for Domestic Food Distribution Programs Purchases
Commercial Item, Sealed Bidding

Effective Date: March 25, 2019

Contents

RICE PRODUCTS

Acquisition Method:	Invitation for Bid
Description:	12-3J14-19-B-0364
Number:	2000006096
Issued date:	April 30, 2019, 1330 Central Time
Offers due:	May 14, 2019, 0900 Central Time
Award Notification	May 16, 2019, by 1500 Central Time
Public Release of Award:	May 17, 2019, by 1500 Central Time

1. Solicitation Information Contact:
Monday through Friday, except Federal Holidays, 8:00 a.m. to 4:00 p.m. CST.

United States Department of Agriculture (USDA)
Agricultural Marketing Service (AMS)
Commodity Procurement Program (CPP)
Domestic Commodity Procurement Division (DCPD)
Dairy, Grains, & Oilseeds Branch (DGO)
Mail Stop 8718
PO Box 419205
Kansas City, MO 64141-6205

Mara Whitaker, Marketing Specialist/Contracting Officer's Representative
Telephone: 816 926 6063
Email: Mara.Whitaker@usda.gov

Alternate Contacts:
Jeffrey F. Jackson, Senior Contracting Officer
Telephone: 816 926 2612
Email: Jeffrey.Jackson@.usda.gov

2. AMS Commodity Procurement Internet Address:
http://www.ams.usda.gov/selling-food

3. This Acquisition is:
// Unrestricted.
/x/ Set-Aside for:
/x/ Small Business Set-Aside in accordance with FAR 19.502-2. Any concern proposing to furnish a product that it did not itself manufacture must furnish the product of a small business manufacturer.

NOTICE OF SMALL BUSINESS SET-ASIDE
If specified in the solicitation, certain quantities are set aside exclusively for small business firms under the Small Business Act (15 U.S.C. 631, et seq.). Bids received for these set-aside quantities from firms who are not small business concerns will not be considered.

RICE PRODUCTS
Solicitation Description: 12-3J14-19-B-0364
Solicitation Number: 2000006096
Tendering Text

4. NAICS Codes/Size Standards:
See Master Solicitation for Commodity Procurements-Domestic Programs at https://www.ams.usda.gov/sites/default/files/media/MSCP.pdf

5. Delivery Type: F.O.B. Destination

6. Submission of offers:
A. WBSCM Service Desk Information
To obtain assistance using WBSCM, please contact the WBSCM Level 1 Service desk at any of the following:
-telephone: 877-WBSCM-4U or 877-927-2648
-email: WBSCM.servicedesk@CACI.com
-Web form link on WBSCM Portal: https://cacifedramp.service-now.com/wbscm/

You need to have the following information available when contacting the WBSCM Level 1 Service Desk:
-Company's Business Partner (BP) number: (if available)
-Company Name:
-Contact Name:
-Phone Number:
-E-mail Address:
-Identify that you are a Domestic Vendor
-Identify that you do business with AMS.
-Identify the deadline; date and time, for the Solicitation you need assistance with from the Service Desk.

Level 1 Service Desk hours are Monday through Friday from 7:00 a.m. to 5:00 p.m. central time.

The WBSCM system is off-line Sunday evenings from 4:00 PM to Midnight central time. Unplanned outages will be communicated through the WBSCM system.

B. WBSCM Offer Information
Only one bid price may be submitted for an item number.

C. Plant Location Requirement.
Plant location and the Place of Performance in Federal Acquisition Regulations provisions **52.214-14** (Apr 1985) and **52.215-6** (Oct 1997) shall match. Representations and Certifications are available online at the System for Award Management at website https://www.sam.gov/SAM/.

D. Supplier Agreement Requirement.

If the offer is for product the offeror will not itself manufacture, offeror shall, by the offer due date/time, submit the corresponding supplier agreement to, Attention: Contracting Officer at the solicitation information contact address shown in this solicitation. The supplier agreement shall be in effect between the offeror and the product manufacturer for the period of contract performance; certify compliance with the applicable solicitation requirements, contain the DUNS number for the product manufacturer, be on the product manufacturer's company letterhead, and be signed by both parties.

A prospective contractor may be required to provide written evidence of a proposed subcontractor's responsibility. The Contracting Officer may directly determine a prospective subcontractor's responsibility.

E. Business Size/Type Designation for Subcontracting.
An offer from a small business to supply manufactured products of small and large businesses shall be divided and submitted separately using separate WBSCM logon IDs. An offer from a farmer-owned cooperative large business to supply manufactured products of both a small business and other than small (i.e., farmer-owned cooperative large business or large business) shall be divided and submitted separately using separate WBSCM logon IDs. See information below.

Examples:
If offeror business size is small business and the manufactured product is subcontracted to a small business, then the WBSCM size designation is small business.

If offeror business size is small business and manufactured product is subcontracted to a Farmer-owned Cooperative large business or a large business, then the WSBCM size designation is large business.

If offeror business size is large business and manufactured product is subcontracted to a small or a large business, then the WBSCM size designation is large business

F. Offshore Items.
Items for delivery to offshore locations require the contractor to arrange and pay for ocean transportation in addition to the land transportation. Offshore examples are Hawaii, Puerto Rico, and the Virgin Islands. Offshore locations are identified by the cities and postal abbreviations shown at the level 3 Item data.

7. Invoices:
The contractor shall use the invoicing function in WBSCM. All invoice documents shall reference the WBSCM Purchase Order (PO) Number and PO Item Number, the Sales Order (SO) Number and SO Item Number or Purchase Requisition (PR) and PR Item Number.

A separate invoice should be submitted for each item number.

The System for Award Management at the website https://www.sam.gov/SAM/ is used for payment purposes. The contractor is responsible for controlling the accuracy of its business information.

8. Shipment/Delivery Schedule:
July 16, 2019 – August 31, 2019

See Schedule of Supplies for period of performance. A WBSCM Purchase Order will be available at least seven (7) calendar days prior to the first day of each period of performance scheduled in the contract. The Contractor shall comply with the instructions in the WBSCM Purchase Order. If a WBSCM Purchase Order is available less than seven (7) calendar days prior to the first day of the contracted period of performance, the performance period shall be extended by the number of days the WBSCM Purchase Order was not available. The Contractor shall not be entitled to any extension of the performance period unless it furnishes evidence satisfactory to the Government that it was prepared to perform during the contracted period of performance.

9. Other Requirements:
A. Bidders shall meet the Qualification Requirements in the Master Solicitation for Commodity Procurements-Domestic Programs (MSCP-D) at
https://www.ams.usda.gov/sites/default/files/media/MSCP.pdf

B. Contractor Past Performance Evaluation is applicable for contracts exceeding the simplified acquisition threshold of $150,000.

C. Rice Products Commodity Requirements Document, Section 1.2 WARRANTY is amended to read: The product shall have a shelf life of at least one year from date of manufacture. Product shall not be manufactured more than 30 days prior to shipping. Contractors are responsible for maintaining the manufacture information.

Contractors have the option of requesting that GIPSA include the RICE manufacturing date in the Applicant states portion of the RICE Grading certificate.

D. Rice Products Commodity Requirements Document, Section 1.1 COMMODITIES is amended to read:

> B. Brown Rice shall be U.S. No. 1 long grain, medium grain, or short grain brown rice for processing, as defined in the "United States Standards for Brown Rice for Processing," which is available at https://www.ecfr.gov/cgi-bin/text-idx?SID=1fb891ea4cd23e305528c37c85cb2a3c&mc=true&node=sp7.7.868.d&rgn=div6#se7.7.868_1261 in effect on the date the solicitation is issued. The Brown Rice for Processing shall have Total Broken Kernels maximum of 4 percent.

RICE PRODUCTS
Solicitation Description: 12-3J14-19-B-0364
Solicitation Number: 2000006096
Tendering Text

10. FAR and Agriculture Acquisition Regulation (AGAR) Provisions and Clauses:
In the event of a conflict between WBSCM and Federal Acquisition Regulation (FAR) terminology, FAR terminology shall take precedence.

A. This solicitation shall be subject to the terms and conditions of the Master Solicitation for Commodity Procurements-Domestic Programs (MSCP-D) in effect as of the date of this solicitation. See attached MSCP-D. The FAR and AGAR provisions and clauses applicable to this solicitation are contained in the MSCP-D and this solicitation.

B. // Applicable if checked. FAR Clause **52.232-18, Availability of Funds** (Apr 1984). Funds are not presently available for this contract. The Government obligation under this contract is contingent upon the availability of appropriated funds from which payment for contract purposes can be made. No legal liability on the part of the Government for any payment may arise until funds are made available to the contracting officer for this contract and until the contractor receives notice of such availability, to be confirmed in writing by the contracting officer.

Jeffrey F. Jackson
Senior Contracting Officer

Bid Certification Questions

Please note answering Bid Certifications Questions in WBSCM is a required component of the offer.

1. Data Universal Numbering System assigned by Dun and Bradstreet (DUNS) or DUNS plus four and Business Size Standard.

2. System for Award Management (SAM): The Offeror has completed entity registration electronically via entry into SAM at the website www.SAM.gov. The offeror is responsible for controlling the accuracy of its business information. The offeror verifies by submission of this offer that the SAM is accurate, complete, and current as of the date of this solicitation

   Yes No

2a. SAM Representations and Certifications (FAR 52.204-8(b): The Offeror has completed the representations and certifications electronically via entry into SAM at the website www.SAM.gov. After reviewing the representations and certifications database information, the offeror verifies by submission of the offer that the representations and certifications currently posted have been entered or updated within the last 12 months are accurate, complete, current, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see Far 4.1201); except for the changes identified below (OFFEROR TO INSERT CHANGES, IDENTIFYING CHANGE BY CLAUSE NUMBER, TITLE, AND DATE). These amended representation(s) and/or certification(s) are also incorporated in this offer and are accurate, complete, and current as of this date of this offer. Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on SAM.

3. Amendments to this Solicitation: If this solicitation is amended, then all terms and conditions which are not modified remain unchanged. The Offerors shall acknowledge receipt of any amendment to this solicitation by identifying the amendment number and date in the space provided: (Enter N/A if not applicable.)

   Amendment number and amendment date
   Non-applicable

4. All USDA contracts with the Offeror that have a Not-Later-Than date prior to solicitation opening

   Have been delivered
   Have not been delivered
   No previous contracts

5. The offeror certifies that the commercial-brand product to be delivered has a history of successful distribution and use in domestic commercial channels, is sold on the commercial market, and has an established level of consumer acceptance. Insert the commercial brand names(s) offered.

   Brand name and pack size

6. Plant location for all items has been verified pursuant to Place of Performance – Sealed Bidding?

   Yes
   No

7. Supplier Agreements; All non-manufacturers pursuant to the Submission of Offers, Supplier Agreement Requirement instructions, must furnish to the Government, at the time of offer, the name, address, telephone number, and business size (i.e., large or small) of the supplier. If the offeror is the manufacturer of the product they are offering under this solicitation, insert N/A.

7a. Supplier Agreement has been submitted pursuant to Capability Requirements.

   Yes
   No
   Not applicable

8. Each commodity offered meets the commodity specifications applicable to this Solicitation.

   Yes
   No

9. Please insert name, title, email, telephone and fax numbers of person submitting the offer.

9a. Please provide a 24-hour emergency Point of Contact (POC) information. The POC information should include: name, title, email, telephone and fax numbers.

United States Department of Agriculture

Agricultural Marketing Service
Commodity Procurement Staff
P.O. Box 419205, MS 8718
Kansas City, MO 64141-6205

USDA COMMODITY REQUIREMENTS

RP5
RICE PRODUCTS
FOR USE IN DOMESTIC PROGRAMS

Effective Date: February 4, 2016

USDA COMMODITY REQUIREMENTS
RP5
RICE PRODUCTS
FOR USE IN DOMESTIC PROGRAMS

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Part 1 COMMODITY SPECIFICATIONS

Section 1.1 COMMODITIES

A. Quality of Rice Products

Rice products delivered shall meet the specifications of the class and grade offered as defined in the "United States Standards for Milled Rice," in effect on the date the solicitation is issued. The standards are available at: http://www.gipsa.usda.gov/fgis/inspectionservices_ricestandards.aspx. Rice products shall be a US No. 2 or better well milled rice, unless so specified.

(1) Rice products, excluding Brown rice products, produced and delivered shall be enriched.

(2) Rice products of special grades "parboiled light" or "parboiled" which meets class and grade specifications of U.S. No. 1 will only be acceptable for those items specifying "parboiled." "Parboiled light" or "parboiled" shall not be substitutable for other classes of rice.

(3) Enriched rice products (including "parboiled light" or "parboiled") shall comply with the standards for enriched rice established by the FDA, in the Code of Federal Regulations, Title 21, Chapter 1, Part 137, Subpart B, Section 137.350, which is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm, except that the optional enrichment ingredients will not be included.

(4) Rice coated with talc and/or glucose, is not acceptable and will be rejected if delivered. No specialty, including but not limited to aromatic rice, will be acceptable unless specified in the solicitation.

B. Brown Rice shall be U.S. No. 1 long grain, medium grain, or short grain brown rice for processing, as defined in the "United States Standards for Brown Rice for Processing," which is available at http://www.gipsa.usda.gov/fgis/inspectionservices_ricestandards.aspx, in effect on the date the solicitation is issued.

C. Parboiled brown rice shall be U.S. No. 1 long grain brown rice or U.S. No. 1 medium grain brown rice which has a cooking time which falls within the range of 10 to 28 minutes.

D. All rice products for delivery to destinations in the State of Hawaii shall be U.S. No. 1 Medium Grain (California-grown) only.

E. Rice products for delivery to destinations in the State of Hawaii shall have a zero tolerance for Aeschynomene indica L., more commonly known as Kat sola, Indian joint vetch, Indian vetch seed or Indigo. The Grain Inspection, Packers & Stockyards Administration (GIPSA) will reject products destined for Hawaii which contain any portion of Aeschynomem indica L.

F. The Government will accept delivery of rice products grading better than the specified contract grade, but no adjustment in contract price will be made for rice products better than the contract grade.

Section 1.2 WARRANTY

Product shall not be manufactured more than 30 days prior to shipping. Manufactured date is defined as the calendar date on which the rice is milled.

A. The milled and parboiled rice products delivered shall have a shelf life of six months from the date of manufacture.

B. The brown rice products delivered shall have the following shelf life:

PRODUCT	TEMPERATURE	SHELF LIFE
Brown Rice	50˚ – 70˚ Fahrenheit	3 months
Brown Rice	30˚ – 40˚ Fahrenheit	6 months

Section 1.3 FUMIGATION

A. Not more than 10 days prior to packaging, the rice products shall be fumigated with the food safe formulations of Aluminum Phosphide, Carbon Dioxide, Methyl Bromide, or Sulfuryl Flouride in a quantity and manner which will effect a kill in all stages of weevil or other insect infestation. All fumigant must be applied according to the Environmental Protection Agency (EPA) label.

B. The contractor shall submit with its invoice for payment, a statement certifying that the rice products were fumigated in accordance with this requirement. The Fumigation Certificate shall indicate the chemical, Aluminum Phosphide, Carbon Dioxide, Methyl Bromide, or Sulfuryl Flouride used in the fumigation process. The Fumigation Certificate shall cite the actual date the rice was fumigated. The fumigator's license number shall be cited on the Fumigation Certification statement.

Section 1.4 INSPECTION

A. Inspection of the product shall be performed by the Grain Inspection, Packers & Stockyards Administration (GIPSA). Procedures to follow and a schedule of fees for this service may be obtained at http://www.gipsa.usda.gov/fgis/gradingprocedures.aspx, select Service Provider Information.

The applicant is responsible for providing all applicable contract documents and specifications to GIPSA. The quality, weight, and packaging of the product shall be evidenced by commodity inspection certificates issued by GIPSA. The GIPSA certificate must cite the Contract/WBSCM Purchase Order (PO), PO Item Number, Sales Order (SO) Number and SO Item Number or Purchase Requisition (PR) and PR Item Number. Contractors are required to notify the Government immediately of lots that fail to meet contract requirements.

B. Enrichment

The GIPSA certificate will also cite whether or not the rice is enriched. Testing of the product for enrichment, if applicable to the commodity, shall be performed by the Grain Inspection, Packers & Stockyards Administration (GIPSA). GIPSA shall verify the presence of enrichment for each inspected lot. Enrichment results will be shown in the factor section of the certificate.

Applicant statements in regard to enrichment will not be accepted by GIPSA.

C. Citations

The GIPSA certificate must cite the Contract/WBSCM Purchase Order (PO), PO Item Number, Sales Order (SO) Number and SO Item Number or Purchase Requisition (PR) and PR Item Number. Contractors are required to notify the Government immediately of lots that fail to meet contract requirements.

D. Shipping

Contractors shall not ship the product unless informed by GIPSA that the containers and markings meet the Acceptable Quality Level (AQL) of the "U.S. Standards for Condition of Food Containers," which are available at: http://www.access.gpo.gov/nara/cfr/waisidx_04/7cfr42_04.html. Notice by GIPSA that a designated lot scheduled for shipment does not meet the AQL will constitute rejection to the contractor of such lot. Except with respect to shipments that do not meet the AQL standards, the contractor may ship the product prior to receipt of the commodity testing and analysis results (when required) in which event the contractor assumes all risks and liabilities that arise with respect to the failure of the shipped product to meet contract specifications.

E. If the product fails to meet contract specifications on one or more factors on the first inspection, the contractor may arrange with GIPSA subsequent inspections of the commodity. The inspections may be conducted at origin or a subsequent point of delivery if the provisions of Title 7 CFR 68.44 through 68.63 issued under the Agricultural Marketing Act of 1946, as amended, with respect to retest, appeal, and new inspections can be met. When subsequent inspections of the product are made, the results of the last inspection will be used as the basis for payment under the contract.

F. Checkloading

All rice shall undergo checkloading. Checkloading shall be performed by the Grain Inspection, Packers & Stockyards Administration (GIPSA) or their authorized designee(s). GIPSA checkloading shall include the process of performing a stowage examination on a carrier, computing the number of filled rice containers loaded aboard the carrier, observing the condition of the rice containers loaded aboard the carrier, witnessing the sealing the carrier, if practicable, and certifying the results.

GIPSA checkloading, including witnessing sealing the carrier, does not release the contractor from, or take the place of the seal requirements, cited in the Master Solicitation for Commodity Procurements, Seals on Transportation Conveyances.

G. Hawaii California-grown

Rice for delivery into the State of Hawaii shall be "California-grown." The Grain Inspection, Packers & Stockyards Administration (GIPSA) will provide one of the following statements, if known not to be false or misleading, in the Remarks Section of the Rice or Commodity Inspection Certificate:

"Applicant states that the variety of this rice is (variety)."
"Applicant states that this rice was grown in the State of (state)."

The Contractor will ensure this information is provided on the Application for Inspection provided to GIPSA's inspector prior to inspection.

Section 1.5 "KOSHER ONLY" PRODUCTS

"Kosher Only" products will be identified in the solicitation. Kosher only products shall comply with applicable dietary (kosher) laws as established by the "613 Council of Kashruth." Manufacturing plants shall be certified for compliance with the aforementioned requirement by contacting the Board of Jewish Education of Greater New York (BJENY) at 646-472-5365. A rabbinic supervisor will be sent to certify compliance of the manufacturing plant with the dietary (kosher) laws.

Offeror shall certify that their manufacturing plant is capable of meeting applicable dietary (kosher) laws as established by the "613 Council of Kashruth" and certification by BJENY.

Part 2 CONTAINER AND PACKAGING REQUIREMENTS

Section 2.1 GENERAL

This part provides the container specifications and packaging materials requirements used under this contract.

Section 2.2 COMMERCIAL PACKAGING

A. Contractors shall supply commercial brand products only and shall certify at the time of submission of an offer that the commercial product being delivered has a history of successful distribution and use in domestic commercial channels and is sold on the commercial market with an established level of consumer acceptance.

B. Container and packaging requirements are those used in the current commercial shipping practices and shall comply with:

(1) Unitization requirements in Section 2.4.
(2) At contractor's option, a statement such as "Not for Retail Sale" may be printed on the principal display panel of the food label.
(3) The manufacturer's lot code/lot identification number shall be shown on the commercial bill of lading.
(4) Shipping containers shall be marked to show the maximum safe stacking height. It is the responsibility of the contractor in cooperation with the shipping container manufacturers to determine the safe stacking height.
(5) For identification upon receipt at delivery warehouses, all commercial-labeled product shipping documents shall specify "FOR USDA FOOD DISTRIBUTION PROGRAMS."

C. All labels shall cite any enrichment ingredients.

Section 2.3 CONTAINERS AND MATERIALS

A. All containers and packaging shall be constructed to meet the requirements of the Food and Drug Administration (FDA) for safe contact with the packaged product. The contractor shall obtain and maintain documentation from the container or packaging material manufacturer to verify that the containers and packaging materials used in this contract were in compliance with the Government's regulatory requirements for safe contact with food products as required in the Master Solicitation for Commodity Procurement, Regulatory Requirements for Commodities and Packaging.

B. Questions concerning the containers and materials should be directed to:
Senior Contracting Officer
Ray Boyd
Telephone (816) 926 2612 or Email Roy.Boyd@ams.usda.gov

C. If the contractor purchases packaging and container ingredients from a foreign country and/or the package and container is manufactured in a foreign country, the package and container SHALL NOT display country of origin labeling. Phrases similar to but not inclusive of, "Made in [Name of Foreign Country.]" or "Product of [Name of Foreign Country.]" are strictly prohibited

Section 2.4 UNITIZATION REQUIREMENTS

Shipments shall comply with the following unitization requirements:

A. Unless otherwise specified by the Government, all shipments of packaged products shall be unitized (palletized and stretch wrapped).

B. Pallets shall be:
(1) Constructed to facilitate the safe handling and transportation of the packaged product, as a unit, without loss or damage.

(2) A Number 2, four-way, reversible flush stringer with no broken runners or slats.
(3) Suitable for use in the shipment of food products.

C. Plastic stretch wrap shall be:
(1) Constructed of a plastic film which is to be stretched a minimum of 50 percent beyond its original length when stretched around the pallet load.
(2) Applied as tightly as possible around all tiers of the palletized shipping containers. The shipping containers shall be held firmly in place by the stretch wrap.

D. Pallet loads shall be:
(1) Stacked in such a way as to minimize the amount that shipping containers overhang the edges of pallets.
(2) Blocked and braced or otherwise loaded into the conveyance in a manner that prevents shifting during transit.

E. USDA does not participate in pallet exchange.

GLIFWC Model Food Code

December 2020

As developed by the Great Lakes Indian Fish and Wildlife Commission as part of its "Chippewa Ceded Territory Traditional Food Regulatory System Project," with funding provided by the Administration for Native Americans and the Bureau of Indian Affairs.

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Chapter 1 – Purpose and Applicability

1.01 Purpose

(1) This Title should be applied to promote the purpose of this ordinance described in subsection (3), below, and to promote the health and general welfare of the _____ [Tribe] people, their culture, economy, and natural resources through food and agricultural production using materials hunted, fished and gathered pursuant to the _____ [Tribe's] rights reserved in the [Treaty of 1836] [Treaty of 1837] [Treaty of 1842] [Treaty of 1854].

(2) It is not the intent of this Title to waive the sovereign immunity of the _____ [Tribe] or any of its agencies or instrumentalities through the passage of this Title or with regards to any provisions contained therein. Nothing in this Title or amendments thereto shall be construed as a waiver of sovereign immunity on the part of the _____ [Tribe] absent a recorded, express waiver of sovereign immunity.

(3) Our traditional foods are derived from the plant, fish, and animal beings living within the Ceded Territories, given as gifts by Gichi-Manidoo, and thus are integral to the spiritual and cultural identity of the Anishinaabeg. Access to these traditional foods, for all Anishinaabeg, is critical for our survival, to decrease incidents of chronic disease and to achieve overall wellness. Without the continued availability of plants, fishes, and animals, the Anishinaabeg would cease to be as Gichi-Manidoo made us.

1.02 Applicability

(1) The provisions contained herein apply to all individuals and facilities involved in the harvesting, processing, transporting, packing and holding of food products derived from wild animals and plants harvested by a member or members of the _____ [Tribe] within the Tribe's Ceded Territories and/or within the exterior boundaries of the _____ Reservation for processing as food for commercial sale and

donation to Indian Tribal Operations and Child Nutrition Programs and do not apply to the following activities:

(a) Informal commercial sale, as defined in Sec. 2.01 [Definitions], located within the exterior boundaries of the _____ Reservation;

(b) Home use of treaty-harvested foods, including informal distribution of treaty-harvested foods among tribal families;

(c) Community feasts, as defined in Sec. 2.01 [Definitions]; and

(d) Sale of whole deer and elk carcasses pursuant to the tribes' applicable off reservation conservation codes.

(2) This Title applies to the processing and production of food derived from treaty-harvested animals, plants and fungi hunted, fished and gathered on-reservation and off-reservation within the _____ Tribe's Ceded Territories, consistent with permits and authorizations of the _____ [Tribe], pursuant to the applicable tribal regulations pertaining to those activities, but does not apply to foods derived from species considered endangered, threatened or protected under applicable tribal laws.

1.03 Territorial Applicability and Jurisdiction

(1) This Title shall apply within the exterior boundaries of the _____ Reservation, and areas outside of the exterior boundaries of the _____ Reservation within the Ceded Territories subject to rights reserved by the [Treaty of 1836] [Treaty of 1837, Treaty of 1842, Treaty of 1854], but not including any part of the Menominee Nation Reservation. The _____ [Tribe] assumes and retains jurisdiction over all lands and waters not within the exterior boundaries of the _____ Reservation as permitted by any law, convention, charter, compact and/or agreement.

(2) The Tribal Court of the _____ [Tribe] shall have exclusive jurisdiction to prosecute violations of this Title.

1.04 Rights Reserved

Nothing in this title, or any regulations adopted pursuant hereto, shall diminish the rights reserved by the _____ [Tribe] and its members by the [Treaty of 1836] [Treaty of 1837, Treaty of 1842, Treaty of 1854] or deprive the [governing body] of the _____ [Tribe] of the right to modify, amend or repeal this title.

Chapter 2 – Definitions

2.01 Definitions

The words in quotations shall be defined within this Title as follows:

(1) **"Adequate"** means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(2) **"Adequately reduce microorganisms of public health significance"** means reduce the presence of such microorganisms to an extent sufficient to prevent illness.

(3) **"Adulteration" or "Adulterated"** means food that:

(a) Bears or contains any poisonous or deleterious substance in a quantity which may render it injurious to human health, including containing any hard, inedible fragments of material measuring 7 mm or larger in any direction; or

(b) Bears or contains any poisonous or deleterious substance for which no safe tolerance has been established by law; or

(c) Consists in whole or in part of any filthy, putrid or decomposed substance, or is otherwise unfit for human consumption; or

(c) Has been processed, packed or held in unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have become injurious to human health; or

(d) Has been processed, prepared, packed or held under any insanitary conditions whereby there is a reasonable probability that it might have been contaminated with filth or rendered injurious to health; or

(e) Is in whole or in part the product of a diseased animal or an animal which has died otherwise than by slaughter or lawful harvest in the wild with the application of appropriate field-dressing techniques; or

(f) Is packaged within a container comprised in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health.

(4) **"Amenable wild-harvest food"** means safe, wholesome and unspoiled foods derived from free-ranging animals, plants and fungus available for harvest by Anishinaabeg of the _____ [Tribe] within the _____ Reservation and ceded territories.

(5) **"Animal excreta"** means liquid or solid animal waste.

(6) **"Class 1 food"** means those foods processed pursuant to this Title, available for sale within the exterior boundaries of the _____ Reservation, to individual tribal members only.

(7) **"Class 2 food"** means those foods processed pursuant to this Title, available for sale to Indian Tribal Organizations and Child Nutrition Programs for which a majority of the consumers served are tribal members.

(8) **"Class 3 food"** means those foods processed pursuant to this Title, available for sale to a general consumer base, which includes non-tribal members and retail institutions.

(9) **"Community feast"** means the provision of ready-to-eat food for an Anishinaabe cultural or spiritual purpose by members of the _____, where no monetary exchange is necessary or expected.

(10) **"Corrective action"** means procedures to be followed when a deviation occurs.

(11) **"Covered produce"** means produce (e.g. blueberries, raspberries, blackberries, salad greens, etc.), which is consumed raw and not subject to commercial processing that adequately reduces the presence of microorganism of public health significance. Covered produce does not include produce that is rarely consumed raw, such as: beach peas, cranberries, hazelnuts, wild mushrooms and fiddlehead ferns.

(12) **“Critical Control Point”** means a point, step or procedure in a food process at which a control can be applied, and a food safety hazard can as a result, be prevented, eliminated or reduced to acceptable levels.

(13) **“Critical limit”** means the maximum or minimum value to which a physical, biological or chemical parameter must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level, the occurrence of the identified food safety hazard.

(14) **“Cross-contact”** means unintentional incorporation of a food allergen into another food through accidental transfer.

(15) **“Cross-contamination”** means transfer of pathogens from food or a surface to another food or food contact surface.

(16) **“Field dressing”** means the removal of internal organs of a wildlife carcass, which is performed at or near the point of kill.

(17) **“Fish”** means a limbless cold-blooded vertebrate animal with gills and fins, living wholly in water.

(18) **“Fishery product”** means any human food product in which fish is a characterizing ingredient.

(19) **“Food”** means any raw, cooked, or processed edible substance, or beverage, or ingredient intended for human consumption and includes ice and water.

(20) **“Food contact surface”** means those surfaces that contact human food, including the surfaces of equipment and utensils, and those surfaces from which drainage, or other transfer, onto food or other food surfaces ordinarily occurs during the normal course of operations.

(21) **“Food processing plant”** means any place used primarily for the processing of class 2 and 3 foods. Food processing plant does not include a residential dwelling or any of the following: (1) a retail

food establishment, restaurant, or other similar establishment if the amenable wild-harvest food processing activities at the establishment are authorized by a license; (2) a harvest vessel, if practices are limited to those such as heading, eviscerating or freezing fish for holding on board; (3) a place used solely for washing or packaging fresh or otherwise unprocessed produce; (4) a place solely used for field-dressing wild game prior to further processing; or (5) a place solely used for processing a limited volume of low-risk foods and/or class 1 meat products and/or class 1 fish products.

(22) **"Food safety hazard"** means any biological, chemical or physical property that may cause a food to be unsafe for human consumption.

(23) **"Game animal"** means an individual of a wildlife species of animal used by the Anishinaabe for food that has not been raised in captivity.

(25) **"HACCP system"** means the HACCP plan in operation, including the HACCP plan itself.

(26) **"Hazard or hazardous"** means any biological or chemical agent that has the potential to cause injury in the absence of its control.

(27) **"Harvest"** when used in reference to wildlife animals, means the killing of the animal.

(28) **"Informal commercial sale"** means the provision of ready-to-eat food, in an irregular or non-reoccurring basis, prepared on behalf of the _____[Tribe] or by members of the _____ [Tribe] for a commercial purpose, where the majority of the consumers are members of the _____ [Tribe].

(29) **"Information fact panel"** or **"IFP"** means a label with required information that appears on a location on the product other than the front of the product.

(30) **"Jerky"** means a ready-to-eat (RTE) dried meat product that is considered shelf stable (i.e. does not require refrigeration after proper processing).

(31) **“Low-acid fruit preserves”** means fruit jelly, fruit jam and fruit preserves with a pH of 4.6 or lower.

(32) **“Low-acid pickled produce”** means produce, which has been pickled or packed in a can or jar for pickling, with a pH of 4.6 or lower.

(33) **“Low-risk food”** means a food item intended for human consumption that does not require a time and temperature control or refrigeration to remain safe, and has been shown to not support the growth of pathogenic bacterial or other foodborne pathogens.

(34) **“Lot”** means the food produced during a period of time indicated by a specific code.

(35) **“Manoomin”** means the ripened seeds of manominagaawanzh (northern wild rice or *Zizania palustris*).

(36) **“Microorganism”** means yeasts, molds, bacteria, viruses, protozoa and microscopic parasites and includes species having public health significance.

(37) **“Monitor”** means to conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement.

(38) **“Package or packaging”** means to contain food within a bottle, can, carton or secure wrapping.

(39) **“Packing”** means placing food into a container other than packaging and also includes activities performed incidental to packing or re-packing a food (e.g. sorting, culling, grading and weighing or conveying incidental to packing or re-packing), but does not include any process that would transform the food from its raw, uncooked state.

(40) **“Plant harvesting”** means the removal of raw wild plant matter or fungi from the place where it grows in order to prepare it for use as human food. Examples of plant harvesting include

brushing off dirt from its surface, cooling, field coring, filtering, gathering, drying, parching, hulling, shelling, threshing, trimming off outer leaves and washing. Plant harvesting does not encompass activities that constitute processing.

(41) **"Preventative measure"** means physical, chemical or other factors that can be used to control an identified food safety hazard.

(42) **"Principal display panel"** or **"PDP"** means the part of the food label most likely to be displayed to the customer when the product is offered for sale, also refers to the front label on a product.

(43) **"Process-monitoring instrument"** means an instrument or device used to indicate conditions during processing at a critical control point.

(44) **"Processing"** means the manufacture or preparation of foods for sale through the process of canning, extracting, fermenting, distilling, pickling, freezing, baking, smoking, grinding, cutting, deboning, mixing, coating, stuffing, bottling, packaging or through any other treatment or preservation process. Processing does not include the following:

(a) Harvesting, transporting or storing wild foods or wild food products, without otherwise engaging in processing;

(b) Practices such as heading, eviscerating or freezing fish, and field-dressing animals, solely to prepare that fish or animal for transportation from the water or the field; or

(c) The operation of a retail food establishment.

(45) **"Processor"** means any person engaged in the processing of food for sale or donation pursuant to this Title.

(46) **"Produce"** means any fruit, vegetable or mushroom and includes tree nuts and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (e.g. blueberry or hazelnut). A vegetable

is the edible part of an herbaceous plant (e.g. fiddlehead fern or wild ramp) or the fleshy fruiting body of a mushroom (e.g. morel mushroom). Produce does not include food grains, such as wild rice and amaranth seeds.

(47) **"Qualified small and very small business"** means a plant harvester that is subject to any of the requirements of Chapter 7 [Produce], and on a rolling basis, the average monetary value of the produce they sold during the last 3 years is no more than $500,000, and the majority of sales are direct sales to consumers of the food; or restaurants, food service institutions or retail food establishments that are located:

(a) in the same state or Indian reservation as that the produce was harvested; or

(b) is located no more than 275 miles from the plant harvester's residence.

(48) "**Raw plant material**" means an agricultural commodity in its raw or natural state, including all fruits, vegetables and mushrooms that are washed, brushed off or otherwise treated in the uncut natural form, and manoomin that is parched, threshed and sorted.

(49) "**Ready-to-eat foods" or "RTE foods**" means foods that require no further processing prior to consumption.

(50) **"Retail food establishment"** means a permanent unit or location within the exterior boundaries of the _____ Reservation within which food is processed on site, or made available, intended for individual consumption, and where goods may be purchased by individuals or entities who are not members of any federally recognized Indian tribe. The term includes any such place whether consumption is on or off premises, including but not limited to the following:

(a) A restaurant or eating/drinking establishment;

(b) A market or grocery;

(c) A catering business;

(d) A bakery or confectionary; or

(e) A convenience store or gas station.

The following entities are excluded from the definition: _____.

(51) **"Sanitize"** means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer**.**

(52) **"Sanitization"** means effective treatment by a process that provides enough accumulative heat or concentration of chemicals for enough time to reduce the count of microorganisms of public health significance to a safe level on clean surfaces, utensils and equipment.

(53) **"Smoked or smoke-flavored fishery products"** means the finished food prepared by:

(a) Treating fish with salt (sodium chloride); and/or

(b) Subjecting it to the direct action of smoke from burning wood, sawdust or similar material and/or imparting to it the flavor by a means such as immersing it in a solution of wood smoke.

(54) **"Syrup"** means a liquid derived from sugar-rich tree sap, which is not less than 66 degrees Brix.

(55) **"Sugar"** means a solid, grainy or viscous substance derived from sugar-rich tree sap, which was boiled beyond 66 degrees Brix and stirred.

(56) **"Toxic"** means any substance which may have an adverse physiological effect on a person or persons.

(57) **"Traditional food"** means foods and beverages from pre-colonization times that are or have become part of the Anishinaabe diet and food ways.

(58) **“Traditionally safe methods”** means a way of producing and/or preparing food using cultural practices specific to the _____ [Tribe] that have been proven to be safe over past generations.

(59) “**Tribal mushroom harvester**” means a member of the _____ who harvests, picks or collects wild mushrooms for sale or donation as a class 1, 2 or 3 food.

(60) **“Utensil”** means any implement used in the storage, preparation, transportation or service of food.

(61) **“Vehicle”** means any van, truck, trailer, cab, bus, cycle, automobile, push cart, wagon or any other means of conveying food on land.

(62) **“Wildlife Animal”** means an undomesticated mammal or bird found within free-ranging populations within the _____ Tribe’s [reservation/Ceded Territories].

Chapter 3 – General Provisions

3.01 Zhawenindiwag; Respect for Traditional Foods and Consumers

(1) All individuals and entities harvesting and processing food pursuant to this Title shall handle that food in a respectful manner in order to prevent their adulteration and to remain consistent with our cultural traditions.

(2) Only food which is amenable wild-harvest food may be donated or sold pursuant to this Title. No adulterated food may be donated or sold pursuant to this Title.

3.02 Debwewin; Truth in Labeling

(1) All foods processed in accordance with this title shall be labeled in a truthful manner and not be labeled in a manner that is false or misleading. The information required to be displayed on labels as described in this subsection shall be prominently displayed in readable format, with letters and numbers measuring no less than one-sixteenth of an inch.

RESPECT IS FOUNDATIONAL

The employment of food safety practices builds upon established cultural norms of the Anishinaabeg that protect both the consumers and the sustainability of the harvest. Wild harvested foods are offered to the Anishinaabeg through a complex network of relationships and obligations: among the Anishinaabeg and their plant and animal relatives; among living Anishinaabeg and past and future generations; and among physical and spiritual beings. “Zhawenindiwag” is the Ojibwe word for the act of reciprocal mercy, compassion and love. Within this Model Code, zhawenindiwag is a reference to the reciprocal generosity that both humans and more-than-humans benefit from in order to strive for Anishinaabe inaadiziwin. In recognition of the interconnected-ness of purposeful existence, respect is a key value.

Section 3.01 sets a general standard related to overall food safety. Keeping food safe requires individuals and entities to respect necessary food safety standards, many of which are contained in this code. Tribes may have specific standards related to the manner in which various foods are harvested or processed. For example, many communities regulate the manner in which manoomin is harvested to ensure that harvesters are engaging in respectful conduct that comports with community standards. Additional protocols can be added to the model code as tribes deem necessary.

In drafting this Model Food Code, attempts have been made to center Anishinaabe traditional customary laws and practices. The production of safe, nutritious food has been essential to achieve and maintain a sovereign and sustainable existence. Food safety and contamination reports produced by GLIFWC as part of the “Chippewa Ceded Territory Traditional Food Regulatory System Project” and other reports produced by GLIFWC and its member Tribes demonstrate that these practices produce consistently safe foods.

(a) Wild rice shall not be labeled “natural wild rice” or “hand-harvested wild rice” unless the contents of the package consist entirely of hand-harvested wild rice and contain no mechanically-harvested wild rice or wild rice grown with the use of chemical fertilizers or herbicides.

(b) Maple syrup shall not be labeled “traditionally processed Ojibwe maple syrup” unless the contents of the package consist entirely of maple sap that was condensed into syrup by the heating of the sap over a wood-burning fire, however a final boil of the sap may occur using a heating element other than a wood-burning fire.

(c) Mushrooms shall be contained within packaging materials consistent with Sec.7.03(2), segregated by mushroom species, bearing a label containing the following information:

(i) Common name of mushroom species (e.g. “black trumpet”), followed by scientific name (e.g. *Craterellus cornucopioides*);

(ii) Harvester name and address;

(iii) The following consumer advisory, “WILD MUSHROOMS: CLEAN WELL AND COOK THOROUGHLY BEFORE CONSUMING”; and

(iv) Date of harvest.

(2) Except for produce, all class 2 and 3 foods shall be labeled according to the following standards.

(a) The following information shall be displayed on the principal display panel (“PDP”) of the label:

(i) Statement of identify, which is the common name for the food contained; and

(ii) Net quantity of contents, which is the amount of food contained in the package, listed in an appropriate measurement.

(b) The following information must be displayed on an information fact panel ("IFP") if it is not displayed on the PDP.

(i) Nutrition facts, unless the food is exempt from nutrition labeling pursuant to Sec. 3.02(g);

(ii) An ingredient statement if the product contains two or more ingredients.

(I) The ingredient statement shall contain the word "INGREDIENTS:" followed by a listing of ingredients in order of decreasing predominance by weight;

(II) if any of the ingredients constitute major allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans), the major allergen shall be clearly and prominently listed on the label, along with the name of the food source from which the major allergen is derived (e.g. "FISH (lake trout)").

(III) if any of the ingredients constitute an added artificial flavoring, coloring or chemical preservative, the name and function of the added flavoring, coloring or chemical preservative shall be listed in the ingredient list;

(iii) Signature line displaying the name and address of the product's manufacturer, packer or distributor.

(iv) A production sales date, or lot or code number identifying the specific product;

(v) If applicable, special handling instructions required to maintain the wholesomeness of the food. The following products must be labeled with special handling instructions:

(I) Frozen fish and meat products shall be labeled with a “KEEP FROZEN” statement (e.g. “Important, keep frozen until used, thaw under refrigeration immediately before use.”)

(II) Smoked fish and fresh, unfrozen fish shall be labeled with the statements “PERISHABLE" and/or “KEEP REFRIGERATED AT 38° F (3.33° C) OR LESS."

(III) Frozen fish that are vacuum sealed shall be labeled: “KEEP FROZEN UNTIL USED; THAW UNDER REFRIGERATION OR CUT PACKAGING WHILE THAWING UNDER COOL RUNNING WATER."

(IV) Uncooked meat products, which are not shelf-stable, shall be labeled: “KEEP REFRIGERATED AND COOK TO A MINIMUM INTERNAL TEMPERATURE OF 160°F.”

(vi) If date labels are included on any food product labels, these date labels must be consistent with the following standards:

(I) “BEST if Used by” and “BEST if Used or Frozen by” shall be used to indicate the quality date of a product.

(II) “USE by” or “USE or FREEZE by” shall be used to indicate the safety date of a product.

(III) “SELL by” dates, printed on product labels which are visible to consumers shall be prohibited [five years from the date that the Code is adopted into tribal law].

(3) Labeling standards for products produced outside of a tribally-licensed food processing plant.

(a) Any class 1, 2, or 3 foods, except manoomin, maple syrup and maple sugar, and produce, which are prepared, processed or packaged outside of a licensed food processing plant shall include the following disclosure in 12-point font, “PROCESSED AND PACKAGED IN A HOME FACILITY.”

(b) If a class 1 food contains any ingredients that constitute major allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans), the major allergen shall be clearly and prominently listed on the label, along with the name of the food source from which the major allergen is derived (e.g. “FISH (lake trout)”).

(4) Inspection Legend.

(a) Meat which has been inspected and passed pursuant to Sec. 5.05 [Post-Mortem Inspection] shall bear a tribal inspection legend. The legend shall be clearly visible to the prospective purchaser on all packages and containers of products.

(b) The legend shall consist of (symbol or shape, as determined by each tribe), enclosing the words, “_____ (tribal licensing authority) INSPECTED” and the tribal food processing plant license number assigned to the facility by the _____ (tribal licensing authority).

(5) Prohibited Labeling Practices.

(a) No person or entity may apply, to any meat or poultry product, any mark, legend or label that is false, deceptive or misleading.

(b) No person or entity may misrepresent that the _____ (tribal licensing authority) has inspected meat products, or misrepresent the _____ (tribal licensing authority)'s inspection findings related to meat products.

(c) No person or entity may misrepresent that any meat products have been processed at a tribally licensed food processing plant, or is derived from meat inspected and passed by the _____ (tribal licensing authority).

(d) No person or entity may wrongfully alter or remove any mark or label applied under this section.

(e) No person or entity may sell, transport or store any class 1, 2 or 3 food that is not marked, labeled or identified according to this section.

3.03 Food Additives

(1) Added Flavors. The label of a Class 2 or 3 food product to which spices or other natural flavors are added shall declare such flavors in the list of ingredients, as required, in order by weight, with the largest quantity listed first.

(a) Spices may be declared either by their specific common or usual name, or declared generally as "spices."

(b) Substances obtained by cutting, grinding, drying, pulping or similar processing of vegetables (e.g. powdered or granulated onions, garlic powder and celery powder) are considered foods rather than spices and shall be declared by their common or usual name.

(c) Any salt (sodium chloride) used as an ingredient shall be declared by its common or usual name "salt."

(d) Water added to food shall be listed as an ingredient.

(2) Added colors and preservatives. Only artificial and natural colors, and preservatives, which are considered food-safe may be added to food products, and may only be added in amounts, and for

purposes, which are safe for human consumption. Added colors and preservatives, and the purpose for which it was added, shall be declared on the list of ingredients, as required, in order by weight, with the largest quantity listed first.

(3) Standard for Packaging. If any Class 1, 2 or 3 food is contained within packaging materials, those packaging material shall be clean, composed of substances that are "generally recognized as safe" or "approved food contact substances" and are appropriate to contain the type of food packaged.

3.04 Personnel

(1) Each individual engaged in the harvesting of plants or animals intended as a class 1, 2 or 3 food, or the processing, packaging, packing, transporting or holding of food donated or sold pursuant to this Title (including temporary and seasonal personnel) or in the supervision thereof must:

(a) Possess the education, training and experience (or a combination thereof) necessary to manufacture, process, pack or hold clean and safe food as appropriate to the individual's assigned duties and as required by this Title; and

(b) Receive training in the principles of food hygiene and food safety, including the importance of health and personal hygiene, as appropriate to the food, the facility or operation, and the individual's assigned duties.

(2) All tribal mushroom harvesters shall successfully complete training on mushroom identification and harvesting as required by the _____ [tribal licensing authority]. Evidence of the completion of this training shall be maintained by each tribal mushroom harvester, with these records available upon request of the _____ [tribal licensing authority].

(3) Cleanliness. All persons working in contact with food, food-contact surfaces and product packaging materials must adhere to hygienic practices while on duty to prevent adulteration of foods sold or donated pursuant to this Title and the creation of unsanitary conditions.

(4) Clothing. Aprons, frocks and other outer clothing worn by persons who handle food sold or donated pursuant to this Title must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent the adulteration of product and the creation of unsanitary conditions.

(5) Disease control. Any person who has or appears to have an infectious disease, open lesion, including boils, sores or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in the adulteration of food and the creation of unsanitary conditions until the condition is corrected.

(6) Records pertaining to a facility's personnel shall be retained pursuant to Sec. 3.10 [Recordkeeping].

3.05 Food Transportation and Storage

(1) No one shall transport or store food under conditions which fail to protect the food against biological, chemical (including radiological) and physical contamination, as well as against deterioration of the food and any food container used.

(2) Containers, such as plastic coolers, used for the transportation and storage of food shall be made of food-grade materials that are either cleanable or designed for single use, are clean and sanitary prior to the addition of foods, and suitable for the type of foods being contained.

(3) If a vehicle, food trailer or container is used for the processing or receiving of a certain type of food (e.g. fresh-caught fish), no one shall use that conveyance for the holding, processing or transportation of a different type of food (e.g. ready to eat food) until and unless that conveyance has been sufficiently cleaned and sanitized. In addition, vehicles, food trailers and containers used for the conveyance of garbage, manure or other debris, may not be used for the storage or transportation of food without first being carefully cleaned and sanitized.

(4) Vehicles, food trailers and containers shall be inspected for cleanliness, odors, obvious dirt and debris before beginning the loading process. All food must be loaded for transport in a manner designed to minimize physical damage to the food and reduces the potential for contamination.

(5) Food storage areas shall be cleaned regularly to remove all visible debris, dirt and soil. No one shall store or transport food without taking precautions to prevent the cross-contamination of ready-to-eat foods and raw agricultural commodities by raw food products and the contamination of food from free-floating dust and other airborne contaminants.

(6) Temperature Control During Transport. If transported foods require time and temperature controls for safety, the following applies:

(a) Adequate monitoring of temperature during transport and storage shall be conducted and reports documenting the monitoring shall be created and maintained according to record maintenance schedules set forth in Sec. 3.10 [Recordkeeping].

(b) The temperature of potentially hazardous foods (non-shelf stable meat, fish, cooked manoomin and other foods which require time and temperature controls for safety) shall be kept at 45°F, or below, or at 140°F, or above, at all times, except as otherwise provided in this Title.

(c) Food needing refrigeration must be loaded in a manner that allows proper refrigerated air circulation.

3.06 Equipment and Utensils

(1) All equipment and utensils used in processing, packing or holding food sold or donated pursuant to this Title must be so designed, and of such material and workmanship, as to be adequately cleaned and sterilized through the application of sanitation SSOPs, HACCP plans or Harvest Safety Plans, as applicable.

(2) Receptacles used for storing equipment and tools must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of unsanitary conditions. Receptacles for storing inedible material may never be used for storing any edible product and must bear conspicuous and distinctive markings identifying permitted uses.

(3) Process-monitoring instruments or controls used to measure, regulate or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be:

(a) accurate and precise as necessary in keeping with their purpose;

(b) adequately maintained; and

(c) adequate in their number for their designated uses.

3.07 Handling of Inedible Food Byproducts

(1) All inedible food bi-products shall be immediately separated from wholesome food products and placed into waste bins clearly marked as “CONDEMNED, NOT FOR USE AS FOOD,” which are covered and disposed of at or before the close of the day upon which they were condemned. These waste bins shall not be used for any other purpose. Inedible fish and plant waste may be disposed of in an off-site composting facility, as appropriate.

(2) Waste generated by any licensed facility or vendor must be regularly removed from the facility and grounds by a waste handler licensed to handle those waste products, or transported to a waste handling facility in a sanitary manner, with care taken to avoid the contamination of any food, or object or container that will come into contact with food.

3.08 Sanitation Control Procedures; Good Manufacturing Practices

(1) Sanitation SOP. Each establishment licensed as a food processing plant (Sec. 3.11), retail food establishment (Sec. 3.12), and each facility of a class 1 meat vendor (Sec. 5.09) or class 1 fish vendor (Sec. 6.05), shall have and implement a written sanitation standard operating procedure (herein

referred to as SSOP) or similar document that is specific to each location (including mobile processing station) where treaty harvested food products are produced, stored and/or sold. The SSOP should specify how the establishment will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section. The SSOP shall be signed and dated by the individual with overall authority in the establishment. This signature shall signify that the establishment will implement the SSOPs in accordance with the requirements set forth in subsection (2). The SSOP shall be signed and dated upon initially implementing the SSOP and upon any modification to the SSOP.

(2) Sanitation monitoring. The individual with overall authority in the establishment shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices that are both appropriate to the plant and the food being processed and relate to the following:

(a) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;

(b) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(c) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;

(d) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(e) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(f) Proper labeling, storage, and use of toxic compounds;

(g) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(h) Exclusion of pests from the food processing and storage premises.

The establishment shall correct in a timely manner, those conditions and practices that are not consistent with the SSOP. SSOPs shall be routinely evaluated for effectiveness and shall be revised both as necessary and current with respect to changes in the facilities, equipment, utensils, operations or personnel.

(3) Sanitation control records. Each establishment licensed as a food processing plant (Sec. 3.11) or retail food establishment (Sec. 3.12), and each class 1 meat vendor (Sec. 5.09) or class 1 fish vendor (Sec. 6.05) shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements set forth in Sec. 3.10 [Recordkeeping].

(4) Relationship to Hazard Analysis Critical Control Point (HACCP) plan. If sanitation controls are monitored in accordance with this part, they need not be included in the food plant's HACCP plan.

3.09 Variance

Operators, owners and agents in charge of a food processing plant, retail food establishment and class 1 meat vendors, class 1 fish vendors, low risk food vendors and non-exempt produce harvester may request from the _____ [tribal licensing authority], a variance from requirements set forth in this Title. All variance requests must be written documents specifying: (1) the provisions that require a variance; (2) the reason for the request; and (3) alternative procedures that will be employed in lieu of the standards in this Title. In making decisions on variance requests, the_____ [tribal licensing authority] shall consider: (1) the type of foods that are handled within the food processing plant, retail food establishment or by that vendor; (2) the food safety risks associated with those foods; and (3) whether the alternative procedures proposed are

sufficiently protective of health and safety. Procedures that are consistent with ways of producing and preparing foods using cultural practices specific to the _____ [Tribe] that have proven to be safe over past generations shall be eligible for the issuance of variances. If a variance is approved by the _____ [tribal licensing authority], the decision shall be issued in writing, and dated. The requestor shall maintain a copy of the decision consistent with the schedules contained within Sec. 3.10 [Recordkeeping].

3.10 Recordkeeping

(1) Sanitation Control Records. Each food processor, which is not exempt from Sec. 3.08 [Sanitation Control Procedures], shall create and maintain sanitation control records that, at a minimum, document the sanitation monitoring and corrections prescribed by Sec. 3.08 [Sanitation Control Procedures], as applicable. Standard Sanitation Operating Procedure (SSOP) records must be maintained for at least six months after their creation.

(2) HACCP, fish and meat processing record retention.

(a) All records required by Chapters 4, 5 and 6, including records generated by harvesters, shall be retained at the processing facility for at least 1 year after the date they were prepared in the case of refrigerated products, and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

(b) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility for at least 2 years after their applicability to the product being produced at the facility.

(c) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the

seasonal pack but shall be returned to the facility for official review, within 24 hours, upon demand.

(3) Low-Risk Food Processing Record Retention.

Records related to the processing of low-risk foods shall be maintained by the manufacturer for two years from the time of their creation.

(4) Education and training record retention.

(a) All facilities and vendors licensed pursuant to this Title shall retain records documenting each worker's relevant training and education, including the completion of any required training conducted by the operation. Workers include every individual engaged in the operations: paid and unpaid, permanent and temporary personnel. These records shall be retained for a minimum of three years from the time of their creation.

(b) Any facility licensed pursuant to this Title which receives carcasses, plant material or fungi from a harvester shall not receive that food until and unless the harvester produces records documenting compliance with the education and training requirements required for the foods and processes undertaken (e.g. field dressing). These records shall be maintained for a minimum of three years from the time of their receipt, and updated as necessary.

(4) Records maintained on computers or electronic databases. The maintenance of records on computers or electronic databases is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(5) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying by the _____ [tribal licensing authority] at reasonable times.

3.11 Food Processing Plants

(1) General requirement. Each licensed food processing plant shall be maintained in a manner sufficient to prevent the creation of unsanitary conditions, to ensure that products produced are not adulterated, and consistent with the following standards.

(2) Licensing and Registration. A valid food processing plant license is required to engage in any activities which must be performed within a food processing plant; however, food processing plants in operation at the time of enactment of this title shall have 90 days to obtain the required food processing plant license. Any operator, owner or agent in charge of a food processing plant engaged in the processing, packing or holding of foods pursuant to this Title annually shall submit an application for registration and licensing to the _____ [tribal licensing authority], certifying that the facility complies with all applicable laws, including the general requirements (Chapters 1-4) and specific requirements related to foods that will be processed in the plant (Chapters 5-8, as applicable), agreeing to open the facility and its records to inspections by the _____ [tribal licensing authority], and providing other required information. A license is not transferrable between persons or locations. A food processing plant license may be suspended or revoked by the _____ [tribal licensing authority] for violations of this Title.

(3) Inspection and Certification. A license to operate a food processing plant will be issued upon satisfactory completion of inspection and certification. An annual inspection will include a walk-through of the facilities and review of the records to determine compliance with applicable laws and conditions in the plant. A facility may be certified to process, pack and hold meat, fish, produce and low-risk foods, or any combination thereof. The _____ [tribal licensing authority] may inspect licensed food plants, and records thereof, upon a reasonable belief that the food produced, packed or distributed at the facility is adulterated and presents a serious threat of adverse health consequences or death to humans or animals.

(4) Water and Plumbing.

(a) Each licensed food processing plant shall be supplied with a source of water that complies with the National Primary Drinking Water regulations (40 CFR 141), at a suitable temperature and pressure as needed for all areas where required (e.g. for processing product, for cleaning rooms and equipment, utensils and packaging material, for employee sanitary facilities, etc.). If a food processing plant uses a municipal or tribal water supply, it must make available to tribal or federal inspectors upon request, a water report, issued under the authority of the tribal or municipal agency, certifying or attesting to the potability of the water supply. If a food processing plant uses a private will for its water supply, it must make available to tribal or federal inspectors, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.

(b) Plumbing systems used by food processing plants shall conform to the following standards:

(i) Carry sufficient quantities of hot and cold water for cleaning, waste disposal, processing, drinking and personnel sanitation needs.

(ii) Properly convey sewage and liquid disposable waste from the establishment.

(iii) Prevent adulteration of product, water supplies, equipment and utensils and prevent the creation of unsanitary conditions throughout the facility.

(iv) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(v) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing.

(vi) Prevent the backup of sewer gases.

(c) Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through means sufficient to prevent backup of sewage into areas where product is processed, handled or stored.

(5) Licensed food processing plants must conform to the following design and maintenance standards:

(a) Facility buildings are suitable in size, construction and design, and are kept in good repair for safe, sanitary and orderly operations, and for easy cleaning.

(b) Walls, floors and ceilings are built of durable materials, reasonably impervious to moisture and are cleaned and sanitized as necessary to prevent adulteration of product or creation of unsanitary conditions.

(c) Walls, floors, ceilings, doors, windows and other outside openings shall be constructed and maintained to prevent the entrance of vermin, such as flies, rats and mice.

(d) Dressing rooms, toilet rooms and urinals must be sufficient in number and size, conveniently located and maintained in a sanitary condition, and in good repair, to ensure the cleanliness of all persons handling food. Any such room shall be separate from the rooms and compartments used to process, store or handle food.

(e) Dedicated handwashing stations, including running water, soap and towels, shall be placed in or near the toilet and urinal rooms and at other such places within the facility to ensure the cleanliness of all persons handling any product.

(f) Storage of Waste Materials. Refuse receptacles shall be constructed and maintained in a manner that protects against the creation of unsanitary conditions, the emanation of foul smells or the adulteration of food products.

(g) Storage of Toxic Materials. Cleaning compounds, sanitizing agents, processing aids and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled and stored in a manner that will not adulterate product or create unsanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available during facility inspections.

(h) Controlled Access. The facility must be fully enclosed to prevent access by dogs, cats, wild animals, rodents, birds and insects. Each door, window or other access point, must be secured with a functioning lock or other security device to prevent unauthorized access. While operations are running, access shall be controlled to necessary personnel.

(6) Sanitary Operations/Good Manufacturing Practices

(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of unsanitary conditions and the adulteration of product.

(b) Buildings, fixtures and other physical facilities must be cleaned and sanitized as frequently as possible to prevent food from becoming adulterated.

(c) The cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against contamination of food products, food-contact surfaces, and food packing materials.

(e) Care must be taken to prevent the cross-contact of allergenic foods, with processes in place to prevent cross-contamination of potential allergens in receiving, storage, handling and production, specific cleaning and sanitizing procedures, and the training of personnel.

(7) Pest Control. The grounds about an establishment shall be maintained to prevent conditions that could lead to unsanitary conditions, adulteration of product or interference with a tribal or federal inspection programs. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of unsanitary conditions.

(8) Waste Disposal. Facility waste must be managed in a manner that prevents the creation of unsanitary conditions and in compliance with applicable law. Waste storage areas shall be kept neat and orderly, and any refuse containers located outside the facility shall be fitted with covers to keep them securely closed when unattended. Waste generated by the plant must be regularly removed from the facility and grounds by a waste handler licensed to handle those waste products, or transported to a waste handling facility in a sanitary manner, with care taken to avoid the contamination of any food, or object or container that will come into contact with food.

(9) Annual inspections.

(a) Inspections of food processing plants by the _____ [tribal licensing authority] shall be scheduled twice a year.

(b) At any time during the term of the license, either upon receipt of a complaint or upon its own volition, the _____ [tribal licensing authority] may conduct an unscheduled inspection of a food processing plant. Any reinspection conducted as a

result of a prior violation of applicable law will result in an additional fee to the establishment and satisfactory action must be taken to cure the violation.

3.12 Retail Food Establishments

(1) A retail food vendor license is required for the retail sale of class 3 foods to individuals who are not members of a federally recognized Indian tribe, except that manoomin, maple syrup and maple sugar may be sold to any individual by a vendor who has not obtained a retail food vendor license.

(2) No person or persons, corporation or firm shall operate a retail food establishment within the exterior boundaries of the _____ Reservation either permanent or temporary without a valid, unsuspended, unrevoked retail food vendor license issued by the _____ [tribal licensing authority]. Only a person or persons, corporation or firm that complies with the requirements of this Section, and the applicable food code pertaining to retail food establishments, shall be entitled to receive and retain a retail food vendor license. The valid license shall be prominently displayed in every retail food establishment.

(3) All retail food establishments must meet the general requirements of the [current FDA Food Code].

(4) The _____ [tribal licensing authority] shall issue a retail food vendor license following receipt of any required fees, inspection of the premises and assurances from the tribal inspector that the applicant has met the conditions required for a satisfactory score pursuant to the Federal Food Code Guidelines with the Hazard Analysis Critical Control Point, Techniques of Quality Control.

(5) Retail food vendor licenses shall be issued by the _____ [tribal licensing authority] for a 12-month period beginning at the Tribe's fiscal year [month, day] and ending [month, day] of every year. Applicants who initiate their business after [month, day (beginning of tribe's fiscal year)] of any given year shall have their fees prorated for that year. Retail establishments selling class 3

foods in operation at the time that this Title is enacted, shall have 6 months to obtain a valid retail food establishment license.

(6) Inspections.

(a) Inspections of food service premises by the _____ [tribal licensing authority] shall occur twice a year.

(b) At any time during the term of the license, either upon receipt of a complaint or upon its own volition, the _____ [tribal licensing authority] may conduct an unscheduled inspection of a vendor's food preparation site. Any reinspection conducted as a result of a prior violation of applicable law will result in an additional fee to the establishment and satisfactory action must be taken to cure the violation.

3.13 Enforcement

(1) Strict compliance with the specific laws found in this Title and any other applicable standards are required to protect the public health, safety and welfare.

(2) License Required. Operating a business which engages in the processing, distribution or sale of amenable wild-harvest food, which requires a specific license as listed below, without a valid, unrevoked and unsuspended license issued by the _____ [tribal licensing authority] within the [boundaries of the _____ Reservation and/or _____ ceded territories] is strictly prohibited and will result in a fine and/or suspension of the right to operate, sell or receive amenable wild-harvested food:

(a) Food processing plant (Sec. 3.11);

(b) Retail food establishment (Sec. 3.12);

(c) Class 1 meat vendor (Sec. 5.09);

(d) Class 1 fish vendor (Sec. 6.05);

(e) Non-exempt produce harvester (Sec. 7.03); and

(f) Low risk food vendor (Sec. 8.01).

(3) The owner, operator or agent in charge of a facility listed in subs. (2)(a)-(f), above, shall submit a registration application to the _____ [tribal licensing authority] on the prescribed form. The _____ [tribal licensing authority] shall compile and maintain an up-to-date list of facilities and vendors that are registered under this Title.

(4) Each registration form shall contain the information necessary to notify the _____ [tribal licensing authority] of the name and address of each facility at which, and all trade names under which, the registrant conducts business, the email address and phone numbers for the contact person of the facility, and the general food category of the foods processed, packed or held at such facility. The registration form shall contain an assurance that the _____ [tribal licensing authority] will be permitted to inspect such facilities at the times and in the same manner as permitted by Section 704 of the Food, Drug and Cosmetic Act. The registrant shall notify the _____ [tribal licensing authority] in a timely manner of changes to such information.

(5) All facilities required to be registered pursuant to this Section shall have six (6) months from the date of adoption of this Title to become compliant. During the period beginning on October 1 and ending on December 31 of each even-numbered year, a registrant that has submitted a registration form under subsection (4), above, shall submit to the _____ [tribal licensing authority] a renewal registration containing the information described in subsection (3), above.

(6) A food production or distribution license will be suspended by the _____ [tribal licensing authority] and the operation closed down if the licensee is non-compliant with any applicable requirement of this Title, any other applicable law or regulation, or for any other reason related to the protection of the community's public health, safety or welfare.

(7) Failure to pass an inspection conducted by the _____ [tribal licensing authority] will be cause for a penalty, revocation or suspension of the license.

(8) The _____ [tribal licensing authority] may close down an operation immediately on an emergency basis upon evidence of an imminent or serious health or safety threat to the community.

(9) Holding order.

(a) The _____ [tribal licensing authority] may issue a holding order preventing the sale or movement of any food if reasonable grounds exist to suspect that the food is adulterated or misbranded, or otherwise fails to meet the standards set forth in this Title. The _____ [tribal licensing authority] may issue a holding order pending further examination or analysis to determine whether the food is adulterated or misbranded, or otherwise fails to meet the standards set forth in this Title.

(b) The _____ [tribal licensing authority] shall serve a holding order by delivering it to the owner or custodian of the food, or by placing a copy in a conspicuous place on or near the food products.

(c) A holding order remains in effect for 14 days unless it is withdrawn. A holding order may be extended by 14 days by re-issuing and serving the re-issued holding order in subsection (b), above.

(d) No person may sell, move or alter any food under holding order, except with the written permission of the _____ [tribal licensing authority]. The _____ [tribal licensing authority] may authorize the owner or custodian to take corrective action.

(e) The _____ [tribal licensing authority] may release a holding order if the _____ [tribal licensing authority] finds that the suspect product is not adulterated or misbranded, or that the violation has been corrected.

(10) Condemnation Order.

(a) If the _____ [tribal licensing authority] finds that food is adulterated, misbranded, or a class 2 or 3 meat product is not derived from a carcass that passed inspection pursuant to Sec. 5.05 [Post-Mortem Inspection], the _____ [tribal licensing authority] may order the owner or custodian to do any of the following:

(i) Correct the violation within a reasonable time period in a manner specified by the _____ [tribal licensing authority] in writing.

(ii) Dispose of the product, in a manner specified by the _____ [tribal licensing authority] in writing. The product may be ordered disposed if a violation cannot be corrected, or if the owner or custodian fails to correct the violation in the time period specified in subsection (i), above.

(b) The _____ [tribal licensing authority] shall serve an order under subsection (a), above, by delivering a copy of the order to the owner or custodian of the food, or by placing a copy in a conspicuous place on or near the food product. An order takes place when served.

(c) No person may sell, move or alter any food covered by a condemnation order, except as directed by the _____ [tribal licensing authority].

(11) The _____ [tribal licensing authority] may order a person to correct a violation of this Title, and may specify a deadline for correcting the violation.

(12) The _____ [tribal licensing authority] may issue an order prohibiting the use of unsanitary facilities, equipment or utensils that may contaminate class 1, 2 or 3 food. The _____ [tribal licensing authority] may issue an order under this subsection by applying a "REJECTED" tag to the facilities, equipment or utensils. A person may not use those facilities, equipment or utensils until the violation is corrected and the order is withdrawn.

(13) Any food processing plant, retail food establishment, or facility of a class 1 meat vendor, class 1 fish vendor, low risk food vendor or non-exempt produce harvester that has been closed down by the _____ [tribal licensing authority] due to evidence of a serious health or safety threat must provide evidence of satisfactorily corrected compliance to the _____ [tribal licensing authority] prior to being reopened for business.

(a) Any food production or distribution establishment that has been closed due to a violation of the applicable law must be re-inspected by the _____ [tribal licensing authority] at the vendor's cost with a resulting satisfactory inspection pursuant to the applicable standards contained in this Title and any other standards that apply to the operations.

(b) Any food production or distribution establishment that has been ordered closed, may only receive a probationary license for six months upon evidence of satisfactory compliance with applicable sections of this Title and any other standards that apply to the operations.

(c) After six months of compliance with applicable sections of this Title and any other standards that apply to the operations, as determined by the _____ [tribal licensing authority], the licensee may apply to receive an annual license.

(d) Any food production or distribution establishment operator who violates any provision of this Title, upon conviction, shall forfeit not less than $5.00 nor more than $500.00, together with the costs of prosecution. In default of payment of such forfeitures and costs, the

food production or distribution establishment shall be closed down or remain closed until such forfeitures and costs are paid and all other areas of non-compliance with this Title or other applicable standards have been cured.

(10) Appeals.

(a) Parties who disagree with the decisions of the _____ [tribal licensing authority] regarding issues of licensing or inspections may appeal to the _____ [tribal court/tribal health department].

(b) Hearings will be conducted according to [the Rules of Civil Procedure] as established by _____.

3.14 Prohibited Practices

(1) Process or sell, as a class 1, 2 or 3 food, any adulterated or food labeled inconsistent with Sec. 3.02 [Debwewin; Truth in Labeling].

(2) Process, store, handle, transport or sell any class 1, 2, or 3 food under conditions that may render the food adulterated.

(3) Make any false, deceptive or misleading statement, when submitting a Harvester Certificate of Guarantee related to any of the following:

(a) The time, date or location of harvest;

(b) The condition of a wildlife animal prior to being killed; or

(c) The manner in which a wildlife animal carcass, fish, plant or fungus was transported, processed or stored.

(4) Obstruct an official of the _____ [tribal licensing authority] performing their duties. Obstruction includes any of the following:

(a) Physical interference.

(b) Verbal or physical assault or abuse.

(c) Threatening behavior or communications.

(d) Refusal to carry out legitimate directives.

(e) Intentional acts that impede the full, effective and efficient performance of the official's duties.

(f) Concealing records, ingredients, food, labels, packaging materials or other items that may be inspected pursuant to Sec. 3.13 [Enforcement].

(5) Wrongfully alter, deface or remove a tribal tag, legend or mark applied under this Title.

Chapter Four – Hazard Analysis Critical Control Point

4.01 Hazard Analysis Critical Control Point (HACCP) Plan

(1) Every food processing plant, class 1 meat vendor and class 1 fish vendor shall conduct, or have conducted for it or them, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of raw and finished food product processed by that facility and to identify the preventative measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during and after entry into the food processing environment. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness, data, scientific reports or other information provide a basis to conclude that there is a reasonable possibility that the hazard will occur in the particular type of product being processed, in absence of those controls.

(2) The HACCP Plan. Every food processing plant, class 1 meat vendor and class 1 fish vendor shall have, and implement, a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in Sec. 4.01(1). At a minimum, HACCP plans shall be specific to:

(a) Each location where raw and/or finished fish or meat products are processed by the processor.

(b) Each kind of raw and finished fish or meat product processed by the processor.

(c) The following processing categories of foods:

(i) Raw product – ground.

(ii) Not heat treated – shelf stable.

(iii) Heat treated – shelf stable.

(iv) Fully cooked – not shelf stable.

(vi) Heat treated but not fully cooked – not shelf stable.

(vii) Product with secondary inhibitors – not shelf stable.

(d) The plan may group kinds of raw and finished food products together, or group kinds of production methods together, if food safety hazards, critical control points, critical limits and procedures required to be identified and performed in Sec. 4.01(3)(d) are identical for all raw and finished food products so grouped, or for all production methods so grouped.

(3) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(a) List the food safety hazards that are reasonably likely to occur, as identified in accordance with of this subsection, and that thus must be controlled for each raw and finished food product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Decomposition in any species where a food safety hazard has been associated with decomposition;

(vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing raw or finished food products which will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels or intends for the product to be so consumed;

(viii) Unapproved use of direct or indirect food or color additives;

(ix) Zoonotic diseases; and

(x) Physical hazards.

(b) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced into the food processing environment; and

(ii) Critical control points designed to control food safety hazards introduced outside of the processing plant environment, including food safety hazards that occur before, during and after entry into the processing plant environment;

(c) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards are met.

(d) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.

(e) Include any corrective action plans that have been developed in accordance with Sec. 4.03(1) [Verification – Overall Verification], to be followed in response to deviations from the critical limits at critical control points.

(f) List the verification procedures, and frequency thereof, that the processors will use in accordance with Sec. 4.03 [Verification].

(g) Provide a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring and shall be made as soon as practically possible after monitoring.

(4) Signing and dating the HACCP plan.

(a) The HACCP plan shall be signed and dated, either by the most responsible individual on-site at the processing facility, or by a higher-level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation.

(b) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification;

(iii) Upon verification of the plan in accordance with Sec. 4.03 [Verification].

(5) Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with Sec. 3.08(2) [Standard Sanitation Operating Procedures - Monitoring], they need not be included in the HACCP plan.

(6) Legal basis. Failure of a food processing plant, class 1 meat vendor or class 1 fish vendor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, may render the food products of that operator adulterated. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processor’s overall implementation of its HACCP plan, if one is required.

4.02 Corrective Actions

(1) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

(a) Following a corrective action plan that is appropriate for the particular deviation; or

(b) Following the procedures in Sec. 4.02(3).

(2) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with Sec. 4.01(3)(e) [HACCP Plan – Contents], by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective

action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(a) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(b) The cause of the deviation is corrected;

(c) Measures to prevent recurrence are established; and

(d) No product that it injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(3) When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(a) Segregate and hold the affected product, at least until the requirements of paragraphs (3)(b) and (3)(c) of this subsection are met;

(b) Perform or obtain a review to determine the acceptability of the affected product for distribution.

(c) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation.

(d) Take corrective action, when necessary, to correct the cause of the deviation;

(e) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Sec. 4.05 [Training on HACCP], to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(4) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Sec. 4.03(1)(c)(ii) [Verification; ongoing verification activities; calibration] and the recordkeeping requirements of Sec. 4.04 [Records].

4.03 Verification.

(1) Overall verification. Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

(a) Reassessment of the HACCP plan. A reassessment of the adequacy of the HACCP plan shall occur annually or whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way. Such changes may include changes in the following: raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 4.05 [Training on HACCP]. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of Sec. 4.01(2).

(b) Ongoing verification activities. Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(ii) The calibration of process-monitoring instruments; and,

(iii) At the option of the processor, the performing of periodic end-product or in-process testing.

(c) Records review. A review, memorialized in a record, including signing and dating, by an individual who has been trained in accordance with Sec. 4.05 [Training on HACCP], of the records that document:

(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;

(ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Sec. 4.02 [Corrective Actions]. This review shall occur within 1 week of the day that the records are made; and

(iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(2) Corrective actions. Processors shall immediately follow the procedures in Sec. 4.02 [Corrective Actions] whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(3) Reassessment of the hazard analysis. Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that

could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 4.05 [Training on HACCP].

(4) Recordkeeping. The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with Sec. 4.03(b) shall be documented in records that are subject to the recordkeeping requirements of Sec. 4.04 [Records].

4.04 Records

(1) General requirements. All records required by this part shall include:

(a) The name and location of the processor or importer;

(b) The date and time of the activity that the record reflects;

(c) The signature or initials of the person performing the operation; and

(d) Where appropriate, the identity of the product and the production code, if any.

Processing and other information shall be entered on records at the time that they are observed.

(2) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(a) The written hazard analysis prescribed in Sec. 4.01(1), including all supporting documentation.

(b) The written HACCP plan, including decision-making documents associated with the selection and development of critical control points and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(c) Records documenting the monitoring of critical control points and their critical limits, including the recording of actual times, temperatures or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product codes and carcass tag numbers. Each of these records shall include the date the record was made.

(3) Prior to shipping product, or transferring it for direct sale, the establishment shall review the records associated with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of the product. Where practicable, this review shall be conducted, with the review memorialized in a record, dated and signed by an individual who did not produce the record(s), preferably someone trained in accordance with Sec. 4.05 [Training on HACCP], or the responsible establishment official.

(4) All records created pursuant to this Part shall be maintained pursuant to Sec. 3.10 [Recordkeeping].

4.05 Training on HACCP

(1) At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to treaty harvested food product processing at least equivalent to that received under standardized curriculum recognized as adequate by the _____ [tribal licensing authority] or who is otherwise qualified through job experience to perform these functions; the individual need not be an employee of the establishment. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of Sec. 4.01(b);

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Sec. 4.02(3)(e), the HACCP plan in accordance with the verification activities specified in Sec. 4.03(1)(a) and the hazard analysis in accordance with the verification activities specified in Sec. 4.03(3); and

(c) Performing the record review required by Sec. 4.04(3).

Chapter 5 - Meat

5.01 Harvesting Wildlife Animals for Processing as a Class 1, 2, and 3 Foods

(1) Only those wildlife animals who are healthy and alive at the time they are harvested, and whose carcasses do not exhibit any signs of injury or disease which pose a risk to human health, shall be suitable for processing for pursuant to this Title. Compliance with Chapter 4 [Hazard Analysis Critical Control Point] is not required for the harvesting and handling wildlife animals outside of tribally-licensed food processing plants; however, wildlife animal carcasses which are not accompanied by a complete Harvester Certificate of Guarantee, signed by the harvester and certifying compliance with all applicable subsections of Sec. 5.01 to 5.04, may not be sold or donated pursuant to this Title.

(2) No member shall hunt wildlife animals for sale as a class 1, 2 or 3 food unless the outdoor air temperature in the tribal deer management unit within which the animal is killed, is 41° Fahrenheit, or cooler, when the animal is slaughtered and field-dressed.

(4) If a wildlife animal is harvested or killed by the use of a firearm, only nontoxic ammunition may be used. Only small game animals may be harvested or killed with projectile shot (pellets).

(5) Harvesters shall comply with all applicable tribal conservation code provisions, including those on tagging and registration. The Harvester Certificate of Guarantee for each wildlife animal sold or donated pursuant to this Title shall reference the sequence of numbers, symbols and/or letters listed on the commercial harvest tag, carcass tag or other registration document, as applicable. The harvester shall also document the following on the Harvester Certificate of Guarantee:

(a) The date, time of location of the kill;

(b) The ambient air temperature at the time of killing, or the range of temperatures in the 24-hour period between trap checks, as applicable, and the ambient air temperature while field dressing;

(c) The manner of killing (i.e. “killed by gunshot wound to the upper right shoulder.”); and

(d) Type of ammunition, or type of killing trap, used.

(6) Humane Handling.

(a) No one shall kill an animal for sale or donation as a class 1, 2 or 3 food in a manner that is cruel or abusive. Killing an animal in a swift and efficient manner through hunting and trapping methods authorized by applicable tribal law shall not be considered cruel or abusive.

(b) No one shall shackle, hoist, throw or cast a game animal intended for sale or donation as a class 1, 2 or 3 food, until the animal is stunned or killed in a manner that causes permanent unconsciousness or death.

(7) Pre-Mortem Inspection.

(a) A pre-mortem inspection is required for Class 2 and 3 food products containing meat from wildlife animals.

(b) When pre-mortem inspection is required, the animal shall be inspected for signs of disease and injury prior to its killing, with observations recorded on the Harvester Certificate of Guarantee. The harvester or designee shall observe the animal intended to be killed, recording the following:

(i) The condition and behavior of the animal at rest and/or in motion;

(ii) The overall condition of the animal, especially the head, eyes, legs and body;

(iii) The degree of alertness, mobility and breathing;

(iv) Any unusual swellings or other abnormalities; and

(v) Location of the harvest by tribal deer management unit (DMU) or equivalent area.

(8) Dead and Diseased Animals. The carcasses of animals which exhibit signs of disease or serious injury, during the pre-mortem inspection, or are dead when discovered by the harvester may not be sold or donated pursuant to this Title. Signs of disease include the following:

(a) Non-ambulatory state, including: broken appendages, severed tendons or ligaments, nerve paralysis, fractured spine or metabolic conditions;

(b) Comatose or semi-comatose;

(c) Clinical signs of central nervous system issue, including unusual excitement or depression, deviation or rotation of the head, droopy lips, eyelids, cheeks or ears, convulsions or tremors, paralysis, sudden onset of fainting, head pressing, aimless walking, loss of balance or uncoordinated gait when walking and blindness;

(d) Clinical signs of injury or infection, including open wounds, the presence of blood or pus on the fur or skin of the animal and bite marks; and

(e) Deer and elk harvested from a Tribal Disease Management Areas for chronic wasting disease and bovine tuberculosis as listed in the tribal administrative document *Tribal Disease Management Areas*, shall be presumed to be diseased, unless the carcass is certified as disease-free following the implementation of procedures specified in Sec. 5.05(3) [Post-Mortem Inspection; deer carcasses presumed to be diseased] and shall be tagged with a TMDA tag supplied by the [tribal natural resource department], or designee.

(9) Harvesters shall comply with any requirement of the _____ [tribal natural resources department] and/or [tribal licensing authority] to collect and submit samples of tissue from the carcass for disease testing.

5.02 Small Game Animal Harvesting

(1) No member shall hunt or trap any small game animals for sale or donation as class 1, 2 or 3 food unless a harvest season is listed for the animal in the _____ [Tribe]'s [applicable conservation codes]; however, food derived from the following species shall not be considered amenable wild-harvest food: bobcat, coyote, grey fox and red fox. Food containing the meat of migratory birds may not be sold.

(2) No member shall trap any game intended for sale as a class 1, 2 or 3 food using kill traps unless the outdoor air temperature of the tribal deer management unit within which the traps are set, is 32° Fahrenheit or less, for the period of time between the trap was last checked and the animal is retrieved from the trap, which may not exceed 24 hours.

(3) Small game which is harvested through the use of a killing trap may be sold or donated as a Class 1 food only.

5.03 Field-Dressing

(1) Field-dressing shall be performed promptly after the animal has been killed, and by an individual(s) certified by the _____ [Tribal licensing authority] to field-dress animals following satisfactory completion of training on field-dressing. The individual's tribal field-dressing certification number must be documented on the Harvester Certificate of Guarantee. If an individual other than the harvester field-dresses a carcass, that individual shall also sign the Harvester Certificate of Guarantee, certifying compliance with this section.

(2) Personnel engaged in field-dressing shall wear clean, washable outer clothing and food handling gloves, with long hair covered or tied back. All personnel shall wash and rinse their hands sufficiently (a field sink or jug of water is sufficient), and refrain from smoking, during the operations to prevent contamination of the carcass.

(3) Equipment and utensils used for field-dressing shall be of sanitary design and construction, and shall be kept clean and sanitary free from contamination by soil, insects, vermin and waste products. Equipment and utensils used for field-dressing shall be cleaned and sanitized after each use, and more frequently as necessary, to keep them clean and sanitary.

(4) Prior to making any incisions into the carcass, loose dirt and debris shall be cleaned from the carcass; and if placed on a surface during evisceration (the removal of internal organs), that surface shall be a non-permeable, clean and sanitized surface (e.g. cleaned and sanitized tarp or game table).

(5) While field-dressing, care shall be taken to avoid contaminating the meat with fluids contained within the intestinal tract and bladder. An examination of the abdominal cavity and the heart, lungs, liver, stomach and intestines, through sight and smell, shall be made. If any organs or parts from the carcass exhibit physical deformation or signs of disease (e.g. cysts, unusual growth, abnormal colors, etc.), those organs and parts shall be collected, and stored at or below 38° Fahrenheit for examination by a licensed veterinarian prior to processing the carcass for sale or donation pursuant to this Title and shall be presented to the tribally-certified meat inspector during the post-mortem inspection.

5.04 Transportation and Storage of Wildlife Carcasses Prior to Processing

(1) The following provisions, in addition to Sec. 3.05 [Food Transportation and Storage], apply to the transportation and storage of wildlife animal carcasses harvested for processing as class 1, 2 or 3 food.

(2) No one may release a wildlife animal carcass to a food processing plant licensed pursuant to this Title, or class 1 meat vendor, unless that carcass has been carried out of the field and transported to the food processing plant in a manner that prevents the spoliation of the meat. Measures shall be taken to protect the carcass from contact with soil, debris or other materials while removing the carcass from the field (e.g. through use of a game cart, or by carrying the carcass suspended from its feet). Wildlife animal carcasses shall be continuously cooled following harvest. If ice is used in cooling, it shall be made

with potable water, and any implements and containers coming into contact with the ice shall be clean and sanitized, and made from food safe materials. If the carcass is held by the harvester, it must be continuously cooled in a secure location and protected from pests and vermin, and the harvester shall actively monitor the air temperature of the smallest container used to hold the carcass.[1]

(3) The harvester shall document the measures taken to protect the carcass during transport from the field to the food processing plant (e.g. "placed carcass in clean game cart and wheeled it to the road; lifted carcass from cart and hoisted it onto the clean truck bed.") in the Harvester Certificate of Guarantee. If the carcass is not immediately released to a tribally-licensed food processing plant, or class 1 meat vendor, the manner in which the carcass is stored shall also be documented on the Harvester Certificate of Guarantee (e.g. "placed sanitary ice within the abdominal cavity," "hung the carcass in fully-enclosed, unheated pole barn," "calibrated thermometer in the shed read 32° F at 17:42 on 10/17/19").

(4) Wildlife animal carcasses intended to be processed as Class 2 and 3 meat products shall be presented to a tribally-certified meat inspector within 24 hours of the animal's killing.

5.05 Post-Mortem Inspection

(1) Prior to the acceptance of a wildlife animal carcass by a tribally-licensed food processing plant, the field-dressed carcass, otherwise complete, and related records shall be presented for inspection to a tribally-certified meat inspector. Tribally-certified meat inspectors may not release to a food processing plant, wildlife animal carcasses exhibiting signs of disease or injury, which are unrelated to the killing and pose a risk to human health, unless approved by a licensed veterinarian.

(2) The following procedures shall be performed during the post-mortem inspection:

[1] If the carcass is being held in a refrigerated unit in an outbuilding, the harvester or designee will need to regularly check the interior air temperature of the refrigerated unit, making a record of those monitoring activities.

(a) An examination of the outside of the carcass, noting any physical deformities and signs of disease or injury, including indications of post-mortem injury to the carcass.

(b) An internal examination of the carcass, and organs collected by the harvester, noting any physical deformities, signs of disease or injury.

(c) An examination of the Harvester Certificate of Guarantee for completeness and indications of time and temperature abuse or any other food safety concern.

(3) At the conclusion of the inspection, the tribally-certified meat inspector shall release the carcass to a tribally-licensed food processing plant, certifying the carcass for processing as class 2 and 3 food, or reject the carcass as not amenable wild-harvest food. Carcasses which have been rejected by a tribally-certified meat inspector may only be accepted by a tribally-licensed food processing plant if accompanied by a certificate of food safety issued by a licensed veterinarian. Carcasses which have been certified for processing as class 2 and 3 food, shall be affixed with a tribal meat inspection legend, on the body of the carcass and within documentation accompanying that carcass.

(4) Deer and elk carcasses presumed to be diseased, and not amenable wild-harvest food, due to the location of harvest within Tribal Disease Management Areas for chronic wasting disease and bovine tuberculosis must undergo post-mortem inspection within 24 hours of the animal's killing to be certified for processing as Class 1, 2 or 3 food and the following additional procedures apply:

(a) The field-dressed carcass shall be presented to the _____ [Tribe's natural resource department], or designee, within 24 hours of the killing to collect samples to test for the disease(s) associated with the Tribal Disease Management Area;

(b) Testing for the disease associated with the Tribal Disease Management Area shall be performed pursuant to a quality assurance project plan (QAPP) as specified by the _____ [Tribal Natural Resource Department] or designee, and the

documentation submitted with the test sample shall identify the sample using identification information from the TMDA tag.

(c) In the time between the presentation of the carcass for post-mortem inspection and testing, and the receipt of the results of the testing, the carcass must be stored in compliance with Sec. 3.05 [Food Transportation and Storage] within a clean, safe and secure apparatus, facility or container, with measures employed to prevent cross-contact between the carcass and other carcasses, or foods, food contact surfaces, etc. The apparatus, facility or container used to hold the carcass shall be maintained at 38° F or lower, with regular temperature monitoring performed and records created and maintained pursuant to Sec. 3.10 [Recordkeeping].

(d) Carcasses which test results return no detection of the disease associated with the Tribal Disease Management Area, and which have been stored in a manner that preserved the integrity of the meat, consistent with subsection (c), above and other requirements, may be transferred to a food processing plant and/or processed by a class 1 meat vendor. Carcasses which test results detect the presence of the disease associated with the Tribal Disease Management Area, and/or have not been stored in a manner that preserves the integrity of the meat, shall not be considered amenable wild-harvest food.

(5) Each wildlife animal carcass or part thereof, which has been found, upon final inspection, to be unsound, unhealthful, unwholesome, or otherwise adulterated, shall be conspicuously marked on the surface tissues, as possible "_____ Tribe Inspected and Condemned." No person or entity may process, store, transport or sell meat as food for human consumption, from a carcass which has been so condemned.

5.06 Release of a Wildlife Animal Carcass to a Food Processing Plant

(1) Upon releasing a wildlife animal carcass to a food processing plant, the harvester shall provide to the food processing plant or class 1 meat vendor a fully-completed Harvester Certificate of Guarantee, which is a signed certificate affirming that the harvester and all others involved in the harvest, transportation and storage of the carcass, adhered to the standards set forth in Sec. 5.01 to 5.04, as applicable.

(2) Harvester Certificates of Guarantee shall be retained by food processing plants and class 1 meat vendors for each carcass, or part of carcass, which enters their facility. Harvest Certificates of Guarantee shall be retained in accordance with the schedules set forth in Sec. 3.10 [Recordkeeping].

5.07 Meat Processing

(1) Wildlife animal carcasses, or parts of those carcasses, which have been released to a food processing plant shall be held in a refrigerated area, physically separated from areas used for cutting or processing meat, jerky or the storage of processed food, ready-to-eat products, or any food contact surfaces used for these products or processes, and stored consistent with Sec. 3.05 [Food Transportation and Storage]. Prior to moving these carcasses, or parts of carcasses, to the other areas of the plant, the skin and feet from carcasses of mammalian animals, and the feathers of bird animals, shall be removed, and each carcass treated with an antimicrobial wash, adequately formulated and applied to the carcass to reduce the levels of *E. Coli* on the entire surface of the carcass.

(2) Specified risk materials (SRMs).

(a) SRMs defined. The following parts are considered SRMs:

(i) The tonsils and distal ileum from all venison carcasses; and

(ii) The brains, eyes, trigemal ganglia, spinal cord, vertebral column (excluding the transverse processes of the thoracic and lumbar vertebrae and wings of the sacrum)

and the dorsal root ganglia from venison carcasses of cervidae aged 12 months and older.

(b) SRMs are not amenable and any meat contaminated with SRMs are not amenable wild-harvest food. Cheek meat, head meat and tongues from cervidae aged 12 months and older are considered adulterated if they have been contaminated with brain matter. Tools and surfaces used in the removal of SRMs shall be dedicated to that process. Cleaning and sanitizing processes employed for those tools and surfaces must be consistent with practices which effectively eliminate or deactivate infectious prions.

(c) Disposal of SRMs. SRMs must be disposed of consistent with Sec. 3.07 [Handling of Inedible Food Byproducts].

(3) Any meat products procured or obtained by a food processing plant or a retail food establishment licensed pursuant to this Title from suppliers other than harvesters of wildlife carcasses, shall not be received unless the food processing plant has a letter of guarantee on file from the supplying establishment. Raw meat and trim should be received in the same manner as wildlife carcasses are received pursuant to subsection (1), above. Letters of guarantee from outside suppliers of meat products shall be retained pursuant to Sec. 3.10 [Recordkeeping].

(4) Meat grinding.

(a) Food processing plants and retail food establishments that grind meat products shall create and maintain the following meat grinding records:

(i) The identifiers of the individuals or entities that supplied the meat used to prepare each lot of ground meat (i.e. names of harvesters or meat dealer);

(ii) Commercial harvest tag numbers and/or supplier lot numbers, and dates of harvest, production or slaughter;

(iii) The names of the supplied materials, including meat components and any materials carried over from one production lot to the next;

(iv) The date and time each lot of ground meat product is produced; and

(v) The date and time grinding equipment and other related food-contact surfaces are cleaned and sanitized.

(b) Meat grinding records shall be maintained consistent with Sec. 3.10 [Recordkeeping].

(c) Care shall be taken to regularly, and frequently, clean and sanitize meat grinding equipment and related food-contact surfaces pursuant to SSOPs and HACCP plans, as applicable.

5.08 Dehydrated Meat Products

(1) Any non-meat ingredients for marinades and spice mixes used in the preparation of dehydrated meat products shall be prepared under good manufacturing practices (GMPs) designed to minimize contamination and the presence and growth of pathogens of public health concern.

(2) If the heating process employed in the preparation of the product does not deliver an adequate lethality, additional interventions shall be employed, such as the following:

(a) Preheating the jerky strips in the marinade, or water, to a minimum internal temperature of 160°F.

(b) Dipping the product in 5% acetic acid for 10 minutes before placing it the marinade.

(c) Dipping the product in 1:2 or 1:3 mixtures of calcium sulfate and water for 30 seconds or dipping in acidified sodium chlorite at concentrations between 500 and 1,200 ppm.

(3) If the product is heated using a low temperature without the application of humidity, to achieve a surface tackiness, this step shall last 30 minutes or less in total.

(4) Lethality treatment.

(a) During the lethality treatment, which is the process step or steps used to destroy pathogenic microorganisms, the establishment's actual processes shall adhere to scientifically-

sound critical operational parameters with respect to product time-temperature combination and relative humidity levels that have been shown to be effective in compliance guidelines issued by the USDA FSIS, journal articles, challenge studies or in-plant data.

(b) The establishment shall regularly monitor relative humidity levels in the sealed oven, and the internal temperature of the product, during the lethality treatment pursuant to HACCP plans. Accurate records of the critical operational parameters (critical control points) shall be created and retained pursuant to Sec. 3.10 [Recordkeeping] and Sec. 4.04 [Records].

(c) Home-style dehydrators do not maintain the necessary humidity levels and may not be used in the lethality treatment for class 3 dehydrated meat products.

(6) Drying.

(a) The upper limit for water activity for jerky stored in aerobic conditions is 0.85 water phase salt (wps), and the upper limit for jerky stored in anaerobic conditions is 0.90 water phase salt (wps), unless the establishment produces scientific support to support higher critical limits.

(b) The product shall not be dried before the lethality treatment.

(c) The establishment shall regularly monitor or verify the water activity of its dried product using an instrument such as a water activity meter pursuant to its HACCP plan for jerky. Accurate records of the critical operational parameters (critical control points) shall be created and retained pursuant to Sec. 3.10 [Recordkeeping] and Sec. 4.04 [Records].

(d) Vacuum packaged jerky products with a water activity of more than 0.85 water phase salt (wps) should be labeled with a statement such as “Refrigerate After Opening.”

(e) A post-drying heating step may be added.

(7) Following the lethality treatment and drying, care shall be taken to avoid contaminating the product by strict implementation of SSOPs, limited handling, elimination of cross-contamination and, for

products which are not shelf stable, to minimize adverse time and temperature effects in all storage and transportation.

5.09 Class 1 Meat Products

(1) Class 1 meat products are limited to fresh and frozen cuts of meat that have not been ground. Chapter 4 [Hazard Analysis Critical Control Point] apply to the production of all Class 1 meat products.

(2) A valid class 1 meat vendor license issued by the _____ [Tribe] is required to produce class 1 meat products outside of a tribally-licensed food processing plant. Class 1 meat vendor licenses shall be issued upon the submission of complete applications and satisfactory inspections, if inspection is required. Class 1 meat vendor licenses may be revoked or suspended for non-compliance with the standards set forth within this Chapter. The _____ [tribal licensing authority] may refuse to issue a class 1 meat vendor license to an individual with ownership or management interest in an operation which has been subject to any serious, or ongoing or unresolved violations of this Chapter. An application for a class 1 meat vendor permit must be submitted to the _____ [tribal licensing authority] annually, for each physical location and mobile processing unit used to process meat as a Class 1 food, containing the following information:

(a) The name of the food producer and mailing address;

(b) Physical address of the facility or residence used to process the meat;

(c) A statement agreeing to comply with the requirements and standards set forth in this Chapter, including any required inspections required by the _____ [tribal licensing authority]; and

(d) Payment of required fees.

(3) Inspections

(a) An annual inspection is required for all facilities used to process and package class 1 meat.

(b) The _____ [tribal regulatory agency] may inspect facilities licensed to process and package class 1 meat upon a reasonable belief that the operation is in violation of the requirements contained in this chapter or in response to a public health emergency (e.g. such as a foodborne illness outbreak associated with the consumption of foods produced by the operation).

(c) Inspections may include a walk-through of the premises used for the cleaning and sanitizing of surfaces, tools and equipment, for processing and packaging cuts of meat and storage areas, and review of the facility's records. Additionally, during the inspection, the vendor must demonstrate an understanding of the applicable food safety standards and the capacity to comply with those standards.

5.10 Class 2 and 3 Meat Products

(1) Class 2 meat products are limited to fresh and frozen cuts of meat, and fresh and frozen ground meat. The provisions of Sec. 3.11 [Food Processing Plants] and Chapter 4 [Hazard Analysis Critical Control Point] apply to the production of all Class 2 meat products.

(2) Class 3 meat products are limited to fresh and frozen cuts of meat, fresh and frozen ground meat and dehydrated meat products. The provisions of Sec. 3.11 [Food Processing Plants] and Chapter 4 [Hazard Analysis Critical Control Point] apply to the production of all Class 3 meat products.

(3) Licensed food processing plants shall make and retain records related to meat from an animal processed by the facility for human consumption, which shall be retained pursuant to Sec. 3.10 [Recordkeeping]. The record shall include the following:

(a) The date and time the animal was harvested;

(b) The date and time the animal was processed;

(c) The type and amount of meat processed, the disposition of that meat, and any lot number or other identifier created for that meat;

(d) The Harvester Certificate of Guarantee; and

(e) Any other information required by the _____ [tribal licensing authority].

(4) All establishments which produce class 2 and 3 meat products shall create a written recall plan to protect the public from products that may cause health problems or possible death. Written recall plans must include the following:

(a) Identification of recall personnel, with their roles and responsibilities specified.

(b) Detailed specification of the procedures that will take place.

(c) Evaluation of the health hazards as identified in the establishment's HACCP plans.

(d) Scope of the recall (dependent on the type of product and risks involved).

(e) Depth of the recall (dependent on the degree of hazard, extent of distribution and the amount of product distributed).

(f) Recall communication plan, including notification of retail and other establishments distributing the product.

(g) Public notification.

(h) Effectiveness checks to ensure that retail and other establishments took the appropriate action.

(i) Returned product control and disposition.

(j) Recall simulations conducted periodically by the establishment.

Chapter 6 – Fish

6.01 Receipt and Processing of Freshly Harvested Fish

(1) Each lot of raw, unfrozen fish received by a food processing plant, and prior to beginning any processing, shall be inspected prior to being received by the food processing plant to ensure that the product is fresh and wholesome, and arrives consistent with one or more of the following:

(a) Accompanied by transportation records that show that the product was held at or below an ambient or internal temperature of 38°F or below throughout transit; or

(b) Completely surrounded by ice at the time of delivery; or

(c) Delivered under a sufficient quantity of chemical cooling media that remain frozen, have kept the product at an internal temperature of 38°F or below throughout transit, and the internal temperature of the product at the time of delivery is 38°F or below; or

(d) Delivered refrigerated with a transit time of 4 hours or less, verified by transportation records, and the internal temperature of the product at the time of delivery is 38°F or less.

(2) Only fish accompanied by proof of legal harvest shall be received by a food processing plant. For Class 1 fish products, produced outside of a fish processing plant, the processor shall receive proof of legal harvest. These records shall be maintained by the processer consistent with the schedules set forth in Sec. 3.10 [Recordkeeping].

(3) All fish sold to anyone, donated to a tribal government program or school, or transferred to a food processing plant shall be accompanied by a Harvester Certificate of Guarantee documenting the waterbody of harvest. Fish harvested from waterbodies with mercury do not eat consumption guidance published by the Great Lakes Indian Fish and Wildlife Commission for pregnant women, women of childbearing age and children under 15 years of age, for that species of fish, may not be sold, donated or received by a food processing plant.

6.02 Fish Processing

Appropriate quality controls must be employed to ensure that fish products sold or donated pursuant to this Title are suitable for human consumption and that fish packaging materials are suitable and safe.

(1) Raw fish and eggs (roe), after being removed from the sac (skein), must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying fish products must be safe and of adequate sanitary quality.

(2) Fish products must be held in clean and sanitized containers designed and constructed so as to protect against contamination.

(3) Preventative measures must be employed to reduce pathogenic bacteria growth and toxin formation, including the following, as applicable:

(a) Storing the product in contact with ice or refrigerated at or below 38°F;

(b) While processing fish and fish products, controlling the amount of time that the product is exposed to temperatures that would permit pathogenic bacteria growth or toxin formation; and

(c) Rapid cooling of the product (including after cooking).

(4) When ice is used in contact with fish, it must be made from water that is safe and of adequate sanitary quality in accordance with 21 C.F.R. § 117.37(a), and must be used only if it has been manufactured in accordance with current sanitation practice as outlined in this Title.

(5) Frozen fish must be kept frozen. If thawing is required prior to its use, it must be done in a manner that prevents the fish from becoming adulterated. Frozen fish packaged in reduced oxygen packaging must be labeled in accordance with Sec. 3.02(2)(b)(v).

6.03 Smoked Fish Products

(1) Any product that will be preserved by salting or drying should be eviscerated prior to processing. Evisceration of fish is the careful and complete removal of all internal organs in the body cavity without puncturing or cutting them, including the gonads.

(2) Critical limits for smoked fish products.

(a) For fish smoked via hot smoking, the internal temperature of the product must be maintained at or above 145°F (throughout entire product) for at least 30 minutes.

(b) Refrigerated smoked fish products offered for sale or donation pursuant to this Title shall have not less than 3.5% water phase salt (wps) for vacuum packaged smoked fish with an approved tribal variance, or 3% water phase salt (wps) packaged with an air permeable membrane, or equivalent packaging.

(c) For smoked fish sausage, commercial pre-mixed seasonings may be used so long as the final product contains a minimum of 100 ppm nitrite. When nitrite is used, it must be included in the ingredient list, along with its function consistent with Sec. 3.02(2)(b)(ii)(III).

(3) Brining loads shall be restricted to a single species and portions of approximately the same size, with brine treated or replaced regularly to minimize harmful microbial contamination.

(4) Finished refrigerated smoked fish products shall be stored at or below 38° F and labeled with handling instructions pursuant to Sec. 3.02(2)(b)(v).

6.04 Fish Egg Products

(1) Fish egg (roe) products shall be processed to limit the growth and formation of toxins controlled by adding sufficient salt to produce a ratio of 1 pound of salt to 33 pounds of roe (skeins removed). The salt must be carefully mixed in with the eggs to ensure that the water phase salt level is uniform throughout the product and media. Canning salt should be used as it is free from anti-caking chemicals which can cause unpleasant flavors.

(2) Strict refrigeration control (maintaining the product at or below 38°F) should be maintained during storage and distribution.

(3) Finished products shall be labeled with handling instructions pursuant to Sec. 3.02(2)(b)(v).

6.05 Class 1 Fish Products

(1) Class 1 fish products are limited to fresh fish filets that have not been frozen.

(2) A valid fresh fish vendor license issued by the _____ [Tribe] is required to produce Class 1 fish products outside of a tribally-licensed food processing plant. Fresh fish vendor licenses shall be issued upon the submission of complete applications and satisfactory inspections, if inspection is required. Fresh fish vendor licenses may be revoked or suspended for non-compliance with the standards set forth within the applicable portions of this Title. The _____ [tribal licensing authority] may refuse to issue a fresh fish vendor license to an individual with ownership or management interest in an operation which has been subject to any serious, or ongoing or unresolved violations. An application for a fish vendor permit must be submitted to the _____ [tribal licensing authority] annually, for each physical location used to process fish as a Class 1 food, containing the following information:

(a) The name of the food producer and mailing address;

(b) Physical address of the facility or residence used to process the fish;

(c) A statement agreeing to comply with the requirements and standards set forth in this Chapter, including any required inspections required by the _____ [tribal licensing authority]; and

(e) Payment of required fees.

(3) Inspections

(a) An annual inspection is required for all facilities used to process and package fresh fish.

(b) The _____ [tribal licensing authority] may inspect facilities licensed to process and package fresh fish upon a reasonable belief that the operation is in violation of the requirements contained in this chapter or in response to a public health emergency (e.g. such as a foodborne illness outbreak associated with the consumption of foods produced by the operation).

(c) Inspections may include a walk-through of the premises used for the cleaning and sanitizing of surfaces, tools and equipment, for processing and packaging fresh fish and storage areas, and an inspection of documents. Additionally, during the inspection, the vendor must demonstrate an understanding of the applicable food safety standards contained within this chapter, and the capacity to comply.

6.06 Class 2 and 3 Fish Products

(1) Class 2 fish products are limited to fresh fish filets and frozen vacuum sealed fish filets.

(2) Class 3 fish products are limited to fresh fish filets, frozen vacuum sealed fish filets, smoked fish and refrigerated or frozen fish egg (roe) products.

(3) Class 2 and class 3 fish products may only be produced within facilities licensed under Sec. 3.07 [Food Processing Plants].

Chapter 7 – Produce

7.01 General Provisions

(1) All personnel engaged in activities that involve the handling of produce sold or donated pursuant to this Title shall:

(a) Wear clean and washable outer clothing, including footwear, and shall wash and rinse their hands sufficiently during the operations to prevent contamination of the harvested foods consistent with Sec. 3.04 [Personnel].

(b) Have access to toilet facilities, which may include transportation to an off-site location for toileting, and an area designated for taking breaks, eating and smoking;

(c) Have received training on, and follow, procedures on proper hand-washing techniques, hygienic practices and how to identify and reduce food safety risks related to their assigned duties consistent with Sec. 3.04 [Personnel].

(d) Be excluded from those activities if the person has an illness or disease that is communicable through the food which will be sold or donated, for the duration of the illness consistent with Sec. 3.04 [Personnel].

(e) Have access to clean, potable drinking water served in a sanitary manner.

7.02 Produce Harvesting

(1) Equipment and tools used for produce harvesting shall be designed and constructed to work effectively and be adequately cleaned consistent with Sec. 3.06 [Equipment and Utensils]. Additionally, any equipment, vehicles and conveyances (e.g. bins, coolers, etc.) used to transport produce shall be adequately cleaned before their use and must be adequate for their use.

(2) Produce that appear to be contaminated by animal excreta or other dangerous or filthy substance may not be sold or donated pursuant to this Title.

(a) Produce matter harvested from the exposed parts of upland plant or fungi species located on land which was flooded during the plant or fungus' current growing cycle shall be deemed contaminated for the purpose of this subsection.

(b) Dropped produce, except for roots (e.g. wild onions) and crops that grow on the ground (e.g. morel mushrooms), shall be considered contaminated for the purpose of this subsection.

(c) Any contaminated produce which was inadvertently harvested shall be kept separate from any food intended for sale or donation. Contaminated plant or fungi matter may be respectfully disposed of, or maintained within physically separate containers clearly marked as "NOT FOR SALE OR DONATION."

7.03 Procedures for Class 2 and 3 Covered Produce Sales

(1) The following only applies to Harvesters of Class 2 and Class 3 covered produce with covered produce sales exceeding $25,000 annually for the past 3 years (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment, and are not exempted as a qualified small or very small business.

(2) A valid non-exempt produce harvester license issued by the _____ [Tribe] is required for the production and sale of treaty-harvested covered produce by individuals and entities covered in subsection (1), above. Non-exempt produce harvester licenses shall be issued upon the submission of complete applications and satisfactory inspection. Non-exempt produce harvester licenses may be revoked or suspended for non-compliance with the standards set forth within this Chapter. The _____ [tribal licensing authority] may refuse to issue a non-exempt produce harvester license to an individual with ownership or management interest in an operation which has been subject to any serious, or ongoing or unresolved violations of this Chapter. An application for a Non-exempt produce harvester license must be submitted to the _____ [tribal

licensing authority] annually, for each physical location used to package covered produce, containing the following information:

(f) The name of the food producer and mailing address;

(g) Physical address of the facility or residence used to package the covered produce;

(h) The type of foods which will be packaged at the facility or residence;

(i) A statement agreeing to comply with the requirements and standards set forth in this Chapter, including any required inspections required by the _____ [tribal licensing authority]; and

(j) Payment of required fees.

(3) Worker Health, Hygiene and Training.

(a) At least one supervising harvester shall have completed food safety training at least equivalent to the standardized curriculum recognized by the FDA for produce safety.

(b) All personnel shall be trained as appropriate to their duties, upon hiring, and periodically thereafter, at least once per year. Personnel training must be supervised by a qualified person and conducted in a manner that is easily understood by the person being trained. In addition to general food handling training topics required by Sec. 3.04 [Personnel], personnel training shall include: (1) recognizing covered produce that should not be harvested due to contamination; (2) inspecting harvest containers, tools and equipment to ensure they are clean and operating appropriately; and (3) correcting food safety problems as they arise, or reporting them to a supervisor.

(c) Personnel engaged in harvesting and handling covered produce shall:

(i) Maintain adequate personal cleanliness to protect against the contamination of covered produce and food contact surfaces;

(ii) Avoid contact with animals;

(iii) Wash hands frequently and adequately, and prior to starting work and after engaging in any activity which may lead to the contamination of their hands;

(iv) Remove or cover any hand jewelry that cannot be adequately cleaned and sanitized; and

(v) Refraining from eating, chewing gum or tobacco, or smoking.

(d) Harvesters shall take measures to protect contamination of covered produce and food contact surfaces from microorganisms of public health significance by:

(i) requiring personnel to report symptoms of illness, or other indicia of illness, which is consistent with infectious disease;

(ii) requiring personnel to report injuries that result in bleeding or open wounds; and

(iii) excluding personnel from food handling activities, or taking other precautions (e.g. requiring a worker with an open wound on their hand to bandage the wound and wear a glove).

(e) Records on personnel training, including persons trained, topics covered, and the date of training sessions, shall be maintained consistent with subsection (6), below.

(4) Preventing the Contamination of Covered Produce by Animals.

(a) The harvester, or designee, shall survey the area to be harvested at least one week in advance of any plant harvesting, documenting any evidence of animal presence (e.g. signs of grazing or significant amounts of excreta) through a visual depiction of the area that is reasonably proportionally accurate (i.e. a map) or a narrative description of the area that effectively describes the layout of the area to be harvested and any notable findings.

(b) Immediately before harvesting covered produce, the harvester or designee shall again survey the area where covered produce will be harvested, physically roping off areas where animal excreta are observed, using flagging material, rope and removable stakes or other similar materials. No covered produce shall be harvested from within the roped-off areas. The materials used to physically separate these areas shall be removed at the end of each harvesting day.

(c) To the extent possible, domesticated animals, including pets, shall be excluded from harvest zones when harvesting activities are taking place. In the event that presence of a domesticated animal is observed within the area to where covered produce will be harvested, the specific areas where domesticated animal presence is observed shall be segregated in the manner described in 7.02(3)(b) and harvest shall not occur within these areas.

(5) Tool and Equipment Maintenance.

(a) All food contact surfaces of equipment and tools used during harvesting, packing and holding covered produce shall be inspected, maintained and cleaned, and when necessary, sanitized, as frequently as necessary to prevent the contamination of covered produce.

(b) All non-food contact surfaces of equipment and tools used for harvesting, packing and holding covered produce shall be maintained and cleaned as frequently as necessary to prevent the contamination of covered produce.

(c) Equipment such as forklifts, utility vehicles and trucks, if used in covered produce operations, shall be used in a manner that minimizes the potential for contamination of covered produce and food contact surfaces with known or reasonably foreseeable hazards.

(6) Post-Harvest Handling and Sanitation.

(a) Covered Produce Packing Areas. The standards articulated in Sec. 3.11 [Food Processing Plants] are not required for facilities dedicated solely for the harvesting, packing and holding of covered produce. Instead, the following standards apply.

(i) Any buildings used for cleaning, packing and storing of covered produce shall be suitable in size, construction and design to reduce the potential for contamination of the covered produce and food contact surfaces due to foreseeable hazards such as: waste water, drip, condensate and other sources of filth or contamination.

(ii) Physical barriers, such as fencing, walls and screens, shall be employed as necessary to exclude wild and domestic animals, and pests (e.g. mice, rats, flies, etc.), and their waste, from entering the buildings.

(iii) Any toilet facilities shall be designed, located and maintained to prevent the contamination of covered produce and shall include hand-washing service.

(iv) The building shall be supplied with an appropriate mechanism or service to convey, store and dispose of trash, litter and waste, in order to minimize the potential to harbor and attract pests and to protect against the contamination of covered produce, food contact surfaces and related items.

(v) If plumbing is employed, it shall operate to perform to the following specifications:

(i) Distribute in sufficient quantity, and under sufficient pressure, potable water for the use in covered activities, and for the toileting and handwashing facilities as applicable;

(ii) Proper conveyance of sewage and liquid disposable waste to the sewage or septic system or other adequate means of controlling and disposing of liquid waste;

(iii) Avoid being a source of contamination of covered produce, food contact surfaces and critical areas; and

(iv) Not allow backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for covered produce activities, maintaining sanitary operations or handwashing.

(b) Water Used for Post-Harvest Activities. Only water with no detectable generic *E. coli* per 100 mL sample may be used for the following post-harvest activities:

(i) Direct contact with covered produce before or after harvest;

(ii) Direct contact with food contact surfaces;

(iii) To make ice; and

(iv) For handwashing during and after harvest activities.

If untreated groundwater is used, a sample of that water shall be tested for generic *E. coli* at least 4 times during the growing season. If water from a public water supply is used, the food producer must retain a copy of the water supply certificate of compliance, documenting that the water meets or exceeds the requirement of the Safe Water Drinking Act, or that it is free of detectable generic *E. coli* in 100 mL of water. Water used must be managed as necessary to maintain its safety to prevent the build-up of organic materials, improper temperature or pH level or other hazardous condition.

(7) Documentation and Records.

(a) The harvester or designee shall document the actions taken in accordance with Sec. 7.01 [General Provisions], Sec. 7.03 (2) to (5) and Sec. 3.05 [Food Transportation and Storage] for each week of covered produce harvesting conducted, assigning that week of harvested food with a unique lot number. All records related to a specific harvest shall bear that same lot number. These written records shall be maintained by the harvester for 2 years after the sale of the covered produce.

(b) The harvester or designee shall also maintain records documenting personnel training, utensil and equipment maintenance, cleaning and sanitizing schedules and performance and the maintenance of a hygienic operation. These records shall be updated frequently and maintained for 2 years from the time of their creation.

(c) The maintenance of records on computers or electronic databases is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(d) All records required by this part and all plans and procedures required by this part shall be available for official review and copying by the _____ (tribal licensing authority) at reasonable times.

7.04 Packaging Produce

(1) Produce, if packaged in a raw and unpreserved state, shall be contained within clean packaging materials that discourage the growth of pathogenic bacteria or fungi. Except for mushrooms, produce is exempt from labeling requirements of Sec. 3.02.

(2) Fresh mushrooms shall be packaged in clean packaging materials, labeled according to Sec. 3.02(2) [Debwewin; Truth in Labeling; mushrooms]. If fresh mushrooms are enclosed within packaging materials, aerobic packaging (i.e. oxygen permeable materials) shall be used to discourage decomposition.

Chapter 8 Low-Risk Foods

8.01 General Provisions

(1) This chapter applies to the production of low-risk foods. Low-risk foods are foods that carry a lower risk of food-borne pathogens and can be safely produced outside of tribally-licensed food processing plants. A non-exclusive list of low-risk foods includes: manoomin (wild rice) and manoomin flours, low-acid fruit preserves, low-acid pickled produce, dried teas or dried tea blends, dried fruit (excepting melons), candy, syrups and sugar made from tree sap.

(2) A valid low-risk food vendor license issued by the _____ [Tribe] is required for the production of low-risk foods produced outside of a tribally-licensed food processing plant, except that Class 1 manoomin and Class 1 syrup and sugar may be processed without a low-risk food vendor license. Low-risk food vendor licenses shall be issued upon the submission of complete applications and satisfactory inspection. Low-risk food vendor licenses may be revoked or suspended for non-compliance with the standards set forth within this Chapter. The _____ [tribal licensing authority] may refuse to issue a low-risk food vendor license to an individual with ownership or management interest in an operation which has been subject to any serious, or ongoing or unresolved violations of any applicable portions of this Title. An application for a low-risk food vendor permit must be submitted to the _____ [tribal licensing authority] annually, for each physical location used to produce a low-risk food, containing the following information:

(a) The name of the food producer and mailing address;

(b) Physical address of the facility or residence used to process the low-risk foods;

(c) The type of food(s) which will be produced at the facility or residence;

(d) A statement agreeing to comply with the applicable requirements and standards set forth in this Title, including any required inspections required by the _____ [tribal licensing authority]; and

(e) Payment of required fees.

(2) Inspections

(a) An annual inspection is required for all facilities used by all licensed low-risk food vendors to prepare and package low-risk foods.

(b) The _____ [tribal regulatory agency] may inspect facilities licensed to produce a low-risk food upon a reasonable belief that the operation is in violation of the requirements contained in this chapter or in response to a public health emergency (e.g. a foodborne illness outbreak associated with the consumption of foods produced by the operation).

(c) Inspections may include a walk-through of the premises used for the cleaning and sanitizing of surfaces, tools and equipment, for preparation and packaging of low-risk foods and any storage areas, and the review of applicable records. Additionally, during the inspection, the vendor must demonstrate an understanding of the applicable food safety standards contained within this chapter, and the capacity to comply.

(3) The following provisions apply to the preparation and packaging of low-risk foods outside of a tribally-licensed food processing plant.

(a) Low-risk foods shall be prepared consistent with traditionally safe methods.

(b) Produce shall be washed, sorted and trimmed as necessary, and inspected before being canned. Waste and by-products shall be stored and handled in a sanitary manner.

(c) If the food is prepared using water, it must be potable water that meets applicable drinking water standards. Potable water must be used to clean surfaces and equipment that will come into contact with the food.

(d) Individuals engaged in the preparing and packaging of low-risk foods shall wear clean and cleanable clothing, wash their hands sufficiently during the operations and not be infected with a reportable communicable illness, experiencing any symptom of acute gastrointestinal illness or have a discharging open wound, sore or lesion on the hand, arm, or other exposed portion of the body. While engaged in the production of low-risk foods, no person may consume food, use tobacco recreationally or drink beverages in any area used for food processing, except in designated areas which are separated from the processing areas. This subsection does not prohibit a sanitary drinking water fountain in a processing, storage or packaging area, or the drinking of water through a straw in an otherwise closed container.

(e) The tools and equipment used to measure the sugar content of syrup and the pH of low-acid fruit preserves and low-acid pickled vegetables shall be maintained in good repair and calibrated prior to each use.

(f) The premises, tools and equipment used for preparing and packaging low-risk foods shall be kept clean and sanitary, to the degree necessary to remain consistent with traditionally safe methods. While preparing and packaging foods intended for sale, pets and other domestic animals shall be excluded from the workspace, and no other domestic activities (e.g. family meal preparation, dishwashing, clothes washing, etc.) shall be conducted.

(g) The materials used to package low-risk foods shall be kept clean and dry prior to their use, and be clean, single-use containers or containers which were cleaned and sterilized prior to their use.

(h) Lead or lead-alloy shall not be used in the construction or repair of food-contact surfaces, including taps and sap-collection devices.

(i) Food contact surfaces of equipment and utensils shall be constructed of stainless steel or of one or more other food-grade materials which are smooth, impervious, nontoxic, non-corrodible, nonabsorbent and durable under normal use conditions. Food contact surfaces shall be easily cleanable, and shall be free of breaks, open seams, cracks or similar defects. Food contact surfaces shall not impart any odor, color, taste or adulterating substance to food. Food contact surfaces shall be readily accessible for manual cleaning.

(4) Low-risk vendors who earn less than $50,000 annually in gross annual sales from low-risk foods during the annual licensing period, and are producing low-risk foods outside of a food processing plant are exempt from the provisions of Chapters 3 and 4 for the preparation, packaging and sale of low-risk foods, except that Sec. 3.01 [Zhawenindiwag; Respect for Traditional Foods and Consumers], Sec. 3.02 [Debwewin; Truth in Labeling], Sec. 3.03 [Food Additives], Sec. 3.05 [Food Transportation and Storage], and Sec. 3.06 [Equipment and Utensils] shall apply, and the retention schedule for low-risk foods in Sec. 3.10 [Recordkeeping] shall apply. Sales of manoomin and syrup and sugar derived from tree sap shall not be included in the calculation of gross annual sales from low-risk foods. The $50,000 limit shall be adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

(5) Except for sales of manoomin, syrup and sugar, all low-risk foods produced outside of a food processing plant must be sold directly to consumers.

8.02 Syrup and Sugar Derived from Tree Sap

(1) Sap that is intended for processing as a low-risk food shall remain covered prior to processing, with care taken to avoid spoilage.

(2) Any filtering and defoaming agents used in the processing of syrup and sugar shall be nontoxic and food grade.

(3) All food contact surfaces used in the condensing of sap into syrup for shall be cleaned and sanitized prior to the addition of unfinished sap and after each batch, not to exceed 40 days of

continuous operation without any interruption exceeding 30 minutes, or more frequently to avoid the adulteration of products. A variance for the use of food contact surfaces for the processing of tree sap that are not stainless steel or comprised of food grade materials should be available as long the materials in contact with the sap, sugar or syrup are nontoxic (i.e. lead or lead-alloy soldering shall not be used).

(4) Syrup and sugar may be sold as Class 2 and Class 3 food as long as the final boiling and packaging of the product occurs in a licensed food processing plant or within premises that are exempt from registering as a food facility pursuant to 21 CFR 1.225. Syrup and sugar sold or donated as Class 1 foods are exempt from this provision.

(5) The sugar content of each batch of finished syrup shall be measured using a refractometer calibrated at 68°F, and to which any applicable temperature correction has been made, or by any other method that gives equivalent results. A record of this measurement shall be created and maintained pursuant to Sec. 3.10 [Recordkeeping].

8.03 Manoomin

(1) Manoomin which is sold pursuant to this Title shall be processed in manner that is consistent with the cultural traditions specific to the _____ [Tribe], and may include the use of machines for parching, threshing and separating hulls from the finished product. A variance for the use of food contact surfaces for the processing of manoomin that are not stainless steel or comprised of food grade materials should be available as long the materials in contact with the manoomin are nontoxic (i.e. lead or lead-alloy soldering shall not be used).

(2) Prior to packaging manoomin harvested for donation or sale pursuant to this Title, the manoomin shall be examined to ensure that it does not contain any fragments of hard, inedible material (e.g. pebbles, mud, metal shavings) exceeding 7 mm in length, with reasonable efforts made to remove all inedible materials.

8.02 Low-acid Fruit Preserves and Low-acid Pickled Vegetables

The pH of each batch of finished low-acid fruit preserves and low-acid pickled vegetables shall be measured using a pH meter, or by any other method that gives equivalent results. A record of this measurement shall be created and maintained pursuant to Sec. 3.10 [Recordkeeping]. When not in use, the probe of the pH meter should be stored in a buffer solution to prolong its use.

Inland and Lake Superior Fish

Chippewa Traditional Food Regulatory System Project

Fish and the Ojibwe People

The Ojibwe have always lived on and around waters abundant with fish. Historically fish has been, and today continues to be, an essential component of the Ojibwe diet. Traditional feasts often feature fish dishes and stories are told of the relationship between humans and fish. Fish are also considered relatives to the Ojibwe people and at least one clan comes from the fish people (name or sturgeon).

The Purpose of the Model Food Code

The Model Food Code aims to provide a general regulatory framework under which the 11 GLIFWC member tribes can develop food regulatory systems for the commercialization of value-added wild harvested foods. The integration of Model Food Code chapters into existing tribal community food structures will enable tribal members to safely engage in commercial activities based around traditional hunting, fishing, and gathering practices (Sec. 1.01 [Purpose]). Model Food Code provisions apply to treaty-harvested food products intended for sale by vendors to individual tribal members, organizations and institutions for which a majority of the consumers served are tribal members, and a general consumer base which includes non-tribal members and retail institutions (Sec. 2.01 [Definitions]). The Model Food Code does not apply to informal commercial sales within reservation boundaries, home use of treaty-harvested food products, community feasts, or the sale of whole deer and elk carcasses pursuant to tribes' applicable off-reservation conservation codes (Sec. 1.02 [Applicability]).

Fish Processing in the Model Food Code

The processing of treaty-harvested fish is primarily regulated in Chapter 6 of the GLIFWC Chippewa Ceded Territory Traditional Model Code (Model Code). A summary of the provisions:

- A license issued by a tribal food regulatory authority is required to engage in the processing of treaty-harvested fish for commercial sale or donation to a tribal program.
- Fish products are regulated by the relative food safety risk posed by the product and how the product is sold. Class 1 licenses limited to lower risk fish products and the class 1 food processing regulations are less stringent. Class 1 fish products may be sold on reservation to tribal members. Class 2 and 3 licenses providing the opportunity to produce more complex products with higher levels of regulation. Class 2 and 3 products are for sales to tribal programs and general retail sale, respectively.

Fish Processing in the Model Food Code, cont.

- All producers will be required to retain documentation of the condition of the fish prior to being processed or received by a fish processing plant (i.e. temperature of fish, time after harvest, held within a climate-controlled environment or in contact with ice, etc.). All fish processing is required to be conducted in clean environments, using equipment and surfaces that have been cleaned and sterilized, and by individuals who are adequately trained. Successful completion of a Fish HACCP program is required for entities and vendors producing processed fish for sale and donation.
- Class 1 sales are limited to fresh filets and fresh whole, gutted fish. Class 1 fish processing may occur outside of a licensed food processing plant and within home facility (e.g. home, community kitchen, etc.) that has been inspected by the tribal food regulatory authority. Class 1 fish products are exempt from most labeling requirements, however the food processor is required to be truthful in any statements about the products. Class 1 fish products may only be sold direct to tribal consumers by the processor.
- Class 2 sales include fresh filets, fresh whole, gutted fish and vacuum-packed frozen filets. Vacuum-packed fish filets are a higher risk product due to their storage within an anaerobic environment and potential to support botulism. Class 2 fish processing may only occur within a tribally-licensed food processing plant; class 2 products have standard retail labeling. Class 2 fish products may be sold direct to tribal consumers and to tribal programs.
- Class 3 products include fresh filets, fresh and whole, gutted fish, vacuumed-packed frozen filets, smoked fish and roe. Strict time and temperature controls are necessary for the safe processing and storage of smoked fish and roe. Class 3 fish products must be processed within a tribally-licensed food processing plant and are labeled with standard retail labeling. Class 3 fish products may be sold in tribally-licensed retail food establishments, and other locations, for sale to anyone.

FOR INFORMATIONAL PURPOSES ONLY. MODEL CODE PROVISIONS DO NOT APPLY UNLESS ADOPTED BY A TRIBAL GOVERNMENT

For more information about the Chippewa Ceded Territory Traditional Food Regulatory Systems Project, please contact Latisha Coffin, ANA SEDS Coordinator, at (715) 682-6619 or lcoffin@glifwc.org.

Manoomin (Wild Rice)

Chippewa Traditional Food Regulatory System Project

Manoomin and the Ojibwe People

Manoomin, the Ojibwe word for wild rice, directly translates into "the good berry." This word reflects the importance of this healthy staple food to the Ojibwe diet. An aquatic grass rich in protein and low in fat, Manoomin has been an important part of feasts and ceremonies since the Ojibwe arrived to the Great Lakes from the East Coast. Manoomin was a key trade good of the Ojibwe valued by both other Native peoples and early European explorers.

Manoomin is also important to many lake and stream ecologies as a valuable food and source of cover for waterfowl. Unfortunately, environmental changes caused by European settlement have destroyed many historic wild rice beds. Since 1984, however, Ojibwe tribes, GLIFWC and other natural resource interest groups have worked to restore historic wild rice beds.

The Purpose of the Model Food Code

The Model Food Code aims to provide a general regulatory framework under which the 11 GLIFWC member tribes can develop food regulatory systems consistent with food science and traditional Ojibwe knowledge. The integration of Model Food Code chapters into existing tribal community food structures will enable tribal members to safely engage in commercial activities based around traditional hunting, fishing and gathering practices (Sec. 1.01).

Model Food Code provisions apply to treaty-harvested food products intended for sale by vendors to tribal members, organizations and institutions for which a majority of the consumers served are tribal members, and a general consumer base which includes non-tribal members and retail institutions (Sec. 2.01). The Model Food Code does not apply to informal commercial sales within reservation boundaries, home use of treaty-harvested food products, community feasts or the sale of whole deer and elk carcasses pursuant to tribes' applicable off-reservation conservation codes (Sec. 1.02).

Manoomin in the Model Food Code

The Model Food Code does not restrict traditional Ojibwe methods of harvesting and processing Manoomin. Harvesting and processing wild rice can occur outdoors or in a semi-enclosed space such as a garage. The model food provisions on manoomin are intended to establish a framework under which tribal members can sell their wild rice to a wider customer base.

Chapter 2 [Definitions]:

- (Sec. 2.01) - Manoomin, meaning the ripened seeds of manominagaawanzh (northern wild rice or *Zizania palustris*), is classified as a low-risk food. This signifies that it does not require time and temperature control to remain safe for human consumption, and has not been shown to support the growth of any foodborne pathogens.

Chapter 3 [General Provisions]:

- (Sec. 3.02) - Manoomin may only be labeled "natural" or "hand-harvested" if the contents of the package consist entirely of hand-harvested wild rice and contains no mechanically-harvested wild rice or wild rice grown with the use of chemical fertilizers or herbicides.
- (Sec. 3.02) - Manoomin is exempt from labeling requirements related to home use facilities.
- (Sec. 3.12) - Vendors may sell manoomin to any individuals without a retail food establishment license.

Chapter 8 [Low-Risk Foods]:

- (Sec. 8.01) - No annual inspection is required for facilities used to prepare and process manoomin.
- (Sec. 8.03) - Processing must be done in a manner that is consistent with the cultural traditions of your community, which may include the use of machines for parching, threshing and separating hulls from the finished product.
- (Sec. 8.03) - The food contact surfaces of processing equipment that are not stainless steel or comprised of food grade materials may qualify for a variance, provided that the food contact surfaces are nontoxic.
- (Sec. 8.03) - Prior to packaging manoomin for donation or sale, the manoomin must be examined for hard, inedible materials (i.e. pebbles, mud or metal shavings) greater than seven millimeters in length, with reasonable efforts made to remove all inedible materials.

FOR INFORMATIONAL PURPOSES ONLY. MODEL CODE PROVISIONS DO NOT APPLY UNLESS ADOPTED BY A TRIBAL GOVERNMENT

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Great Lakes Indian Fish & Wildlife Commission Traditional Food Regulatory System Project 2020 Supplement to the 2018 First Food Code Guidance Report

Table of Contents

I. Executive Summary

In this report, we identify and analyze food safety regulations that govern the small-scale harvesting, processing, and sale of Treaty-harvested wild foods for the Great Lakes Indian Fish & Wildlife Commission's ("GLIFWC") Chippewa Ceded Territory Traditional Food Regulatory System Project ("Project"). We understand that the Project seeks to address limitations on the use of Treaty-harvested wild foods by Member Tribes[1] and their tribal members for tribally-operated federal food programs and commercial sale. As affirmed in multiple federal court decisions, Member Tribes and their members have the right to hunt, fish, and gather in the ceded territories for subsistence purposes and commercial sale. But Member Tribes and tribal members are limited in their use of wild foods for federal food programs or broader marketing because there is a lack of tribal standards and regulatory systems to ensure the safety of wild food. In the absence of tribal standards, a system of food safety regulation by the federal and state governments is effectively imposed on tribal uses of wild foods.

At the federal level, the Food and Drug Administration ("FDA") is the principal agency with jurisdiction over wild foods relevant to this report. The FDA has established a broad regime of food safety regulation for harvesting, processing, and distribution of food which applies up to the point that it reaches the food establishment that sells or serves food to the consumer. The FDA's requirements apply to wild foods, such as fish, wild rice, and plants, and may be referenced for a tribal regulatory system.

Wild game presents unique food safety issues because animals typically must be inspected before and after slaughter, which is not possible for wild game that is hunted. Although wild game falls under the FDA's jurisdiction, currently there are limited federal standards for wild game that can be utilized to increase its commercial sale. Section 4033 of the 2014 Farm Bill provides standards for wild game to be donated to certain federal food programs, but this authority does not extend to federal reimbursement or commercial sale.

Tribal and state governments regulate food processing and distribution operations within their jurisdictions alongside the FDA. Tribal, state, and local governments also regulate the food establishments that sell or serve food to the consumer through food codes patterned off a Model Food Code issued by the FDA. Although the FDA does not directly regulate food establishments, the Model Food Code is intended for adoption by tribal, state, and local governments to ensure consistency with national food standards in the retail segment of the industry. The Model Food Code contains a provision that allows for food establishments to obtain field-dressed wild game

[1] The Member Tribes of GLIFWC include the following 11 sovereign tribal governments: Fond du Lac Band of Lake Superior Chippewa, Bad River Band of the Lake Superior Chippewa, Bay Mills Indian Community, Keweenaw Bay Indian Community, Lac Courte Oreilles Band of Lake Superior Chippewa, Lac du Flambeau Band of Lake Superior Chippewa, Lac Vieux Desert Band of Lake Superior Chippewa, Mille Lacs Band of Ojibwe, Red Cliff Band of Lake Superior Chippewa, Sokaogon Chippewa Community, and St. Croix Chippewa Indians.

from processors for sale and service. The Project may want to consider how to design model standards around this provision in the Model Food Code.

State and local governments generally do not have regulatory authority over food operations conducted by tribes or tribal members on their reservations. The exception is the State of Wisconsin, which is currently authorized to enforce its food laws on the sale of wild game to non-members pursuant to a stipulation made in the *Voigt* litigation, until such time as a Tribe subject to *Voigt* adopt their own food standards. Otherwise, tribes are the regulatory authority for food processing operations and retail sales within their jurisdiction. We found examples of tribal regulatory systems, including requirements for licensing, inspections, and the incorporation of federal food safety standards. We found few examples of tribes which have adopted their own food safety regulations for wild foods. One example is the Pokagon Band of Potawatomi Indians, which has enacted a health and safety act to allow food establishments to sell or serve uninspected wild game, so long as the animal is field-dressed, transported, and processed according to standards established by the Pennsylvania State University Cooperative Extension for the proper processing of wild game and fish. Similarly, the Project may want to consider standards for wild foods for incorporation into model provisions, and we have included examples in the Appendix to this report.

Accordingly, we offer the following recommendations for the Project's second year:

1. Consider potential conservation measures that could be incorporated into a tribal regulatory system to address food safety concerns regarding wild foods. One example is Michigan's use of Chronic Wasting Disease surveillance zones for guidelines on venison processing. Other restrictions could be considered such as limitations on lead ammunition for Treaty harvesters who intend to harvest wild game for commercial sale, or the use of information regarding areas known to contain potential contaminants.

2. The Project should design model provisions to govern the field-dressing and transportation of wild game. Wild game presents unique food safety issues as compared to other wild foods, because the undocumented life history of wild game provides no assurance that the animal is free from disease or other viruses that may cause illness in humans. As for other wild foods, such as fish, wild rice, and plants, the FDCA's standards may be referenced because general and specific standards already exist for these foods. Model provisions should also provide for enforcement through tribal licensing and inspection of small-scale processors that intend to sell wild food products to food establishments or for use in federal food programs. Section 4033's standards may be used where they apply, but thus far Section 4033 has not expanded beyond donation in certain food programs.

3. The Project should incorporate the model provisions it designs into the FDA's Food Code. Member Tribes may then adopt the amended Food Code as a basis to assert jurisdiction over food establishments within their jurisdiction. The model provisions for food processors do not necessarily need to be in the Food Code itself, as they can be located in separate Tribal Code provisions and then referenced in the Food Code. The Food Code governs food establishments, not food processors. Of course, the Project is free to incorporate all requirements into a Food Code for simplification.

4. The Project should account for exemptions of certain types of food operations and intra-tribal uses of wild food that are not appropriate for formal regulation. Member Tribes have been regulating wild foods to ensure food safety since time immemorial through their subsistence practices that form an essential component of their Treaty rights. In designing a tribal regulatory system, it will be important for Member Tribes to identify the activities that should remain unregulated, because there is more flexibility for unregulated uses of wild food if it is not intended for sale to non-members or use in federal food programs.

Below, Part II discusses the Member Tribes' off-reservation hunting, fishing, and gathering rights. Part III discusses the food safety regulation system in the United States for wild foods, including regulation by the federal government, state and local governments, and tribal governments. Part IV offers conclusions and recommendations.

2020 Supplement: As part of the Project's third year, we reviewed and updated this Report to account for regulatory and other changes since June 2018. During the past two years, the FDA has continued to implement the Food Safety Modernization Act through additional guidance. Congress also passed a new Farm Bill in December 2018 that expands on traditional food provisions enacted in the 2014 Farm Bill. This supplemental information is identified and discussed as the 2020 Supplement where relevant throughout the Report.

II. Background on Member Tribes' Off-Reservation Hunting, Fishing, and Gathering Rights

We first discuss the Member Tribes' off-reservation hunting, fishing, and gathering rights, which secure tribal members the right to harvest food resources for subsistence and commercial purposes. The Member Tribes reserved hunting, fishing, and gathering rights in territories ceded in 1837, 1842, and 1854 Treaties with the United States. These rights were affirmed through multiple federal court cases, including the *Voigt* decision,[2] the *Mille Lacs* decision,[3] and the

[2] *Lac Courte Oreilles Band of Lake Superior Chippewa Indians v. Voigt*, 700 F.2d 341 (7th Cir. 1983).
[3] *Mille Lacs Band of Chippewa Indians v. Minnesota*, 124 F.3d 904 (8th Cir. 1997).

decision in *Fond du Lac Band of Chippewa v. Carlson*.[4] The cases principally arose as an effort by the Tribes to enjoin state regulation of Treaty hunting, fishing, and gathering rights in the ceded territories.[5] These decisions held that the Tribes retain their hunting, fishing, and gathering rights in the ceded territories.[6]

Courts in both *Voigt* and *Mille Lacs* recognized that the rights include the right to harvest Treaty resources for commercial sale, even to non-members. The federal district court in the *Voigt* litigation specifically found that "[t]he fruits of the exercise of their usufructuary rights may be traded and sold today to non-Indians, employing modern methods of distribution and sale."[7] Likewise, the federal district court in *Mille Lacs* found the Tribes retained "the right to harvest the resources for commercial purposes."[8] So, the commercial sale of wild food harvested under the Treaty rights is a component of those rights.

Voigt and *Mille Lacs* both deferred a decision on the extent to which the States of Wisconsin and Minnesota, respectively, could regulate the off-reservation rights, including the sale and service of harvested food.[9] The issue of permissible state regulation was set for trial in subsequent phases and the parties later made stipulations to narrow the issues to be tried. As relevant to this report, the parties to the *Voigt* litigation stipulated to matters regarding the sale of Treaty-harvested deer in the subphase for the permissible scope of state regulation of white-tailed deer (the "Deer Trial Stipulation").[10] The Deer Trial Stipulation provided that, as of 1989, the Tribes which were parties to *Voigt* did not have food regulations similar to enumerated provisions in Wisconsin law applicable to the processing of deer for human consumption, including the regulation of food processing and retail food establishments.[11]

The Deer Trial Stipulation authorized Wisconsin to enforce its food laws "both on- and off-reservation, in the interest of public health," so long as there is reason to believe that deer is

[4] *Fond du Lac Band of Chippewa v. Carlson*, 68 F.3d 253 (8th Cir. 1995), *on remand* Mem. Op. and Order, No. 92-159 (D. Minn. Mar. 18, 1996) (recognizing the 1854 Treaty rights).
[5] *Voigt*, 700 F.2d at 343; *Mille Lacs*, 124 F.3d at 910; *Carlson*, 68 F.3d at 254-55.
[6] *See Voigt*, 700 F.2d at 365; *Mille Lacs*, 124 F.3d at 928; *Carlson*, Mem. Op. and Order, No. 92-159 (D. Minn. Mar. 18, 1996).
[7] 653 F. Supp. 1420, 1435 (W.D. Wis. 1987).
[8] 861 F. Supp. 784, 838 (D. Minn. 1994).
[9] *Mille Lacs*, 124 F.3d 909; *Lac Courte Oreilles Band of Lake Superior Chippewa Indians v. Wisconsin*, 653 F. Supp. 1420, 1435 (W.D. Wis. 1987).
[10] *Lac Courte Oreilles Band of Lake Superior Chippewa v. Wisconsin*, No. 74-C-313 (W.D. Wis. 1989) (Deer Trial Stipulation).
[11] Deer Trial Stipulation at 17. The incorporated provisions include Wis. Stat. §§ 97.02; 97.03; 97.10(1); 97.12; 97.29; 97.30 (except for license fees under §§ 97.29 and 97.30); 97.42; 97.43; 97.46; 97.53; Wis. Admin. Code Ag ch. 32 (May 1984) (except §§ 32.12-.13); Ag §§ 47.01-.10, 47.12-.13, 47.15, 47.17-.185, 47.20-.45 (May 1986), and Ag ch. 48 (Dec. 1985), as they "relate to wild game." These provisions have changed over time but they represent Wisconsin's food laws.

marketed with "the reasonable expectation that nontribal member consumption will occur."[12] The parties agreed, however, that Wisconsin law applied only until such time as a Tribe adopted "corollary regulations" and "employ[ed] trained and qualified personnel to enforce such regulations."[13] The Deer Trial Stipulation applies only to "wild game,"[14] not to other Treaty resources such as wild rice, fruits, or vegetables. It also applies only to marketing for non-member consumption, not to consumption by tribal members in, for example, a tribally-operated food program.

The practical effect of the Deer Trial Stipulation is to prohibit the commercial sale of processed wild game meat to non-members among Tribes subject to *Voigt*, because Wisconsin law allows the service of wild game only in limited, private and non-profit settings.[15] In fact, the Deer Trial Stipulation illustrates the problem that the Project seeks to address. Namely, that the absence of tribal standards or regulatory systems for wild food limits its use, because federal and state food safety regulations are imposed in the place of tribal regulation. Federal and state food safety regulations are not typically designed to address food that is harvested in the wild and act more to limit, rather than to facilitate, the broader use of Treaty-harvested wild food.

The modern food safety regulation system in the United States has largely developed around food that is commercially grown or raised, not harvested in the wild. For Member Tribes, conservation measures could be incorporated into a tribal food regulatory system as a replacement for food safety requirements that apply to producers that grow crops or raise animals for food. GLIFWC has developed model conservation codes for adoption by Member Tribes in order to implement the *Voigt* and *Mille Lacs* decisions. The model codes generally provide for potential limitations on commercial harvests based on resource management, not food safety.[16] However, the model codes, as adopted by Member Tribes, establish a regulatory scheme that could be used to facilitate the subsequent processing and sale of wild food, since the codes provide a method of regulating the source of wild food at the top of the food distribution chain. Conservation measures

[12] *Id.* at 18.
[13] *Id.* at 18. If a Member Tribe adopts "corollary regulations," the Deer Trial Stipulation provides a process for a Tribe to return to the federal district court for an injunction against Wisconsin's enforcement of state law on the sale of wild game. *Id.* The district court may need to decide the issue if Wisconsin objects to the adequacy of tribal regulation. *Id.* It is unclear why the parties used the term "corollary," which is defined to mean "an inference or deduction" or "anything that follows as a normal result." Webster's New World Dictionary 113 (3d ed. 1994). In any event, we do not interpret "corollary" to require Tribes to adopt regulations identical to state law, as long as Tribes develop standards that demonstrate food safety.
[14] Although the Deer Trial Stipulation was made for purposes of white-tailed deer, the stipulation provided that it "shall also be incorporated into any other order resulting from a trial in this case concerning regulatory issues relating to the harvest of any other species of wild game." Deer Trial Stipulation at 16.
[15] *See* Part III.B *infra*.
[16] *See, e.g.*, *Voigt* Code §§ 6.17(4), 6.18(4)(e), 6.18(5)(g), 6.19(8).

could be utilized to assist with demonstrating the initial safety of wild foods as they are harvested to enter a food safety regulation system for processing, distribution, and eventual retail sale or service to the consumer.

III. Regulation of Wild Foods in the United States

In the United States, a patchwork of regulation by the federal, tribal, state, and local governments governs the food distribution system from production to the final retail sale or service to a consumer. As noted above, certain regulatory requirements for food production do not apply to wild foods because the regulated activities do not occur, such as the growing of crops or the slaughter of animals. Nevertheless, wild food intended for human consumption falls under the jurisdiction of agencies that regulate food. We first discuss federal regulation; then we turn to state and local regulation; and finally, we discuss tribal regulation.

A. Federal regulation of wild foods

At the federal level, the Food and Drug Administration ("FDA") and the United States Department of Agriculture ("USDA") are the principal agencies with jurisdiction over food production, processing, and distribution in interstate commerce. The USDA does not have primary jurisdiction over wild foods relevant to this report, because wild game is not subject to the USDA's jurisdiction under the Federal Meat Inspection Act or the Poultry Products Inspection Act.[17] Instead, these wild foods fall under the FDA's jurisdiction over food sold or received in interstate commerce under the Federal Food, Drug, and Cosmetic Act ("FDCA").[18]

Under the FDCA, the FDA regulates food for human consumption as an article of interstate commerce. The FDCA was enacted in 1938 and has since been amended many times, including in 2011 by the Food Safety Modernization Act ("FSMA").[19] The FSMA increased the FDA's regulatory authority under the FDCA and required the agency to promulgate new regulations, some of which have recently started to go into effect, such as a new rule that governs produce.

The FDCA defines "food" as a general term so it applies to wild food if the food is intended for human consumption and marketed in interstate commerce.[20] Federal regulations promulgated pursuant to the FDCA are complex and can burden small-scale food producers to the point that compliance makes the business unviable. Local communities have therefore asserted food

[17] As discussed further below, the USDA administers various federal food programs and indirectly regulates the safety of food that is used for these programs by imposing programmatic requirements on the types of food that may be sold or served. These requirements usually rely on compliance with other applicable food safety laws.
[18] 21 U.S.C. § 301 *et seq.*
[19] Pub. L. No. 111-353 (Jan. 4, 2011).
[20] 21 U.S.C. § 321(f). The FSMA amended the FDCA to broaden the FDA's authority beyond interstate commerce in certain respects, as discussed below.

sovereignty as a basis to reject a federal regime that is unresponsive to local needs.[21] This gains additional force for sovereign tribes exercising rights of self-government and Treaty rights to harvest, use, and sell food resources.

Nevertheless, the FDA states it is "rare" for food products intended for sale to fall outside its jurisdiction under the FDCA.[22] As for Indian reservations, the FDA's position is that it "has complete jurisdiction over products . . . that are manufactured on an Indian reservation," because the agency considers the food products to be in interstate commerce within the meaning of the FDCA "at all times."[23] Although Treaty harvesters have a potential basis to claim the FDA does not have the authority to enforce the FDCA against small-scale processing and distribution of wild foods,[24] the FDCA's methods of regulation are relevant to all levels of the food distribution system.

[21] *See* Michael T. Roberts, *Food Law in the United States* 448 (2016) ("*Food Law*") (discussing food sovereignty ordinances enacted by local communities based on "the right to shape and develop their own food system").

[22] The FDA's position is that most sales of food products will be made in interstate commerce because "at least some of your ingredients or packaging most likely originate from out of state" and "it is foreseeable that your products will leave the state." What the FD&C Act Means by "Interstate Commerce," U.S. Food & Drug Admin., *available at* https://www.fda.gov/Cosmetics/GuidanceRegulation/Laws Regulations/ucm074248.htm.

[23] FDA Jurisdiction on Indian Reservations, Compliance Policy Guides, U.S. Food & Drug Admin., *available at* https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073822.htm.

The FDA considers Indian reservations to be a "possession of the United States," such that they come within the FDCA's definition of "Territories." *See id.* § 100.350; *see also* 21 U.S.C. § 321(a)(2). The FDCA then defines "interstate commerce" to include "commerce within . . . any other Territory not organized with a legislative body." 21 U.S.C. § 321(b) (emphasis added). The FDA's policy on Indian reservations was last amended in 1987 and has apparently never been challenged. The FDA's policy is questionable to the extent that it views an Indian reservation as a "Territory not organized with a legislative body." The Department of Interior has opined that Indian reservations are not territories within the meaning of similar definitions under the Wholesome Meat Act. *Applicability of the Wholesome Meat Act of 1967 on Indian Reservations*, 78 Interior Dec. 18, 20, 1971 WL 18464, at *2 (Feb. 1, 1971). The Department of Interior thus concluded that the USDA was "not authorized or required to conduct meat inspection programs on Indian reservations." *Id.*

[24] In addition to the claim that small-scale marketing of wild foods within a state is not interstate commerce, Treaty harvesters could also claim that the FDCA is silent as to Treaty-harvested foods and therefore inapplicable. *See United States v. Dion*, 476 U.S. 734, 739-40 (1986) ("What is essential is clear evidence that Congress actually considered the conflict between its intended action on the one hand and Indian treaty rights on the other, and chose to resolve that conflict by

Unregulated wild foods create a barrier to acceptance of the product by federal regulators for use in federal food programs. The marketability of an unregulated wild food product is also limited, because the retail segment of the industry must obtain food from approved sources under most food codes. For some wild foods, there may also be no regulatory standards currently in place, creating effective prohibitions on the sale of these foods, because no accepted method has been developed for ensuring food safety. This presents the opportunity for tribes to adopt their own standards to facilitate broader marketing of wild foods if they demonstrate food safety and the standards become accepted. With these considerations in mind, we turn next to the federal regulatory regime that applies to food under the FDCA.

The main standard by which the FDCA regulates food safety is adulteration.[25] The FDCA makes it unlawful for adulterated food to be received in, or enter interstate commerce for human consumption.[26] Generally, food can be deemed adulterated in a number of ways, including when (1) the food contains a harmful substance that poses a safety risk; (2) the food contains a harmful substance added during production; (3) the food contains a substance that has been intentionally added but which has not been approved by the FDA; or (4) the food has been handled under unsanitary conditions, creating a risk of contamination with a substance that poses a safety threat.[27]

The FDA regulates the processing and distribution of food to prevent adulterated food from reaching the establishments that sell or serve food to consumers. This regulation takes the form of current good manufacturing practices,[28] hazard preventive controls,[29] standards for produce,[30] and sanitary transportation requirements,[31] among others. There are requirements that apply to food generally, as well as to specific types of foods, such as fish.[32] A food processing operation is subject to both the general requirements and those applicable to the type of food it processes, stores, or distributes.[33]

abrogating the treaty."). A claim to a Treaty-based exemption from the FDCA is likely strongest for sales and uses of wild foods among tribal members within a reservation.

[25] 21 U.S.C. § 342. The FDCA also prohibits misbranding, which is addressed by extensive labeling requirements applicable to all foods, as well as by specific labeling requirements for certain types of foods. *See id.* § 342(d)(3); *see also* 21 C.F.R. part 101 (food labeling). Wild food products must also be appropriately labeled.

[26] 21 U.S.C. § 331(a), (c).

[27] *Food Law* at 82-83.

[28] *See* 21 C.F.R. part 110.

[29] *See* 21 C.F.R. part 117.

[30] *See* 21 C.F.R. part 112.

[31] *See* 21 C.F.R. §§ 1.900-1.934.

[32] *See* 21 C.F.R. part 123 (fish and fishery products).

[33] 21 C.F.R. § 110.5(b).

The FDA has the authority to inspect facilities to ensure that these standards are met and that food is processed, stored, or distributed under sanitary conditions.[34] In practice, the FDA often relies on relationships with state and local regulators, as the majority of inspections in food facilities are conducted by state and local agencies under contract with the FDA.[35] On Indian reservations, the Indian Health Service's Division of Environmental Health Services can contract with tribes to perform inspections of tribal food operations, though tribes may assert this authority if they have the capacity to do so.[36]

1. Current good manufacturing practices

General requirements, called current good manufacturing practices, apply to food plants, which are the buildings used for processing, packing, labeling, or holding food.[37] For example, a building that processes wild rice for distribution is a food plant and must do so in accordance with the current good manufacturing practices. These standards include requirements such as employee hygiene,[38] pest control,[39] sanitation of food-contact surfaces,[40] cleanable equipment and utensils,[41] and practices for handling and preparing food.[42] In the event of an inspection, a food plant's adherence to these general practices is used to determine whether food processed or stored in the plant is adulterated.[43] Current good manufacturing practices do not apply to operations that only

[34] 21 U.S.C. §§ 374; 350j.
[35] *Food Law* at 175; *see* Human Food Inspection Contract Program, U.S. Food & Drug Admin., *available at* https://www.fda.gov/ForFederalStateandLocalOfficials/FundingOpportunities/Contracts/ucm475166.htm; FDA Fact Sheet, Human Food Inspectional Contract Program, U.S. Food & Drug Admin., *available at* https://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FundingOpportunities/Contracts/UCM576318.pdf. Within the FDA, the Division of Partnership Investments and Agreements administers the contract program. *Id.* Currently, Wisconsin, Minnesota, and Michigan have contracts with the FDA. *Id.*
[36] *See* Food Safety, Div. of Envtl. Health Servs., Indian Health Serv., *available at* https://www.ihs.gov/dehs/includes/themes/responsive2017/display_objects/documents/priorities/FoodSafety.pdf.
[37] 21 C.F.R. part 110; *id.* § 110.3 (definition of "plant").
[38] 21 C.F.R. § 110.10.
[39] 21 C.F.R. § 110.35(c).
[40] 21 C.F.R. § 110.35(d).
[41] 21 C.F.R. § 110.40(a).
[42] 21 C.F.R. § 110.80(b), (c).
[43] 21 C.F.R. § 110.6(a).

harvest, store, or distribute food in its raw or natural state, such as unprocessed fruits and vegetables.[44]

There are also specific current good manufacturing practices to address food safety concerns for certain types of food. For example, any person engaged in the commercial processing of fish must follow practices specific to fish.[45] There are no specific exemptions for small-scale fish processors, except that these regulations do not apply to (1) harvesting or transporting fish without engaging in processing; (2) harvesting, eviscerating, or freezing fish solely to hold on a boat; or (3) to operations in a food establishment (e.g., a restaurant).[46]

2. Hazard Analysis Critical Control Point

In response to well-publicized food safety concerns regarding fish, the FDA mandated fish processors to adopt and implement a Hazard Analysis Critical Control Point ("HACCP") plan.[47] HACCP is not unique to fish products. Rather, HACCP is a method of food regulation that attempts to ensure food safety by preventing hazards that could contaminate food at critical points of processing and preparation.[48] HACCP addresses physical, chemical, and biological hazards at each stage of the food production and preparation process, rather than relying solely on inspection of the finished product.[49] A HACCP plan typically requires a food processor to identify "critical control points," which are specific points in a food process where uncontrolled hazards may affect food safety (e.g., cooking, chilling, cross contamination). The processor must adopt limits for the critical control points (e.g., cooking time, temperature); verification procedures to make sure the controls are working; and corrective actions in the event they are not.[50]

[44] 21 C.F.R. § 110.19; *see also* 21 U.S.C. § 321(r).
[45] 21 C.F.R. § 123.5.; *id.* § 123.3(l) (definition of "processor"). Fish include "fresh or saltwater finfish, crustaceans, other forms of aquatic animal life . . . where such animal life is intended for human consumption." *Id.* § 123.3(d). The FDA's regulations on fish processing have special requirements for molluscan shellfish. *See id.* §§ 123.20-123.28. Specifically, processors may only obtain molluscan shellfish from waters that have been approved by a federal, tribal, or state agency that regulates molluscan shellfish harvesting. *Id.* §§ 123.28; 123.3. The FDA recognizes the National Shellfish Sanitation Program, which is a cooperative federal-state program that produces guidelines, certification programs, and growing area classifications. *See* Guide for the Control of Molluscan Shellfish, Nat'l Shellfish Sanitation Program (2015), *available at* https://www.fda.gov/downloads/food/guidanceregulation/federalstatefoodprograms/ucm505093.pdf.
[46] 21 C.F.R. § 123.3(k)(2).
[47] 21 C.F.R. § 123.6.
[48] *Food Law* at 141.
[49] *Food Law* at 141.
[50] 21 C.F.R. §§ 123.6-123.8.

The USDA also requires HACCP systems for meat and poultry processors under the Federal Meat Inspection Act and the Poultry Products Inspection Act.[51] As discussed further below, the USDA's requirements for meat and poultry do not apply to wild game, but the FDA's Model Food Code provides for these requirements to be used for the processing of field-dressed wild game.

3. Preventive controls

Pursuant to the FSMA, the FDA promulgated regulations that require food safety plans as preventive controls in "food facilities."[52] A food facility includes any facility that manufactures, processes, packs, or holds food for human consumption.[53] A food safety plan is very similar to the HACCP method of regulation, though the FDA contends the FSMA's requirements are not identical.[54] The FDA's regulations require food facilities to adopt and implement food safety plans even if their products do not enter interstate commerce.[55] However, the regulations do not apply to food establishments that sell or serve food directly to consumers, such as grocery stores, farmers' markets, and restaurants.[56] The regulations are also inapplicable to farms, which effectively exempts certain activities associated with harvesting wild foods, such as removing a vegetable or fruit from the ground, as well as basic trimming and washing.[57]

Small-scale processors may also take advantage of modified requirements intended for small businesses that sell their products locally or within the same Indian reservation. Specifically, a small-scale processor is not subject to full preventive controls if, as averaged over the prior three years, the processor sold more food to consumers or food establishments within the same Indian reservation or 250 miles, than the amount of food it sold to all other purchasers (and averaged less than $500,000 in total sales during the same period).[58] This qualified exemption allows a small-scale processor to submit an attestation to the FDA that it has incorporated HACCP principles into

[51] *See* 9 C.F.R. part 417.
[52] 21 C.F.R. § 117.126; *id.* § 117.3 (definitions of "facility" and "you").
[53] 21 U.S.C. § 350d(a)(1). Fish processors are subject to the preventive controls rule, except for activities that are regulated more specifically by the fish processing rules discussed above. *See id.* § 117.5(b); *see also Seafood HACCP and the FDA Food Safety Modernization Act: Guidance for Industry*, U.S. Food & Drug Admin. (Aug. 2017), *available at* https://www.fda.gov/downloads/Food/Guidance Regulation/GuidanceDocumentsRegulatoryInformation/UCM569798.pdf.
[54] *See* 80 Fed. Reg. 55,908, 55,911 (Sept. 17, 2015) ("Although there are similarities between these requirements of FSMA and the requirements of food safety systems known as [HACCP] systems, not every provision in FSMA is identical to the provisions of HACCP systems . . . .").
[55] 21 C.F.R. § 117.3 (a facility means any facility that must register with the FDA); *see also id.* § 1.225(b) (facility must register even if its products do not enter interstate commerce).
[56] 21 C.F.R. § 1.226(c).
[57] *See* 21 C.F.R. § 1.227 (definition of "farm").
[58] 21 C.F.R. § 117.3 (definitions of "qualified facility" and "qualified end-user").

its operations and complies with food regulations overseen by the applicable tribal, state, or local government.[59]

4. Food Facility Registration

Food facilities must also register with the FDA and renew such registration biennially.[60] This registration requirement is intended to provide information to the FDA to facilitate enforcement in the event of a food safety problem, such as an outbreak of contaminated food. The registration requirement applies to a food facility even if its products do not enter interstate commerce.[61] The FDA provides an exemption from food facility registration requirements for establishments that sell food directly to consumers and if their annual direct sales exceed annual sales to all other buyers (e.g., businesses).[62] This establishment would qualify as a "retail food establishment" and be exempt from registration.

2020 Supplement: The FDA has updated its guidance on food facility registration to account specifically for maple syrup operations.[63] The FDA's guidance discusses the types of maple syrup producing activities that require registration. In particular, the FDA's guidance states that gathering sap is harvesting, which falls under the activity of a "farm," and is exempt from registration requirements.[64] The FDA states that boiling the sap to make maple syrup is a form of "manufacturing/processing" that is an activity of a food facility which requires registration.[65] Nevertheless, a maple syrup producer that is engaged in manufacturing and processing may still be exempt from registration if the producer operates from his or her own property on which their private residence is located.[66] In this circumstance, the producer's private residence is not a "facility" and is not required to register.[67]

5. The Produce Rule: wild fruits and vegetables

The FSMA also required the FDA to promulgate regulations to provide minimum standards for most fruits and vegetables.[68] As a result, the FDA issued its produce rule in 2015 to govern

[59] 21 C.F.R. § 117.201(2).
[60] 21 U.S.C. § 350d(a)(2); 21 C.F.R. § 1.230.
[61] 21 C.F.R. § 1.225(b).
[62] 21 C.F.R. § 1.227; *see also* Retail Food Establishment Exemption Flowchart, U.S. Food & Drug Admin. (May 2018), *available at* https://www.fda.gov/media/112967/download.
[63] *Questions & Answers Regarding Food Facility Registration (7th ed.): Guidance for Industry* (Aug. 2018), *available at* https://www.fda.gov/media/85043/download.
[64] *Id.* at 9 (FAQ B.1.13).
[65] *Id.*
[66] *Id.* at 22 (FAQ C.1.5).
[67] *Id.*
[68] 21 U.S.C. § 350h.

growing, harvesting, packing, and holding produce for human consumption.[69] The produce rule applies to most fruits and vegetables,[70] except for certain types that are rarely consumed raw, such as potatoes, squash, cranberries, hazelnuts, and many types of beans.[71]

Harvesters of wild fruits and vegetables do not grow them and are therefore exempt from the produce rule's requirements applicable to growers.[72] But the produce rule also regulates harvesting, so a Treaty harvester would harvest covered produce any time he or she removed the produce from the ground and performed basic trimming and washing.[73] Under the produce rule, a harvester must take measures "reasonably necessary" to identify, and not harvest, produce that is "reasonably likely" to be contaminated with a known or reasonably foreseeable hazard, such as taking steps to not harvest produce that is visibly contaminated with animal excreta.[74] A similar requirement could be incorporated into model provisions for a tribal regulatory system. Information developed by GLIFWC regarding areas known to contain contaminants could be used as a basis to help Treaty harvesters make this determination.

Small-scale harvesters may qualify for an exemption from the produce rule.[75] Small-scale harvesters who average less than $25,000 in sales per year over the prior three years of covered produce sold are exempt from the produce rule.[76] Similar to the regulations on preventive controls, a Treaty harvester could also seek a qualified exemption if he or she sold more produce to local consumers (either within the same Indian reservation or 250 miles) than all other buyers in a three-year period (and averaged less than $500,000 in total sales of produce during the same period).[77]

[69] 21 C.F.R. part 112.
[70] 21 C.F.R. § 112.1(b)(1). Examples include blueberries, gooseberries, cucumbers, and herbs such as basil. *See id.*
[71] *See* 21 C.F.R. § 112.2(a)(1). Because these types of food are not consumed raw, food safety is ensured by processing requirements.
[72] In rulemaking, the FDA specifically addressed harvesters of wild foods and concluded that "the standards in part 112 relating to growing activities do not apply" to harvesters of "covered produce grown in the wild." 80 Fed. Reg. 74,354, 74,397 (Nov. 27, 2015).
[73] 21 C.F.R. § 112.3 (harvesting means "removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food"). For example, removing carrots from the ground is harvesting, but if the carrots are then chopped and placed into consumer-ready bags, the activity is now manufacturing/processing. *See* Questions & Answers Regarding Food Facility Registration: Guidance for Industry, U.S. Food & Drug Admin. (7th ed. 2016) (FAQ B.1.13), *available at* https://www.fda.gov/downloads/food/guidanceregulation/ucm332460.pdf.
[74] 21 C.F.R. § 112.112.
[75] Based on exemptions in the produce rule, the FDA concluded that "those that harvest covered produce grown in the wild . . . may not be covered under this rule." 80 Fed. Reg. at 74,397.
[76] 21 C.F.R. § 112.4(a).
[77] 21 C.F.R. § 112.5(a); *see also id.* § 112.3 (definition of "qualified end-user").

6. Wild game

As compared to domesticated animal food products, wild game is somewhat of an anomaly at the federal level.[78] The USDA's Food Safety and Inspection Service ("FSIS") is required to inspect meat under the Federal Meat Inspection Act[79] ("FMIA") and poultry under the Poultry Products Inspection Act ("PPIA").[80] The FSIS's mandatory inspections are different than the FDA's periodic inspections under the FDCA. The FSIS's inspections require an ante mortem inspection (prior to slaughter) and post-mortem inspection (after slaughter) of every animal,[81] which necessitates an inspector to be continuously on-site at the facility where slaughtering and processing takes place. The mandatory inspections determine whether the carcasses of these animals are not adulterated and fit for human consumption. A carcass that passes an inspection receives a round mark of approval, designating the carcass as inspected and passed, which allows the meat or poultry product to be sold in interstate commerce.[82]

The FMIA and PPIA do not apply to wild game.[83] As such, wild game is excluded from the USDA's jurisdiction under the FMIA and PPIA and the USDA does not conduct mandatory inspections of wild game. Instead, the FDA has jurisdiction over wild game as food under the FDCA. But, as a means to facilitate the sale of certain types of game, the USDA's FSIS established a voluntary inspection program for "exotic animals," which include reindeer, elk, deer, antelope, water buffalo, and bison.[84] The carcasses of exotic animals that are inspected and passed under the voluntary inspection program receive a triangular mark of approval from the USDA,

[78] Fish are not considered wild game when sold commercially. The FDA regulates fish under the FDCA. Fish are not required to be inspected but must be processed under the FDA's requirements for fish and fishery products, including the HACCP requirements discussed above. *See* 21 C.F.R. part 123; *see also id.* § 123.3(l) (processor is "any person engaged in commercial, custom, or institutional processing of fish or fishery products").
[79] 21 U.S.C. §§ 601-695.
[80] 21 U.S.C. §§ 451-472.
[81] 21 U.S.C. §§ 603(a) (FMIA ante mortem inspection); 604 (FMIA post mortem inspections); 455(a), (b) (PPIA ante and post mortem inspections).
[82] 21 U.S.C. §§ 606(a), 607(a); 9 C.F.R. § 381.96.
[83] By their terms, the FMIA and PPIA do not cover wild game. *See* 21 U.S.C. §§ 453(e) (poultry "means any domesticated bird"); 601(j) (meat food product "means . . . any meat or other portion of the carcass of any cattle, sheep, swine, or goats").
[84] 9 C.F.R. § 352.1(k). The FSIS established this program under the Agricultural Marketing Act of 1946, which gives the FSIS authority to provide voluntary inspection for non-amendable species. *See* 7 U.S.C. § 1622(h). These animals are referred to as non-amenable species because they are not amenable to mandatory inspection under the FMIA and PPIA. *See* Denise Amann, *Harvesting Wild Game*, FSIS, USDA, *available at* https://www.fsis.usda.gov/wps/wcm/connect/fsis-content/internet/main/newsroom/meetings/newsletters/small-plant-news/small-plant-news-archive/volume-5/spn-vol5-no4#1.

distinguishing these animals from the round mark given to amenable species under the FMIA and PPIA. The voluntary inspection program is intended to facilitate the sale of exotic animals, as the mark of inspection provides assurances to buyers of exotic meat products that they are safe for human consumption and allows these food products to move more freely in interstate commerce.

Producers must pay for voluntary inspections of exotic animals, in contrast to mandatory inspections under the FMIA and PPIA, which are funded by the federal government.[85] Similar to inspections under the FMIA and PPIA, the voluntary inspection program requires ante and post mortem inspections.[86] Although the FSIS's regulations allow for ante mortem inspections to be conducted in the field, these field inspections are intended to apply to farm-raised game animals, not to wild game that is hunted.[87]

In sum, federal law does not require inspections of wild game animals. Although federal law does not expressly prohibit the sale of wild game, the unregulated sale of wild game meat is difficult in practice, given how the retail segment of the industry is typically required to obtain food from approved sources under most food codes.[88] Federal reimbursement for wild game served in federal food programs is also difficult because programmatic requirements often require inspection of wild game meat by the USDA or an equivalent state program,[89] and no such program relevant to this Project currently inspects wild game that is hunted.

7. Federal food programs

The federal government administers various food programs, some of which may be operated by tribes or tribal organizations. Federal agencies have programmatic requirements to govern the food that may be purchased and served in federal food programs. For example, the USDA's Food and Nutrition Service administers multiple child nutrition programs, including the National School Lunch Program, which reimburses public and private schools for eligible meals

[85] 9 C.F.R. § 352.5.
[86] 9 C.F.R. §§ 352.10, 352.11.
[87] *See* 9 C.F.R. § 352.10(a). In rulemaking, the FSIS stated that "it would be very difficult if not impossible to trap and remove an exotic animal from the wild [for ante mortem inspection] without tranquilizing the animal. Because animals which have been treated with tranquilizers are not permitted for slaughter, any person who attempted such action would gain nothing for their efforts." 54 Fed. Reg. 1,328, 1,329 (Jan. 13, 1989).
[88] *See also Harvesting Wild Game*, *supra* n.76 (noting that "[t]here is not sufficient knowledge about [an animal killed by a hunter] necessary to conclude that the meat from the animal is not adulterated").
[89] States may contract with the FSIS to operate their own meat and poultry inspection programs ("MPI program"), which typically apply to small processing operations. *See* 21 U.S.C. §§ 661; 454. A state's MPI program must have standards at least equal to the FSIS's standards under the FMIA and PPIA, including ante and post mortem inspections. Wisconsin and Minnesota operate MPI programs, but neither program inspects wild game.

served in these facilities.[90] The USDA's Buying Guide for the National School Lunch Program requires programs to purchase game meat from establishments inspected by the USDA or state MPI programs.[91] As discussed above, the USDA does not inspect wild game, and no relevant state program does either. Consequently, the programmatic requirements for the National School Lunch Program limit schools from receiving federal reimbursement for uninspected wild game meat purchased for their programs.

Under Section 4033 of the 2014 Farm Bill, wild game, along with other traditional foods, may be donated to certain federal food programs. Section 4033 directed the FDA and USDA to allow the donation (but not federal reimbursement) of traditional food for service in specified food programs.[92] Food programs operated by tribes and tribal organizations that service primarily Indians may receive donated traditional foods for service if the program follows criteria specified in Section 4033 to ensure food safety.[93] Tribes may now use this authority to increase the use of traditional foods in eligible federal food programs. Moreover, Section 4033 was the product of standards for traditional and wild foods that originated in Alaska's food code.[94] These standards have now been incorporated into federal legislation and apply nationally. Section 4033 is an example of how standards that are developed in response to tribal needs can eventually effect changes to the federal food regime.

Specifically, the Maniilaq Association, a tribal organization that operates federal programs on behalf of twelve tribes in Alaska, sought to serve traditional foods in its elder program. Maniilaq's facility was subject to food safety requirements issued by the Centers for Medicare & Medicaid Services ("CMS"), which required the facility to obtain food from sources approved by "federal, state or local authorities."[95] At first it was unclear which agency had jurisdiction in terms of approving the source of food, but federal agencies eventually deferred to Alaska's Department

[90] *See* 7 C.F.R. part 210.
[91] *See* Meat/Meat Alternates, USDA Buying Guide for Child Nutrition Programs, *available at* https://foodbuyingguide.fns.usda.gov/Content/TablesFBG/USDA_FBG_Section1_MeatsAndMeatAlternates.pdf.
[92] *See* Pub. L. No. 113-79, § 4033 (Feb. 7, 2014). Section 4033 applies to the USDA's School Meal Programs, Child and Adult Care Food Program, and Summer Food Service Program. Section 4033 does not apply to the Food Distribution Program on Indian Reservations. Section 4033 defines traditional food as that which "has been traditionally prepared and consumed by an Indian tribe," including wild game meat, fish, seafood, marine mammals, plants, and berries. *Id.* § 4033(b)(5).
[93] *See id.* § 4033(c)(1)-(8). We have included the criteria in the Appendix to this report.
[94] For a discussion of how limitations on traditional foods in elder food programs for Alaska Natives led to the enactment of Section 4033, *see* Jonathan Reisman, The Fight for the Right to Eat Seal Blubber, Slate (Oct. 9, 2017), *available at* http://www.slate.com/articles/health_and_science/medical_examiner/2017/10/the_fight_for_the_right_to_eat_seal_blubber.html.
[95] 42 C.F.R. § 483.60(i)(1).

of Environmental Conservation ("DEC"), which has authority over food establishments under Alaska's food code.[96]

Alaska's DEC relied on a provision in its food code that allowed the donation of traditional foods to programs if certain requirements were met.[97] This authorized Maniilaq to begin serving donated traditional foods in its elder program, and it has since built a food processing plant to expand its program.[98] Maniilaq has continued to work with Alaska's DEC to develop safety standards for other types of traditional foods.[99]

As discussed below, Member Tribes can assert jurisdiction over tribally-operated programs as food establishments on tribal land through a food code.

2020 Supplement: In December 2018, Congress passed the 2018 Farm Bill with a few provisions relevant to traditional foods.[100] In particular, Section 4003(b) of the 2018 Farm Bill authorized the USDA to establish a demonstration project for tribal organizations administering the Food Distribution Program on Indian Reservations ("FDPIR") to enter into self-determination contracts to purchase foods to be issued as part of food packages. The USDA is in the process of implementing this demonstration project.[101] The demonstration project will also require an additional appropriation of $5 million by Congress.[102] The 2018 Farm Bill provides that food purchased by tribes will need to "meet any other criteria" established by the Secretary of Agriculture.[103] As such, it remains to be seen whether the demonstration project will offer any

[96] *See* Sigluaq, Maniilaq Ass'n (Dec. 15, 2015), *available at* https://www.maniilaq.org/sigluaq/; *see also* 18 AAC ch. 31 (Alaska food code).
[97] *See* 18 AAC 31.205. As discussed above, Alaska's requirements are substantially similar to Section 4033 because the latter was based on Alaska's food code.
[98] *See* Sigluaq, *supra* n.88.
[99] For Member Tribes, the extent to which a state agency could assert regulatory jurisdiction over a tribally-operated facility would depend on the location of the facility and the federal programmatic requirements for the relevant program. Maniilaq's facility is not located within Indian country, which is a term of art used for purposes of determining jurisdiction between tribal and state governments. *See Alaska v. Native Village of Venetie Tribal Government*, 522 U.S. 520, 527 (1998) (noting that Indian country "generally applies to questions of civil jurisdiction"); *see also* 18 U.S.C. § 1151 (Indian country includes land within Indian reservations, dependent Indian communities, and individual Indian allotments). A tribally-operated facility located within an Indian reservation would present a different jurisdictional analysis and may affect how CMS would interpret its requirement for food sources to be approved by "federal, state or local authorities." 42 C.F.R. § 483.60(i)(1).
[100] Pub. L. No. 115-334 (Dec. 20, 2018).
[101] *See* 84 Fed. Reg. 67,424 (Dec. 10, 2019) (request for information on the criteria for the self-determination demonstration project).
[102] Pub. L. No. 115-334, § 4003(b)(6).
[103] *Id.* § 4003(b)(4)(D).

more flexibility for tribes to incorporate traditional wild foods into the FDPIR than under current law.

Nevertheless, the demonstration project is a positive development towards authorizing tribes to purchase foods for their FDPIR programs rather than have the USDA perform this function. This will allow tribes to focus on purchasing traditional foods for distribution in their FDPIR programs.

The 2018 Farm Bill also included a provision that directs the Secretary of Agriculture to seek greater inclusion of tribal food producers in international trade missions.[104] This provision is intended to increase opportunities for tribal food producers to sell traditional foods overseas in international markets. The Secretary of Agriculture is to submit a report to Congress on this initiative before the end of this year by December 20, 2020.[105]

Finally, the 2018 Farm Bill expanded the liability protections for the donation and service of traditional foods in federal food programs.[106] The 2014 Farm Bill only extended protection against civil liability to the federal government and tribes or tribal organizations for donation and service of traditional foods. The 2018 Farm Bill expands these protections to eliminate civil liability for "an entity or person authorized to facilitate the donation, storage, preparation, or serving of traditional food by the operator of a food service program."[107] This provision is important to encourage individuals to facilitate traditional foods in federal food programs by ensuring they are immune from civil liability for those activities.

8. The FDA's Model Food Code

In 1993, the FDA issued the Model Food Code ("Food Code") and the most recent version was issued in 2017.[108] The Food Code does not have the status of federal law, nor is it preemptive of tribal, state, or local law.[109] Nevertheless, the Food Code is "designed to be consistent with federal food laws and regulations" and its standards serve as the basis upon which tribal, state, and local governments design their own food safety programs.[110]

[104] *Id.* § 3312(a).
[105] *Id.* § 3312(b)(1).
[106] *Id.* § 4203.
[107] *Id.*
[108] Food Code, U.S. Food & Drug Admin. ("2017 Food Code"), *available at* https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM595140.pdf.
[109] 2017 Food Code preface iii ("The model Food Code is neither federal law nor federal regulation and is not preemptive.").
[110] 2017 Food Code preface iii.

The Food Code represents best practices for food storage, handling, and preparation for the retail and service segments of the industry. The Food Code is encouraged for adoption by all jurisdictions that have authority over retail food stores and food service operations, including tribal governments. There is no standard process for adopting or implementing a food code in a specific jurisdiction, and it would be an act of self-government if Member Tribes were to do so.[111] In other words, Member Tribes may adopt a food code according to Tribal law and which is tailored to Tribal institutions and traditional foods.

The Food Code applies to "food establishments," which include operations that store, prepare, pack, serve, or sell food directly to the consumer.[112] The Food Code defines food establishments in such a way that essentially any establishment that serves or provides food to the person who consumes it is subject to the Food Code.[113] For example, a government-run program is generally a food establishment if it provides or serves food to a person for his or her consumption – such as Maniilaq's facility for its elder program. The Food Code has limited exemptions, such as for a produce stand that only offers whole, uncut fruits and vegetables, as well as for food prepared in a kitchen at a private home if it is sold or served at a charitable function.[114] Accordingly, some governments amend the model provisions to include additional exemptions for specific food functions as appropriate to the jurisdiction.

The Food Code has requirements regarding management and personnel; the storing, preparation, and service of food; the equipment, utensils, and materials used for the food; and the utilities and physical construction of the facilities.[115] The Food Code also encourages food establishments to implement HACCP principles,[116] including requirements for HACCP plans for certain types of activities.[117] The requirements apply to wild foods just as they would any other food sold or served in a food establishment.[118] However, the Food Code has a few provisions that are particularly relevant to how food processors may distribute wild foods to food establishments under the model provisions.

First, the Food Code requires food establishments to obtain food from approved sources. Specifically, food establishments must obtain food from a source that complies with applicable

[111] Generally, state governments adopt food codes as an exercise of the police power. Similarly, Member Tribes may adopt food codes pursuant to their inherent authority.
[112] 2017 Food Code § 1-201.10 (definition of "food establishment").
[113] 2017 Food Code § 3-201-11(B).
[114] *See* 2017 Food Code § 1-201.10 (exclusions from definition of "food establishment").
[115] *See generally* 2017 Food Code Chapters 2-7.
[116] *See* 2017 Food Code at 320-21 (Annex 2 – References).
[117] 2017 Food Code § 8-201.13.1.
[118] *See* 2017 Food Code § 1-201.10 (definition of "food").

law, and they must ensure that they receive food from approved sources.[119] Under this framework, a food establishment cannot obtain food from sources that do not comply with requirements that apply to the sources' operations, such as HACCP requirements for fish processors. Likewise, a Treaty harvester who does not comply with a Member Tribe's conservation code when harvesting wild rice is not a source which has complied with applicable law. The Food Code notes that wild game animals "may be available as a source of food only if a regulatory inspection program is in place to ensure that wild animal products are safe."[120] Thus, unregulated wild game meat is not from an approved source, because a regulatory authority has made no determination that it conforms to recognized standards that protect public health. On tribal land within an Indian reservation, the regulatory authority is the tribe because it has jurisdiction over the food establishment.[121] This framework provides a basis for tribes to approve sources of wild foods within their jurisdiction according to standards designed to ensure food safety.

Second, the Food Code has a provision that governs how food establishments may obtain wild game animals for sale or service.[122] The Food Code specifically includes game animals such as elk, deer, rabbit, opossum, and nonaquatic reptiles.[123] The Food Code allows a food establishment to sell or serve meat from a field-dressed wild game animal under a routine inspection program[124] that ensures the animal:

- Receives a postmortem examination by an approved veterinarian; or
- Is field-dressed and transported according to requirements to be specified by the agency with animal health jurisdiction and the agency that conducts the inspection program, and
- Is processed according to laws governing meat and poultry.[125]

This provision is notable because it does not require an ante mortem inspection, which is particularly difficult for wild animals. Instead, the animal must either receive a postmortem inspection by a veterinarian or be field-dressed and transported according to requirements established by relevant agencies. The animal must then be processed as any other meat or poultry product, which effectively applies the safety standards from the FMIA and PPIA on the processing

[119] 2017 Food Code §§ 3-201.11; 2-103.11(E), (F); *see also id.* § 1-201.10 (approved "means acceptable to the regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health").
[120] 2017 Food Code at 412 (Annex 3 – Public Health Reasons/Administrative Guidelines).
[121] 2017 Food Code § 1-201.10 (definition of "regulatory authority").
[122] 2017 Food Code §§ 3-201.17; 1-201.10 (definition of "game animal").
[123] 2017 Food Code § 1-201.10.
[124] The Food Code's use of the term "routine inspection program" refers to "periodic inspections conducted as part of an on-going regulatory scheme." 2017 Food Code at 590 (Annex 5 – Conducting Risk-based inspections).
[125] 2017 Food Code § 3-201.17(4).

of wild game, including requirements for HACCP plans and sanitation standards.[126] The inclusion of this provision in the Food Code shows that a program patterned off the model provision, and acceptable to federal regulators, would be consistent with federal food safety policy.[127] This provision contemplates the sale of wild game, not just donation. Moreover, the Food Code already includes safety standards for cooking raw wild game meat. The Food Code provides that raw game meat must be heated to 165°F for less than one second.[128]

In short, a regulatory program for the sale of wild game may be developed by incorporating adequate food safety standards for the field-dressing and transportation of wild game so that it may be obtained by food establishments. There must then be an agency that conducts "periodic inspections" as part of an "on-going regulatory scheme" to ensure that the source of wild game adheres to these standards. Finally, we note that the Food Code is a model to start from, and that the Project and Member Tribes may tailor its provisions as appropriate to facilitate the use of wild foods.

B. State and local regulation of wild foods

State and local governments vary in terms of how or whether they regulate wild foods. Some states regulate certain types of wild foods that are relevant to their economy, such as wild rice in Wisconsin and Minnesota.[129] Wisconsin and Minnesota also have "cottage food" exemptions, which exclude home-based operations from licensing and inspection requirements.[130] These exemptions generally cover only products made from fruits and vegetables because the exemptions do not apply to potentially hazardous food, such as animal food products.[131] Cottage food operations are also limited to selling their products directly to consumers and may not sell their products outside the state.[132] A cottage food operation must appropriately label their products

[126] *See, e.g.*, 9 C.F.R. parts 416 (sanitation), 417 (HACCP).
[127] *See* 2017 Food Code preface iii (stating that the model provisions are "designed to be consistent with federal food laws and regulations").
[128] 2017 Food Code § 3-401.11(A)(3). The FDA's rationale for this standard is that the time and temperature requirement for killing potential pathogens will be "exceeded before the temperature can be determined," and the overall heating and cooling process "adds to the margin of safety." *Id.* at 435.
[129] Wisconsin and Minnesota require licenses for distributors who purchase wild rice for resale to anyone but the consumer. *See* Wis. Stat. § 29.607; Minn. Stat. § 84.152. Minnesota also provides labeling requirements for wild rice. *See* Minn. Stat. § 30.49.
[130] *See* Wis. Stat. § 97.29(b); Minn. Stat. § 28A.152.
[131] Wis. Stat. § 92.29(b); Minn. Stat. § 28A.152(1)(a)(1).
[132] Wis. Stat. § 97.29(b)(2)(b); Minn. Stat. § 28A.152(2)(a).

and provide notice so that consumers are warned that the products are homemade and have not been inspected by the state.[133]

Otherwise, wild food falls under state regulatory regimes for food, just as it does under federal law. States regulate food production and processing alongside the FDA and USDA, except that the federal standards discussed above are preemptive of conflicting state law. Thus, many states, including Wisconsin, Minnesota, and Michigan, have food laws that mirror the FDCA and effectively incorporate the federal standards for food processing.[134]

State governments typically require licenses and inspections for food processing, sale, and service operations that occur within their jurisdiction. As noted above, state and local governments also regulate the retail segment of the food industry under food codes patterned off the FDA's Food Code. While the institutional structure varies from state-to-state, a department of agriculture or a department of public health (or an equivalent) is generally tasked with the same food safety functions of the USDA and FDA at the state level. The extent of local government regulation can vary, depending on how much authority is delegated or inherent to local governments, but boards or departments of health generally perform food safety functions at the local level, including inspection and licensing of food establishments.

In Wisconsin, for example, the Department of Agriculture, Trade, and Consumer Protection ("ATCP") regulates and licenses food processing and food establishments.[135] The ATCP may designate a local health department as its agent for the purposes of licensing and inspecting food establishments.[136] For example, the ATCP has contracted with Sawyer County to designate its Department of Health and Human Services as the State's agent for regulating, licensing, and inspecting food establishments in the county.[137] The Sawyer County Department of Health and Human Services issues licenses for food establishments and carries out inspections in order to determine compliance with Wisconsin's regulations.[138]

[133] Wis. Stat. § 97.29(b)(2)(d) (must display sign at point of sale stating: "These canned goods are homemade and not subject to state inspection."); Minn. Stat. § 28A.152(1)(a)(ii) (must display sign at point of sale stating: "These products are homemade and not subject to state inspection.").
[134] For example, Wisconsin's regulations fish processors require a HACCP plan that complies with the FDA's regulations discussed above. *See* Wis. Admin. Code § ATCP 70.18.
[135] Wis. Stat. §§ 97.29 (food processing plants); 97.30 (retail food establishments).
[136] Wis. Stat. § 97.41.
[137] *See* Sawyer Cnty. Health & Human Servs., *available at* https://www.sawyercountygov.org/DocumentCenter/View/1163/HHS-Ordinance-Public-Notice.
[138] *See* Sawyer Cnty. Code of Ordinance, Health & Human Servs., ch. 1, §§ 2.01(G)(1) (inspections), 2.02(G) (incorporating ATCP 75 and Chapter 97, Subchapter II of Wis. Stat.), *available at* https://www.sawyercountygov.org/DocumentCenter/View/1338/FINAL-Sawyer-County-Public-Health-Hazards-Ordinances-IIes.

Wisconsin and Minnesota have amended their food codes to omit the model provision that allows the sale of field-dressed wild animals. The commercial sale of hunted wild game is effectively prohibited in these states because food establishments cannot obtain this food for sale. Minnesota only allows unprocessed wild game to be donated to charitable organizations, so long as the wild game was dressed within two hours of harvest; is cooked to 165°F; the establishment is licensed; the wild game is processed in accordance with Minnesota laws for meat, poultry, and fish; and the establishment maintains a written sanitation procedure to eliminate cross-contamination with other foods.[139] Similarly, Wisconsin only allows wild game to be served in a food establishment if profit is not the principal purpose or any proceeds are used for public purposes.[140] The food establishment needs a permit from the Department of Natural Resources,[141] and it must be closed to the general public while the wild game is served.[142] The wild game must be stored and prepared separately from other food,[143] and cooked to 145°F.[144]

Michigan has maintained the model provision in its food code for field-dressed wild game received for sale,[145] but only private processing of wild game and service at charitable functions are actually permitted.[146] Michigan's Department of Agriculture has established rules for food establishments that process deer for hunters (not for commercial sale), including guidelines for deer harvested in Chronic Wasting Disease surveillance areas and avoiding contamination from lead ammunition.[147]

As for the relationship between a tribal regulatory system and state and local food regulation, state and local governments generally do not have regulatory jurisdiction over activities by tribes or tribal members within Indian country absent express authorization from Congress.[148] Although Congress granted Wisconsin and Minnesota criminal and civil adjudicatory jurisdiction

[139] Minn. R. 4626.0160(C). These requirements are somewhat similar to Section 4033 of the 2014 Farm Bill.
[140] Wis. Admin. Code § ATCP 75, App. § 3-201.17(B).
[141] *Id.* § 3-201.17(B)(2).
[142] *Id.* § 3-201.17(B)(3). A tribal food program arguably comes within this provision, though program recipients might not be considered "guests." *See id.* § 3-201.17(B)(2) (department may issue permits "to serve lawfully taken and possessed wild game to guests at restaurants, clubs, hotels, boarding houses and taverns") (emphasis added).
[143] *Id.* § 3-201.17(B)(8).
[144] *Id.* 3-401.11(A)(1)(b).
[145] *See* Mich. Modified Food Code § 3-201.17(A)(4) (2012), *available at* https://www.michigan.gov/documents/mdard/MI_Modified_2009_Food_Code_396675_7.pdf.
[146] *See* Mich. Stat. § 289.6143; Sanitation Requirements in the Food Code for Processing Venison in a Retail Food Establishment, Mich. Dep't of Agric., *available at* https://www.michigan.gov/documents/MDA_FSPR_VP_Deer_Processing_K_49407_7.pdf.
[147] *Id.* (Checklist for Processing Venison in a Retail Food Establishment).
[148] *E.g.*, *Williams v. Lee*, 358 U.S. 217 (1959); *New Mexico v. Mescalero Apache Tribe*, 462 U.S. 324 (1983); *see also* 18 U.S.C. § 1151 (definition of "Indian country").

within Indian country located in these two states,[149] this grant of jurisdiction does not extend to civil regulatory laws.[150] Accordingly, Wisconsin and Minnesota are generally precluded from exercising regulatory authority over the processing or sale of wild foods by Treaty harvesters within an Indian reservation. However, tribes and Treaty harvesters that sell or serve wild foods in a state or local jurisdiction are subject to nondiscriminatory state and local laws.[151]

Wisconsin currently has authority over sales of wild game to non-members both on- and off-reservation through the Deer Trial Stipulation for parties to the *Voigt* litigation, until such time as a Member Tribe adopts "corollary regulations." While this stipulation currently presents a barrier to the sale of wild game meat to non-members on a reservation in Wisconsin, the development of a tribal regulatory system for the safety of wild game is the approach for replacing the stipulated application of state law.

C. Tribal regulation of wild foods

Tribes are the regulatory authority for food processing operations and food establishments within their jurisdiction.[152] Although the level and form of regulation varies, tribes may license, inspect, and enforce food safety standards on operations within their jurisdiction. Accordingly, tribes have the authority to establish their own food safety standards that respond to the needs of their communities.

[149] 18 U.S.C. § 1162(b); 25 U.S.C. §§ 1321(b); 1322(b); 28 U.S.C. § 1360(b).

[150] *See Bryan v. Itasca Cnty.*, 426 U.S. 373 (1976); *California v. Cabazon Band of Mission Indians*, 480 U.S. 202 (1987). Public Law 280 does not grant Wisconsin or Minnesota jurisdiction over "hunting, trapping, or fishing or the control, licensing, or regulation thereof." 18 U.S.C. § 1162(b). In addition, Public Law 280 also does not include local regulatory laws. *See, e.g., Santa Rosa Band v. Kings Cnty.*, 532 F.2d 655, 659-64 (9th Cir. 1975), *cert. denied* 429 U.S. 1038 (1977); *United States v. Cnty. of Humboldt*, 615 F.2d 1260 (9th Cir. 1980) (rejecting application of local zoning laws and building codes).

[151] *See, e.g., Mescalero Apache Tribe v. Jones*, 411 U.S. 145, 148-49 (1973). The extent to which the off-reservation Treaty rights would provide a basis to exempt sales of processed wild foods occurring outside a reservation from state law is unclear. The ability of tribes or tribal members to sell processed wild foods into a state or local jurisdiction would likely depend on acceptance by the state and local government of the tribal standards.

[152] *See United States v. Wheeler*, 435 U.S. 313, 323 (1978) (Tribes have "sovereignty over both their members and their territory").

1. Pokagon Band of Potawatomi Indians

The Pokagon Band of Potawatomi Indians in Michigan has adopted a health and safety act, which includes provisions on wild game.[153] Under this provision, a food establishment may serve or sell wild game so long as the establishment ensures that the animal is field-dressed, transported, and processed according to standards recommended by the Pennsylvania State University Cooperative Extension regarding the proper handling and processing of wild game and fish.[154] The food establishment must also post a prominent notice in the area where the wild game is served that states as follows: "The Wild Game served at this location has not been inspected by the Pokagon Band."[155] This is similar to the "cottage food" laws in Wisconsin and Minnesota discussed above, which allow limited types of sales of uninspected food, so long as consumers are notified that they are consuming food from uninspected sources and do so at their own risk.

2. Keweenaw Bay Community

Another example is the Keweenaw Bay Indian Community, which requires applicants for a commercial fishing license to prove that they have completed certification for HACCP management training offered by the FDA.[156] Keweenaw Bay also requires any person selling fish at retail to obtain a business license from the tribe and to comply with "the applicable provisions of the FDA Food Code and HAACP [sic] management training regulations."[157]

[153] Health & Safety Act, Pokagon Band of Potawatomi Indians, § 2.02, *available at* http://www.pokagon.com/sites/default/files/assets/department/government/form/2015/health-and-safety-act-current-150126-2130.pdf.

[154] *Id.* § 2.02(e)(1). These publications are attached in the Appendix to this Report. *See also* Proper Processing of Wild Game & Fish, Penn State Extension, *available at* https://extension.psu.edu/proper-processing-of-wild-game-and-fish.

[155] *Id.* § 2.02(e)(2).

[156] Keweenaw Bay Indian Cmty. Tribal Code of Law §§ 10.204(D). The FDA offers training materials for HACCP. *See* Seafood HACCP, Food & Drug Admin., *available at* https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006764.htm. The USDA's Food Safety Research Information Office also has guidance for locating HACCP training courses. *See* Frequently asked questions, USDA Nat'l Argic. Library ("Where can I find HACCP training courses in my area?"), *available at* https://www.nal.usda.gov/fsrio/faq.

[157] Keweenaw Bay Tribal Code § 10.211.

3. Columbia River Inter-Tribal Fish Commission

Likewise, the Columbia River Inter-Tribal Fish Commission provides guidelines for Treaty fishermen to comply with HACCP standards in order to enhance the marketability of harvested salmon.[158]

4. Red Cliff Band

The Red Cliff Band requires a fish dealers' license for any tribal member who obtains Treaty-caught fish for the purpose of subsequent resale.[159] Red Cliff Band's requirements further provide that a fish dealer's facilities used for storage, processing, and transportation "shall be kept sufficiently clean and free of vermin to ensure that the products offered for sale are wholesale [sic] and of high quality."[160] A fish dealer must also consent to inspections performed by "tribal law enforcement personnel" of the dealer's facilities used for fish marketing "at any reasonable time and place."[161]

5. Leech Lake Band of Ojibwe

Finally, the Leech Lake Band of Ojibwe has a commercial wild rice business that sells wild rice at various brick and mortar stores and online.[162] The Leech Lake Band processes its wild rice in facilities that are inspected according to the FDA's standards, which indicates that the facilities are licensed and inspected just as any other food processing operation selling its products in interstate commerce.[163]

In short, the examples discussed above show varying approaches by tribes, including Red Cliff Band's requirements for licensing and inspections of fish dealers, and the incorporation of federal food safety standards by Keweenaw Bay, the Columbia River Inter-Tribal Fish Commission, and the Leech Lake Band. The Pokagon Band is an example of a tribe adopting its own food safety standards for wild game by referencing non-governmental standards. This demonstrates the regulatory challenges associated with wild game, as there are few federal or state standards that can be utilized for wild game that is hunted. We have included the following in the

[158] *See* Food Quality Guidelines, Columbia River Inter-Tribal Fish Comm'n, *available at* http://www.critfc.org/for-tribal-fishers/food-quality-guidelines/.

[159] Red Cliff Band Code of Laws, ch. 24 § 24.1. The Red Cliff Band has comprehensive regulations governing commercial fishing, but these requirements do not address fish processing and food safety concerns that are the subject of regulation by the FDA under the FDCA discussed above. *See generally* Red Cliff Band Code of Laws, ch. 7 §§ 7.1-7.20.

[160] *Id.* § 24.1.2.

[161] *Id.* § 24.1.3.

[162] *See* Purchase Leech Lake Wild Rice Today!, Leech Lake Band of Ojibwe, *available at* https://www.llwildrice.com/wild-rice-products.html.

[163] *See* Naturally Grown & Carefully Harvested, Leech Lake Band of Ojibwe, *available at* https://www.llwildrice.com/our-wild-rice.html.

Appendix as examples of standards for wild foods that the Project may want to consult in its second year:

1. The Pokagon Band of Potawatomi Indians Health and Safety Act.

2. Cutter, Catherine N. *Proper Processing of Wild Game and Fish*. The Pennsylvania State University Cooperative Extension (2011). As noted above, the Pokagon Band references these standards for wild game served or sold in food establishments under its jurisdiction.

3. Codex Alimentarius Recommended International Code of Practice. *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005), included in the international standards for food safety published by the Codex Alimentarius Commission.[164] The Codex Alimentarius Commission was established by the Food and Agriculture Organization of the United Nations and the World Health Organization. This Code treats wild game as other types of meat for purposes of food safety.

4. Health Canada. *Food Safety for First Nations People of Canada: A Manual for Healthy Practices* (2011), which is used by public health authorities in Canada and First Nations regarding the safe handling, preparation, and storage practices of traditional foods.

5. United States Department of Agriculture. *Memorandum on Service of Traditional Foods in Public Facilities* (July 31, 2015), which was issued pursuant to Section 4033 of the 2014 Farm Bill.

6. Michigan Department of Agriculture. *Venison Processing Guide and Sanitation Requirements for Retail Food Establishments* (October 2010).

7. Wisconsin Food Code: Game Animals. Wis. Admin. Code § ATCP 75, App. § 3-201.17.

8. Minnesota Food Code: Wild Game. Minn. R. 4626.0160.

9. The Columbia River Inter-Tribal Fish Commission. *Sanitation Checklist for Salmon*.

10. Alaska Department of Environmental Conservation. *Let's Eat More of Alaska's Traditional Foods!* (2015).

[164] *See* Codes of Practice, Int'l Food Standards Codes Alimentarius, *available at* http://www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/en/.

IV. Conclusion and Recommendations

Food safety is the primary challenge for increasing the use of wild foods in federal food programs or for commercial sale to non-members. Food safety regulation in the United States is complex and involves agencies at all levels of government. Tribes are the regulatory authority for food processing and retail operations on tribal land within their reservations. However, unregulated wild food presents food safety issues for its use in federal food programs or broader marketing to non-members. In these areas, federal and state regulators may seek to enforce federal and state food safety regulations in the absence of tribal standards. The Deer Trial Stipulation illustrates this problem, as it imposes Wisconsin's food safety regulations on the sale of wild game to non-members until a Tribe adopts its own regulations. A tribal regulatory system designed to ensure the safety of wild foods is therefore essential to increasing the use of wild foods. Moreover, tribal standards provide an opportunity to effect changes to the federal food regime, as well as create economic development in what could be an emerging market for wild foods.

Accordingly, we offer the following recommendations for the Project's second year:

1. Consider potential conservation measures that could be incorporated into a tribal regulatory system to address food safety concerns regarding wild foods. One example is Michigan's use of Chronic Wasting Disease surveillance zones for guidelines on venison processing. Other restrictions could be considered such as limitations on lead ammunition for Treaty harvesters who intend to harvest wild game for commercial sale, or the use of information regarding areas known to contain potential contaminants.

2. The Project should design model provisions to govern the field-dressing and transportation of wild game. Wild game presents unique food safety issues as compared to other wild foods, because the undocumented life history of wild game provides no assurance that the animal is free from disease or other viruses that may cause illness in humans. As for other wild foods, such as fish, wild rice, and plants, the FDCA's standards may be referenced because general and specific standards already exist for these foods. Model provisions should also provide for enforcement through tribal licensing and inspection of small-scale processors that intend to sell wild food products to food establishments or for use in federal food programs. Section 4033's standards may be used where they apply, but thus far Section 4033 has not expanded beyond donation in certain food programs.

3. The Project should incorporate the model provisions it designs into the FDA's Food Code. Member Tribes may then adopt the amended Food Code as a basis to assert jurisdiction over food establishments within their jurisdiction. The model provisions for food processors do not necessarily need to be in the Food Code itself, as they can be located in separate Tribal Code provisions and then referenced in the Food Code. The Food Code governs food establishments, not food processors. Of course, the Project is free to incorporate all requirements into a Food Code for simplification.

4. The Project should account for exemptions of certain types of food operations and intra-tribal uses of wild food that are not appropriate for formal regulation. Member Tribes have been regulating wild foods to ensure food safety since time immemorial through their subsistence practices that form an essential component of their Treaty rights. In designing a tribal regulatory system, it will be important for Member Tribes to identify the activities that should remain unregulated, because there is more flexibility for unregulated uses of wild food if it is not intended for sale to non-members or use in federal food programs.

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Great Lakes Indian Fish & Wildlife Commission Traditional Food Regulatory System Project 2020 Supplement to the 2019 Second Food Code Guidance Report

I. Introduction.

In this report, we analyze food safety regulations related to labeling, packaging, and sales of Treaty-harvested wild foods. This report adds to our Food Code Guidance Report submitted as part of the first year of the Great Lakes Indian Fish & Wildlife Commission's ("GLIFWC") Chippewa Ceded Territory Traditional Food Regulatory System Project ("Project"). In particular, we discuss the requirements for labeling, packaging, and ultimately selling products of Treaty-harvested wild foods.

In our first Food Code Guidance Report ("Year 1 Report"), we found that the U.S. Food and Drug Administration ("FDA") is the principal agency with regulatory jurisdiction over wild foods relevant to the Project.[1] Our Year 1 Report outlined the federal regulatory system that governs most food sales in the United States under the Federal Food, Drug, and Cosmetic Act ("FDCA").[2] We found that Treaty-harvested wild foods are regulated under the FDCA. Likewise, we found for this report that the FDCA's requirements for labeling, packaging, and sales apply in most instances to Treaty-harvested wild foods intended for sale.

For labeling, the FDA requires each label of a consumer food product to be appropriately labeled to prevent the product from being deemed misbranded in violation of the FDCA. At a minimum, each label must include the food product's name, net quantity of contents, the nutrition facts, the ingredient and allergen list, and the name and address of the manufacturer, packer, or distributor.

The FDA's packaging requirements address concerns related to the possibility that packaging materials can adulterate food and render it unfit for human consumption. Food packaging operations must ensure they use packaging materials that are safe and suitable. The FDA requires that packaging operations follow current good manufacturing practices and use appropriate quality control operations. Food packaging operations must also ensure they obtain materials from reputable suppliers of FDA-approved packaging materials.

Finally, sales requirements include compliance with the FDCA as a predicate to a lawful sale in most situations. In other words, a food product must be harvested, processed, transported, packaged, and labeled in compliance with the FDCA's requirements and FDA's regulations. Many of these requirements are discussed in our Year 1 Report and are further noted below.

Below, Part II discusses the FDA's labeling requirements for food products; Part III discusses the FDA's packaging requirements; and Part IV discusses sales requirements.

[1] We understand that the Project has identified 14 traditional wild foods, including white-tailed deer, rabbit/hare, duck, wild turkey, whitefish, walleye, fresh berries, wild leeks (ramps), wild beach pea, hazelnut, morel mushroom, wild rice, berry jams/jellies, maple syrup, animal fat, venison jerky. These foods are subject to the FDA's jurisdiction under the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. § 321(f).
[2] 21 U.S.C. § 301 *et seq.*

2020 Supplement: As part of the Project's third year, we reviewed and updated this Report to account for regulatory and other changes since July 2019. This supplemental information is identified and discussed as the 2020 Supplement where relevant throughout the Report.

II. Labeling requirements.

A. Labeling requirements for food primarily seek to ensure that the consumer is adequately informed about a food product in order for the consumer to make an educated food choice. To that end, the FDCA prohibits the sale of misbranded food products in interstate commerce.[3] A food product is deemed misbranded if its labeling is false or misleading, it is offered for sale under the name of another food, or its label does not have the required information.[4]

Based on the FDCA's prohibition against misbranded food, federal requirements comprise the vast majority of labeling requirements that apply to food sold throughout the United States. The FDA has jurisdiction to promulgate and enforce labeling requirements to prevent the sale of misbranded food. We note that the United States Department of Agriculture ("USDA") has separate authority to regulate labeling of meat and poultry products under the Federal Meat Inspection Act[5] and the Poultry Products Inspection Act.[6] The USDA's labeling requirements share many characteristics as the FDA's, but there are some differences.[7] However, the USDA's labeling requirements do not apply to the Treaty-harvested wild foods relevant to the Project, because the USDA does not have jurisdiction over wild game, as discussed in more detail in our Year 1 Report.[8] Consequently, wild foods relevant to the Project are subject to the FDA's labeling requirements under the FDCA if they are intended for sale in interstate commerce and not otherwise exempt from the requirements.[9]

B. FDA's general labeling requirements.

The FDA requires each food product to include specific information on the label. Specifically, a label must include 5 categories of information: (1) the food's statement of identity; (2) the net quantity of contents; (3) the nutrition facts; (4) the ingredient and allergen list; and (5) the name and address of the manufacturer, packer, or distributor. The FDA then requires that this information be located on certain areas of the package. The FDA has published a guidance document for food labeling called *Guidance for Industry: Food Labeling Guide* ("Food Labeling Guide"), which we include in the appendix to this report. We recommend you refer to the Food

[3] 21 U.S.C. §§ 331, 343.
[4] *Id.* § 343.
[5] 21 U.S.C. §§ 601-695.
[6] 21 U.S.C. §§ 451-472.
[7] For example, the FDA and USDA have different labeling requirements for added colors. If a food product contains added coloring, the USDA requires a statement next to the product name, whereas the FDA requires the color to be disclosed in the ingredient statement.
[8] *See* Year 1 Report at 17-19.
[9] *See* 21 C.F.R. § 101.100 (exemptions from labeling).

Labeling Guide for its various depictions of labeling requirements. We summarize here the FDA's general requirements for labels.

1. Principal Display Panel

The Principal Display Panel ("PDP") is the regulatory term for the front label of a food product.[10] The PDP is the label that is most readily observed by the consumer at the time of purchase.[11] The FDA requires PDPs to include the following components:

- Statement of identity: The common name of the food (e.g., wild rice).[12]
- Net quantity of contents: The amount of food in the appropriate measurement (e.g., weight, fluid measurement, number of items).[13]

The lettering on the PDP must be easily readable. Other information or artwork on the PDP must not hide or detract from the visibility of the statement of identity and the net quantity.[14]

2. Information Fact Panel

The information fact panel ("IFP") must be located to the right of the PDP, as seen by consumer facing the product.[15] The IFP is not required if the information can fit on the PDP. The IFP includes the following information:[16]

- Nutrition facts: The food manufacturer is responsible for determining appropriate values for the product's nutrition facts. We note that the USDA Agricultural Research Service maintains an online Food Composition Database, which could be referenced for nutritional information of various wild game meat.[17] Raw seafood, fruits, and vegetables are exempt from nutrition labeling. The FDA has voluntary nutrition labeling guidelines for these products.[18]

2020 Supplement: The FDA has issued guidance on sugar labeling for maple syrup.[19] The FDA states it will exempt single-ingredient packages of pure maple syrup from the requirement to include the words "Includes Xg Added Sugars" on the label for nutrition facts.[20]

[10] 21 C.F.R. § 101.1.
[11] *Id.*
[12] *Id.* § 101.3(a)
[13] *Id.* § 101.7(a).
[14] *Id.* §§ 1.21(a)(1); 101.3(a); 101.105(h).
[15] *Id.* § 101.2(a).
[16] *Id.* § 101.2(b).
[17] USDA Food Composition Databases, https://ndb.nal.usda.gov/ndb/search/list?format=&count=&max=25&sort=&fg=&man=&lfacet=&qlookup=game+meat&offset=25 (search "game meat").
[18] *See* 21 C.F.R. § 101.42.
[19] *The Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products: Guidance for Industry* (2019), *available at* https://www.fda.gov/media/127928/download.
[20] *Id.* at 3.

However, packages of pure maple syrup must still be labeled with the percent daily value for added sugar on the label.[21] Under the FDA's labeling requirements, the percent daily value refers to the amount of nutrients in one serving of food expressed as a percentage of the amount of that nutrient you need each day. The FDA's guidance responds to concerns that labeling sugar in a container of maple syrup as "added" would mistakenly imply that table sugar had been added to the product.

- Ingredient and allergen list: The package must list the ingredients by their common name in descending order by weight.[22] There are special rules for certain types of ingredients, such as preservatives, which must include the name and its function.[23] As for allergens, federal law identifies eight foods that must be clearly identified on a label if it is present as an ingredient in the food.[24] The eight foods subject to mandatory allergen labeling are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.

FDA guidance provides alternative approaches for labeling of allergens.[25] First, a label's ingredient list may include the allergen in parenthesis following the common or usual name of the major food allergen, e.g., "lecithin (soy), flour (wheat), whey (milk)." Second, a label may include a "contain" statement with the name of the major food allergen placed immediately after or adjacent to the ingredient list, e.g., "Contains: Wheat, Milk, Egg, and Soy."

Under federal law, we note that supplemental disclosures regarding whether a product is manufactured in a facility that also processes other products that contain allergens are voluntary. As such, the FDA does not require labeling such as: "may contain [allergen]" or "produced in a facility that also uses [allergen]."[26] In fact, the FDA states that these supplemental disclosures should not be used as a substitute for properly identifying major food allergens present in a food product.[27] Nevertheless, many food manufacturers include these supplemental disclosures in an attempt to be transparent to the consumer and to comply with labeling requirements in state and local jurisdictions throughout the United States that require these disclosures.[28]

- Signature line: The signature line is simply the name and address of the product's manufacturer, packer, or distributor.[29] This requirement is important to identify the source of a

[21] *Id.*
[22] *Id.* § 101.4(a).
[23] *See, e.g., id.* § 101.22(j).
[24] 21 U.S.C. § 343(w).
[25] Food Labeling Guide at 23.
[26] *See* What You Need to Know about Food Allergies, U.S. Food & Drug Admin. ("Food Allergen 'Advisory' Labeling"), *available at* https://www.fda.gov/food/buy-store-serve-safe-food/what-you-need-know-about-food-allergies.
[27] *See id.* (general disclosures "should not be used as a substitute for adhering to current good manufacturing practices and must be truthful and not misleading").
[28] For example, Wisconsin's DATCP provides criteria for determining whether to include a supplemental allergen statement, *see* Labeling Language, Wisconsin Food Allergen Fact Sheet #5, *available at* https://datcp.wi.gov/Documents/AllergenLabelLanguage.pdf.
[29] 21 C.F.R. § 101.5.

food product in the event that there is a food safety issue. This information provides consumers and regulators with information to track the source of the food product.

- Leech Lake's wild rice is an example of a packaged wild food that adheres to the FDA's labeling requirements:

Principal Display Panel

1. Statement of identity
2. Net quantity of contents

Information Fact Panel

1. Nutrition Facts
2. Signature Line

* Note: This information fact panel does not have an ingredient list. Ingredients may be listed on the principal display panel (21 C.F.R. §101.4 (a)(1)).

3.

Warning and safe handling statements for specific foods.

Certain foods must be labeled with an appropriate warning or safe handling statement.[30] Examples of FDA warning and safe handling requirements for relevant foods include:

- Shell eggs: "SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly."[31]
- Unpasteurized juices: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."[32]

[30] *See* 21 C.F.R. § 101.17.
[31] *Id.* § 101.17(h)(1).
[32] 21 C.F.R. § 101.17(g)(2)(ii).

- Fish products: We note that the FDA suggests that processors of frozen fish products implement a control strategy for labeling that seeks to prevent the formation of the *C. botulinum* toxin. The FDA's control strategy for frozen fish products provides that all finished product labels contain a "keep frozen" statement, such as: "Important, keep frozen until used, thaw under refrigeration immediately before use."[33] In order to further reduce the possibility of the formation of *C. botulinum*, additional labeling should be placed on packaging to instruct the consumer or end user to cut or otherwise break the vacuum seal of the packaging during the thawing process.

C. Tribal and state labeling requirements.

The FDA's labeling requirements are widely incorporated by tribal and state governments. Indeed, tribal or state labeling requirements would be preempted if in conflict with federal requirements. For example, the Tribal Model Fish Processing Code, which we include in the appendix, reflects the FDA's labeling requirements.[34] Likewise, the Wisconsin Department of Agriculture, Trade and Consumer Protection's regulations are consistent with the FDCA's labeling requirements.[35]

The Tribal Model Fish Processing Code contains a labeling requirement for fish fillets, smoked fish, or roe that are packaged in vacuum packed jars or plastic bags. The Tribal Model Fish Processing Code requires these packages to have a label that states:

"KEEP REFRIGERATED AT 38º F (3.33º C) OR LESS."

Similarly, the Project may want to consider a model labeling requirement for wild game. The FDA's general labeling requirements do not specifically address safe handling concerns regarding wild game. The Project could consider the USDA's safe handling instructions for labels of meat and poultry products, which address similar food safety concerns.[36]

In some cases, tribes and states have additional labeling requirements directed at consumer protection concerns related to marketing. These types of labeling requirements do not address food safety, but seek to prevent false or misleading claims about a food product. Member Tribes may want to consider regulating marketing claims on labels for products made from Treaty-harvested wild foods to prevent false or misleading claims. For example, Wisconsin has special labeling requirements for wild rice, which prohibits suppliers from selling any rice labeled as "100 percent natural wild rice," unless that rice is actually wild rice and not blended with any other rice.[37] A supplier must include a qualifying label if the product contains paddy-grown rice, which

[33] *Fish and Fishery Products Hazards and Controls Guidance*, U.S. Food & Drug Admin., Chapter 13: Clostridium botulinum Toxin Formation, at 282 (4th ed. 2011), https://www.fda.gov/media/80637/download.
[34] *See* Draft Tribal Model Fish Processing Code, chapter 5.
[35] Wis. Stat. § 97.10(1); *see* ATCP 90.02 (declaration of product identity), 90.03 (declaration of responsibility), 90.04 (declaration of net quantity).
[36] *See* 9 C.F.R. § 317.2(l) (meat); 9 C.F.R. § 381.125(b) (poultry).
[37] Wis. Stat. § 97.57(3).

is rice that is mechanically planted, harvested, or cultivated with the use of chemical fertilizers or herbicides.[38] By definition, wild rice is rice that is not mechanically harvested and is cultivated without the use of any chemical fertilizer or herbicides.[39]

III. Packaging requirements.

Packaging requirements seek to prevent adulteration of the food contained in a package. Food packaging may adulterate food by making the food unsafe, unfit for human consumption, or qualifying as an unapproved food additive.[40] Packaging can be a food additive because it contains substances that can reasonably be expected to become a component of the food or otherwise affect the characteristic of the food. The FDA generally must give prior approval to a food additive to recognize its safety before it can be used.[41] Use of an unapproved food additive constitutes per se adulteration and is prohibited.[42]

Most packaging materials fall under an exception for substances classified as "generally recognized as safe" ("GRAS") or are approved as a "food contact substance" ("FCS"). Substances classified as GRAS achieve this status if grandfathered in as safe for use prior to 1958 or subsequently accorded the status through a scientific determination by the FDA or a manufacturer's self-determination.[43] Substances in packaging are more commonly approved as FCSs, which include materials such as plastics, paper, adhesives, and coatings that are used for packaging food but are not intended to have any technical effect on the food.[44] An FCS receives approval through the FDA's Food Contact Notification Program administered by the Center for Food Safety and Applied Nutrition's Office of Food Additive Safety.[45]

In practice, the FDA's regulations place a significant burden for complying with packaging requirements on the manufacturers of food packaging materials. Indeed, a typical food packaging operation is not in the business of manufacturing the materials used to package the food nor the scientific regulatory approval processes. Instead, food packaging operations must ensure they obtain their materials from a reputable supplier such that they can be assured that the materials have been approved for use.

Food packaging operations must then adhere to the FDA's current good manufacturing practices, which generally require that packaging operations use appropriate quality control operations to ensure that food packaging materials are safe and suitable.[46] The FDA's current

[38] *Id.* § 97.57(2).
[39] *Id.* § 97.57(1)(b).
[40] *See* 21 U.S.C. §§ 342(a)(1) (adulterated food); 321(s) (definition of "food additive").
[41] *Id.* § 321(a)(1).
[42] *See id.* § 342(a)(1).
[43] 21 C.F.R. § 170.30(
[44] 21 U.S.C. § 348(h)(6).
[45] *See* Anna P. Shanklin & Elizabeth R. Sanchez, *Regulatory Report: FDA's Food Contact Substance Notification Program*, Food Safety Magazine (Oct./Nov. 2005), *available at* https://www.foodsafetymagazine.com/magazine-archive1/octobernovember-2005/fdas-food-contact-substance-notification-program/.
[46] 21 C.F.R. § 110.80, (13)(iii).

good manufacturing practices include requirements such as employee hygiene,[47] pest control,[48] sanitation of food-contact surfaces,[49] cleanable equipment and utensils,[50] and sanitary practices for handling and preparing food.[51] The current good manufacturing practices also provide general processes and controls for packaging that seek to ensure adequate sanitation principles are applied to packaging operations.[52] We include the current version of the FDA's current good manufacturing practices in the appendix to this report.

In addition to the general standards in the current good manufacturing practices, the FDA's regulations provide specific processes and controls for thermally processed[53] low-acid foods that are packaged in airtight containers,[54] acidified foods,[55] and canned fruits[56] and vegetables.[57] A food packaging operation needs to comply with these standards if it engages in these packaging activities.

The FDA also has requirements for specific types of food products and to address food safety concerns associated with packaging such as botulism. For most fruits and vegetables, the FDA's produce rule requires that packagers use food packing material that is adequate for its intended use, cleanable or designed for single use, and unlikely to support growth or transfer of bacteria.[58] The produce rule requires produce to be packaged in a manner that prevents the formation of *Clostridium botulinum* ("*C. botulinum*") toxin if the toxin is a known or reasonably foreseeable hazard, such as in the case of mushrooms.[59]

For fish products, the fish processor's HACCP plan[60] must list controls to prevent food safety hazards associated with the formation of *C. botulinum* toxin in the finished, packaged product.[61] The FDA has published guidance for preparation and packaging of fish products to prohibit the formation of *C. botulinum* toxin.[62] We attach this guidance in the appendix to this

[47] *Id.* § 110.10.
[48] *Id.* § 110.35(c).
[49] *Id.* § 110.35(d).
[50] *Id.* § 110.40(a).
[51] *Id.* § 110.80(b), (c).
[52] *See* 21 C.F.R. 110.80.
[53] Thermal processing is a food sterilization technique through which the food is heated to destroy microorganisms.
[54] 21 C.F.R. pt. 113.
[55] 21 C.F.R. pt. 114.
[56] 21 C.F.R. pt. 145.
[57] 21 C.F.R. pt. 155.
[58] 21 C.F.R. § 112.116(a).
[59] *Id.* § 112.115.
[60] As discussed in our Year 1 Report at 13, the FDA requires processors of fish to adopt and implement a HACCP plan. *See* 21 C.F.R. § 123.6.
[61] 21 C.F.R. § 123.6(e).
[62] *Fish and Fishery Products Hazards and Controls Guidance*, U.S. Food & Drug Admin., Chapter 13: Clostridium botulinum Toxin Formation, at 245-291 (4th ed. 2011), https://www.fda.gov/media/80637/download.

report. This guidance can be used by processors to develop relevant controls in their HACCP plans to ensure consistency with FDA requirements for packaged fish products. We also note and attach in the appendix Wisconsin's regulations for processing smoked fish, which provide suggested procedures for preparing smoked fish products to address botulism risks.[63]

IV. Sales requirements.

The sale of food is governed by all sorts of regulation that apply in various contexts and seek to achieve different regulatory goals. The sale of food is regulated in contexts as diverse as zoning, business licensing, and taxation. Not all of this regulation concerns food safety and is outside the scope of this report. Indeed, the principal impediment to broader sales of wild foods concerns the need for regulation to ensure the safety of wild food for human consumption. We discussed the regulatory framework that governs food safety in our Year 1 Report. In this report, we seek to further delineate the jurisdictional scope of food sales requirements under the FDCA. We also discuss regulatory approaches that seek to promote food sovereignty and local control for small-scale sales of food.

A. Sales in interstate commerce.

As discussed in our Year 1 Report, the FDCA governs food sales in interstate commerce, which is defined as "commerce between any State or Territory and any place outside thereof" and "commerce . . . within any other Territory not organized with a legislative body."[64] The FDA has taken a very broad view of its jurisdiction to enforce the FDCA within an Indian reservation, concluding that it has "complete jurisdiction over products . . . that are manufactured on an Indian reservation," because the agency considers the food products to be in interstate commerce "at all times."[65] The FDA has also stated that it is "rare" for food products intended for sale to fall outside its jurisdiction under the FDCA, because "at least some of [the] ingredients or packaging most likely originate from out of state and it is foreseeable that [the] products will leave the state."[66]

Consequently, the FDCA applies to most food sales and compliance with these federal requirements is a predicate to a lawful sale. This compliance includes, unless exempted, the requirements discussed in our Year 1 Report and the packaging and labeling requirement discussed above. The FDA also provides an overview of the basics to starting a food business that can assist Treaty harvesters with understanding the scope of the FDCA's requirements and exemptions.[67] In order to facilitate broader sales of wild foods, Member Tribes need to ensure they implement regulatory systems with requirements that fill the role that state and local governments play within

[63] ATCP ch. 70, Appendix A.
[64] 21 U.S.C. § 321(b).
[65] FDA Jurisdiction on Indian Reservations, Compliance Policy Guides, U.S. Food & Drug Admin., *available at*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-100350-fda-jurisdiction-indian-reservations.
[66] What the FD&C Act Means by "Interstate Commerce," U.S. Food & Drug Admin., *available at* https://www.fda.gov/cosmetics/cosmetics-laws-regulations/key-legal-concepts-cosmetics-industry-interstate-commerce-adulterated-and-misbranded.
[67] How to Start a Food Business, U.S. Food & Drug Admin., https://www.fda.gov/food/food-industry/how-start-food-business.

the FDCA's food safety regulatory regime. These concepts are discussed at further length in our Year 1 Report, but the general functions by jurisdiction are listed in the table below.

Sales Requirements Related to Food Safety		
FDA	**Tribal/State**	**Tribal/Local**
• Food facility registration • Current good manufacturing practices • Hazard preventive controls • Sanitary transportation rule • HACCP plan (fish, wild game,[68] juice) • Produce rule (fruits/vegetables) • Inspections (processing, manufacturing)[69] • Labeling	• Food processing licenses • Food handling licenses • Retail food establishment licenses • Inspections (processing, manufacturing)	• Retail food establishment licenses • HACCP plan (retail food establishments) • Inspections (retail food establishments)

B. Exemptions from the FDCA and Food Sovereignty laws.

The FDCA's extensive requirements do not govern all food sales within an Indian reservation or within a state. As discussed in our Year 1 Report, a Member Tribe may appropriately exclude certain intra-tribal transactions of food from the scope of formal regulation.[70] In addition, direct-to-consumer sales may also be exempt from certain FDA and other requirements. Specifically, the FDA provides an exemption from food facility registration requirements for establishments that sell food directly to consumers and if their annual direct sales exceed annual sales to all other buyers (e.g., businesses).[71] As discussed in our Year 1 Report, the FDA also excludes small-scale processors from the full FDA preventive controls rule if the processor has more average sales to consumers within the same Indian reservation than to all other purchasers.

[68] A HACCP plan is not technically required for processing wild game by FDA regulation. However, the Model FDA Food Code suggests that wild game should be processed according to laws governing meat and poultry, as discussed in our Year 1 Report at 25. The USDA's regulations for processing meat and poultry require HACCP plans. *See* 9 C.F.R. parts 416, 417.

[69] In practice, the FDA often relies on relationships with state and local regulators, as the majority of inspections in food facilities are conducted by state and local agencies under contract with the FDA. On Indian reservations, the Indian Health Service's Division of Environmental Health Services can contract with tribes to perform inspections of tribal food operations, though tribes may assert this authority if they have the capacity to do so.

[70] *See* Year 1 Report at 10, 35.

[71] 21 C.F.R. § 1.227; *see also* Retail Food Establishment Exemption Flowchart, U.S. Food & Drug Admin. (May 2018), *available at* https://www.fda.gov/media/112967/download.

Tribal and state governments also often enact "cottage food" exemptions for home-based operations that exclude them from licensing and inspection requirements.[72] "Cottage food" exemptions are typically limited to direct-to-consumer sales of products made from fruits and vegetables and exclude potentially hazardous food, such as animal food products.[73] However, we note that the Pokagon Band of Potawatomi Indians in Michigan has adopted a provision that is essentially a cottage food law for wild game. This provision allows food establishments to sell wild game from uninspected sources in limited circumstances. We discussed this provision in our Year 1 Report,[74] but it is unclear whether it has been successfully implemented by the Pokagon Band such that sales of uninspected wild game food products occur without objection by the FDA.

2020 Supplement: In 2019, the Bay Mills Indian Community enacted its Jiibaakwaan Production Ordinance ("Jiibaakwaan Ordinance") for cottage foods sold at the Bay Mills Farmers' Market.[75] The Jiibaakwaan Ordinance provides for the sale of homemade food at the Bay Mills Farmers' Market that is "non-potentially hazardous."[76] This includes foods such as baked goods without cream or meat fillings; candies; dried fruits, pastas, and spices; maple syrup; and granola, cereals, and nuts.[77] Similar to many other cottage food laws, the Jiibaakwaan Ordinance does not permit the sale of "potentially hazardous food," which is defined as food "that has generally been shown to support the growth of pathogenic bacteria or other foodborne pathogens without a time and temperature control."[78] This effectively includes animal food products that are typically excluded from sale under cottage food laws.

The Jiibaakwaan Ordinance provides that "non-potentially hazardous" food may be sold if it is "prepared in a traditionally safe manner."[79] A food is prepared in a "traditionally safe manner" if it is produced "using cultural practices specific to the Bay Mills Indian Community peoples that have proved to be safe over past generations."[80] The Jiibaakwaan Ordinance also requires annual licenses for vendors and enforcement by an appointed "Market Master."[81]

The Jiibaakwaan Ordinance has labeling requirements to indicate that the food product is homemade and uninspected:

[72] *See, e.g.*, Wis. Stat § 97.29(b); Minn. Stat. § 28A.152.
[73] Wis. Stat. § 92.29(b); Minn. Stat. § 28A.152(1)(a)(1).
[74] *See* Year 1 Report at 31.
[75] Jiibaakwaan Production Ordinance (July 23, 2019), *available at* https://baymillstribalcourt.org/wp-content/uploads/2019/08/JiibaakwaanProductionOrdinance.pdf.
[76] *Id.* § 104(A)(1).
[77] *Id.* § 103(H).
[78] *Id.* § 103(G).
[79] *Id.* § 104(A)(2).
[80] *Id.* § 103(J).
[81] *See id.* § 105.

> "Made in a home kitchen not inspected by the Bay Mills Indian Community and processed in a traditional manner."
>
> "Not for resale beyond the Bay Mills Indian Community boundaries."
>
> "Made in a home kitchen not inspected by the Bay Mills Indian Community."[82]

The Jiibaakwaan Ordinance is notable for its incorporation of Anishinaabe practices into a system of food safety regulation. Nevertheless, the Jiibaakwaan Ordinance has a limited scope in terms of geographic sales and the types of food permitted for sale. This is another example of the limits imposed on sales by federal food laws.

The State of Maine has gone further than "cottage food" laws by enacting a food sovereignty law in 2017 to encourage local control over food systems for sales of locally-produced food.[83] The Maine Food Sovereignty Act ("MFSA") declares Maine's policy on food sovereignty, including the policies to "encourage food self-sufficiency for its citizens"; "[e]nsure the preservation of family farms and traditional foodways through small-scale farming and food production"; to "[i]mprove the health and well-being of citizens of this State by reducing hunger and increasing food security through improved access to wholesome, nutritious foods supporting family farms and encouraging sustainable farming and fishing"; to "[p]romote self-reliance and personal responsibility by ensuring the ability of individuals, families and other entities to prepare, process, advertise and sell foods directly to customers intended solely for consumption by the customers or their families"; and to "[e]nhance rural economic development and the environmental and social wealth of rural communities."[84]

The MFSA provides that Maine will not enforce state food laws for direct-to-consumer transactions if a municipality has enacted an ordinance to govern those transactions.[85] In turn, municipalities enact ordinances to implement the MFSA within the local jurisdiction. Because most licensing and inspection requirements are carried out by state authorities,[86] the MFSA effectively exempts local food producers from licensing and inspection requirements for food sales between the producers and customer for the customer's personal consumption. It also forces the FDA to enforce federal food laws itself, because the State does not undertake its role of enforcing federal requirements that form the basis of state food regulation.

[82] *Id.* § 106.
[83] Me. Rev. Stat. tit. 7, §§ 281-286.
[84] *Id.* § 283.
[85] *Id.* § 284.
[86] This arrangement is not entirely analogous to an Indian reservation because not all tribes have assumed primary responsibility for licensing and inspecting food operations within their jurisdiction.

However, the MFSA does not exempt licensing and inspection requirements for meat and poultry products.[87] This exclusion was in direct response to the USDA's objection to the original MFSA, which applied to meat and poultry products. The USDA objected to the original MFSA as falling below federal requirements for meat and poultry in the Federal Meat Inspection Act and Poultry Products Inspection Act. This is an example of how federal authorities take issue with attempts to sell food products from potentially hazardous food. This would likely be the response from the FDA if Member Tribes attempt to encourage the sale of unregulated food products made from fish and wild game.

C. Sales into state and local jurisdictions.

Finally, we note the particular problem of sales into, or within state and local jurisdictions. Treaty harvesters that sell or serve food in a state or local jurisdiction are subject to nondiscriminatory state and local laws.[88] As discussed in our Year 1 Report, retail food establishments that sell or serve food to consumers (e.g., grocery stores, restaurants) are generally regulated by food codes modeled off the FDA's Model Food Code. Under the Model Food Code, retail food establishments must obtain food only from approved sources. Moreover, some states, such as Wisconsin and Minnesota, have amended the model provisions to effectively prohibit retail food establishments from receiving products made from field-dressed wild game for sale or service to consumers.[89] In these cases, it is very unlikely that retail food establishments will be willing to purchase wild game food products for sale or service in their establishments.

However, there may be more of an opportunity for direct-to-consumer sales in state and local jurisdictions. It is critical that Treaty harvesters comply with the FDCA's requirements if they intend to sell their products directly to consumers in jurisdictions outside an Indian reservation. This is due to the preemptive force of the FDCA for food products being sold in interstate commerce. A Treaty harvesters' compliance with the FDCA makes it more difficult for state and local jurisdictions to take issue with a food product made from wild foods. Nevertheless, the ability to market food products made from wild game throughout the United States is largely untested and certain to draw attention from federal, state, and local regulators. This presents the opportunity for Member Tribes to adopt their own standards to facilitate broader marketing of wild foods if they demonstrate food safety and the standards become accepted more broadly.

[87] *Id.* § 285.

[88] *See, e.g.*, *Mescalero Apache Tribe v. Jones*, 411 U.S. 145, 148-49 (1973). The extent to which the off-reservation Treaty rights would provide a basis to exempt sales of wild foods occurring outside a reservation from state law is unclear. The ability of Treaty harvesters to sell wild foods into a state or local jurisdiction would likely depend on acceptance by the state or local government of tribal standards.

[89] *See* Minn. R. 46260160(C); Wis. Admin Code § ATCP 75, App. § 3-201.17(B).

V. Conclusion

A product of Treaty-harvested wild food needs to comply with the FDCA's labeling, packaging, and sales requirements if intended to be marketed in interstate commerce. Only certain types of sales may be properly exempted from the FDCA's requirements and these are generally limited to intra-tribal transactions and small-scale producer-to-consumer sales of non-hazardous foods (i.e., fruits, vegetables, and wild rice). Tribes and state often reference federal requirements for labeling, packaging, and sales, as the federal requirements preempt conflicting requirements and govern sales throughout the United States in any event. A model code for Treaty-harvested wild foods may likewise reference the federal requirements and then address specific food safety concerns for wild game.

Respectfully submitted,

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Appendix to
Great Lakes Indian Fish & Wildlife Commission
Chippewa Ceded Territory Traditional Food Regulatory System Project
Second Food Code Guidance Report

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1. Model Tribal Model Fish Processing Code
    - See "Table of Contents" in Training Manual

2. FDA's Current Good Manufacturing Practices, 21 C.F.R. part 110
    - https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements

3. ATCP ch. 70, Appendix A, Smoked Fish Processing (Wisconsin)
    - https://docs.legis.wisconsin.gov/code/admin_code/atcp/055/70_a

4. *Guidance for Industry: Food Labeling Guide*, U.S. Food & Drug Admin.
    - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide

5. *Fish and Fishery Products Hazards and Controls Guidance*, U.S. Food & Drug Admin.
    - https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls (most recent edition March 2020)

TRADITIONAL FOOD REGULATORY SYSTEMS

BY

SONOSKY, CHAMBERS, SACHSE, ENDRESON & PERRY, LLP

FOR *THE GREAT LAKES INDIAN FISH AND WILDLIFE COMMISSION*

2

GREAT LAKES INDIAN FISH AND WILDLIFE COMMISSION (GLIFWC)

The Member Tribes of GLIFWC include the following 11 sovereign tribal governments: Bad River Band of the Lake Superior Tribe of Chippewa Indians, Bay Mills Indian Community, Keweenaw Bay Indian Community, Fond du Lac Band of the Lake Superior Tribe of Chippewa Indians, Lac Courte Oreilles Band of Lake Superior Chippewa Indians, Lac du Flambeau Band of Lake Superior Chippewa, Lac Vieux Desert Band of Lake Superior Chippewa, Mille Lacs Band of Ojibwe, Red Cliff Band of Lake Superior Chippewa, Sokaogon Chippewa Community, and the St. Croix Band of Chippewa Indians.

3

GLIFWC's Chippewa Ceded Territory Traditional Food Regulatory System Project

Project seeks to address limitations on the use of Treaty-harvested wild foods for commercial sale and in federal food programs.

Principal challenge is ensuring food safety of Treaty-harvested wild foods.

4

THE TREATY RIGHT

The GLIFWC Member Tribes reserved hunting, fishing, and gathering rights in territories ceded in 1837, 1842, and 1854 Treaties with the United States.

5

THE TREATY RIGHT

- The Treaty Right includes right to commercially harvest the resources.
- The Federal Court recognized that the right include the right to harvest Treaty resources for commercial sale, even to non-members. The federal district court in the *Voigt* litigation specifically found that "[t]he fruits of the exercise of their usufructuary rights may be traded and sold today to non-Indians, employing modern methods of distribution and sale." *Lac Courte Oreilles Band v. Wisconsin*, 653 F. Supp. 1420, 1435 (W.D. Wis. 1987).

VOIGT DEER TRIAL STIPULATION

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- In the *Voigt* Deer Trial Stipulation, the parties agreed that Wisconsin food laws would apply to tribal venison products "both on-and off-reservation, in the interest of public health," so long as there is reason to believe that deer is marketed with "the reasonable expectation that nontribal member consumption will occur."
- The parties agreed, however, that Wisconsin law applied only until such time as a Tribe adopted "corollary regulations" and "employ[ed] trained and qualified personnel to enforce such regulations."
- The Deer Trial Stipulation applies only to "wild game," not to other Treaty resources such as wild rice, fruits, or vegetables. It also applies only to marketing for non-member consumption, not to consumption by tribal members in, for example, a tribally-operated food program.

REGULATING WILD FOOD SAFETY?

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- The Deer Trial Stipulation illustrates the work Tribes still need to do. The exercise of food sovereignty necessarily includes the *adoption and implementation of tribal laws to establish a regulatory scheme that can be used to facilitate the sale of wild meat* (a similar agreement is in place for inland fish sales).
- Key to this effort is ensuring a method of regulating the source of wild food at the top of the food distribution chain.
- Conservation regulations can be used to demonstrate the initial safety of wild foods as they are harvested prior to entering a food safety regulation system for processing, distribution, and eventual retail sale or service to the consumer. An example of this could be the limitation on the use of lead ammunition.

8

HOW IS WILD FOOD REGULATED?

In the United States, a patchwork of regulation by the federal, tribal, state, and local governments governs the food distribution system from production to the final retail sale or service to a consumer.

This framework is oriented around (plant) food that is made from intentionally grown crops and (meat) food that is from farm-raised animals, where a landowner maintains control over the plants/animals throughout the growing cycle.

Wild food is regulated just as any other type of food but in a different setting and context where the harvester does not have the same control over the inputs (i.e. food that was consumed by the animal, chemical residue on plants, etc.).

9

WHICH FEDERAL AGENCIES REGULATE FOOD SAFETY?

- FDA

  Wild foods fall under the FDA's jurisdiction over food sold or received in interstate commerce under the Federal Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. §§ 301-*et seq*, as amended by the Food Safety Modernization Act, Pub. L. No.11-353 (Jan. 4, 2011) (FSMA).

- USDA

  Wild game is not subject to the USDA's jurisdiction under the Federal Meat Inspection Act, 21 U.S.C. § 601-695, or the Poultry Products Inspection Act, 21 U.S.C. §§ 451-472.

10

HOW DO THE FEDERAL AUTHORITIES INTERSECT WITH THE TRIBAL AUTHORITY TO REGULATE FOOD?

- The FDA states it is "rare" for food products intended for sale to fall outside its jurisdiction under the FDCA. As for Indian reservations, the FDA's position is that it "has complete jurisdiction over products . . . that are manufactured on an Indian reservation," because the Agency considers the food products to be in interstate commerce within the meaning of the FDCA "at all times."
- Although Treaty harvesters have a potential basis to claim the FDA does not have the authority to enforce the FDCA against small-scale processing and distribution of wild foods, the FDCA's methods of regulation are relevant to all levels of the food distribution system.
  - It is difficult to market food products if they do not adhere to federal standards.

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HOW DO THE FEDERAL AUTHORITIES INTERSECT WITH THE TRIBAL AUTHORITY TO REGULATE FOOD? (CONT'D)

- Treaty harvesters could also claim that the FDCA is silent as to Treaty-harvested foods and therefore inapplicable. *See United States v. Dion*, 476 U.S. 734, 739-40 (1986).
- A claim to a Treaty-based exemption from the FDCA is likely strongest for sales and uses of wild foods *among tribal members within a reservation*.

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WHAT IS THE IMPORTANCE OF ROBUST REGULATION?

- *FOOD SAFETY*
- *Unregulated* wild foods will be barred by federal regulators for use in federal food programs.
- The marketability of an unregulated wild food product is also limited, because the retail and service segment of the industry must obtain food from approved sources under most food codes.
- For some wild foods, there may also be no regulatory standards currently in place, which creates effective prohibitions on the sale of these foods, because no accepted method has been developed for ensuring food safety.
- This presents the **opportunity** for Tribes to facilitate broader marketing of wild foods by adopting their own regulatory standards that assure the safety of wild foods.

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THE FDCA AND ADULTERATION

The FDCA makes it unlawful for *adulterated* food to be received in or enter interstate commerce for human consumption.

- Adulteration is defined as:
  1) the food contains a harmful substance that poses a safety risk;
  2) the food contains a harmful substance added during production;
  3) the food contains a substance that has been intentionally added but which has not been approved by the FDA; or
  4) the food has been handled under unsanitary conditions, which creates a risk of contamination with a substance that poses a safety threat.

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HOW DO YOU PREVENT ADULTERATION?

1) good manufacturing practices;
2) hazard preventive controls;
3) standards for produce;
4) sanitary transportation requirements; and
5) HACCP (if applicable).

There are requirements that apply to food generally, as well as to specific types of foods, such as fish. A food processing operation is subject to both the general requirements and those applicable to the type of food it processes, stores, or distributes.

The GLIFWC Model Food Processing Code includes regulations covering these areas.

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WHAT ARE GOOD MANUFACTURING PRACTICES?

- General requirements, called current good manufacturing practices, apply to food plants, which are the buildings used for processing, packing, labeling, or holding food.
- These standards include requirements for:
  1) employee hygiene;
  2) pest control;
  3) sanitation of food-contact surfaces, cleanable equipment and utensils; and
  4) practices for handling and preparing food.

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WHAT ARE GOOD MANUFACTURING PRACTICES? (CONT'D)

- There are specific requirements for specific foods.
- For example, GLIFWC's model food code includes a provision for ground meat products which requires food processors to maintain logs on the cleaning and sanitizing of grinding equipment that identify the carcasses that were ground together as one batch, between stopping to clean and sanitize the equipment. This standard is meant to address the problem of e. coli contamination of ground meat.

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HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP)

- HACCP is a method of food regulation that attempts to ensure food safety by requiring processors to identify and address hazards that could contaminate food at critical points of processing and preparation.
- Controls hazards at each stage of the food production and preparation process, rather than relying solely on inspection of the finished product.
- Processors are required to document the steps they have taken to analyze risks (HACCP Plan) and document how their HACCP Plan is implemented when processing specific foods (i.e. smoked fish that carry the risk of botulism if not processed safely).

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HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) (CONT'D)

- A HACCP plan typically requires a food processor to identify "critical control points," which are specific points in a food process where uncontrolled hazards may affect food safety (e.g., cooking, chilling, cross contamination).
- The processor must adopt limits for the critical control points (e.g., cooking time, temperature); verification procedures to make sure the controls are working; and corrective actions in the event they are not.

PRODUCE RULE

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- The FDA promulgated regulations to provide minimum standards for most fruits and vegetables.
- The Produce Rule governs the:
  1) growing;
  2) harvesting;
  3) packing; and
  4) holding of produce for human consumption.
- Exception to the Produce Rule for certain types of fruits and vegetables that are rarely consumed raw, such as potatoes, squash, cranberries, hazelnuts, and many types of beans.

PRODUCE RULE (CONT'D)

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WHAT ABOUT WILD FRUITS AND VEGETABLES?

- Harvesters of wild fruits and vegetables do not grow produce and are therefore exempt from the Produce Rule's requirements applicable to growers.

IS HARVESTING WILD FRUITS AND VEGETABLES COVERED?

- The Produce Rule does regulate harvesting, so a Treaty harvester "harvests" covered produce any time he or she removes the produce from the ground and performs basic trimming and washing.
- Under the Produce Rule, a harvester must take measures "reasonably necessary" to identify, and not harvest, produce that is "reasonably likely" to be contaminated with a known or reasonably foreseeable hazard, such as taking steps to not harvest produce that is visibly contaminated with animal excrete.

SMALL-SCALE HARVESTERS EXEMPTION FROM THE PRODUCE RULE

21

What is a small-scale harvester?

- Small-scale harvesters who average less than $25,000 in sales per year over the prior three years of covered produce sold are exempt from the Produce Rule.
- Treaty harvester could also seek a qualified exemption if he or she sold more produce to local consumers (either within the same Indian reservation or 250 miles) than all other buyers in a three-year period (and averaged less than $500,000 in total sales of produce during the same period).

WILD GAME

22

- USDA's Food Safety and Inspection Service ("FSIS") is required to inspect meat under the Federal Meat Inspection Act ("FMIA") and poultry under the Poultry Products Inspection Act ("PPIA"). These statutes do not apply to wild game.
- While Federal law does not expressly prohibit the sale of wild game, the unregulated sale of wild game meat is difficult in practice, given how the retail segment of the industry is typically required to obtain food from approved sources under most food codes.

WHAT ABOUT FISH AND SHELLFISH?

- Fish are not considered wild game. The FDA regulates fish under the FDCA. Fish are not required to be inspected but must be processed under the FDA's requirements for fish and fishery products, including applicable HACCP requirements.

HOW DOES VENISON END UP ON A MENU?

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- In order to facilitate the sale of certain types of "wild" game, the USDA's FSIS established a voluntary inspection program for "exotic animals," which includes reindeer, elk, deer, antelope, water buffalo, and bison.
- This inspection requires: An ante mortem inspection (prior to slaughter) and postmortem inspection (after slaughter) of every animal.
- The FSIS's regulations allow for ante mortem inspections to be conducted in the field (FSIS intends for this to apply to farm-raised game animals).

HOW DOES VENISON END UP ON A MENU? (CONT'D)

24

- The carcasses of exotic animals that are inspected and passed under the voluntary inspection program receive a triangular mark of approval from the USDA, distinguishing these animals from the round mark given to amenable species (e.g., cattle) under the FMIA and PPIA.
- The voluntary inspection program is intended to facilitate the sale of exotic animals, as the mark of inspection provides assurances to buyers of exotic meat products that they are safe for human consumption and allows these food products to move more freely in interstate commerce.
- Producers must pay for voluntary inspections of "exotic animals."
- This process is really intended to support commercial "wild" game farms.

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LABELING

- The FDCA also regulates labeling by prohibiting the sale of misbranded food
- The FDA requires each food product to include specific information on the label:

  1) The food's statement of identity;
  2) The net quantity of contents;
  3) The nutrition facts;
  4) The ingredients and allergens; and
  5) Name of manufacturer, packer, or distributor.

- This information is placed on certain areas of the package:
  - Principal Display Panel
  - Information Fact Panel

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LABELING (CONT'D)

- There are also warning and safe handling statements for specific foods.
  - Example of safe handling statement for fish products: "Important, keep frozen until used, thaw under refrigeration immediately before use."
- Allergens: federal law identifies 8 foods that must be clearly identified on a label if present as an ingredient

1) Milk
2) Eggs
3) Fish
4) Crustacean shellfish
5) Tree nuts
6) Peanuts
7) Wheat
8) Soybeans

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FDA'S PREVENTIVE CONTROLS

- Pursuant to the FSMA, the FDA promulgated regulations require food safety plans as preventive controls in "food facilities."
- A food facility includes any facility that manufactures, processes, packs, or holds food for human consumption.
- Requires a food safety plan, which is very similar to the HACCP method of regulation.
- The FDA's regulations require food facilities to adopt and implement food safety plans even if their products do not enter interstate commerce.

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SMALL SCALE PROCESSORS' EXEMPTION FROM PREVENTIVE CONTROLS

Small-scale processors may take advantage of modified requirements intended for small businesses that sell their products locally or within the same Indian reservation.

Who is Small Scale Processor?

- A small-scale processor is not subject to full preventive controls if, as averaged over the prior three years, the processor sold more food to consumers or food establishments within the same Indian reservation or 250 miles, than the amount of food it sold to all other purchasers (and averaged less than $500,000 in total sales during the same period).

What does the exemption allow?

- This qualified exemption allows a small-scale processor to submit an attestation to the FDA that it has incorporated HACCP principles into its operations and complies with food regulations overseen by the applicable tribal, state, or local government.

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Who performs the FDA inspections mandated by FMSA?

- The FDA has the authority to inspect all facilities producing food within the scope of the FDCA to ensure that federal standards are met, and that food is being processed, stored, and distributed under sanitary conditions.
- The FDA often relies on relationships with state and local regulators, as most inspections in food facilities are conducted by state and local agencies under contract with the FDA.
- On Indian reservations, the Indian Health Service's Division of Environmental Health Services can contract with tribes to perform inspections of tribal food processing operations.
- It's possible that tribal agencies could also carry out these inspections if they can demonstrate the capacity and make a formal arrangement with the FDA.

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FDA MODEL FOOD CODE

- The FDA Model Food Code (Food Code) is "designed to be consistent with federal food laws and regulations" and its standards serve as the basis upon which tribal, state, and local governments can design their own food safety programs.
- The Food Code represents best practices for food storage, handling, and preparation for the retail and service segments of the industry.
- The Food Code is intended to be adopted by tribal, state and local governments to regulate retail and service operations (e.g., restaurants, grocery stores).

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WHO DOES IT APPLY TO?

- The Food Code applies to "food establishments," which include operations that store, prepare, pack, serve, or sell food directly to the consumer.
- The Food Code defines food establishments in such a way that essentially any establishment that serves or provides food to a person who consumes it is subject to the Food Code.

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WHAT DOES THE FOOD CODE REQUIRE?

The Food Code has provisions regarding:

1) management and personnel;
2) the storing, preparation, and service of food;
3) the equipment, utensils, and materials used for the food; and
4) the utilities and physical construction of the facilities.

The Food Code also encourages food establishments to implement HACCP principles, including requirements for HACCP plans.

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WHAT DOES THE FOOD CODE REQUIRE? (CONT'D)

These requirements apply to wild foods just as they would any other food sold or served in a food establishment.

WHAT ARE THE EXEMPTIONS IN THE MODEL CODE?

- Produce stand that only offers whole, uncut fruits and vegetables (e.g., farmers' markets).
- Food prepared in a kitchen at a private home if it is sold or served at a charitable function.
- Governments can amend the model provisions to include additional exemptions (i.e., Tribes can exempt certain food activities from regulation).

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HOW DOES THE FOOD CODE IMPACT WILD FOODS?

- The Food Code notes that wild game animals "may be available as a source of food only if a regulatory inspection program is in place to ensure that wild animal products are safe."
- The Food Code has a provision that governs how food establishments may obtain wild game animals for sale or service, including elk, deer, rabbit, opossum, and nonaquatic reptiles.

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HOW DOES THE FOOD CODE IMPACT WILD FOODS?

- The Food Code allows a food establishment to sell or serve meat from a field-dressed wild game animal under a routine inspection program that ensures the animal:
  1) Receives a postmortem examination by an approved veterinarian; or
  2) Is field-dressed and transported according to requirements to be specified by the agency with animal health jurisdiction and the agency that conducts the inspection program, and
  3) Is processed according to laws governing meat and poultry.
- This provision contemplates the sale of wild game, not just donation.

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TRIBAL MODEL FOOD CODES

- Primary regulatory challenges for Tribes with regard to the sale of traditional foods, including wild game, are:
  1) Development of adequate food safety standards for the field-dressing and transportation of wild game;
  2) Development of HACCP plans;
  3) Development of standards for the harvesting of wild fruits and vegetables; and
  4) Development of standards for the processing, labeling and sale of these resources.
- These standards must be consistent with federal law for any food intended to be sold to the public.

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"COTTAGE FOOD" LAWS

- Tribes can exclude certain operations from more complex licensing and inspection requirements with "cottage food" laws.
  1) Applies to non-hazardous food (e.g., fruits, maple syrup, and other low risk foods)
  2) Typically does not apply to animal food products (e.g., wild game)
  3) Limited to direct-to-consumer sales (e.g., farmers' markets)
  4) Special labeling requirements to notify consumers that the products were not made in an inspected facility
- Tribes can use a "cottage food" model to facilitate local sales of non-hazardous food prepared in a traditional manner.

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WHAT DO TRIBES NEED TO BE AWARE OF AS THEY DRAFT FOOD CODES?

- Inspection Capacity
- HACCP
- Labeling
- Sales Requirements
- Scope of Regulation

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Governmental regulatory roles related to Food Safety		
FDA	Tribal/State	Tribal/Local
• **Food facility registration** • **Current good manufacturing practices** • **Hazard preventive controls** • **Sanitary transportation rule** • **HACCP plan (fish, wild game, juice)** • **Produce rule (fruits/vegetables)** • **Inspections (processing, manufacturing)** • **Labeling**	• Food processing licenses • Food handling licenses • Retail food establishment licenses • Inspections (processing, manufacturing)	• Retail food establishment licenses • HACCP plan (retail food establishments) • Inspections (retail food establishments) • Perform the ministerial function of inspection and licensing.

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STATE AND LOCAL LAWS

- State and local governments vary in terms of how or whether they regulate wild foods. Some states regulate certain types of wild foods that are relevant to their economy, such as wild rice in Michigan, Minnesota, and Wisconsin.
- For example, in Wisconsin:
  - Department of Agriculture, Trade, and Consumer Protection (ATCP) regulates and licenses food processing and food establishments.
  - ATCP may designate a local health department for licensing and inspecting food establishments (e.g., ATCP contracts with Sawyer County Department of Health & Human Services to license and inspect food establishments in Sawyer County).
  - Wisconsin had adopted the FDA's Model Food Code with state-specific amendments (e.g., wild game served only in certain nonprofit settings).

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STATE AND LOCAL LAWS

- Sales into a state or local jurisdiction are generally subject to nondiscriminatory state and local laws.
- An issue for wild game:
  - Wisconsin, Minnesota, and Michigan effectively prohibit field-dressed wild game from commercial sale.
  - These states only allow wild game to be served in nonprofit settings.

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FEDERAL FOOD PROGRAMS

- Federal law allows wild game meat, along with other traditional foods, to be donated to certain tribally-run federal food programs:
  1) USDA's School Meal Programs;
  2) Child and Adult Care Food Program;
  3) Summer Food Service Program.

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FEDERAL FOOD PROGRAM DONATIONS

The law requires that the program:

(1) ensures the food is received whole, gutted, gilled, as quarters, or as a roast, without further processing;

(2) makes a reasonable determination that the animal was not diseased, was butchered, dressed, and transported, and stored to prevent contamination, and the food will not cause a significant health hazard or potential illness;

(3) carries out any further preparation or processing of the food at a different time or in a different space from the preparation or processing of other food for the applicable program to prevent cross-contamination;

(4) cleans and sanitizes food-contact surfaces of equipment and utensils after processing the traditional food;

(5) labels donated traditional food with the name of the food;

(6) stores the traditional food separately from other food for the applicable program;

(7) follows federal, state, local, and tribal law for the safe preparation and service of food;

(8) follows other criteria established by the USDA and FDA.

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FEDERAL FOOD PROGRAMS

- The establishments that serve food as part of federal food programs are typically regulated as "food establishments"
- Federal law also allows the Secretary of Agriculture to purchase traditional food for the Food Distribution Program on Indian Reservations (FDPIR) so long as those foods may be "procured cost-effectively."
  - 2018 Farm Bill authorized a demonstration project for Tribes to enter into self-determination contracts to purchase food for their FDPIR programs.

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SUMMARY

GOAL OF THIS INITIATIVE:

REAFFIRMATION OF TRIBAL FOOD SOVEREIGNTY

- The lack of tribal regulatory systems allows other sovereigns to govern tribal community's food supply.
- Why is the growth and expansion of food sovereignty important?

  If we can't control our food, we can't control our:

  - Culture
  - Health, or
  - Economies

Great Lakes Indian Fish & Wildlife Commission

Model Hazard Analysis Critical Control Point Plans, Record Templates, & Model Standard Sanitation Operating Procedure

The following plans are sample or model plans designed to represent the type of information required in a Hazard Analysis and Critical Control Point (HACCP) plan and Standard Sanitation Operating Procedures (SSOP). Each facility will need to assess and develop their own plans and procedures to reduce risks for there individual facility or product. HACCP plans should be developed by HACCP personnel who have completed a HACCP course for their industry or otherwise meet the regulatory requirments to conduct a Hazard Analysis and develop HACCP plans. HACCP teams are welcome to use the following models as tools to help in that endeavor.

Additionally, record templates have been provided and are available for downloading and modifying to for use.

Whitefish Model HACCP Plan

Frozen Fillet- Reduced Oxygen Packaging

PRODUCT DESCRIPTION

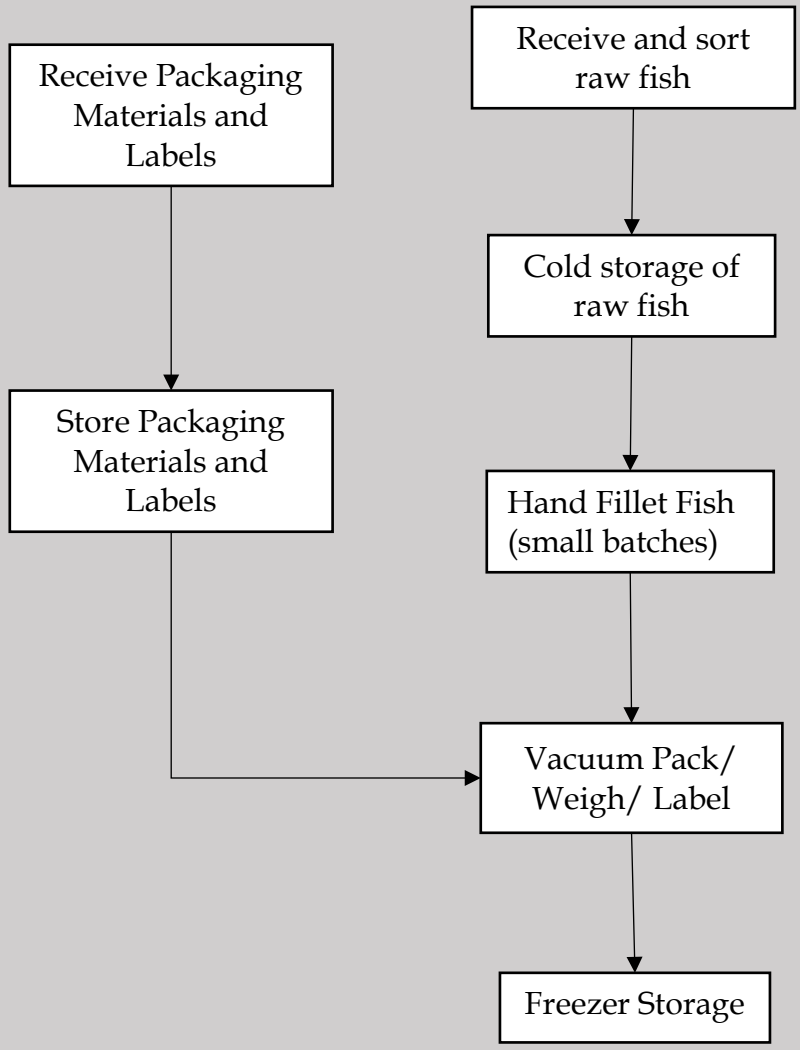
Establishment's Name	INSERT ESTABLISHMENT'S NAME
Establishment's Address	INSERT ESTABLISHMENT'S ADDRESS

Product Name	Wild Caught, Frozen Lake Superior Lake Whitefish Fillets
Brief Description	Frozen, Vacuum Packed, Lake Whitefish Fillets
Ingredients	Fresh Lake Whitefish (*Coregonus clupeaformis*)
Allergens	Fish
Packaging	ROP/ Vacuum Packaging
Distribution	Freezer truck delivery to retail outlets
Intended Use	To be cooked
Target Consumer	General Public

Date:		
HACCP Team Member(s)	**Position**	**Signature**

Establishment's Name:	**Intended Use:** to be cooked
Establishment's Address:	**Product:** Vacuum Packed, Frozen, Lake Superior Lake Whitefish Fillets
	Method of Distribution & Storage: Freezer truck; Freezer

Process Flow Chart: Vacuum Packed, Raw, Frozen Whitefish Fillets



Establishment's Name:	**Intended Use to Consumer:** to be cooked
Establishment's Address:	**Product Description:** Vacuum Packed, Frozen, Lake Superior Lake Whitefish Fillets
	Method of Storage & Distribution: Refrigerator, Freezer, and freezer truck

PROCESS FLOW FORM

The color coded Flow Chart on the following page(s) integrates daily production activities, SSOP activities, and HACCP records that must be maintained.

1) Daily operational tasks are identified in black colored font.
2) Staff food safety tasks/warnings are identified in red colored font.
3) Daily production Standard Sanitation Operating Plan (SSOP) tasks are identified green colored font.
4) Maintenance of daily HACCP records identified in the HACCP plan in blue colored font.

Process Name:	**Vacuum Packed, Frozen, Wild Caught Lake Whitefish (*Coregonus clupeaformis*) Fillets**

STEP	DESCRIPTION
Daily Tasks **<u>Prior to Start-up</u>** (Processing Days Only)	• Check and record temperature of all **coolers** on corresponding *Cooler Temperature Log*. o If temperature exceeds 38°F, contact Owner, and ensure temperatures of all product are less than 38°F. • Check and record temperature of all **freezers** on corresponding *Freezer Temperature Log*. o If temperature exceeds -3°F, contact Owner, and ensure temperatures of all product are less than -3°F. • On the *Sanitation Audit Form* enter the date and note the individual completing the form this day. On the form record: o **Safety of water –** ensure the fish shop has a copy of city water testing on file each year. o **Condition and cleanliness of food-contact services and equipment** – inspect the processing area and record time and pass/fail on form - if the processing area and equipment are not in a

STEP	DESCRIPTION
Daily Tasks **<u>Prior to Start-up</u>** (Processing Days Only)	clean and sanitary condition, clean and sanitize the processing area and record this was done in the comment section of the form. o **Cross contamination** – ensure raw products (fresh fish filets or fish chunks) are not processed in the same areas as smoked ready to eat products. Ensure all fresh fish and fresh fish chunks are stored below any "ready to eat" smoked fish product at all times. o **Maintenance of hand washing and toilet facilities** – inspect the facility and record pass/fail on form. If conditions do not pass, correct them and note under comments on the form. Ensure a sign is posted stating, "all employees must wash their hands before returning to work". o **Protection from adulterants (i.e. pesticides, cleaners, etc.)** – inspect the processing facility and record proper storage of adulterants in relation to food products (i.e. fresh and smoked fish), food packaging materials (i.e. vacuum pack bags). o **Employee health conditions** – medical problems or sick employees. o **Exclusion of pests** – inspect for pests including rodents and habitats/clutter that harbors pests. • Wash hands for a minimum of 20 seconds with hot soapy water.
Daily Tasks **<u>Through the Day</u>**	• Throughout the day: o Wash hands for a minimum of 20 seconds with hot soapy water, as needed. o Clean and sanitize processing station(s) every 4 hours when processing for more than 4 hours, and as needed. Record cleaning and sanitizing on *Sanitation Audit Form*. o Complete the *Sanitation Audit Form* after breaks as indicated on the form. o Complete corrective action logs as needed. • After breaks (including lunch) and as needed: o Check and record temperature of all **coolers** on corresponding *Cooler Temperature Log*. ▪ If temperature exceeds 38°F, contact Owner, and ensure temperatures of all product are less than 38°F. o Check and record temperature of all **freezers** on corresponding *Freezer Temperature Log*. ▪ If temperature exceeds -3°F, contact Owner, and ensure temperatures of all product are less than -3°F.

<table>
<tr><th>STEP</th><th>DESCRIPTION</th></tr>
<tr><td>Receive Packaging Materials and Labels</td><td>

Receive packing materials from vetted vendors at the loading dock.
All incoming materials are evaluated according to company procedures including:

Visual inspection of Letters of Guaranty and any other requested documents.
Visual inspection of shipping materials for signs of damage or tampering.
Verify items and quantity match order.

</td></tr>
<tr><td>Store Packaging Materials and Labels</td><td>

Packaging materials and labels are stored in accordance with company procedures to include:

Storing in a cool dry place and in accordance with manufacturers’ instructions.
Storing all items at least 6 inches off the floor.

</td></tr>
<tr><td>Receive and Sort Fish

(raw, iced whitefish)</td><td>

Receive fresh, wild caught lake whitefish (Coregonus clupeaformis) from fishermen, at dock location, in fish boxes or other containers packed with ice.
Evaluate all incoming fish according to company procedures including:

Check for adequate ice and spot-checking internal temperatures.
Inspect fish for wholesomeness:

<table>
<tr><th></th><th>Grade A:</th><th>Grade B:</th><th>Grade C:</th></tr>
<tr><td>Eyes</td><td>Clear, bright, slightly bulging</td><td>Dull and flat, not cloudy or milky</td><td>Cloudy, sunken</td></tr>
<tr><td>Flesh</td><td>Firm to the touch, in indentations</td><td>May have some indentation</td><td>Soft to the touch</td></tr>
<tr><td>Scales</td><td>Tightly adhere to fish</td><td>60% of scales are intact</td><td>Less than 60% of scales are intact</td></tr>
<tr><td>Gills</td><td>Bright red, odorless</td><td>Red, neutral smell</td><td>Pink to buff</td></tr>
<tr><td>Smell</td><td>A clean or cucumber smell, no odor</td><td>Neutral smell</td><td>Slight Ammonia or “fishy” smell, slight odor present</td></tr>
</table>

Request and inspect necessary documentation.

</td></tr>
</table>

STEP	DESCRIPTION

Receive and Sort Fish
 	
(raw, iced whitefish)
	• Sort fish based on quality:
	  o Grade A: Highest quality (will be used for raw, fresh or frozen fillets)
	  o Grade B: Good quality (will be used for smoked fish products)
	  o Grade C: Lowest quality/ unsuitable (will not be purchased)
	• Maximum transit time from fishermen dock location to processing plant, 2 hours.

Cold Storage of Fish	• Re-ice fish awaiting processing and stored in cooler set at 38°F or less. • Processed all fish within 24 hours of arrival at the plant facility. • Trained technician(s) record refrigerator temperature during start of operations procedures, after breaks, and during closing procedures.
Hand Fillet Fish	• Clean and sanitize processing/fillet areas and equipment before and after processing and every 4 hours if processing/filleting longer than 4 hours. • Remove individual boxes (i.e. 25 pounds) of fish from cooler as needed. • Head, gut, and fillet each fish by hand with a knife in batches of approximately 50 pounds of fish fillets. • Keep processing time short, less than 30 minutes, to reduce the amount of time fillets are exposed to temperatures above 38°F. • Place fillets in clean, sanitized, food grade tubs. Approximately 25 pounds to each tub. • Clean and sanitize transport containers daily according to company SSOP.
Vacuum Pack/ Weigh/ Label/Box	• Inspect vacuum packages to ensure each one contains a label that includes the following information. Record information on the *Vacuum Packaged Fish Labeling Form*: o Safe Handling and Thawing: **"Keep frozen until ready to use. To thaw, cut bag open and thaw under refrigeration or cool running water."**

STEP	DESCRIPTION
	o Market name of fish species o Lot number including day/month/year of packing o Company name and address • Pack fillets in clear, pre-labeled, food safe, 4 millimeter, and vacuum sealing packages. • Vacuum seal filled bags and weight • Write or apply weight to each package. • Place final products in prelabeled cardboard freezer boxes. Add batch number to exterior of box. o No more than 26 pounds per box, 2 boxes per batch. • Weigh/pack/label/box step for each batch is 45 minutes or less.
Freezer Storage	• Store final product in freezer until delivery as needed. Storage temperature is set to -3°F.
Daily Tasks **<u>End of Day</u>** (Processing Days Only)	• Ensure all tubs, containers, processing areas, and equipment are cleaned and sanitized. o Sanitizing solutions should between 100-200 ppm. Start with ½ ounce of bleach in one gallon of water and then check bleach concentration with test strips to ensure reading is between 100-200 ppm. If the reading is not at least 100 ppm on the strip, add another ¼ ounce of bleach to the water pail and retest with a new testing strip. Do not exceed 200 ppm in the sanitation solution. Use only Clorox bleach without any fragrance enhancers. • Check and record temperature of all **coolers** on corresponding *Cooler Temperature Log*. o If temperature exceeds 38°F, contact Owner, and ensure temperatures of all product are less than 38°F. • Check and record temperature of all **freezers** on corresponding *Freezer Temperature Log*. o If temperature exceeds -3°F, contact Owner, and ensure temperatures of all product are less than -3°F.

STEP	DESCRIPTION
	• Complete last column of the *Sanitation Audit Form*. • Ensure the *Sanitation Audit Form*, *Corrective Action Logs*, and all Temperature Logs are completed and in appropriate file for Owner to review. • Place blank *Sanitation Audit Form*, *Corrective Action Logs*, and all Temperature Logs in predetermined locations, to be completed during next processing day.

Establishment's Name:	Intended Use to Consumer: to be cooked
Establishment's Address:	Product Description: Vacuum Packed, Frozen, Lake Superior Lake Whitefish Fillets
	Method of Storage & Distribution: Refrigerator, Freezer, and freezer truck

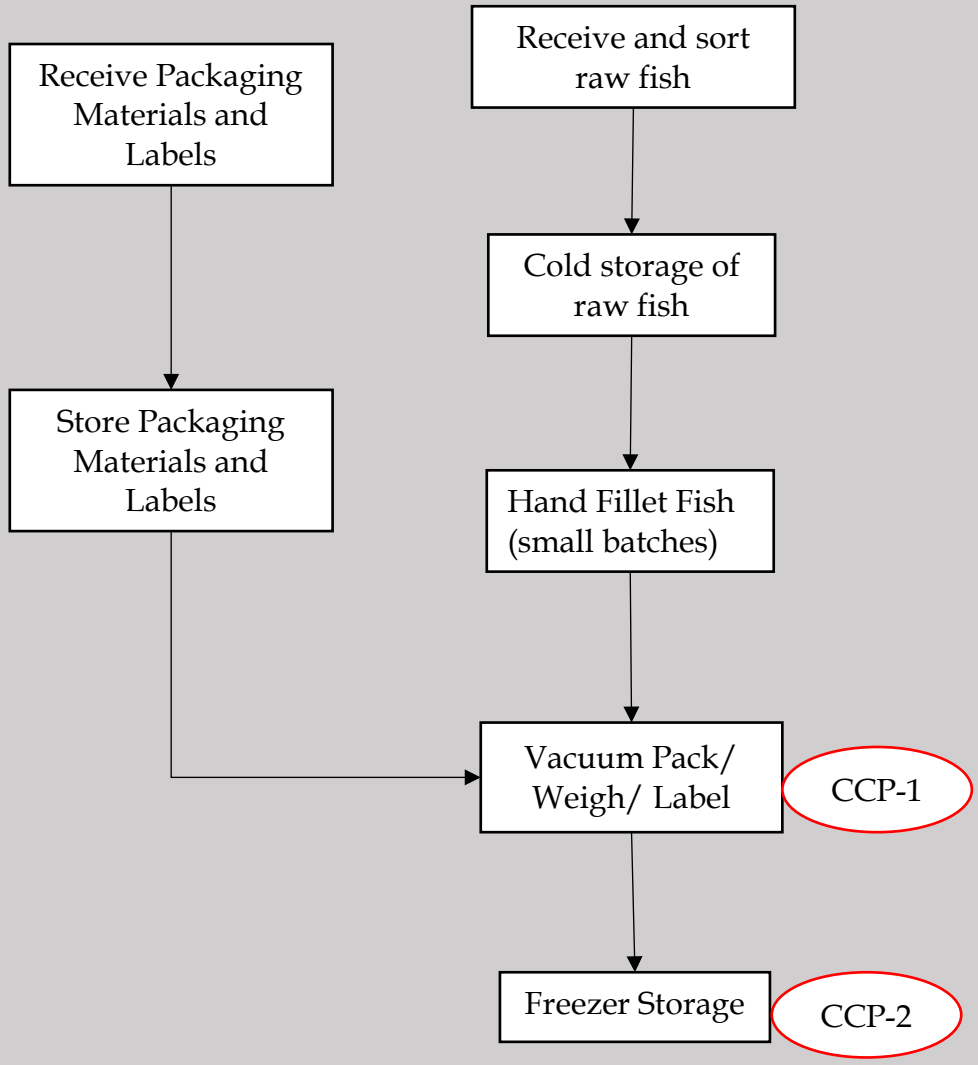
Hazard Analysis Worksheet					
(1) Processing Step	(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process	(3) Is this potential hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point? (Yes or No)
Receiving	**BIOLOGICAL:** Pathogenic bacteria, viruses, and parasites	Yes	Pathogens are naturally occurring in fish	Inspection of fish; Adequate ice around fish; product will be cooked	No
	CHEMICAL: None (see GLIFWC research in office)	No	See GLIFWC research on chemical contaminants in the Great Lakes	n/a	No
	PHYSICAL: none	No	n/a	n/a	No

Hazard Analysis Worksheet					
(1) Processing Step	**(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3) Is this potential hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)**	**(4) Justify the decision that you made in column 3**	**(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6) Is this step a Critical Control Point? (Yes or No)**
Cold Storage of Fish	**BIOLOGICAL:** Pathogenic bacteria, viruses, and parasites	Yes	Pathogens are naturally occurring in fish	Inspect fish to ensure adequate ice; fish stored below 38°F; control bacteria through SSOP; Final product will be cooked;	No
	CHEMICAL: none	No	n/a	n/a	No
	PHYSICAL: none	No	n/a	n/a	No
Filleting (by hand)	**BIOLOGICAL:** Pathogenic bacteria, viruses, and parasites	Yes	Pathogens are naturally occurring in fish	Process fish in <2 hours; product will be cooked	No
	CHEMICAL: none	n/a	n/a	No	No
	PHYSICAL: metal fragmentation	No	NRLTO: Fish are fillet by hand by fillet technicians	Prior to start up, after breaks, and at the end of day knives are visually inspected by fillet technicians.	No
Weigh, Pack, & Label	**BIOLOGICAL:** *Clostridium botulinum*	Yes	*C. botulism* spores can become activated in anaerobic environments	Include thawing instructions on label **"Keep frozen until ready to use. To thaw, cut bag open and thaw under**	**Yes**

Hazard Analysis Worksheet					
(1) Processing Step	**(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3) Is this potential hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)**	**(4) Justify the decision that you made in column 3**	**(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6) Is this step a Critical Control Point? (Yes or No)**
Weigh, Pack, & Label (cont.)			during improper thawing.	**refrigeration or cool running water."**	
	CHEMICAL: none	n/a	n/a	No	No
	PHYSICAL: none	n/a	n/a	No	No
Freezer Storage	**BIOLOGICAL:** *Clostridium botulinum*	Yes	Time and temperature abuse could result in *C. botulism* spore activation.	Product stored in freezer set at -3°F.	**Yes**
	CHEMICAL: none	n/a	n/a	No	No
	PHYSICAL: none	n/a	n/a	n/a	No

Establishment's Name:	**Intended Use:** to be cooked
Establishment's Address:	**Product:** Vacuum Packed, Frozen, Lake Superior Lake Whitefish Fillets
	Method of Distribution & Storage: Freezer truck; Freezer

Process Flow Chart with CCPs: Vacuum Packed, Raw, Frozen Whitefish Fillets



HACCP Plan									
(1) Critical Control Point (CCP)	**(2) Hazard(s)**	**(3) Critical Limits for each Control Measure**	**Monitoring**				**(8) Corrective Action(s)**	**(9) Verification**	**(10) Records**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
Labeling	*Clostridium botulinum*	Correct label affixed to each finished product package	Include thawing instructions on label **"Keep frozen until ready to use. To thaw, cut bag open and thaw under refrigeration or cool running water."**	Visual inspection	Each package	Packing Manager	Remove and replace labels from mislabeled product prior to storing in freezer	Weekly review of labelling logs	• Labelling inspection log • Corrective action reports • Verification reports (Once per week) • Purchasing records including copy of label purchased
Freezer Storage of Final Product	*C. botulism* toxin formation during power or freezer failure	Freezer temperature held at -3˚F or less	Freezer temperature	Thermometer	Two times/day (early AM, and late PM)	Packing Technician	Decrease temperature and hold and evaluate based on time and temperature of exposure	Floor Manager will review temperature records weekly. Floor Manager	• Time and temperature logs • CA reports • Training records for Company Packing and Storage.

HACCP Plan									
(1) Critical Control Point (CCP)	**(2) Hazard(s)**	**(3) Critical Limits for each Control Measure**	**Monitoring**				**(8) Corrective Action(s)**	**(9) Verification**	**(10) Records**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
Freezer Storage of Final Product (cont.)	*C. botulism* toxin formation during power or freezer failure	Freezer temperature held at -3˚F or less	Freezer temperature	Thermometer	Two times/day (early AM, and late PM)	Packing Technician	Decrease temperature and hold and evaluate based on time and temperature of exposure	will have freezer thermometer verified with a certified thermometer at -10˚F, -5˚F, 0˚F, 10˚F annually.	• Maintenance and repair records • Thermometer calibration records.
Signature:					Print Name:				

Whitefish Model HACCP Plan

Smoked Fillet

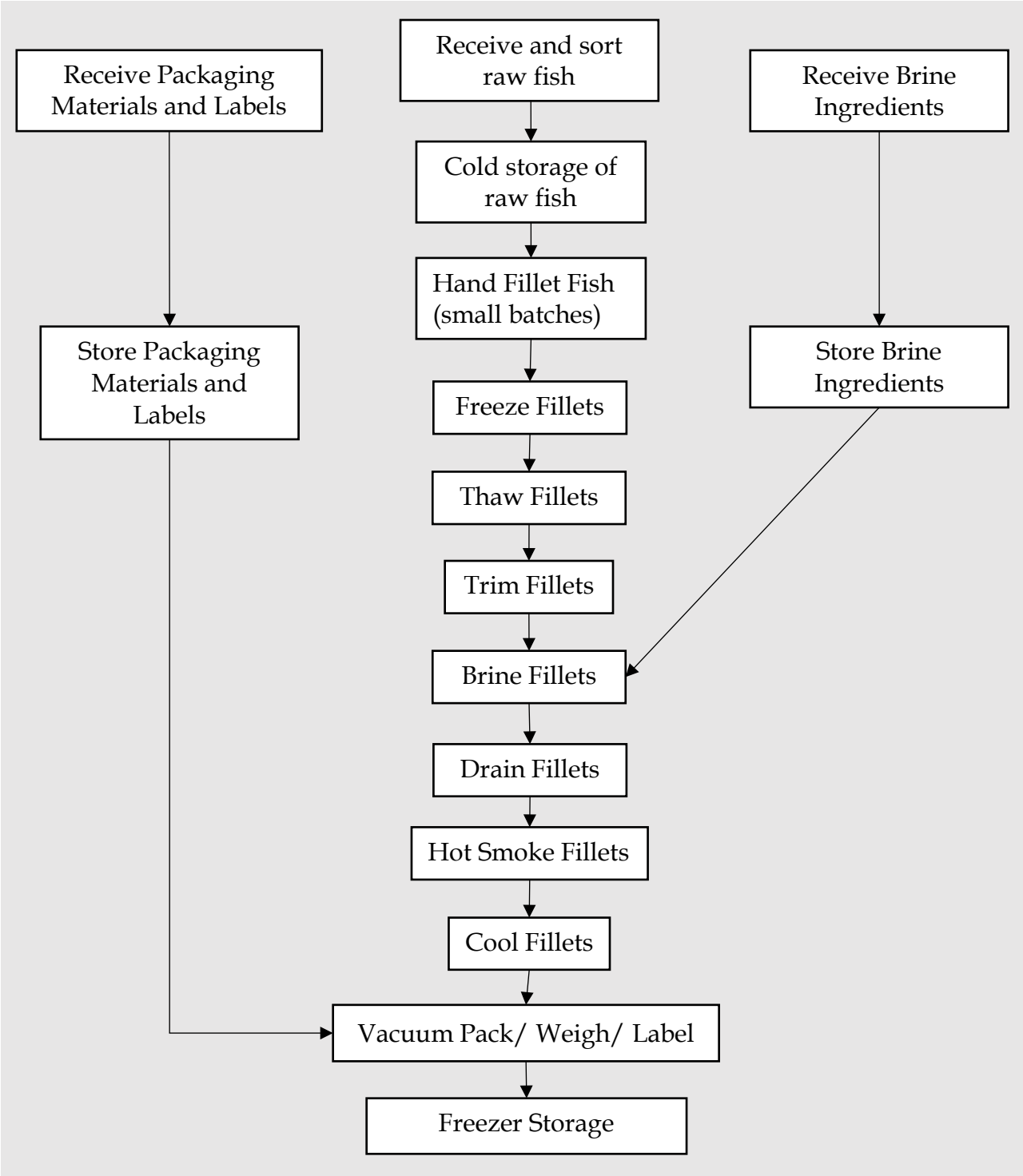
PRODUCT DESCRIPTION

Establishment's Name	INSERT ESTABLISHMENT'S NAME
Establishment's Address	INSERT ESTABLISHMENT'S ADDRESS

Product Name	Wild Caught, Hot Smoked, Lake Superior Lake Whitefish Fillets
Brief Description	Frozen, Vacuum Packed, Hot Smoked, Lake Whitefish Fillets
Ingredients	Smoked Lake Whitefish (*Coregonus clupeaformis*), salt, and sugar
Allergens	Fish
Packaging	ROP/ Vacuum Packaging
Distribution	Freezer truck delivery to retail outlets or ice packed coolers
Intended Use	Ready to eat
Target Consumer	General Public

Date:		
HACCP Team Member(s)	**Position**	**Signature**

Establishment's Name:	**Intended Use:** Ready to eat
Establishment's Address:	**Product Description:** Frozen, Vacuum Packed, Hot Smoked, Lake Whitefish Fillets
	Method of Storage & Distribution: Freezer; Freezer truck or ice packed coolers



Establishment's Name:	Establishment's Address:
Est. Number:	
Phone:	

PROCESS FLOW FORM

The color coded Flow Chart on the following page(s) integrates daily production activities, SSOP activities, and HACCP records that must be maintained.

1) Daily operational tasks are identified in black colored font.
2) Staff food safety tasks/warnings are identified in red colored font.
3) Daily production Standard Sanitation Operating Plan (SSOP) tasks are identified green colored font.
4) Maintenance of daily HACCP records identified in the HACCP plan in blue colored font.

Process Name:	**Vacuum Packed, Hot Smoked, Frozen, Wild Caught Lake Whitefish (*Coregonus clupeaformis*) Fillets**

STEP	DESCRIPTION
Daily Tasks **<u>Prior to Start-up</u>** (Processing Days Only)	• Check and record temperature of all **coolers** on corresponding *Cooler Temperature Log*. o If temperature exceeds 38°F, contact Owner, and ensure temperatures of all product are less than 38°F. • Check and record temperature of all **freezers** on corresponding *Freezer Temperature Log*. o If temperature exceeds -3°F, contact Owner, and ensure temperatures of all product are less than -3°F. • On the *Sanitation Audit Form* enter the date and note the individual completing the form this day. On the form record: o **Safety of water –** ensure the fish shop has a copy of city water testing on file each year.

STEP	DESCRIPTION
Daily Tasks **<u>Prior to Start-up</u>** (Processing Days Only) (continued)	o **Condition and cleanliness of food-contact services and equipment** – inspect the processing area and record time and pass/fail on form - if the processing area and equipment are not in a clean and sanitary condition, clean and sanitize the processing area and record this was done in the comment section of the form. o **Cross contamination** – ensure raw products (fresh fish filets or fish chunks) are not processed in the same areas as smoked ready to eat products. Ensure all fresh fish and fresh fish chunks are stored below any "ready to eat" smoked fish product at all times. o **Maintenance of hand washing and toilet facilities** – inspect the facility and record pass/fail on form. If conditions do not pass, correct them and note under comments on the form. Ensure a sign is posted stating, "all employees must wash their hands before returning to work". o **Protection from adulterants (i.e. pesticides, cleaners, etc.)** – inspect the processing facility and record proper storage of adulterants in relation to food products (i.e. fresh and smoked fish), food packaging materials (i.e. vacuum pack bags). o **Employee health conditions** – medical problems or sick employees. o **Exclusion of pests** – inspect for pests including rodents and habitats/clutter that harbors pests. • Wash hands for a minimum of 20 seconds with hot soapy water.
Working with Smoked Fish	• Smoked fish is a Ready to Eat product. • Processing of smoked fish must only be done after the processing area and equipment has been cleaned and sanitized. o Sanitizing solutions should between 100-200 ppm. Start with ½ ounce of bleach in one gallon of water and then check bleach concentration with test strips to ensure reading is between 100-200 ppm. If the reading is not at least 100 ppm on the strip, add another ¼ ounce of bleach to the water pail and retest with a new testing strip. Do not exceed 200 ppm in the sanitation solution. Use only Clorox bleach without any fragrance enhancers. • Smoked fish cannot be processed at the same time raw fish is being processed due to cross contamination risk. • All employees must wash hands and wear a new pair of food service gloves when working with fish that has been smoked. To include moving from smoker, cooling, and packaging.

STEP	DESCRIPTION
Daily Tasks **<u>Through the Day</u>**	• Throughout the day: o Wash hands for a minimum of 20 seconds with hot soapy water, as needed. o Clean and sanitize processing station(s) every 4 hours when processing for more than 4 hours, and as needed. Record cleaning and sanitizing on *Sanitation Audit Form*. o Complete the *Sanitation Audit Form* after breaks as indicated on the form. o Clean and sanitize all coolers, fish boxes, tubs, and any other fish containers as needed. o Complete corrective action logs as needed. • After breaks (including lunch) and as needed: o Check and record temperature of all **coolers** on corresponding *Cooler Temperature Log*. ▪ If temperature exceeds 38˚F, contact Owner, and ensure temperatures of all product are less than 38˚F. o Check and record temperature of all **freezers** on corresponding *Freezer Temperature Log*. ▪ If temperature exceeds -3°F, contact Owner, and ensure temperatures of all product are less than -3°F.
Receive Packaging Materials and Labels	• Receive packing materials from vetted vendors at the loading dock. • All incoming materials are evaluated according to company procedures including: o Visual inspection of Letters of Guaranty and any other requested documents o Visual inspection of shipping materials for signs of damage or tampering. o Verify items and quantity match order
Store Packaging Materials and Labels	• Packaging materials and labels are stored in accordance with company procedures to include: o Storing in a cool dry place and in accordance with manufacturers' instructions. o Storing all items at least 6 inches off the floor.

<table>
<tr><th>STEP</th><th>DESCRIPTION</th></tr>
<tr><td>Receive Brine Ingredients</td><td>

Receive brine ingredients (salt and sugar) from vetted vendors at the loading dock.
All incoming materials are evaluated according to company procedures including:

Visual inspection of Letters of Guaranty and any other requested documents.
Visual inspection of shipping materials for signs of damage or tampering.
Verify items and quantity match order.

</td></tr>
<tr><td>Store Brine Ingredients</td><td>

Brine ingredients are stored in accordance with company procedures to include:

Storing in a cool dry place and in accordance with manufacturers’ instructions.
Storing all items at least 6 inches off the floor.

</td></tr>
<tr><td>Receive and Sort Fish

(raw, iced whitefish)</td><td>

Receive fresh, wild caught lake whitefish (Coregonus clupeaformis) from fishermen, at dock location, in fish boxes or other containers packed with ice.
Evaluate all incoming fish according to company procedures including:

Check for adequate ice and spot-checking internal temperatures.
Inspect fish for wholesomeness:

<table>
<tr><th></th><th>Grade A:</th><th>Grade B:</th><th>Grade C:</th></tr>
<tr><td>Eyes</td><td>Clear, bright, slightly bulging</td><td>Dull and flat, not cloudy or milky</td><td>Cloudy, sunken</td></tr>
<tr><td>Flesh</td><td>Firm to the touch, in indentations</td><td>May have some indentation</td><td>Soft to the touch</td></tr>
<tr><td>Scales</td><td>Tightly adhere to fish</td><td>60% of scales are intact</td><td>Less than 60% of scales are intact</td></tr>
<tr><td>Gills</td><td>Bright red, odorless</td><td>Red, neutral smell</td><td>Pink to buff</td></tr>
<tr><td>Smell</td><td>A clean or cucumber smell, no odor</td><td>Neutral smell</td><td>Slight Ammonia or “fishy” smell, slight odor present</td></tr>
</table>
</td></tr>
</table>

STEP	DESCRIPTION
Receive and Sort Fish (raw, iced whitefish) (continued)	• Request and inspect necessary documentation. • Sort fish based on quality: o Grade A: Highest quality (will be used for raw, fresh or frozen fillets) o Grade B: Good quality (will be used for smoked fish products) o Grade C: Lowest quality/ unsuitable (will not be purchased) o Maximum transit time from fishermen dock location to processing plant, 2 hours.
Cold Storage of Fish	• Re-ice fish awaiting processing and stored in cooler set at 38°F or less. • Processed all fish within 24 hours of arrival at the plant facility. • Record refrigerator temperature during start of operations procedures, after breaks, and during closing procedures.
Hand Fillet Fish	• Clean and sanitize processing/fillet areas and equipment before and after processing and every 4 hours if processing/filleting longer than 4 hours. • Remove individual boxes (i.e. 25 pounds) of fish from cooler as needed. • Head, gut, and fillet each fish by hand with a knife in batches of approximately 50 pounds of fish fillets. • Keep processing time short, less than 30 minutes, to reduce the amount of time fillets are exposed to temperatures above 38°F. • Place fillets in single layers on cleaned and sanitized sheet pans or other food safe container. • Clean and sanitize transport containers daily according to company SSOP.
Freeze Fillets	• Place pan or container onto a rolling rack. • Cover rack with a single use, rack cover. This allows airflow but protects fillets from contamination via condensation or dripping.

STEP	DESCRIPTION
Freeze Fillets (continued)	• Roll covered rack into the freezer and store for of 24 hours or until fillets are completely frozen. Freezer is set to -3°F. • Record freezer temperature during start of operations procedures, after breaks, and during closing procedures.
Thaw Fillets	• Roll covered racks of frozen fillets from freezer to cooler set at 38˚F. • Store fillets in cooler until thawed completely. • Record refrigerator temperature during start of operations procedures, after breaks, and during closing procedures.
Trim Fillets	• Roll covered rack of thawed fillets from refrigerated storage as needed. • Sort and hand trim oversized fillets, with a knife, to a uniform thickness of ¾-inch and 7 inches long. Fillets are trimmed to a uniform size to meet validated brining and smoking process. • Time at this step is 30 minutes or less.
Brine Fillets	• Remove salt and sugar from dry food storage as need and mixed with 50 gallons of ambient temperature water to reach a salinometer reading of 60˚. Prepare brine according to the validated brining mixture, time, and smoking process. No additional ingredients or additives may be used. o Validated Brine Mixture for 3.5% water phase salt: [insert validated mixture directions here] • Place 50 pounds or less of trimmed fillets into a cleaned and sanitized brine tank. • Add 50 gallons of brine solution (that has a minimum 60˚ salinometer reading) to fish in brine tank. • Roll filled brine tank into cooler, set at 38˚F, and store for a minimum of 24 hours. Complete *Brine Log*. • Record refrigerator temperature during start of operations procedures, after breaks, and during closing procedures.

STEP	DESCRIPTION
Drain Fillets	• After brining is, complete, remove fillets and place in cleaned and sanitized smoking racks. • Rinse fillets in rinse area with ambient temperature water. • Place smoking racks on rolling rack(s) and cover with a single use rack cover. • Roll rack(s) into cooler, set at 38˚F, and store until the fillets are surface dry. About 2 hours. • Record temperature during start of operations procedures, after breaks, and during closing procedures.
Hot Smoke Fillets	• Once all fillets on rolling rack(s) are surface dried, roll rack(s) into hot smoker for smoking. • Smoke fish using the a preprogrammed drying, smoking, cooking cycle for approximately 4 hours to achieve internal temperature of 145˚F for 30 continuous minutes in the thickest part of the fish in the coolest part of the smoker. This process is in accordance with validated smoking process. • Trained smoker operator(s) monitor smoker and record temperatures on *Hot Smoking Log* during start of smoking process, twice during smoking cycle, and at the end of smoking cycle. o If fillets do not reach or maintain 145˚F for 30 continuous minutes or the smoker is malfunctioning, contact owner, and complete corrective action log.
Cool Fillets	• After smoking roll rack to pre-cooling area which is to the left of the smoker. Set kitchen timer and allow fillets to cool for 30 minutes in ambient temperatures (50ºF-70ºF). • After the 30 minutes, take internal temperature of the thickest part of the thickest fillet on the middle rack and record on *Fillet Cooling Log.* • Cover rack with single use rack cover and roll rack into cooler. Allow fillets to cool to 40˚F or less. Time at this step is approximately 6 hours or less. Fillets can remain in cooler until ready to package. • Perform a second temperature check within 1 hour of moving fillets to cooler; take internal temperature of three fillets on each rolling rack. Record temperatures on *Cooling Temperature Log*. o If fillets are not 70˚F or less, contact owner and move rolling rack(s) to freezer until temperature is less than 70˚F.

STEP	DESCRIPTION
	• Perform a third temperature check within 4 hour of second temperature recording. Take internal temperature of three fillets on each rolling rack. Record temperatures on *Cooling Temperature Log*. o If fillets are not 40˚F or less, contact owner and move rolling rack(s) to freezer until temperature is less than 40˚F.

Vacuum Pack/ Weigh/ Label/Box	• Inspect vacuum packages to ensure each one contains a label that includes the following information. Record information on the *Vacuum Packaged Fish Labeling Form*:
	  o Safe Handling and Thawing: **"Keep frozen until ready to use. To thaw, cut bag open and thaw under refrigeration or cool running water."**
	  o **"Contains Allergen: Fish"**
	  o Market name of fish species
	  o Lot number including day/month/year of packing
	  o Company name and address
	• After fillets have cooled to 40°F or less, roll rack(s) to packing areas as needed.
	• Pack cooled fillets in clear, pre-labeled, food safe, 4 millimeter, and vacuum sealing packages.
	• Vacuum seal filled bags and weigh.
	• Write or apply weight to each package.
	• Place final products in prelabeled cardboard freezer boxes. Add batch number to exterior of box.
	  o No more than 26 pounds per box, 2 boxes per batch.
	• Weigh/pack/label/box step for each batch is 45 minutes or less.

Freezer Storage	• Store final product in freezer until delivery as needed. Storage temperature is set to -3˚F or less. • Record freezer temperature during start of operations procedures, after breaks, and during closing procedures.

STEP	DESCRIPTION

Daily Tasks
 	
<u>End of Day</u>
 	
(Processing Days Only)
	• Ensure all tubs, containers, processing/rinsing/cooling areas, and equipment are cleaned and sanitized.
	  o Sanitizing solutions should between 100-200 ppm. Start with ½ ounce of bleach in one gallon of water and then check bleach concentration with test strips to ensure reading is between 100-200 ppm. If the reading is not at least 100 ppm on the strip, add another ¼ ounce of bleach to the water pail and retest with a new testing strip. Do not exceed 200 ppm in the sanitation solution. Use only Clorox bleach without any fragrance enhancers.
	• Check and record temperature of all **coolers** on corresponding *Cooler Temperature Log*.
	  o If temperature exceeds 38˚F, contact Owner, and ensure temperatures of all product are less than 38˚F.
	• Check and record temperature of all **freezers** on corresponding *Freezer Temperature Log*.
	  o If temperature exceeds -3˚F, contact Owner, and ensure temperatures of all product are less than -3˚F.
	• Complete last column of the *Sanitation Audit Form*.
	• Ensure the *Sanitation Audit Form*, *Corrective Action Logs*, *Brine Log*, *Hot Smoking Log*, *Fillet Cooling Log*, *Vacuum Packaged Fish Labeling Form*, and all Temperature Logs are completed and in appropriate file for Owner to review.
	• Place blank *Sanitation Audit Form*, *Corrective Action Logs*, and all Temperature Logs in predetermined locations, to be completed during next processing day.

Establishment's Name:	Intended Use to Consumer: Ready to Eat
Establishment's Address:	Product Description: Frozen, Vacuum Packed, Hot Smoked, Lake Whitefish Fillets
	Method of Storage & Distribution: Freezer; Freezer truck or ice packed coolers

Hazard Analysis Worksheet

(1) Processing Step	(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process	(3) Is this potential hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point? (Yes or No)
Receiving Packaging Materials and Labels	**B:** Pathogenic bacteria, viruses, and mold	No	NRLTO-Letter of Guaranty (LOG) includes pathogen testing frequency and results. 3rd Party testing verifies LOG. Shipping packages visually inspected for signs of damage or moisture.	n/a	No
	C: non-food safe materials or deleterious chemicals	No	NRLTO- Letter of Guaranty (LOG) on file.	n/a	No
	P: Foreign material	No	Visual inspection of shipping packaging for damage. Visual inspection during vacuum packing.	n/a	No

Hazard Analysis Worksheet					
(1) **Processing Step**	**(2)** **List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3)** **Is this potential hazard significant (introduced, enhanced, or eliminated) at this step?** **(Yes or No)**	**(4)** **Justify the decision that you made in column 3**	**(5)** **What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6)** **Is this step a Critical Control Point?** **(Yes or No)**
Receiving Packaging Materials and Labels	**B:** Pathogenic bacteria, viruses, and mold	No	NRLTO- packages stored in accordance to manufacture's instruction and away from moisture.	n/a	No
	C: non-food safe materials or deleterious chemicals	No	NRLTO- Chemical storage SOP, Facility Zoning, and Packaging Material Storage SOP make hazard unlikely to occur	n/a	No
	P: none	n/a	n/a	n/a	No
Receiving Brine Ingredients	**B:** Pathogenic bacteria, viruses, and mold	No	NRLTO-Letter of Guaranty (LOG) includes pathogen testing frequency and results. 3rd Party testing verifies LOG. Shipping packages visually inspected for signs of damage or moisture.	n/a	No

Hazard Analysis Worksheet					
(1) **Processing Step**	**(2)** **List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3)** **Is this potential hazard significant (introduced, enhanced, or eliminated) at this step?** **(Yes or No)**	**(4)** **Justify the decision that you made in column 3**	**(5)** **What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6)** **Is this step a Critical Control Point?** **(Yes or No)**
Receiving Brine Ingredients (cont.)	**C:** non-food safe materials or deleterious chemicals	No	NRLTO- Letter of Guaranty (LOG) on file.	n/a	No
	P: Foreign material	No	Visual inspection of shipping packaging for damage. Visual inspection during brine mixing.	n/a	No
Storing Brine Ingredients	**B:** Pathogenic bacteria, viruses, and mold	No	NRLTO- packages stored in accordance to manufacture's instruction and away from moisture.	n/a	No
	C: non-food safe materials or deleterious chemicals	No	NRLTO- Chemical storage SOP, and Packaging Material Storage SOP make hazard unlikely to occur	n/a	No
	P: none	n/a	n/a	n/a	No
Receiving Fish	**B:** Pathogenic bacteria, viruses, and parasites	No	SOPs for receiving properly iced and cooled fish make pathogen growth NRLTO; Kill step later in process..	Inspection of fish SOPs; Adequate ice around fish; product will be cooked in later step	No

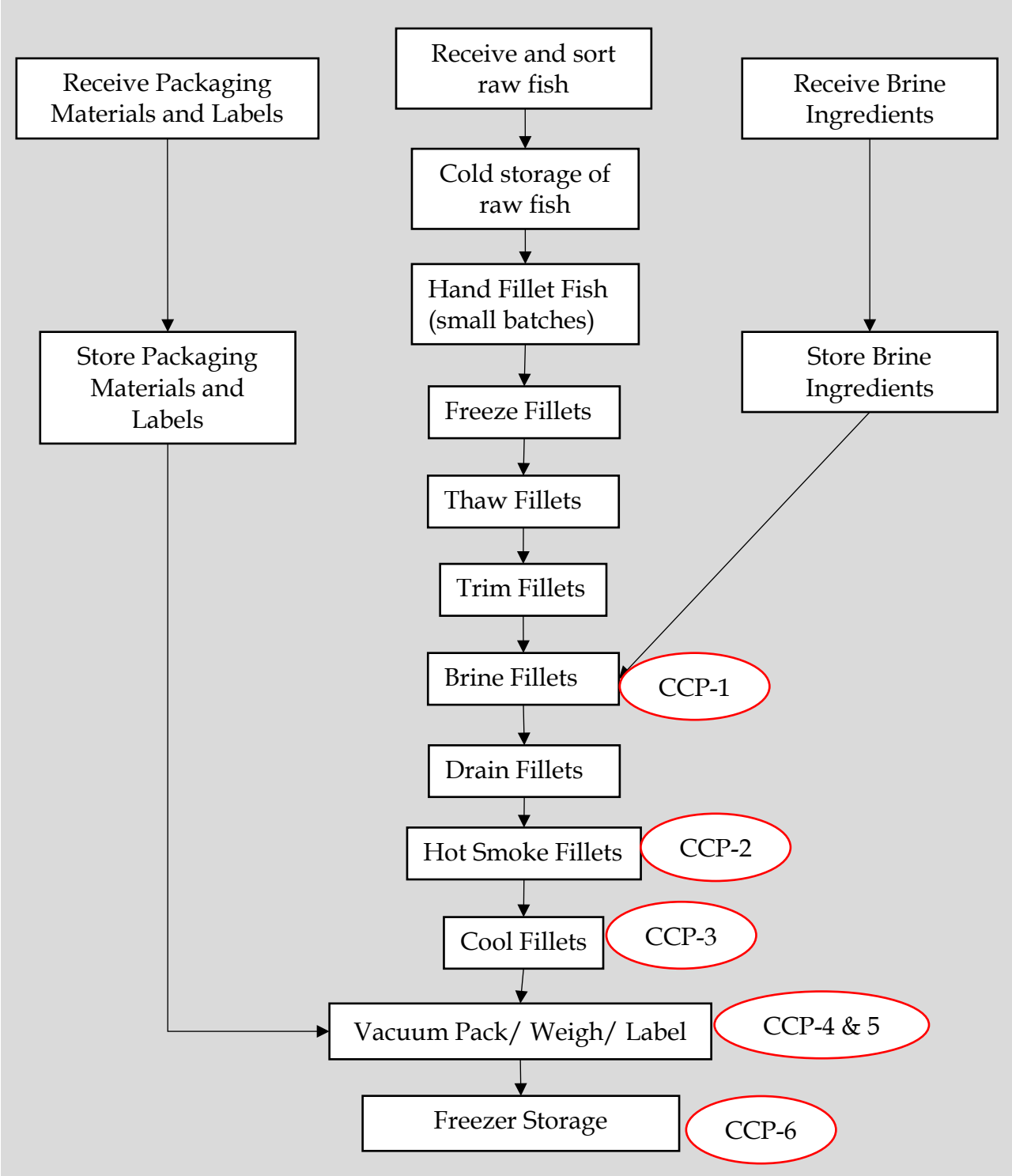
Hazard Analysis Worksheet					
(1) Processing Step	**(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3) Is this potential hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)**	**(4) Justify the decision that you made in column 3**	**(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6) Is this step a Critical Control Point? (Yes or No)**
Receiving Fish (cont.)	**C:** None (see GLIFWC research in office)	No	See GLIFWC research on chemical contaminants in the Great Lakes (on file in main office)	n/a	No
	P: none	n/a	n/a	n/a	No
Cold Storage of Fish	**B:** Pathogenic bacteria, viruses, and parasites	Yes	Pathogens are naturally occurring in fish.	Inspect fish to ensure adequate ice; fish stored below 38˚F; control bacteria through SSOP; Hot smoking is a kill step that will occur after this step.	No
	C: none	No	n/a	n/a	No
	P: none	No	n/a	n/a	No
Filleting (by hand)	**BIOLOGICAL:** Pathogenic bacteria, viruses, and parasites	Yes	Pathogens are naturally occurring in fish	Process fish in <2 hours; product will be cooked	No
	CHEMICAL: none	n/a	n/a	n/a	No
	PHYSICAL: metal fragmentation	No	NRLTO: Fish are fillet by hand by fillet technicians	Prior to start up, after breaks, and at the end of day knives are visually inspected by fillet technicians.	No
Freezing Fillets	**B:** Pathogenic bacteria, viruses, and parasites	No	Pathogens naturally occurring in fish.	Hot smoking is a kill step that will occur after this step.	No
	C: none	n/a	n/a	n/a	No
	P: none	n/a	n/a	n/a	No

Hazard Analysis Worksheet					
(1) Processing Step	**(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3) Is this potential hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)**	**(4) Justify the decision that you made in column 3**	**(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6) Is this step a Critical Control Point? (Yes or No)**
Thawing Fillets	**B:** Pathogenic bacteria, and viruses	No	Pathogens are naturally occurring in fish. Thawing temperature below 38°F. Kill step later in process.	n/a	No
	C: none	n/a	n/a	n/a	No
	P: none	n/a	n/a	n/a	No
Brining Fillets	**B:** C. bot.	Yes	C. bot in fish occurs naturally	Brine will be mixed in accordance with SOP to ensure proper salinity in accordance with validated brining and smoking process. Brining fillets will be done under refrigeration.	**Yes**
	C: none	n/a	n/a	n/a	No
	P: none	n/a	n/a	n/a	No
Draining Fillets	**B:** C. bot.	No	NRLTO- Short amount of time makes pathogen growth unlikely. Fillets are drained quickly and moved to next step. Kill step later in process.	n/a	No
	C: none	n/a	n/a	n/a	No
	P: none	n/a	n/a	n/a	No

Hazard Analysis Worksheet					
(1) Processing Step	**(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3) Is this potential hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)**	**(4) Justify the decision that you made in column 3**	**(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6) Is this step a Critical Control Point? (Yes or No)**
Hot Smoking Fillets	**B:** C. bot.	Yes	If time and temperature abuse occur, C. bot. are likely to grow and develop toxins.	Smoking SOP ensures fillets are cooked to an internal temperature of 145˚F for a min of 30 minutes.	**Yes**
	C: none	n/a	n/a	n/a	No
	P: none	n/a	n/a	n/a	No
Cool Fillet	**B:** *Clostridium botulinum* spores	Yes	Time and temperature abuse could result in *C. botulinum* growth and toxin formation. Recontamination controlled by rack cover and prerequisite program.	Product will be cooled to 70°F within 2 hours; Product will be further cooled to less than 40˚F within an additional 4 hours.	**Yes**
	C: none	n/a	n/a	n/a	No
	P: none	n/a	n/a	n/a	No
Weigh, Pack, & Label	**B:** *Clostridium botulinum*	Yes	*C. botulism* spores can become activated in anaerobic environments during improper thawing.	Include thawing instructions on label **"Keep frozen until ready to use. To thaw, cut bag open and thaw under refrigeration or cool running water."**	**Yes**

Hazard Analysis Worksheet					
(1) **Processing Step**	**(2)** **List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3)** **Is this potential hazard significant (introduced, enhanced, or eliminated) at this step?** **(Yes or No)**	**(4)** **Justify the decision that you made in column 3**	**(5)** **What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6)** **Is this step a Critical Control Point?** **(Yes or No)**
Weigh, Pack, & Label (cont.)	**C:** Allergens	Yes	Fish is an allergen	Label includes allergen warning "Contains Allergen: Fish"	**Yes**
	P: none	n/a	n/a	n/a	No
Freezer Storage	**B:** *Clostridium botulinum*	Yes	Time and temperature abuse could result in *C. botulism* spore activation.	Product stored in freezer set at -3°F or less.	**Yes**
	C: none	n/a	n/a	n/a	No
	P: none	n/a	n/a	n/a	No

Establishment's Name:	**Intended Use:** Ready to eat
Establishment's Address:	**Product Description:** Frozen, Vacuum Packed, Hot Smoked, Lake Whitefish Fillets
	Method of Storage & Distribution: Freezer; Freezer truck delivery or ice packed coolers



Establishment's Name:	Intended Use: Ready to eat
Establishment's Address:	Product Description: Frozen, Vacuum Packed, Hot Smoked, Lake Whitefish Fillets
	Method of Distribution & Storage: Freezer; Freezer truck or ice packed coolers

HACCP Plan									
(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Brining Fillets *brining procedure has been validated through a validation study to ensure a water salt phase conc. Of 3.5%	*C. botulism* and *Salmonella* growth and survival; Pathogenic bacteria growth and survival	Minimum brine time of 24 hours; 50 gallons of brine with 60° salinometer reading at start of process; and No more than 50 pounds of fish of fillets not larger than 5 pounds added to the brine tank.	Start and end time of brine; Volume of brine and degrees salt; weight of total fillets put in brine; Cooler temperature	Visual check of time; visual scale reading; Fill to pre-measure mark; and salinometer; Thermometer	Each batch	Brine Operator Trained in brining process	1. IF Brining time is not met; THEN, Hold in brine until 24 hours is reached Add more salt and mix until salinometer reads 60°; Divert fillets > 5 pounds to another batch process. Remove fillets until weight is 50 lbs. or less; Move brine tanks to another cooler and	Quarterly lab analysis to verify that finished products have 3.5% water phase salt; Daily accuracy check of scale; and Annual calibration of food scale 2. Check accuracy of thermometer before initial use and then daily, and then annual calibration. Brine validation study used to develop	• Brine Logs • Temperature recording chart with visual checks • Brine Validation Study • Training Records • Accuracy check and calibration records • CA records

HACCP Plan									
(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Brining Fillets (cont.)							fix cooler or adjust thermostat. Retrain involved staff. 2. Determine safety of product based on time and temperature exposure	brine recipe & time Weekly review of brine logs, and corrective action records.	
Hot Smoking Fillets	*C. botulism* growth; Pathogenic bacteria growth and survival	145°F internal temperature of fillets for a min. of 30 continuous minutes	Internal temperature of 3 fillets. Time once target temperature is reached.	Continuous temperature recording device with 3 probes	Continuous during smoking. Visual checks of record during each batch.	Fish Smoking Operator trained in smoking process	Immediately re-cook batch that do not reach target time and temperature or destroy batch and repair equipment.	Floor Manager or Owner reviews logs and CA reports weekly. Annual calibration of temperature probe device.	• Temperature recording charts. • Smoking logs • CA reports • Temperature probe calibration records • Maintenance and repair logs • Training records

HACCP Plan									
(1) Critical Control Point (CCP)	**(2) Hazard(s)**	**(3) Critical Limits for each Control Measure**	**Monitoring**				**(8) Corrective Action(s)**	**(9) Verification**	**(10) Records**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
Cooling Fillets	*C. botulism* growth; Pathogenic bacteria growth and survival	Product will be cooled to 70°F within 2 hours; Product will be further cooled to less than 40°F within an additional 4 hours.	Internal temperature of 3 fillets	Thermometer	Once per batch within between minute 60 and 110; Once between minute 240 and 360.	Employee trained in cooling process	If temperature abuse review Table A-2 in Hazards Guide to determine safety of product.	Floor Manager or Owner reviews logs and CA reports weekly. Thermometer calibration records.	• Temperature logs • CA reports • Training records • Maintenance and repair logs for walk-in cooler
Labeling	*Clostridium botulinum*	Correct label affixed to each finished product package	Label includes instructions **"Keep frozen until ready to use. To thaw, cut bag open and thaw under refrigeration or cool running water."**	Visual inspection	Each package	Packing Manager	Remove and replace labels from mislabeled product prior to storing in freezer	Weekly review of labelling logs	• Labelling inspection log • Corrective action reports • Verification reports (Once per week) • Purchasing records including copy of label purchased

HACCP Plan									
(1) Critical Control Point (CCP)	**(2) Hazard(s)**	**(3) Critical Limits for each Control Measure**	**Monitoring**				**(8) Corrective Action(s)**	**(9) Verification**	**(10) Records**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
Labeling	Undeclared Allergen	Label includes allergen declaration "**Contains Allergens: Fish**"	Label containing allergen declaration	Visual inspection	Each package	Trained Packing Employee	Add label to unlabeled product. Remove and replace labels from mislabeled product prior to storing in freezer.	Weekly review of labelling logs by Packing Manager or Owner	• Labelling inspection log • Corrective action reports • Verification reports (once per week) • Purchasing records including copy of label purchased
Freezer Storage of Final Product	*C. botulism* toxin formation during power or freezer failure	Freezer temperature held at -3°F or less	Freezer temperature	Thermometer	Two times/day (early AM, and late PM)	Packing Technician	Decrease temperature and hold and evaluate based on time and temperature of exposure	Floor Manager will review temperature records weekly. Floor Manager will have freezer thermometer verified with a certified thermometer	• Time and temperature logs • CA reports • Training records for Company Packing and Storage. • Maintenance and repair records

HACCP Plan									
(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Freezer Storage of Final Product (cont.)								at -10°F, -5°F, 0°F, 10°F annually.	• Thermometer calibration records.
Signature:					Print Name:				

Walleye Model HACCP Plan

Frozen Fillet- Reduced Oxygen Packaging

PRODUCT DESCRIPTION

Establishment's Name	Mino Wiisinidaa
Establishment's Address	123 Wiigwaas Ave. Odanah, WI 54861

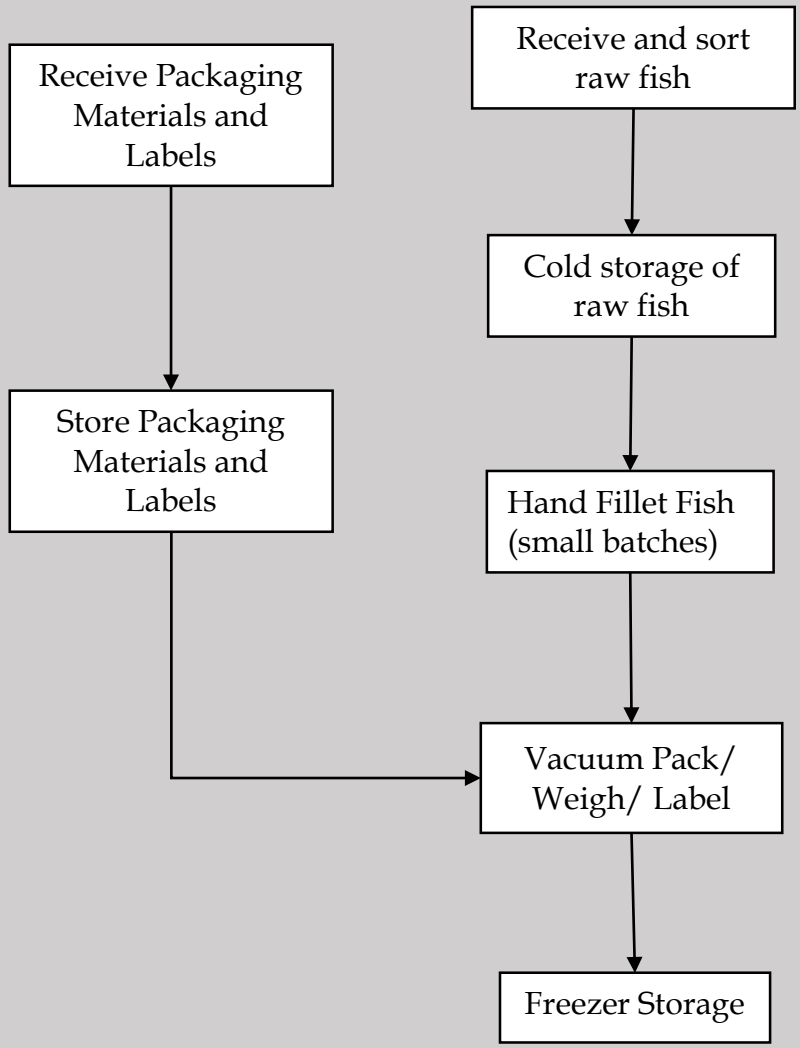
Product Name	Wild Caught, Frozen Walleye Fillets
Brief Description	Frozen Vacuum Packed Inland Walleye Fillets
Ingredients	Fresh Walleye (*Sander vitreus*)
Allergens	Fish is an allergen
Packaging	ROP/ Vacuum Packaging
Distribution	Freezer truck delivery to retail outlets
Intended Use	To be cooked
Target Consumer	General Public

Date: 02/25/2019

HACCP Team Member(s)	Position	Signature
John Doe	Owner	John Doe

Establishment's Name: Mino Wiisinidaa	**Intended Use:** to be cooked
Establishment's Address: 123 Wiigwaas Ave. Odanah, WI 54861	**Product:** Vacuum Packed, Frozen, Inland Walleye Fillets
	Method of Distribution & Storage: Freezer truck; Freezer

Process Flow Chart: Vacuum Packed, Raw, Frozen Walleye Fillets



Establishment's Name: Mino Wiisinidaa	**Intended Use to Consumer:** to be cooked
Establishment's Address: 123 Wiigwaas Odanah, WI 54861	**Product Description:** Vacuum Packed, Frozen, Inland Walleye Fillets **Method of Storage & Distribution:** Refrigerator, Freezer, and freezer truck

PROCESS FLOW FORM

The color coded Flow Chart on the following page(s) integrates daily production activities, SSOP activities, and HACCP records that must be maintained.

1) Daily operational tasks are identified in black colored font.
2) Staff food safety tasks/warnings are identified in red colored font.
3) Daily production Standard Sanitation Operating Plan (SSOP) tasks are identified green colored font.
4) Maintenance of daily HACCP records identified in the HACCP plan in blue colored font.

Process Name:	**Vacuum Packed Frozen Wild Caught Walleye (*Sanders vitreus*) Fillets**

STEP	DESCRIPTION

Daily Tasks
 	
<u>Prior to Start-up</u>
 	
(Processing Days Only)
	• Check and record temperature of all **coolers** on corresponding *Cooler Temperature Log*.
	  o If temperature exceeds 38ºF, contact Owner, and ensure temperatures of all product are less than 38ºF.
	• Check and record temperature of all **freezers** on corresponding *Freezer Temperature Log*.
	  o If temperature exceeds -3°F, contact Owner, and ensure temperatures of all product are less than -3°F.
	• On the *Sanitation Audit Form* enter the date and note the individual completing the form this day. On the form record:
	  o **Safety of water –** ensure the fish shop has a copy of city water testing on file each year.
	  o **Condition and cleanliness of food-contact services and equipment** – inspect the processing area and record time and pass/fail on form - if the processing area and equipment are not in a clean and sanitary condition, clean and sanitize the processing area and record this was done

STEP	DESCRIPTION
Daily Tasks **Prior to Start-up** (Processing Days Only)	in the comment section of the form. o **Cross contamination** – ensure raw products (fresh fish filets or fish chunks) are not processed in the same areas as smoked ready to eat products. Ensure all fresh fish and fresh fish chunks are stored below any "ready to eat" smoked fish product at all times. o **Maintenance of hand washing and toilet facilities** – inspect the facility and record pass/fail on form. If conditions do not pass, correct them and note under comments on the form. Ensure a sign is posted stating, "all employees must wash their hands before returning to work". o **Protection from adulterants (i.e. pesticides, cleaners, etc.)** – inspect the fish processing facility and record proper storage of adulterants in relation to food products (i.e. fresh and smoked fish), food packaging materials (i.e. vacuum packer bags). o **Employee health conditions** – medical problems or sick employees. o **Exclusion of pests** – inspect for pests including rodents and habitats/clutter that harbors pests. • Wash hands for a minimum of 20 seconds with hot soapy water.
Daily Tasks **Through the Day**	• Throughout the day: o Wash hands for a minimum of 20 seconds with hot soapy water, as needed. o Clean and sanitize processing station(s) every 4 hours when processing for more than 4 hours, and as needed. Record cleaning and sanitizing on *Sanitation Audit Form.* o Complete the *Sanitation Audit Form* after breaks as indicated on the form. o Complete corrective action logs as needed. • After breaks (including lunch) and as needed: o Check and record temperature of all **coolers** on corresponding *Cooler Temperature Log*. ▪ If temperature exceeds 38ºF, contact Owner, and ensure temperatures of all product are less than 38ºF. o Check and record temperature of all **freezers** on corresponding *Freezer Temperature Log*. ▪ If temperature exceeds -3°F, contact Owner, and ensure temperatures of all product are

STEP	DESCRIPTION
	less than -3°F.
Receive Packaging Materials and Labels	• Receive packing materials from vetted vendors at the loading dock. • All incoming materials are evaluated according to company procedures including: o Visual inspection of Letters of Guaranty and any other requested documents o Visual inspection of shipping materials for signs of damage or tampering. o Verify items and quantity match order
Store Packaging Materials and Labels	• Packaging materials and labels are stored in accordance with company procedures to include: o Storing in a cool dry place and in accordance with manufacturers' instructions. o Storing all items at least 6 inches off the floor.
Receive and Sort Fish (raw, iced walleye)	• Receive fresh wild caught walleye (*Sander vitreus*) from fishermen at dock location, in fish boxes or other containers packed with ice. • Request and inspect necessary documentation. Do not accept fish harvested from lakes closed to commercial fishing. Used most recent "Closed Lakes" list provided by owner. • Sort fish by size. Only accept fish **14.5-inches and smaller**. • Evaluate all incoming fish according to company procedures including: • Check for adequate ice and spot-checking internal temperatures. • Sort fish based on quality: o Grade A: Highest quality (will be used for raw, fresh or frozen fillets) o Grade B: Good quality (will be used for smoked fish products) o Grade C: Lowest quality/ unsuitable (will not be purchased)

<table>
<tr><th>STEP</th><th>DESCRIPTION</th></tr>
<tr><td>Receive and Sort Fish

(cont.)</td><td>
<table>
<tr><th></th><th>Grade A:</th><th>Grade B:</th><th>Grade C:</th></tr>
<tr><td>Eyes</td><td>Clear, bright, slightly bulging</td><td>Dull and flat, not cloudy or milky</td><td>Cloudy, sunken</td></tr>
<tr><td>Flesh</td><td>Firm to the touch, in indentations</td><td>May have some indentation</td><td>Soft to the touch</td></tr>
<tr><td>Scales</td><td>Tightly adhere to fish</td><td>60% of scales are intact</td><td>Less than 60% of scales are intact</td></tr>
<tr><td>Gills</td><td>Bright red, odorless</td><td>Red, neutral smell</td><td>Pink to buff</td></tr>
<tr><td>Smell</td><td>A clean or cucumber smell, no odor</td><td>Neutral smell</td><td>Slight Ammonia or “fishy” smell, slight odor present</td></tr>
</table>
Maximum transit time from fishermen dock location to processing plant, 2 hours.
</td></tr>
<tr><td>Cold Storage of Fish</td><td>
Re-ice fish awaiting processing and stored in cooler set at 38°F or less.
Processed all fish within 24 hours of arrival at the plant facility.
Trained technician(s) record refrigerator temperature during start of operations procedures, after breaks, and during closing procedures.
</td></tr>
<tr><td>Hand Fillet Fish</td><td>
Clean and sanitize processing/fillet areas and equipment before and after processing and every 4 hours if processing/filleting longer than 4 hours.
Remove individual boxes (i.e. 25 pounds) of fish from cooler as needed.
Head, gut, and fillet each fish by hand with a knife in batches of approximately 50 pounds of fish fillets.
Keep processing time short, less than 30 minutes, to reduce the amount of time fillets are exposed to temperatures above 38°F.
Place fillets in clean, sanitized, food grade tubs. Approximately 25 pounds to each tub.
Clean and sanitize transport containers daily according to company SSOP.
</td></tr>
</table>

STEP	DESCRIPTION
Vacuum Pack/ Weigh/ Label/Box	• Inspect vacuum packages to ensure each one contains a label that includes the following information. Record information on the *Vacuum Packaged Fish Labeling Form*: o Safe Handling and Thawing: **"Keep frozen until ready to use. To thaw, cut bag open and thaw under refrigeration or cool running water."** o Market name of fish species o Lot number including day/month/year of packing o Company name and address • Pack fillets in clear, pre-labeled, food safe, 4 millimeter, and vacuum sealing packages. • Vacuum seal filled bags and weight • Write or apply weight to each package. • Place final products in prelabeled cardboard freezer boxes. Add batch number to exterior of box. o No more than 26 pounds per box, 2 boxes per batch. • Weigh/pack/label/box step for each batch is 45 minutes or less.
Freezer Storage	• Store final product in freezer until delivery as needed. Storage temperature is set to -3°F or less.
Daily Tasks **<u>End of Day</u>** (Processing Days Only)	• Ensure all tubs, containers, processing areas, and equipment are cleaned and sanitized. o Sanitizing solutions should between 100-200 ppm. Start with ½ ounce of bleach in one gallon of water and then check bleach concentration with test strips to ensure reading is between 100-200 ppm. If the reading is not at least 100 ppm on the strip, add another ¼ ounce of bleach to the water pail and retest with a new testing strip. Do not exceed 200 ppm in the sanitation solution. Use only Clorox bleach without any fragrance enhancers. • Check and record temperature of all **coolers** on corresponding *Cooler Temperature Log*. o If temperature exceeds 38ºF, contact Owner, and ensure temperatures of all product are less than 38ºF.

STEP	DESCRIPTION
Daily Tasks **<u>End of Day</u>** (Processing Days Only)	• Check and record temperature of all **freezers** on corresponding *Freezer Temperature Log*. o If temperature exceeds -3ºF, contact Owner, and ensure temperatures of all product are less than -3ºF. • Complete last column of the *Sanitation Audit Form*. • Ensure the *Sanitation Audit Form*, *Corrective Action Logs*, and all Temperature Logs are completed and in appropriate file for Owner to review. • Place blank *Sanitation Audit Form*, *Corrective Action Logs*, and all Temperature Logs in predetermined locations, to be completed during next processing day.

Establishment's Name: Mino Wiisinidaa	**Intended Use to Consumer:** to be cooked
Establishment's Address: 123 Wiigwaas Odanah, WI 54861	**Product Description:** Vacuum Packed Frozen Inland Walleye Fillets **Method of Storage & Distribution:** Freezer and freezer truck

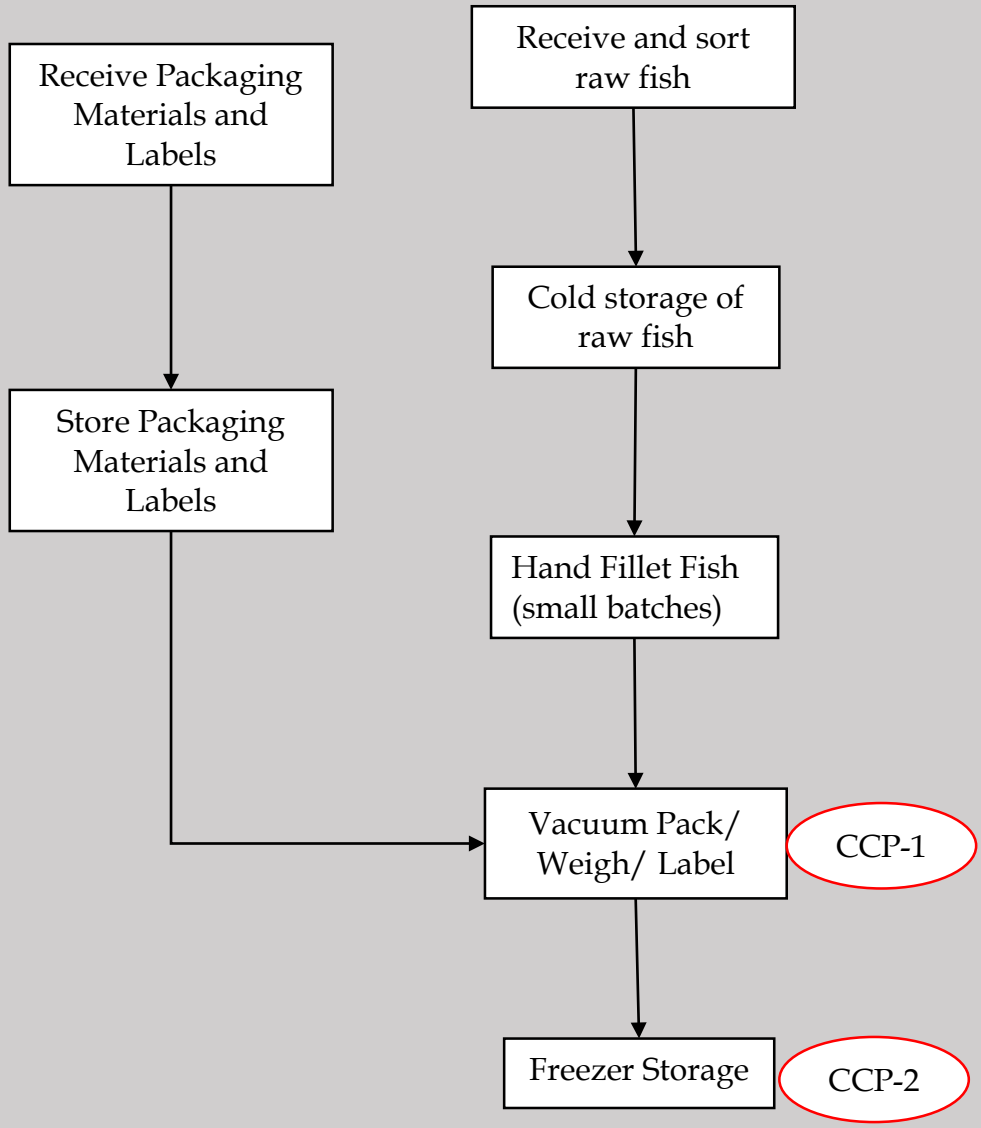
Hazard Analysis Worksheet

(1) Processing Step	(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process	(3) Is this potential hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point? (Yes or No)
Receiving	**BIOLOGICAL:** Pathogenic bacteria, viruses, and parasites	Yes	Pathogens are naturally occurring in fish	Inspection of fish; Adequate ice around fish; product will be cooked	No
	CHEMICAL: Allergen	Yes	This food is an allergen.	Labeled at weigh, pack, label step with correct market name	No
	PHYSICAL: none	No	n/a	n/a	No
Cold Storage of Fish	**BIOLOGICAL:** Pathogenic bacteria, viruses, and parasites	Yes	Pathogens are naturally occurring in fish	Inspect fish to ensure adequate ice; fish stored below 38˚F; control bacteria through SSOP; Final product will be cooked;	No
	CHEMICAL: none	No	n/a	n/a	No
	PHYSICAL: none	No	n/a	n/a	No
Filleting (by hand)	**BIOLOGICAL:** Pathogenic bacteria, viruses, and parasites	Yes	Pathogens are naturally occurring in fish	Process fish in <2 hours; product will be cooked	No
	CHEMICAL: none	n/a	n/a	No	No

Hazard Analysis Worksheet					
(1) Processing Step	**(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3) Is this potential hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)**	**(4) Justify the decision that you made in column 3**	**(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6) Is this step a Critical Control Point? (Yes or No)**
Filleting (by hand) (cont.)	**PHYSICAL:** metal fragmentation	No	NRLTO: Fish are fillet by hand by fillet technicians	Prior to start up, after breaks, and at the end of day knives are visually inspected by fillet technicians.	No
Weigh, Pack, & Label	**BIOLOGICAL:** *Clostridium botulinum*	Yes	*C. botulinum* spores can become activated in anaerobic environments during improper thawing.	Include thawing instructions on label **"Keep frozen until ready to use. To thaw, cut bag open and thaw under refrigeration or cool running water."**	**Yes**
	CHEMICAL: none	n/a	n/a	No	No
	PHYSICAL: none	n/a	n/a	No	No
Freezer Storage	**BIOLOGICAL:** *Clostridium botulinum*	Yes	Time and temperature abuse could result in *C. botulinum* spore activation.	Product stored in freezer set at -3°F or lower.	**Yes**
	CHEMICAL: none	n/a	n/a	No	No
	PHYSICAL: none	n/a	n/a	n/a	No

Establishment's Name: Mino Wiisinidaa	**Intended Use:** to be cooked
Establishment's Address: 123 Wiigwaas Ave. Odanah, WI 54861	**Product:** Vacuum Packed, Frozen, Inland Walleye Fillets
	Method of Distribution & Storage: Freezer truck; Freezer

Process Flow Chart with CCPs: Vacuum Packed Frozen Walleye Fillets



HACCP Plan									
(1) Critical Control Point (CCP)	**(2) Hazard(s)**	**(3) Critical Limits for each Control Measure**	**Monitoring**				**(8) Corrective Action(s)**	**(9) Verification**	**(10) Records**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
Labeling	*Clostridium botulinum*	Correct label affixed to each finished product package	Include thawing instructions on label **"Keep frozen until ready to use. To thaw, cut bag open and thaw under refrigeration or cool running water."**	Visual inspection	Each package	Packing Manager	Remove and replace labels from mislabeled product prior to storing in freezer	Weekly review of labelling logs	• Labelling inspection log • Corrective action reports • Verification reports (Once per week) • Purchasing records including copy of label purchased

HACCP Plan									
(1) Critical Control Point (CCP)	**(2) Hazard(s)**	**(3) Critical Limits for each Control Measure**	**Monitoring**				**(8) Corrective Action(s)**	**(9) Verification**	**(10) Records**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
Freezer Storage of Final Product	*C. botulism* toxin formation during power or freezer failure	Freezer temperature held at -3°F or less	Freezer temperature	Thermometer	Two times/day (early AM, and late PM)	Packing Technician	Decrease temperature and hold and evaluate based on time and temperature of exposure	Floor Manager will review temperature records weekly. Thermometer verified with a certified thermometer at -10°F, -5°F, 0°F, 10°F annually.	• Time and temperature logs • CA reports • Training records: Packing and Storing SOPs • Maintenance and repair records • Thermometer calibration records. • Verification reports (once per week)
Signature:						Print Name:			

Walleye Model HACCP Plan

Smoked Fillet

PRODUCT DESCRIPTION

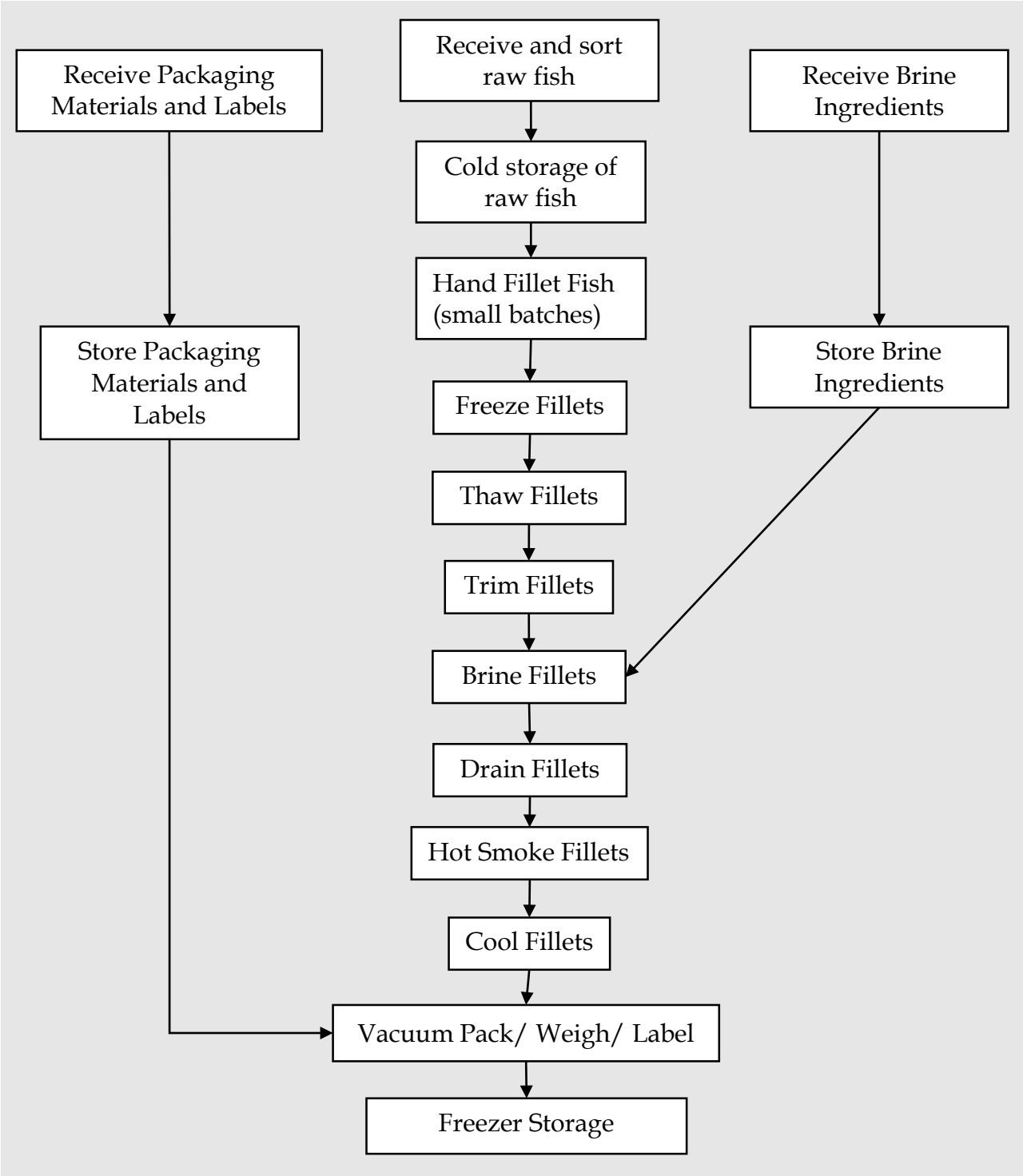
Establishment's Name	Mino Wiisinidaa
Establishment's Address	123 Wiigwaas Ave. Odanah, WI 54861

Product Name	Wild Caught, Hot Smoked, Walleye Fillets
Brief Description	Frozen, Vacuum Packed, Hot Smoked, Lake Whitefish Fillets
Ingredients	Smoked Lake Walleye (*Sander vitreus*), salt, and sugar
Allergens	Fish
Packaging	ROP/ Vacuum Packaging
Distribution	Freezer truck delivery to retail outlets or ice packed coolers
Intended Use	Ready to eat
Target Consumer	General Public

Date: 02/25/2019

HACCP Team Member(s)	Position	Signature
John Doe	Owner	John Doe

Establishment's Name: Mino Wiisinidaa	**Intended Use:** Ready to eat
Establishment's Address: 123 Wiigwaas Ave. Odanah, WI 54861	**Product Description:** Frozen, Vacuum Packed, Hot Smoked, Lake Walleye Fillets
	Method of Storage & Distribution: Freezer; Freezer truck or ice packed coolers



Establishment's Name: Mino Wiisinidaa	**Intended Use to Consumer:** Ready to Eat
Establishment's Address: 123 Wiigwaas Odanah, WI 54861	**Product Description:** Frozen, Vacuum Packed, Hot Smoked, Lake Walleye Fillets **Method of Storage & Distribution:** Freezer; Freezer truck or ice packed coolers

PROCESS FLOW FORM

The color coded Flow Chart on the following page(s) integrates daily production activities, SSOP activities, and HACCP records that must be maintained.

1) Daily operational tasks are identified in black colored font.
2) Staff food safety tasks/warnings are identified in red colored font.
3) Daily production Standard Sanitation Operating Plan (SSOP) tasks are identified green colored font.
4) Maintenance of daily HACCP records identified in the HACCP plan in blue colored font.

Process Name:	**Vacuum Packed, Hot Smoked, Frozen, Wild Caught Lake Walleye (*Sanders vitreus*) Fillets**

STEP	DESCRIPTION

Daily Tasks
 	
Prior to Start-up
 	
(Processing Days Only)
	• Check and record temperature of all **coolers** on corresponding *Cooler Temperature Log*.
	  o If temperature exceeds 38°F, contact Owner, and ensure temperatures of all product are less than 38°F.
	• Check and record temperature of all **freezers** on corresponding *Freezer Temperature Log*.
	  o If temperature exceeds -3°F, contact Owner, and ensure temperatures of all product are less than -3°F.
	• On the *Sanitation Audit Form* enter the date and note the individual completing the form this day. On the form record:
	  o **Safety of water –** ensure the fish shop has a copy of city water testing on file each year.
	  o **Condition and cleanliness of food-contact services and equipment** – inspect the processing area and record time and pass/fail on form - if the processing area and equipment are not in a clean and sanitary condition, clean and sanitize the processing area and record this was done

STEP	DESCRIPTION
Daily Tasks **<u>Prior to Start-up</u>** (Processing Days Only) (continued)	in the comment section of the form. o **Cross contamination** – ensure raw products (fresh fish filets or fish chunks) are not processed in the same areas as smoked ready to eat products. Ensure all fresh fish and fresh fish chunks are stored below any "ready to eat" smoked fish product at all times. o **Maintenance of hand washing and toilet facilities** – inspect the facility and record pass/fail on form. If conditions do not pass, correct them and note under comments on the form. Ensure a sign is posted stating, "all employees must wash their hands before returning to work". o **Protection from adulterants (i.e. pesticides, cleaners, etc.)** – inspect the processing facility and record proper storage of adulterants in relation to food products (i.e. fresh and smoked fish), food packaging materials (i.e. vacuum pack bags). o **Employee health conditions** – medical problems or sick employees. o **Exclusion of pests** – inspect for pests including rodents and habitats/clutter that harbors pests. • Wash hands for a minimum of 20 seconds with hot soapy water.
Working with Smoked Fish	• Smoked fish is a Ready to Eat product. • Processing of smoked fish must only be done after the processing area and equipment has been cleaned and sanitized. o Sanitizing solutions should between 100-200 ppm. Start with ½ ounce of bleach in one gallon of water and then check bleach concentration with test strips to ensure reading is between 100-200 ppm. If the reading is not at least 100 ppm on the strip, add another ¼ ounce of bleach to the water pail and retest with a new testing strip. Do not exceed 200 ppm in the sanitation solution. Use only Clorox bleach without any fragrance enhancers. • Smoked fish cannot be processed at the same time raw fish is being processed due to cross contamination risk. • All employees must wash hands and wear a new pair of food service gloves when working with fish that has been smoked. To include moving from smoker, cooling, and packaging.
Daily Tasks	• Throughout the day: o Wash hands for a minimum of 20 seconds with hot soapy water, as needed.

STEP	DESCRIPTION
<u>Through the Day</u>	o Clean and sanitize processing station(s) every 4 hours when processing for more than 4 hours, and as needed. Record cleaning and sanitizing on *Sanitation Audit Form*. o Complete the *Sanitation Audit Form* after breaks as indicated on the form. o Clean and sanitize all coolers, fish boxes, tubs, and any other fish containers as needed. o Complete corrective action logs as needed. • After breaks (including lunch) and as needed: o Check and record temperature of all **coolers** on corresponding *Cooler Temperature Log*. ▪ If temperature exceeds 38°F, contact Owner, and ensure temperatures of all product are less than 38°F. o Check and record temperature of all **freezers** on corresponding *Freezer Temperature Log*. ▪ If temperature exceeds -3°F, contact Owner, and ensure temperatures of all product are less than -3°F.
Receive Packaging Materials and Labels	• Receive packing materials from vetted vendors at the loading dock. • All incoming materials are evaluated according to company procedures including: o Visual inspection of Letters of Guaranty and any other requested documents o Visual inspection of shipping materials for signs of damage or tampering. o Verify items and quantity match order
Store Packaging Materials and Labels	• Packaging materials and labels are stored in accordance with company procedures to include: o Storing in a cool dry place and in accordance with manufacturers' instructions. o Storing all items at least 6 inches off the floor.
Receive Brine Ingredients	• Receive brine ingredients (salt and sugar) from vetted vendors at the loading dock. • All incoming materials are evaluated according to company procedures including: o Visual inspection of Letters of Guaranty and any other requested documents.

<table>
<tr><th>STEP</th><th>DESCRIPTION</th></tr>
<tr><td></td><td>o Visual inspection of shipping materials for signs of damage or tampering.
o Verify items and quantity match order.</td></tr>
<tr><td>Store Brine Ingredients</td><td>• Brine ingredients are stored in accordance with company procedures to include:
o Storing in a cool dry place and in accordance with manufacturers’ instructions.
o Storing all items at least 6 inches off the floor.</td></tr>
<tr><td>Receive and Sort Fish

(raw, iced walleye)

Receive and Sort Fish</td><td>• Receive fresh, wild caught lake walleye (Sanders vitreus) from fishermen, at dock location, in fish boxes or other containers packed with ice.
• Evaluate all incoming fish according to company procedures including:
o Check for adequate ice and spot-checking internal temperatures.
o Inspect fish for wholesomeness:
<table>
<tr><th></th><th>Grade A:</th><th>Grade B:</th><th>Grade C:</th></tr>
<tr><td>Eyes</td><td>Clear, bright, slightly bulging</td><td>Dull and flat, not cloudy or milky</td><td>Cloudy, sunken</td></tr>
<tr><td>Flesh</td><td>Firm to the touch, in indentations</td><td>May have some indentation</td><td>Soft to the touch</td></tr>
<tr><td>Scales</td><td>Tightly adhere to fish</td><td>60% of scales are intact</td><td>Less than 60% of scales are intact</td></tr>
<tr><td>Gills</td><td>Bright red, odorless</td><td>Red, neutral smell</td><td>Pink to buff</td></tr>
<tr><td>Smell</td><td>A clean or cucumber smell, no odor</td><td>Neutral smell</td><td>Slight Ammonia or “fishy” smell, slight odor present</td></tr>
</table>
• Request and inspect necessary documentation.
• Sort fish based on quality:
o Grade A: Highest quality (will be used for raw, fresh or frozen fillets)</td></tr>
</table>

STEP	DESCRIPTION
(raw, iced walleye) (continued)	o Grade B: Good quality (will be used for smoked fish products) o Grade C: Lowest quality/ unsuitable (will not be purchased) o Maximum transit time from fishermen dock location to processing plant, 2 hours.
Cold Storage of Fish	• Re-ice fish awaiting processing and stored in cooler set at 38°F or less. • Processed all fish within 24 hours of arrival at the plant facility. • Record refrigerator temperature during start of operations procedures, after breaks, and during closing procedures.
Hand Fillet Fish	• Clean and sanitize processing/fillet areas and equipment before and after processing and every 4 hours if processing/filleting longer than 4 hours. • Remove individual boxes (i.e. 25 pounds) of fish from cooler as needed. • Head, gut, and fillet each fish by hand with a knife in batches of approximately 50 pounds of fish fillets. • Keep processing time short, less than 30 minutes, to reduce the amount of time fillets are exposed to temperatures above 38°F. • Place fillets in single layers on cleaned and sanitized sheet pans or other food safe container. • Clean and sanitize transport containers daily according to company SSOP.
Freeze Fillets Freeze Fillets (continued)	• Place pan or container onto a rolling rack. • Cover rack with a single use, rack cover. This allows airflow but protects fillets from contamination via condensation or dripping. • Roll covered rack into the freezer and store for of 24 hours or until fillets are completely frozen. Freezer is set to -3°F. • Record freezer temperature during start of operations procedures, after breaks, and during closing procedures.

STEP	DESCRIPTION
Thaw Fillets	• Roll covered racks of frozen fillets from freezer to cooler set at 38°F. • Store fillets in cooler until thawed completely. • Record refrigerator temperature during start of operations procedures, after breaks, and during closing procedures.
Trim Fillets	• Roll covered rack of thawed fillets from refrigerated storage as needed. • Sort and hand trim oversized fillets, with a knife, to a uniform thickness of ¾-inch and 7 inches long. Fillets are trimmed to a uniform size to meet validated brining and smoking process. • Time at this step is 30 minutes or less.
Brine Fillets	• Remove salt and sugar from dry food storage as need and mixed with 50 gallons of ambient temperature water to reach a salinometer reading of 60°. Prepare brine according to the validated brining mixture, time, and smoking process. No additional ingredients or additives may be used. o Validated Brine Mixture for 3.5% water phase salt: [insert validated mixture directions here] • Place 50 pounds or less of trimmed fillets into a cleaned and sanitized brine tank. • Add 50 gallons of brine solution (that has a minimum 60° salinometer reading) to fish in brine tank. • Roll filled brine tank into cooler, set at 38°F, and store for a minimum of 24 hours. Complete *Brine Log*. • Record refrigerator temperature during start of operations procedures, after breaks, and during closing procedures.
Drain Fillets	• After brining is, complete, remove fillets and place in cleaned and sanitized smoking racks. • Rinse fillets in rinse area with ambient temperature water. • Place smoking racks on rolling rack(s) and cover with a single use rack cover. • Roll rack(s) into cooler, set at 38°F, and store until the fillets are surface dry. About 2 hours.

STEP	DESCRIPTION
	• Record temperature during start of operations procedures, after breaks, and during closing procedures.
Hot Smoke Fillets	• Once all fillets on rolling rack(s) are surface dried, roll rack(s) into hot smoker for smoking. • Smoke fish using the a preprogrammed drying, smoking, cooking cycle for approximately 4 hours to achieve internal temperature of 145°F for 30 continuous minutes in the thickest part of the fish in the coolest part of the smoker. This process is in accordance with validated smoking process. • Trained smoker operator(s) monitor smoker and record temperatures on *Hot Smoking Log* during start of smoking process, twice during smoking cycle, and at the end of smoking cycle. o If fillets do not reach or maintain 145°F for 30 continuous minutes or the smoker is malfunctioning, contact owner, and complete corrective action log.

Cool Fillets	• After smoking roll rack to pre-cooling area which is to the left of the smoker. Set kitchen timer and allow fillets to cool for 30 minutes in ambient temperatures (50oF-70oF).
	• After the 30 minutes, take internal temperature of the thickest part of the thickest fillet on the middle rack and record on *Fillet Cooling Log.*
	• Cover rack with single use rack cover and roll rack into cooler. Allow fillets to cool to 40°F or less. Time at this step is approximately 6 hours or less. Fillets can remain in cooler until ready to package.
	• Perform a second temperature check within 1 hour of moving fillets to cooler; take internal temperature of three fillets on each rolling rack. Record temperatures on *Cooling Temperature Log*.
	  o If fillets are not 70°F or less, contact owner and move rolling rack(s) to freezer until temperature is less than 70°F.
	• Perform a third temperature check within 4 hour of second temperature recording. Take internal temperature of three fillets on each rolling rack. Record temperatures on *Cooling Temperature Log*.
	  o If fillets are not 40°F or less, contact owner and move rolling rack(s) to freezer until temperature is less than 40°F.

STEP	DESCRIPTION
Vacuum Pack/ Weigh/ Label/Box	• Inspect vacuum packages to ensure each one contains a label that includes the following information. Record information on the *Vacuum Packaged Fish Labeling Form*: o Safe Handling and Thawing: **"Keep frozen until ready to use. To thaw, cut bag open and thaw under refrigeration or cool running water."** o **"Contains Allergen: Fish"** o Market name of fish species o Lot number including day/month/year of packing o Company name and address • After fillets have cooled to 40°F or less, roll rack(s) to packing areas as needed. • Pack cooled fillets in clear, pre-labeled, food safe, 4 millimeter, and vacuum sealing packages. • Vacuum seal filled bags and weigh. • Write or apply weight to each package. • Place final products in prelabeled cardboard freezer boxes. Add batch number to exterior of box. o No more than 26 pounds per box, 2 boxes per batch. • Weigh/pack/label/box step for each batch is 45 minutes or less.
Freezer Storage	• Store final product in freezer until delivery as needed. Storage temperature is set to -3°F or less. • Record freezer temperature during start of operations procedures, after breaks, and during closing procedures.
Daily Tasks **<u>End of Day</u>**	• Ensure all tubs, containers, processing/rinsing/cooling areas, and equipment are cleaned and sanitized. o Sanitizing solutions should between 100-200 ppm. Start with ½ ounce of bleach in one gallon of water and then check bleach concentration with test strips to ensure reading is between 100-200 ppm. If the reading is not at least 100 ppm on the strip, add another ¼ ounce of bleach to

STEP	DESCRIPTION
(Processing Days Only)	the water pail and retest with a new testing strip. Do not exceed 200 ppm in the sanitation solution. Use only Clorox bleach without any fragrance enhancers. • Check and record temperature of all **coolers** on corresponding *Cooler Temperature Log*. o If temperature exceeds 38°F, contact Owner, and ensure temperatures of all product are less than 38°F. • Check and record temperature of all **freezers** on corresponding *Freezer Temperature Log*. o If temperature exceeds -3°F, contact Owner, and ensure temperatures of all product are less than -3°F. • Complete last column of the *Sanitation Audit Form*. • Ensure the *Sanitation Audit Form*, *Corrective Action Logs*, *Brine Log*, *Hot Smoking Log*, *Fillet Cooling Log*, *Vacuum Packaged Fish Labeling Form*, and all Temperature Logs are completed and in appropriate file for Owner to review. • Place blank *Sanitation Audit Form*, *Corrective Action Logs*, and all Temperature Logs in predetermined locations, to be completed during next processing day.

Establishment's Name: Mino Wiisinidaa	**Intended Use to Consumer:** Ready to Eat
Establishment's Address: 123 Wiigwaas Odanah, WI 54861	**Product Description:** Frozen, Vacuum Packed, Hot Smoked, Lake Walleye Fillets
	Method of Storage & Distribution: Freezer; Freezer truck or ice packed coolers

Hazard Analysis Worksheet

(1) Processing Step	(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process	(3) Is this potential hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point? (Yes or No)
Receiving Packaging Materials and Labels	**B:** Pathogenic bacteria, viruses, and mold	No	NRLTO-Letter of Guaranty (LOG) includes pathogen testing frequency and results. 3rd Party testing verifies LOG. Shipping packages visually inspected for signs of damage or moisture.	n/a	No
	C: non-food safe materials or deleterious chemicals	No	NRLTO- Letter of Guaranty (LOG) on file.	n/a	No
	P: Foreign material	No	Visual inspection of shipping packaging for damage. Visual inspection during vacuum packing.	n/a	No

Hazard Analysis Worksheet					
(1) **Processing Step**	**(2)** **List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3)** **Is this potential hazard significant (introduced, enhanced, or eliminated) at this step?** **(Yes or No)**	**(4)** **Justify the decision that you made in column 3**	**(5)** **What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6)** **Is this step a Critical Control Point?** **(Yes or No)**
Receiving Packaging Materials and Labels	**B:** Pathogenic bacteria, viruses, and mold	No	NRLTO- packages stored in accordance to manufacture's instruction and away from moisture.	n/a	No
	C: non-food safe materials or deleterious chemicals	No	NRLTO- Chemical storage SOP, Facility Zoning, and Packaging Material Storage SOP make hazard unlikely to occur	n/a	No
	P: none	n/a	n/a	n/a	No
Receiving Brine Ingredients	**B:** Pathogenic bacteria, viruses, and mold	No	NRLTO-Letter of Guaranty (LOG) includes pathogen testing frequency and results. 3rd Party testing verifies LOG. Shipping packages visually inspected for signs of damage or moisture.	n/a	No

Hazard Analysis Worksheet					
(1) Processing Step	**(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3) Is this potential hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)**	**(4) Justify the decision that you made in column 3**	**(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6) Is this step a Critical Control Point? (Yes or No)**
Receiving Brine Ingredients (cont.)	**C:** non-food safe materials or deleterious chemicals	No	NRLTO- Letter of Guaranty (LOG) on file.	n/a	No
	P: Foreign material	No	Visual inspection of shipping packaging for damage. Visual inspection during brine mixing.	n/a	No
Storing Brine Ingredients	**B:** Pathogenic bacteria, viruses, and mold	No	NRLTO- packages stored in accordance to manufacture's instruction and away from moisture.	n/a	No
	C: non-food safe materials or deleterious chemicals	No	NRLTO- Chemical storage SOP, and Packaging Material Storage SOP make hazard unlikely to occur	n/a	No
	P: none	n/a	n/a	n/a	No
Receiving Fish	**B:** Pathogenic bacteria, viruses, and parasites	No	SOPs for receiving properly iced and cooled fish make pathogen growth NRLTO; Kill step later in process..	Inspection of fish SOPs; Adequate ice around fish; product will be cooked in later step	No

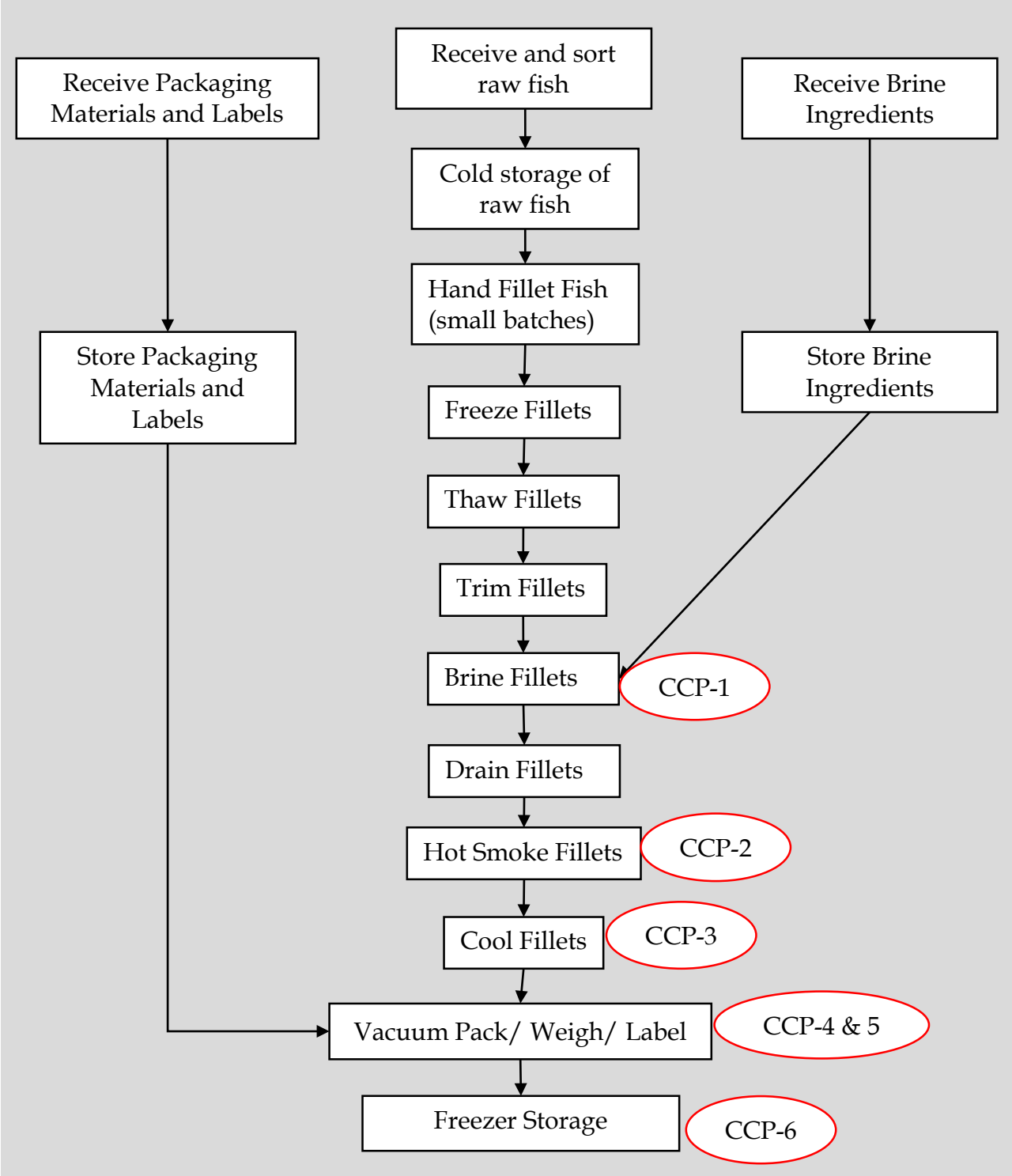
Hazard Analysis Worksheet					
(1) Processing Step	**(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3) Is this potential hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)**	**(4) Justify the decision that you made in column 3**	**(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6) Is this step a Critical Control Point? (Yes or No)**
Receiving Fish (cont.)	**C:** None (see GLIFWC research in office)	No	See GLIFWC research on chemical contaminants in the Great Lakes (on file in main office)	n/a	No
	P: none	n/a	n/a	n/a	No
Cold Storage of Fish	**B:** Pathogenic bacteria, viruses, and parasites	Yes	Pathogens are naturally occurring in fish.	Inspect fish to ensure adequate ice; fish stored below 38°F; control bacteria through SSOP; Hot smoking is a kill step that will occur after this step.	No
	C: none	No	n/a	n/a	No
	P: none	No	n/a	n/a	No
Filleting (by hand)	**BIOLOGICAL:** Pathogenic bacteria, viruses, and parasites	Yes	Pathogens are naturally occurring in fish	Process fish in <2 hours; product will be cooked	No
	CHEMICAL: none	n/a	n/a	n/a	No
	PHYSICAL: metal fragmentation	No	NRLTO: Fish are fillet by hand by fillet technicians	Prior to start up, after breaks, and at the end of day knives are visually inspected by fillet technicians.	No
Freezing Fillets	**B:** Pathogenic bacteria, viruses, and parasites	No	Pathogens naturally occurring in fish.	Hot smoking is a kill step that will occur after this step.	No
	C: none	n/a	n/a	n/a	No
	P: none	n/a	n/a	n/a	No

Hazard Analysis Worksheet					
(1) Processing Step	**(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3) Is this potential hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)**	**(4) Justify the decision that you made in column 3**	**(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6) Is this step a Critical Control Point? (Yes or No)**
Thawing Fillets	**B:** Pathogenic bacteria, and viruses	No	Pathogens are naturally occurring in fish. Thawing temperature below 38°F. Kill step later in process.	n/a	No
	C: none	n/a	n/a	n/a	No
	P: none	n/a	n/a	n/a	No
Brining Fillets	**B:** C. bot.	Yes	C. bot in fish occurs naturally	Brine will be mixed in accordance with SOP to ensure proper salinity in accordance with validated brining and smoking process. Brining fillets will be done under refrigeration.	**Yes**
	C: none	n/a	n/a	n/a	No
	P: none	n/a	n/a	n/a	No
Draining Fillets	**B:** C. bot.	No	NRLTO- Short amount of time makes pathogen growth unlikely. Fillets are drained quickly and moved to next step. Kill step later in process.	n/a	No
	C: none	n/a	n/a	n/a	No
	P: none	n/a	n/a	n/a	No

Hazard Analysis Worksheet					
(1) Processing Step	**(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3) Is this potential hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)**	**(4) Justify the decision that you made in column 3**	**(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6) Is this step a Critical Control Point? (Yes or No)**
Hot Smoking Fillets	**B:** C. bot.	Yes	If time and temperature abuse occur, C. bot. are likely to grow and develop toxins.	Smoking SOP ensures fillets are cooked to an internal temperature of 145°F for a min of 30 minutes.	**Yes**
	C: none	n/a	n/a	n/a	No
	P: none	n/a	n/a	n/a	No
Cool Fillet	**B:** *Clostridium botulinum* spores	Yes	Time and temperature abuse could result in *C. botulinum* growth and toxin formation. Recontamination controlled by rack cover and prerequisite program.	Product will be cooled to 70°F within 2 hours; Product will be further cooled to less than 40°F within an additional 4 hours.	**Yes**
	C: none	n/a	n/a	n/a	No
	P: none	n/a	n/a	n/a	No
Weigh, Pack, & Label	**B:** *Clostridium botulinum*	Yes	*C. botulism* spores can become activated in anaerobic environments during improper thawing.	Include thawing instructions on label **"Keep frozen until ready to use. To thaw, cut bag open and thaw under refrigeration or cool running water."**	**Yes**

Hazard Analysis Worksheet					
(1) **Processing Step**	**(2)** **List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3)** **Is this potential hazard significant (introduced, enhanced, or eliminated) at this step?** **(Yes or No)**	**(4)** **Justify the decision that you made in column 3**	**(5)** **What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6)** **Is this step a Critical Control Point?** **(Yes or No)**
Weigh, Pack, & Label (cont.)	**C:** Allergens	Yes	Fish is an allergen	Label includes allergen warning "Contains Allergen: Fish"	**Yes**
	P: none	n/a	n/a	n/a	No
Freezer Storage	**B:** *Clostridium botulinum*	Yes	Time and temperature abuse could result in *C. botulism* spore activation.	Product stored in freezer set at -3°F or less.	**Yes**
	C: none	n/a	n/a	n/a	No
	P: none	n/a	n/a	n/a	No

Establishment's Name: Mino Wiisinidaa	**Intended Use:** Ready to eat
Establishment's Address: 123 Wiigwaas Ave. Odanah, WI 54861	**Product Description:** Frozen, Vacuum Packed, Hot Smoked, Lake Walleye Fillets
	Method of Storage & Distribution: Freezer; Freezer truck delivery or ice packed coolers



Establishment's Name: Mino Wiisinidaa	**Intended Use:** Ready to eat
Establishment's Address: 123 Wiigwaas Odanah, WI 54861	**Product Description:** Frozen, Vacuum Packed, Hot Smoked, Lake Walleye Fillets
	Method of Distribution & Storage: Freezer; Freezer truck or ice packed coolers

HACCP Plan									
(1) Critical Control Point (CCP)	**(2) Hazard(s)**	**(3) Critical Limits for each Control Measure**	**Monitoring**				**(8) Corrective Action(s)**	**(9) Verification**	**(10) Records**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
Brining Fillets *brining procedure has been validated through a validation study to ensure a water salt phase conc. Of 3.5%	*C. botulism* and *Salmonella* growth and survival; Pathogenic bacteria growth and survival	Minimum brine time of 24 hours; 50 gallons of brine with 60° salinometer reading at start of process; and No more than 50 pounds of fish of fillets not larger than 5 pounds added to the brine tank.	Start and end time of brine; Volume of brine and degrees salt; weight of total fillets put in brine; Cooler temperature	Visual check of time; visual scale reading; Fill to pre-measure mark; and salinometer; Thermometer	Each batch	Brine Operator Trained in brining process	1. IF Brining time is not met; THEN, Hold in brine until 24 hours is reached Add more salt and mix until salinometer reads 60°; Divert fillets > 5 pounds to another batch process. Remove fillets until weight is 50 lbs. or less; Move brine tanks to another cooler and	Quarterly lab analysis to verify that finished products have 3.5% water phase salt; Daily accuracy check of scale; and Annual calibration of food scale 2. Check accuracy of thermometer before initial use and then daily, and then annual calibration. Brine validation study used to develop	• Brine Logs • Temperature recording chart with visual checks • Brine Validation Study • Training Records • Accuracy check and calibration records • CA records

HACCP Plan									
(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Brining Fillets (cont.)							fix cooler or adjust thermostat. Retrain involved staff. 2. Determine safety of product based on time and temperature exposure	brine recipe & time Weekly review of brine logs, and corrective action records.	
Hot Smoking Fillets	*C. botulism* growth; Pathogenic bacteria growth and survival	145°F internal temperature of fillets for a min. of 30 continuous minutes	Internal temperature of 3 fillets. Time once target temperature is reached.	Continuous temperature recording device with 3 probes	Continuous during smoking. Visual checks of record during each batch.	Fish Smoking Operator trained in smoking process	Immediately re-cook batch that do not reach target time and temperature or destroy batch and repair equipment.	Floor Manager or Owner reviews logs and CA reports weekly. Annual calibration of temperature probe device.	• Temperature recording charts. • Smoking logs • CA reports • Temperature probe calibration records • Maintenance and repair logs • Training records

HACCP Plan									
(1) Critical Control Point (CCP)	**(2) Hazard(s)**	**(3) Critical Limits for each Control Measure**	**Monitoring**				**(8) Corrective Action(s)**	**(9) Verification**	**(10) Records**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
Cooling Fillets	*C. botulism* growth; Pathogenic bacteria growth and survival	Product will be cooled to 70°F within 2 hours; Product will be further cooled to less than 40°F within an additional 4 hours.	Internal temperature of 3 fillets	Thermometer	Once per batch within between minute 60 and 110; Once between minute 240 and 360.	Employee trained in cooling process	If temperature abuse review Table A-2 in Hazards Guide to determine safety of product.	Floor Manager or Owner reviews logs and CA reports weekly. Thermometer calibration records.	• Temperature logs • CA reports • Training records • Maintenance and repair logs for walk-in cooler
Labeling	*Clostridium botulinum*	Correct label affixed to each finished product package	Label includes instructions **"Keep frozen until ready to use. To thaw, cut bag open and thaw under refrigeration or cool running water."**	Visual inspection	Each package	Packing Manager	Remove and replace labels from mislabeled product prior to storing in freezer	Weekly review of labelling logs	• Labelling inspection log • Corrective action reports • Verification reports (Once per week) • Purchasing records including copy of label purchased

HACCP Plan									
(1) Critical Control Point (CCP)	**(2) Hazard(s)**	**(3) Critical Limits for each Control Measure**	**Monitoring**				**(8) Corrective Action(s)**	**(9) Verification**	**(10) Records**
			(4) What	**(5) How**	**(6) Frequency**	**(7) Who**			
Labeling	Undeclared Allergen	Label includes allergen declaration "**Contains Allergens: Fish**"	Label containing allergen declaration	Visual inspection	Each package	Trained Packing Employee	Add label to unlabeled product. Remove and replace labels from mislabeled product prior to storing in freezer.	Weekly review of labelling logs by Packing Manager or Owner	• Labelling inspection log • Corrective action reports • Verification reports (once per week) • Purchasing records including copy of label purchased
Freezer Storage of Final Product	*C. botulism* toxin formation during power or freezer failure	Freezer temperature held at -3°F or less	Freezer temperature	Thermometer	Two times/day (early AM, and late PM)	Packing Technician	Decrease temperature and hold and evaluate based on time and temperature of exposure	Floor Manager will review temperature records weekly. Floor Manager will have freezer thermometer verified with a certified thermometer	• Time and temperature logs • CA reports • Training records for Company Packing and Storage. • Maintenance and repair records

HACCP Plan									
(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Freezer Storage of Final Product (cont.)								at -10°F, -5°F, 0°F, 10°F annually.	• Thermometer calibration records.
Signature:					Print Name:				

Venison Model HACCP Plan

Raw Butcher Cuts

PRODUCT DESCRIPTION

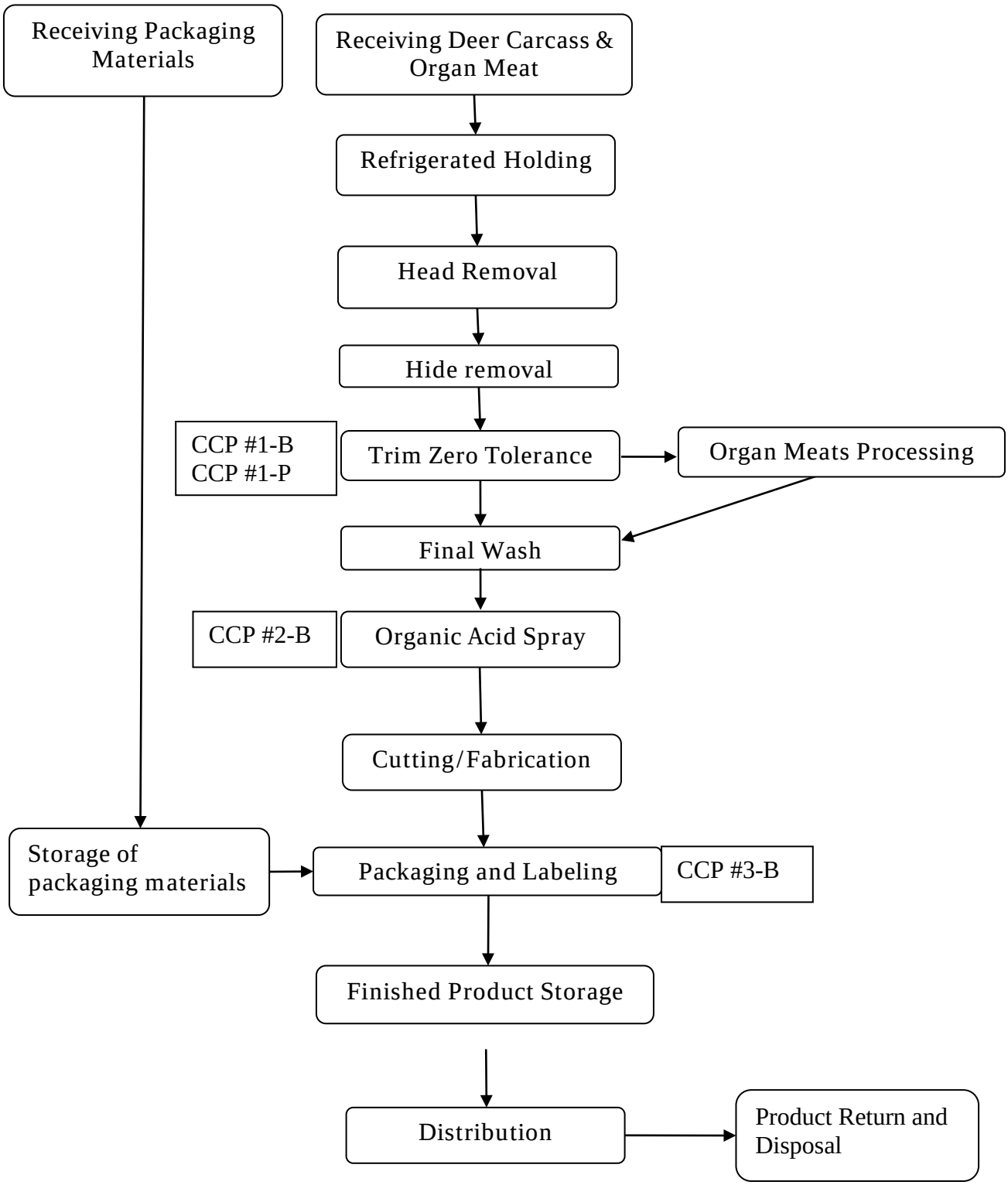
Establishment's Name	Mino Wiisinidaa
Establishment's Address	123 Wiigwaas Ave. Odanah, WI 54861

Product Name	Wild Harvested, Venison
Brief Description	Raw, Refrigerated, Whitetail Deer Whole Muscle Retail Meat Cuts
Ingredients	Whitetail Deer (*Odocoileus virginianus*)
Allergens	None
Packaging	Food safe tray, moisture absorbent pad, plastic wrap
Distribution	Refrigerator truck delivery to retail outlets
Intended Use	To be cooked
Target Consumer	General Public

Date: 02/25/2019

HACCP Team Member(s)	Position	Signature
John Doe	Owner	John Doe

Process Flow Diagram



Hazard Analysis Worksheet					
Establishment's Name: Mino Wiisinidaa		**Intended Use to Consumer:** To be cooked			
Establishment's Address: 123 Wiigwaas Ave. Odanah, WI 54861		**Product Description:** Raw, Refrigerated, Whitetail Deer Whole Muscle Retail Meat Cuts			
		Method of Storage & Distribution: Refrigerated truck delivery to retail outlets			
(1) Processing Step	**(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)**	**(4) Justify the decision that you made in column 3**	**(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6) Is this step a Critical Control Point (Yes or No)?**
Receiving Packaging Materials	**B:** Contamination with biological material and pathogens	No	Materials are purchased from approved sources. Proper receiving procedures.	Proper receiving procedures (SOP). Letter of guarantee for materials purchased.	No
	C: Non-food grade materials or allergens	No	Materials are purchased from approved sources. Proper receiving procedures.	Proper receiving procedures (SOP). Letter of guarantee for materials purchased.	No
	P: Foreign material	No	Materials are purchased from approved sources. Proper receiving procedures.	Proper receiving procedures (SOP). Letter of guarantee for materials purchased.	No
Storage of Packing Materials	**B:** Contamination with biological material and pathogens	No	Storage area kept clean	Proper storage procedures (SOP)	No
	C: Non-food grade materials or allergens	No	Storage area kept clean	Proper storage procedures (SOP)	No
	P: Foreign material	No	Storage area kept clean	Proper storage procedures (SOP)	No

Receiving and Weighing Deer Carcass & Organ Meat	**B: (1)** Pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC) **(2)** CWD prions in Specified Risk Materials (SRMs)	**(1)** No **(2)** No	**(1)** Raw meat and animal hides are known sources of pathogens. Venison is received from an approved Harvester. **(2)** Risk of CWD prions in deer populations varies by location of harvest. Deer harvested in areas deemed by the state Department of Natural Resources to be areas effected by CWD will be rejected, deer harvested in adjacent counties will be held for testing. Carcasses testing positive for CWD will be rejected.	**(1)** Letter of guaranty from Harvester documenting animal health at time of harvest, sanitary evisceration, and transport makes hazard unlikely to occur. Refrigerated Holding, Zero Trim Tolerance, and Organic Acid Spray steps control pathogens. Receiving meat SOP and carcass inspection. All carcasses not passing inspection will be rejected. **(2)** CWD sample extraction SOP, Holding for testing SOP, Disposal SOP, and Negative test results.	**(1)** No **(2)** No
	C: Lead	No	Deer harvested with lead ammunition is likely to contain lead fragmentation from the bullet (w. Grainger Hunt et. al. 2009). Deer harvested with lead bullets will be rejected.	none	No

Receiving and Weighing Deer Carcass & Organ Meat (cont.)	**P:** bullet fragments	Yes	Deer harvested with ammunition is likely to contain bullet fragmentation.	Hazard will be controlled by later CCP, which removes bullet fragments that pose a physical risk.	No
Refrigerated Holding	**B:** Pathogen growth: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	No	Pathogen introduction and growth is not reasonably likely at this step.	Time and temperature control (SOP for temperature controlled storage). Correct clean up and sanitizing procedures (SSOP).	No
	C: none				No
	P: none				No
Head Removal	**B: (1)** Prions – Chronic Wasting Disease	**(1)** Yes	**(1)** Chronic Wasting Disease is a degenerative disease caused by prions and can impact deer.	**(1)** SOP for CWD related SRMs. Pre-Requisite program for CWD and Specific Risk Material.	**(1)** No

Head Removal (cont.)	**(2)** Introduction and growth of Pathogens : Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	**(2)** Yes (Introduction) No (Growth)	**(2)** Hide opening and removal of head may introduce pathogens onto the carcass. Heads are processed rapidly enough to next step to prevent pathogen growth.	**(2)** Correct practices for production and processing controls (SOP) control growth. Introduction pathogens controlled at CCP 2-B. Correct clean up and sanitizing procedures (SSOP).	**(2)** No
	C: none				No
	P: none				No
Hide Removal / Sanitary Dressing	**B:** Introduction or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	No (Introduction) No (Growth)	Hides are a known source of pathogens. Sanitary hide removal practices incorporate a quick hide removal and carcasses are moved rapidly enough to next step to prevent pathogen growth.	Correct practices for production and processing controls (SOP) control growth. Introduction pathogens controlled at CCP 2-B. Correct clean up and sanitizing procedures (SSOP).	No
	C: none				No
	P: none				No
Trim Zero Tolerance (may be done concurrently with step for organ meats)	**B:** Presence or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Yes (Presence) No (Growth)	Pathogens are known to be present on venison carcasses, and are also reasonably likely to be present on organ meats. Carcasses and organ meats	All visible fecal material, milk, ingesta, and visible contaminants are trimmed off carcasses and organ meats as required by insert	**Yes CCP 1-B**

Trim Zero Tolerance (cont.)			are moved rapidly enough to next step to prevent pathogen growth during this step.	model code section. Correct clean up and sanitizing procedures (SSOP).	
	C: none				No
	P: bullet fragment	Yes	Animals harvested with a bullet may contain the bullet or fragments larger than allowable (7mm).	A two-inch diameter area encircling the bullet entry point will be removed and properly disposed (L. Cornicelli, M Grund).	**Yes CCP 1-P**
Final wash	**B:** Presence or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Yes (Presence) No (Growth)	Pathogens are known to be present on venison carcasses, and are also reasonably likely to be present on organ meats. Prior step (Trim Zero Tolerance) reduced likelihood of hazard occurring. Carcass and organ meats are moved rapidly enough to next step to prevent pathogen growth during this step.	Correct clean up and sanitizing procedures (SSOP).	No
	C: none				No
	P: none				No
Organic Acid Spray	**B:** Presence or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Yes (Presence) No (Growth)	Pathogens are known to be present on venison carcasses, and are also reasonably likely	Organic Acid Spray treatments are well known to reduce pathogen numbers. Organic acid	**Yes CCP 2-B**

Organic Acid Spray (cont.)			to be present on organ meats. .	spray prepared and applied according to the Organic Acid Spray SOP will reduce pathogen numbers to non-detectable level. Correct clean up and sanitizing procedures (SSOP).	
	C: Excessive organic acid	No	SOP for preparing organic acid rinse solution makes hazard unlikely. Organic acid used is food-grade	Organic Acid Spray preparation and application procedures in accordance with manufacturer's instruction (Organic Acid Spray SOP)	No
	P: none				No
Cutting/ Fabrication	**B: (1)** Presence or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC); **(2)** CWD Prions	**(1)** Yes (Presence) No (Growth) **(2)** No (prions)	**(1)** Raw meat is a known source of pathogens. Carcasses are moved rapidly enough to next step to prevent pathogen growth during this step. **(2)** Accepted carcasses are not reasonably likely to contain CWD prions.	**(1)** Correct clean up and sanitizing procedures (SSOP). Temperature control of product (Product Temperature Control SOP) **(2)** Proper procedures for removing and disposing Specific Risk Material (SOP for SRM Removal) Correct clean up and sanitizing procedures (SSOP).	No

Cutting/ Fabrication (cont.)	**C:** none				No
	P: none				No
Packaging and Labeling	**B:** Presence or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Yes (Presence) Yes (Growth)	Raw meat is known source of pathogens. Growth may occur if product is not handled properly.	Correct clean up and sanitizing procedures (SSOP). Temperature control of product (Product Temperature Control SOP) Label includes proper handling and cooking instructions.	**Yes CCP 3-B**
	C: none				No
	P: none				No
Finish Product Refrigerated Storage	**B:**Presence or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	No (Presence) No (Growth)	Raw meat is known source of pathogens. Growth may occur if product exposed for an excessive time to and temperature that allows pathogen growth.	Correct cleaning and sanitizing procedures (SSOP) Time and temperature control (SOP for temperature controlled storage)	No
	C: none				No
	P: none				No

Distribution	**B:** Presence or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	No (Presence) No (Growth)	Pathogen introduction and growth is not reasonably likely at this step.	Time and temperature control (SOP for temperature controlled storage)	No
	C: none				No
	P: none				No
Returned Product	**B:** Presence or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	No (Presence) No (Growth)	Product has been outside of the control of the establishment.	Product will be disposed of according to disposal SOP.	No
	C: Presence of contaminant and/ or allergen	No	Product has been outside of the control of the establishment.	Product will be disposed of according to disposal SOP.	No
	P: Foreign Material	No	Product has been outside of the control of the establishment.	Product will be disposed of according to disposal SOP.	No

HACCP Plan	
Establishment's Name: Mino Wiisinidaa	**Intended Use to Consumer:** To be cooked
Establishment's Address: 123 Wiigwaas Ave. Odanah, WI 54861	**Product Description:** Raw, Refrigerated, Whitetail Deer Whole Muscle Retail Meat Cuts **Method of Storage & Distribution:** Refrigerated truck delivery to retail outlets

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Trim Zero Tolerance 1-B	Pathogens: Salmonella; E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Zero visible fecal material, ingesta, or milk present	visible fecal material, ingesta, or milk present	visual inspection	Each carcass and edible organs	Shift Leader or other trained designee	Fecal material, ingesta, or milk will be trimmed away until Trim Zero Tolerance is achieved or the carcass is rejected and disposed. Shift Leader will retrain Trim employee to prevent recurrence or adjust process.	Daily review of trim log by Facility Manager or designee	• Training log • Trim log • Rejection and Disposal log • Corrective action log • Verification reports

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Trim Zero Tolerance 1-P	Bullet Fragments	Zero visible fragment and 2 inch radius bullet entry point is removed	Number of visible fragments and less than 2-inch radius around bullet entry point is removed and disposed	visual inspection	Each carcass and affected edible organs	Shift Leader or other trained designee	Visible fragments will be removed. Bullet entry point will be trimmed away until a minimum of 2 inch radius is removed from entry point. Shift Leader will retrain Trim employee employee to prevent recurrence or adjust process.	Daily review of trim log by Facility Manager or designee	• Training log • Trim log • Rejection and Disposal log • Corrective action log • Verification reports

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Organic Acid Spray 2-B	Pathogens: Salmonella; E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC),	Each carcass, carcass half, and edible organ is sprayed thoroughly in accordance with the Organic Acid Spray SOP.	Pathogen reduced to a non-detectable level	Organic acid application is prepared and applied to carcass according to the Organic Acid Application SOP.	Each carcass and organ	Trained Spray Applicatoror other trained designee	The cause of misapplication will be identified and eliminated. Affected carcasses will be washed and receive a second application. Any meat suspected of misapplication that cannot be reconditioned will be disposed of.	Daily review of organic acid application log by Shift Leader or designee	• Training log • Organic acid spray log • Corrective action log • Verification reports • Purchasing records and Safety Data Sheet • Organic Acid Application SOP

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Labeling	Pathogen growth due to unsafe handling and improper cooking	Correct label affixed to each finished product package	Label containing safe handling instructions and "cook through to 160°F internal temperature"	Visual inspection	Each package	Trained packing employee	Remove and replace labels from mislabeled product prior to storing in refrigerator	Daily review of labelling logs by Shift Leader or designee	• Training logs • Labelling inspection log • Corrective action reports • Verification reports • Purchasing records including copy of label purchased
Signature:					**Print Name:**				

Rabbit Model HACCP Plan

Raw, Whole

PRODUCT DESCRIPTION

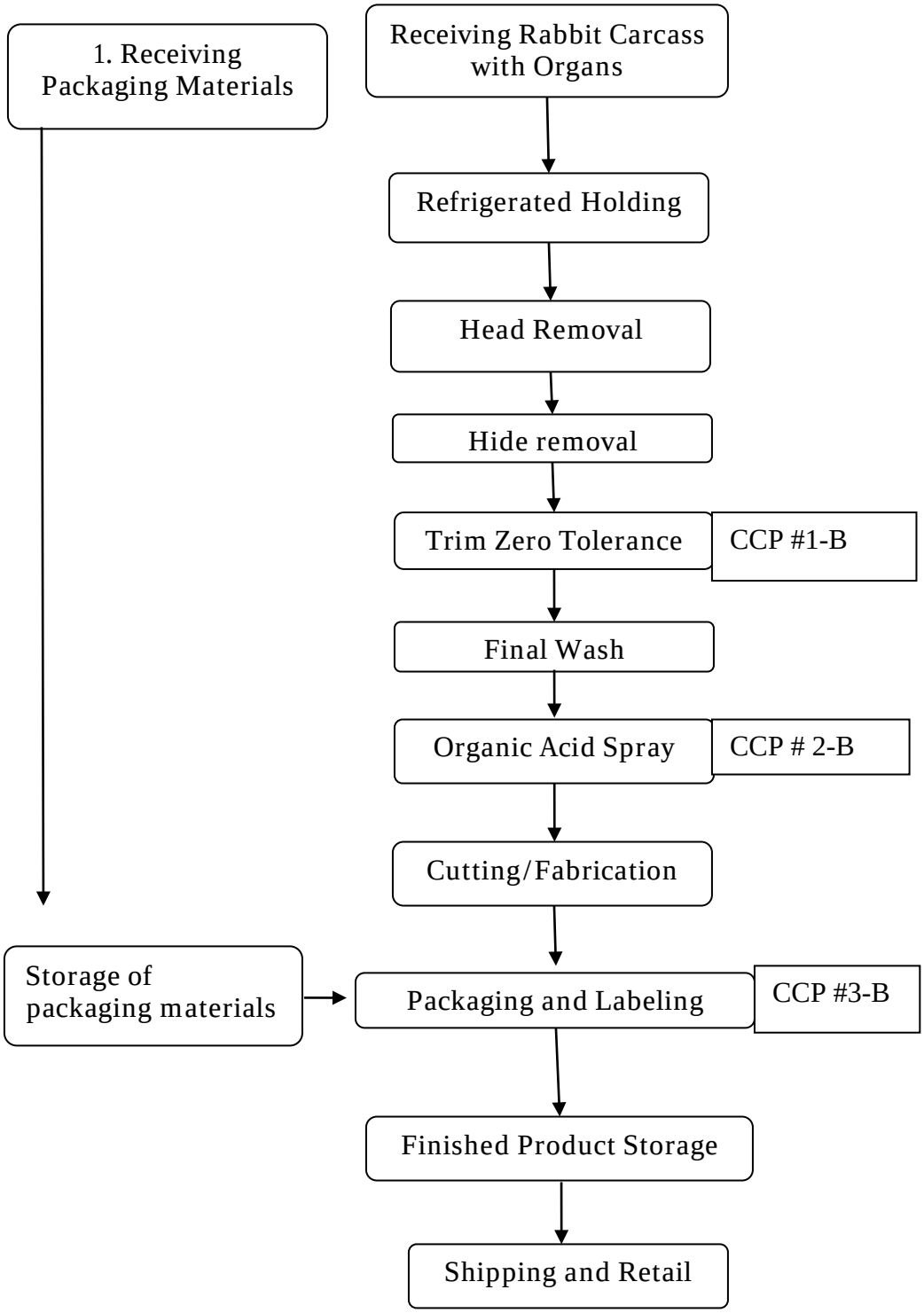
Establishment's Name	Mino Wiisinidaa
Establishment's Address	123 Wiigwaas Ave. Odanah, WI 54861

Product Name	Wild Harvested Rabbit
Brief Description	Raw, Refrigerated Rabbit meat on bone
Ingredients	Rabbit (*Sylvilagus floridanus*)
Allergens	None
Packaging	Food safe tray, moisture absorbent pad, plastic wrap
Distribution	Refrigerated truck delivery to retail outlets
Intended Use	To be cooked
Target Consumer	General Public

Date: 02/25/2019

HACCP Team Member(s)	Position	Signature
John Doe	Owner	John Doe

Process Flow Diagram



Hazard Analysis Worksheet					
Establishment's Name: Mino Wiisinidaa			**Intended Use to Consumer: General Public**		
Establishment's Address: 123 Wiigwaas Ave. Odanah, WI 54861			**Product Description**: Raw, Whole, Refrigerated Rabbit **Storage & Distribution:** Refrigerated truck delivery to retail outlets		
(1) Processing Step	**(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process**	**(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)**	**(4) Justify the decision that you made in column 3**	**(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?**	**(6) Is this step a Critical Control Point (Yes or No)?**
Receiving Packaging and Non meat Materials	**B:** Contamination with biological material and pathogens	No	Materials are purchased from approved sources. Proper receiving procedures.	Proper receiving procedures (SOP). Letter of guarantee for materials purchased.	No
	C: Non-food grade materials or allergens	No	Materials are purchased from approved sources. Proper receiving procedures.	Proper receiving procedures (SOP). Letter of guarantee for materials purchased.	No
	P: Foreign material	No	Materials are purchased from approved sources. Proper receiving procedures.	Proper receiving procedures (SOP). Letter of guarantee for materials purchased.	No
Storage of Packing and Non meat Materials	**B:** Contamination with biological material and pathogens	No	Storage area kept clean	Proper storage procedures (SOP)	No
	C: Non-food grade materials or allergens	No	Storage area kept clean	Proper storage procedures (SOP)	No
	P: Foreign material	No	Storage area kept clean	Proper storage procedures (SOP)	No

Receiving, Inspecting, and Weighing Rabbit Carcass & Organ Meat	**B:** Presence of pathogens: Salmonella: E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC), and staphylococcus aureus	No	Rabbits are known to carry disease that can negatively impact human health. Meat is being received from an approved Harvester.	Letter of guaranty from Harvester documenting animal health at time of harvest, sanitary evisceration, and transport makes hazard unlikely to occur. Refrigerated Holding, Zero Trim Tolerance, and Organic Acid Spray steps control pathogens. Receiving meat SOP and carcass inspection. All carcasses not passing inspection will be rejected..	No
	C: none	No			No
	P: none	No			No
Refrigerated Holding	**B: G**rowth of pathogens (see list in step 3)	No (Growth)	Pathogen growth is not reasonably likely at this step.	Time and temperature control (SOP for temperature controlled storage).	No

Refrigerated Holding (cont.)	**C:** none				No
	P: none				No
Head Removal	**B:** Pathogens (see list in step 3)	Yes (Presence) No (Growth)	Hide opening and removal of head may introduce pathogens onto the carcass. Heads are processed rapidly enough to next step to prevent pathogen growth.	Correct practices for production and processing controls (SOP) control growth. Introduction pathogens controlled at CCP 2-B. Correct clean up and sanitizing procedures (SSOP).	No
	C: none	No			No
	P: none	No			No
Hide Removal / Sanitary Dressing	**B:** Presence or growth of pathogens (see list in step 3)	Yes (Presence) No (Growth)	Hides are a known source of pathogens. Sanitary hide removal practices incorporate a quick hide removal and carcasses are moved rapidly enough to next step to prevent pathogen growth.	Correct practices for production and processing controls (SOP) control growth. Introduction pathogens controlled at CCP 2-B. Correct clean up and sanitizing procedures (SSOP).	No
	C: none	No			No
	P: none	No			No

Trim Zero Tolerance (may be done concurrently with step for organ meats)	**B:** Presence or growth of pathogens (see list in step 3)	Yes (Presence) No (Growth)	Pathogens are known to be present on rabbit carcasses, and are also reasonably likely to be present on organ meats. Removal of visible contamination is required by insert model code section. Carcasses and organ meats are moved rapidly enough to next step to prevent pathogen growth during this step.	All visible fecal material, milk, ingesta, visible contaminants are trimmed off carcasses and organ meats. Correct clean up and sanitizing procedures (SSOP).	**Yes CCP 1-B**
	C: none				No
	P: none				No
Final wash	**B:** Presence or growth of pathogens (see list in step 3)	Yes (Presence) No (Growth)	Pathogens are known to be present on rabbit carcasses, and are also reasonably likely to be present on organ meats. Prior step (Trim Zero Tolerance) reduced likelihood of hazard occurring. Carcass and organ meats are moved rapidly enough to next	Correct clean up and sanitizing procedures (SSOP).	No

			step to prevent pathogen growth during this step.		
	C: none				No
	P: none				No
Organic Acid Spray	**B:** Presence or growth of pathogens (see list in step 3)	Yes (Presence) No (Growth)	Pathogens are known to be present on rabbit carcasses, and are also reasonably likely to be present on organ meats.	Organic Acid Spray treatments are well known to reduce pathogen numbers. Organic acid spray prepared and applied according to the Organic Acid Spray SOP will reduce pathogen numbers to non-detectable level. Correct clean up and sanitizing procedures (SSOP).	**Yes** **CCP 2-B**
	C: Excessive organic acid	No	SOP for preparing organic acid rinse solution makes hazard unlikely. Organic acid used is food-grade	Organic Acid Spray preparation and application procedures in accordance with manufacturer's instruction (Organic Acid Spray SOP)	No
	P: none				No

Packaging and Labeling	**B:** Introduction or growth of pathogens (see list in step 3)	No (Introduction) Yes (Growth)	Raw meat is known source of pathogens. Growth may occur if product is not handled properly.	Correct clean up and sanitizing procedures (SSOP). Temperature control of product (Product Temperature Control SOP) Label includes proper handling and cooking instructions.	**Yes CCP 3-B**
	C: none				
	P: none				No
Finish Product Storage	**B:** Introduction or growth of pathogens (see list in step 3)	No (Introduction) No (Growth)	Pathogen introduction and growth is not reasonably likely at this step.	Temperature control (Temperature control for refrigerator SOP)	No
	C: none				No
	P: none				No
Distribution	**B:** Introduction or growth of pathogens (see list in step 3)	No (Introduction) No (Growth)	Pathogen introduction and growth is not reasonably likely at this step.	Temperature control (Temperature control for refrigerator SOP)	No
	C: none				No

	P: none		Product is handled according to SOP for Finished Product Storage		No
Returned Product	**B:** Presence or growth of pathogens (see list in step 1)	No (Presence) No (Growth)	Product has been outside of the control of the establishment.	Product will be disposed of according to disposal SOP.	No
	C: Presence of contaminant and/ or allergen		Product has been outside of the control of the establishment.	Product will be disposed of according to disposal SOP.	No
	P: Foreign Material		Product has been outside of the control of the establishment.	Product will be disposed of according to disposal SOP.	No

HACCP Plan	
Establishment's Name: Mino Wiisinidaa	**Intended Use to Consumer:** To be cooked
Establishment's Address: 123 Wiigwaas Ave. Odanah, WI 54861	**Product Description:** : Raw, Whole, Refrigerated Rabbit
	Method of Storage & Distribution: Refrigerated truck delivery to retail outlets

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Trim Zero Tolerance 1-B	Pathogens: Salmonella; E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Zero visible fecal material, ingesta, or milk present	visible fecal material, ingesta, or milk present	visual inspection	Each carcass and edible organs	Shift Leader or other trained designee	Fecal material, ingesta, or milk will be trimmed away until Trim Zero Tolerance is achieved or the carcass is rejected and disposed. Shift Leader will retrain Trim employee to prevent recurrence or adjust process.	Daily review of trim log by Facility Manager or designee	• Training log • Trim log • Rejection and Disposal log • Corrective action log • Verification reports

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Organic Acid Spray 2-B	Pathogens: Salmonella; E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC),	Each carcass, carcass half, and edible organ is sprayed thoroughly in accordance with the Organic Acid Spray SOP.	Pathogen reduced to a non-detectable level	Organic acid application is prepared and applied to carcass according to the Organic Acid Application SOP.	Each carcass and organ	Trained Spray Applicator or other trained designee	The cause of misapplication will be identified and eliminated. Affected carcasses will be washed and receive a second application. Any meat suspected of misapplication that cannot be reconditioned will be disposed of.	Daily review of organic acid application log by Shift Leader or designee	• Training log • Organic acid spray log • Corrective action log • Verification reports • Purchasing records and Safety Data Sheet • Organic Acid Application SOP

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Labeling	Pathogen growth due to unsafe handling and improper cooking	Correct label affixed to each finished product package	Label containing safe handling instructions and "cook through to 160°F internal temperature"	Visual inspection	Each package	Trained packing employee	Remove and replace labels from mislabeled product prior to storing in refrigerator	Daily review of labelling logs by Shift Leader or designee	• Training logs • Labelling inspection log • Corrective action reports • Verification reports • Purchasing records including copy of label purchased
Signature:					**Print Name:**				

Turkey Model HACCP Plan

Raw, Whole

PRODUCT DESCRIPTION

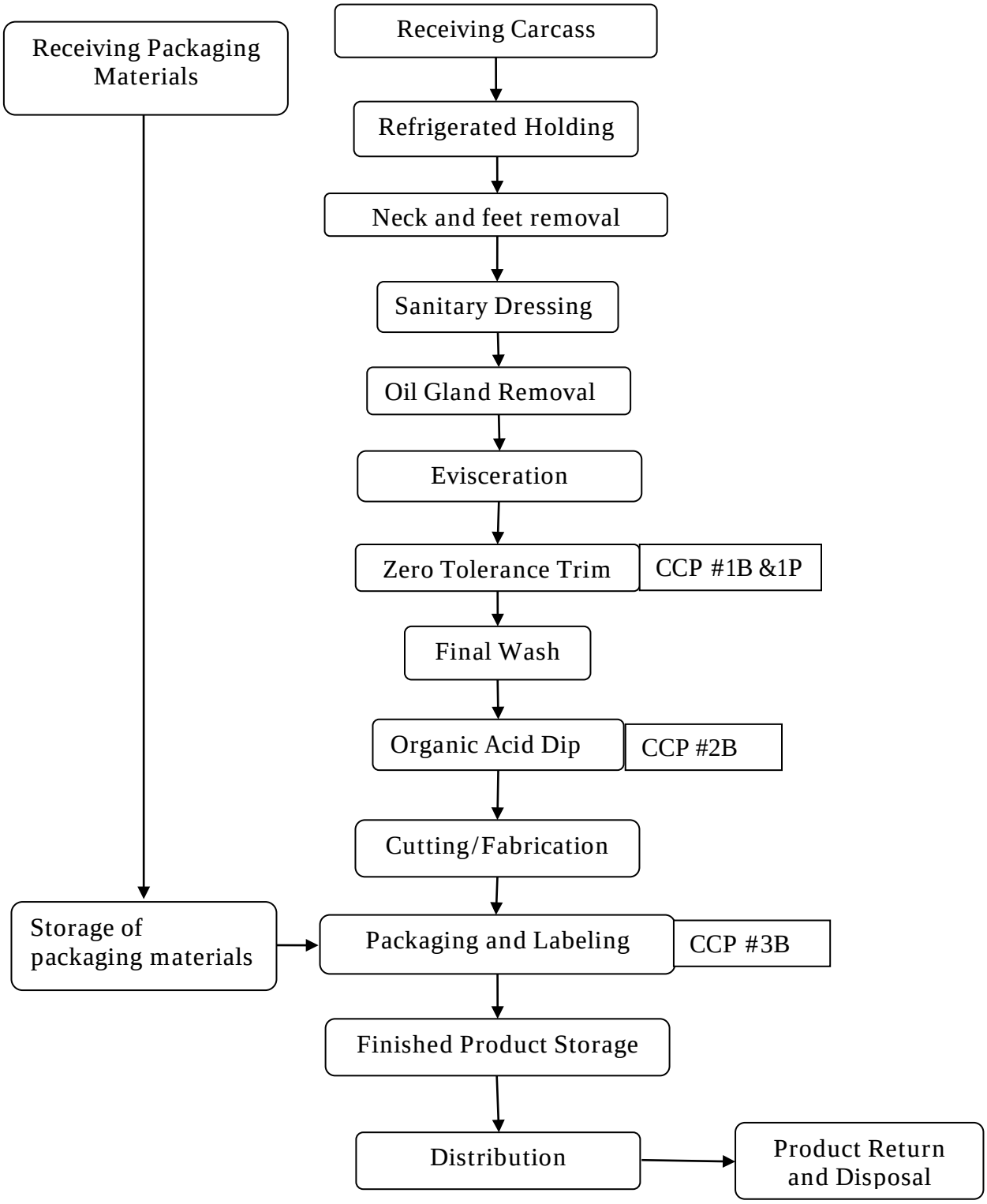
Establishment's Name	Mino Wiisinidaa
Establishment's Address	123 Wiigwaas Ave. Odanah, WI 54861

Product Name	Wild Harvested Turkey
Brief Description	Raw, Refrigerated, Turkey, Breast Meat
Ingredients	Turkey (*Meleagris gallopavo*)
Allergens	None
Packaging	Food safe tray, moisture absorbent pad, plastic wrap
Distribution	Refrigerator truck delivery to retail outlets
Intended Use	To be cooked
Target Consumer	General Public

Date: 02/25/2019

HACCP Team Member(s)	Position	Signature
John Doe	Owner	John Doe

Process Flow Diagram



Hazard Analysis Worksheet	
Establishment's Name: Mino Wiisinidaa	**Intended Use to Consumer:** To be cooked
Establishment's Address: 123 Wiigwaas Ave. Odanah, WI 54861	**Product Description:** Raw, Refrigerated, Wild Harvested Poultry, Breast Meat
	Method of Storage & Distribution: Refrigerated truck delivery to retail outlets

(1) Processing Step	(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Receiving Packaging Materials	**B:** Contamination with biological material and pathogens	No	Materials are purchased from approved sources. Proper receiving procedures.	Proper receiving procedures (SOP). Letter of guarantee for materials purchased.	No
	C: Non-food grade materials or allergens	No	Materials are purchased from approved sources. Proper receiving procedures.	Proper receiving procedures (SOP). Letter of guarantee for materials purchased.	No
	P: Foreign material	No	Materials are purchased from approved sources. Proper receiving procedures.	Proper receiving procedures (SOP). Letter of guarantee for materials purchased.	No
Storage of Packing Materials	**B:** Contamination with biological material and pathogens	No	Storage area kept clean	Proper storage procedures (SOP)	No
	C: Non-food grade materials or allergens	No	Storage area kept clean	Proper storage procedures (SOP)	No
	P: Foreign material	No	Storage area kept clean	Proper storage procedures (SOP)	No

Receiving and Weighing Carcass	**B:** Pathogens: Salmonella, Campylobacter spp.	No	Raw meat and animal feathers are known sources of pathogens. Carcass is received from an approved Harvester.	Letter of guaranty from Harvester documenting animal health at time of harvest and transport makes hazard unlikely to occur.	No
	C: Lead	No	Poultry harvested with lead ammunition is likely to contain lead (GLIFWC Addendum on file). Poultry harvested with lead ammunition will be rejected.	none	No
	P: Shot Pellets	Yes	Poultry harvested with shot is likely to contain shot pellets.	Hazard will be controlled by later CCP that removes shot pellets that pose a physical risk.	No

Refrigerated Holding	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Pathogen introduction and growth is not reasonably likely at this step.	Time and temperature control (SOP for temperature controlled storage). Correct clean up and sanitizing procedures (SSOP).	No
	C: none				No
	P: none				No
Head and Feet Removal	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	Yes (Introduction) No (Growth)	Skin opening and removal of head or feet may introduce pathogens onto the carcass. Head and feet are processed rapidly enough to next step to prevent pathogen growth.	Correct practices for production and processing controls (SOP) control growth. Introduction pathogens controlled at CCP 2-B. Correct clean up and sanitizing procedures (SSOP).	No
	C: none				No
	P: none				No
Sanitary Dressing	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	Yes (Introduction) No (Growth)	Skin opening and removal of head or feet may introduce pathogens onto the carcass. Sanitary dressing practices incorporate a quick skin	Correct practices for production and processing controls (SOP) control growth.	No

Sanitary Dressing (cont.)			removal and carcasses are moved rapidly enough to next step to prevent pathogen growth.	Introduction pathogens controlled at CCP 2-B. Correct clean up and sanitizing procedures (SSOP).	
	C: none				No
	P: none				No
Oil Gland Removal	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	Yes (Introduction) No (Growth)	Skin opening and removal of head or feet may introduce pathogens onto the carcass. Oil gland remove is done quickly and carcasses are moved rapidly enough to next step to prevent pathogen growth.	Correct practices for production and processing controls (SOP) control growth. Introduction pathogens controlled at CCP 2-B. Correct clean up and sanitizing procedures (SSOP).	No
	C: none				No
	P: none				No
Trim Zero Tolerance	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Pathogen introduction is not reasonably likely to occur at this step. Carcass are moved rapidly enough to next step to prevent pathogen growth during this step.	All visible fecal material, ingesta, and visible contaminants are trimmed off carcasses and organ meats as required by insert model code section. Correct	**Yes CCP 1-B**

Trim Zero Tolerance (cont.)				clean up and sanitizing procedures (SSOP).	
	C: none				No
	P: bullet fragment	Yes	Animals harvested with a shot ammunition may contain shot in the meat.	Meat will be inspected for visible shot. All visible shot will be removed.	**Yes CCP 1-P**
Final wash	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Pathogen introduction is not reasonably likely to occur at this step. Carcass are moved rapidly enough to next step to prevent pathogen growth during this step.	Correct clean up and sanitizing procedures (SSOP).	No
	C: none				No
	P: none				No
Organic Acid Dip	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Pathogen introduction and growth are not reasonably likely to occur at this step.	Organic Acid Dip treatments are well known to reduce pathogen numbers. Organic acid Dip prepared and applied according to the Organic Acid Dip SOP will reduce pathogen	**Yes CCP 2-B**

Organic Acid Dip (cont.)				numbers to non-detectable level. Correct clean up and sanitizing procedures (SSOP).	
	C: Excessive organic acid	No	SOP for preparing organic acid rinse solution makes hazard unlikely. Organic acid used is food-grade	Organic Acid Dip preparation and application procedures in accordance with manufacturer's instruction (Organic Acid Dip SOP)	No
	P: none				No
Cutting/ Fabrication	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Pathogen introduction and growth are not reasonably likely to occur at this step. Carcasses are moved rapidly enough to next step to prevent pathogen growth during this step.	**(1)** Correct clean up and sanitizing procedures (SSOP). Temperature control of product (Product Temperature Control SOP)	No
	C: none				No
	P: none				No

Packaging and Labeling	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) Yes (Growth)	Pathogen growth may occur if product is not handled properly.	Correct clean up and sanitizing procedures (SSOP). Temperature control of product (Product Temperature Control SOP) Label includes proper handling and cooking instructions.	**Yes CCP 3-B**
	C: none				No
	P: none				No
Finish Product Refrigerated Storage	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Pathogen introduction and growth is not reasonably likely at this step.	Time and temperature control (SOP for temperature controlled storage) Product is handled according to SOP for Finished Product Storage	No
	C: none				No
	P: none				No

Distribution	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Pathogen introduction and growth is not reasonably likely at this step.	Time and temperature control (SOP for temperature controlled storage)	No
	C: none				No
	P: none				No
Returned Product	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Product has been outside of the control of the establishment.	Product will be disposed of according to disposal SOP.	No
	C: Presence of contaminant and/ or allergen	No	Product has been outside of the control of the establishment.	Product will be disposed of according to disposal SOP.	No
	P: Foreign Material	No	Product has been outside of the control of the establishment.	Product will be disposed of according to disposal SOP.	No

HACCP Plan	
Establishment's Name: Mino Wiisinidaa	**Intended Use to Consumer:** To be cooked
Establishment's Address: 123 Wiigwaas Ave. Odanah, WI 54861	**Product Description:** Raw, Refrigerated, Wild Harvested Poultry, Breast Meat
	Method of Storage & Distribution: Refrigerated truck delivery to retail outlets

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Trim Zero Tolerance 1-B	Pathogens: Salmonella; E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Zero visible fecal material, or ingesta, present	visible fecal material, or ingesta present	visual inspection	Each carcass	Shift Leader or other trained designee	Fecal material, or ingesta will be trimmed away until Trim Zero Tolerance is achieved or the carcass is rejected and disposed. Shift Leader will retrain Trim employee to prevent recurrence or adjust process.	Daily review of trim log by Facility Manager or designee	• Training log • Trim log • Rejection and Disposal log • Corrective action log • Verification reports

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Trim Zero Tolerance 1-P	Shot Pellets	Zero visible pellets	Number of visible pellets	visual inspection	Each carcass and	Shift Leader or other trained designee	Visible pellets will be removed. Shift Leader will retrain Trim employee employee to prevent recurrence or adjust process.	Daily review of trim log by Facility Manager or designee	• Training log • Trim log • Rejection and Disposal log • Corrective action log • Verification reports
Organic Acid Dip 2-B	Pathogens: Salmonella, Campyl-obacter spp.	Each carcass is dipped thoroughly in accordance with the Organic Acid Dip SOP.	Pathogen reduced to a non-detectable level	Organic acid application is prepared and applied to carcass according to the Organic Acid Dip SOP.	Each carcass	Trained Dip Applicator other trained designee	The cause of misapplication will be identified and eliminated. Affected carcasses will be washed and receive a second application. Any meat suspected of misapplication that cannot be reconditioned will be disposed of.	Daily review of organic acid dip log by Shift Leader or designee	• Training log • Organic acid dip log • Corrective action log • Verification reports • Purchasing records and Safety Data Sheet • Organic Acid Dip SOP

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Labeling 3-B	Pathogen growth due to unsafe handling and improper cooking	Correct label affixed to each finished product package	Label containing safe handling instructions and "cook through to 165°F internal temperature"	Visual inspection	Each package	Trained packing employee	Remove and replace labels from mislabeled product prior to storing in refrigerator	Daily review of labelling logs by Shift Leader or designee	• Training logs • Labelling inspection log • Corrective action reports • Verification reports • Purchasing records including copy of label purchased
Signature:					**Print Name:**				

Duck Model HACCP Plan

Raw, Whole

PRODUCT DESCRIPTION

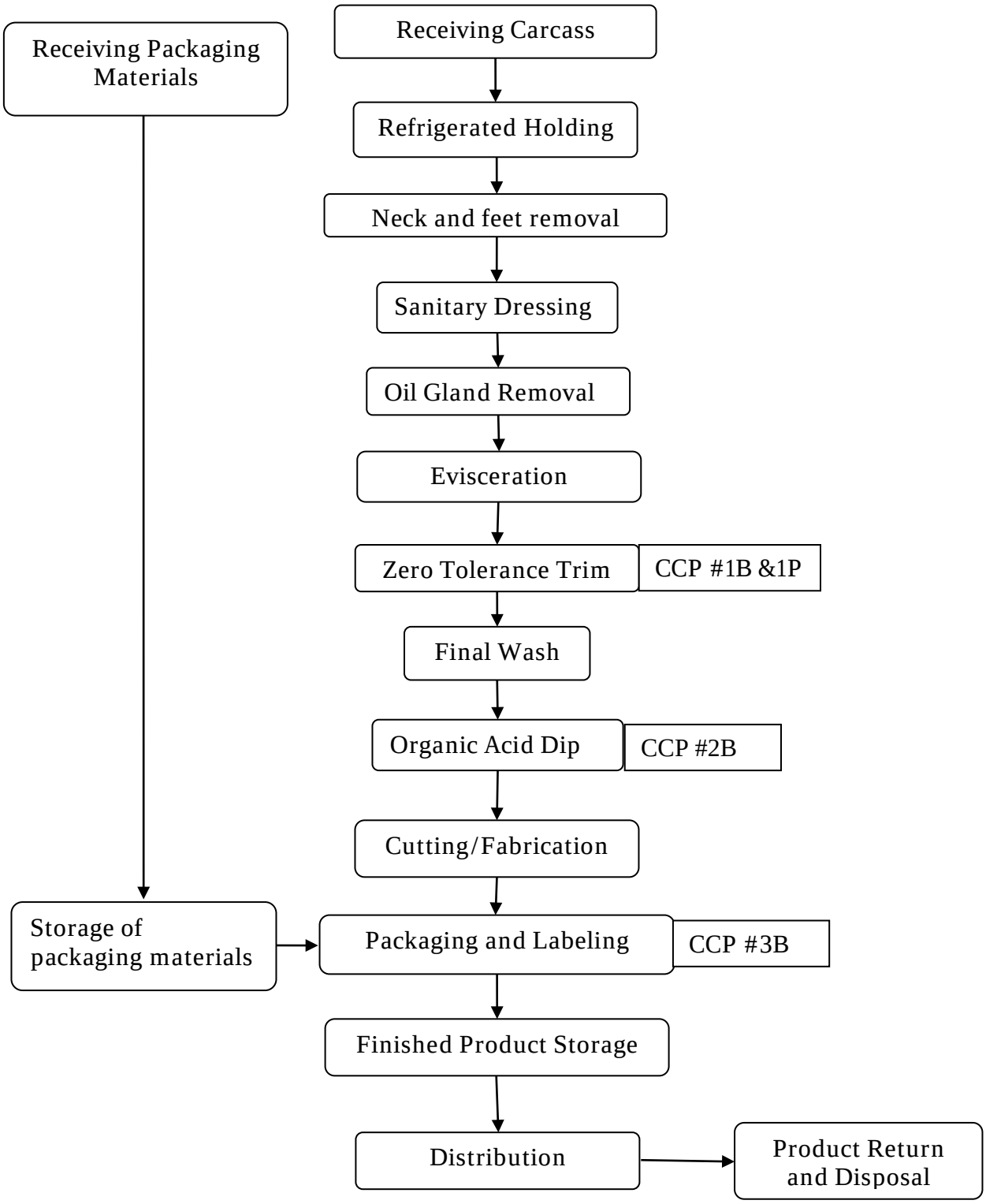
Establishment's Name	Mino Wiisinidaa
Establishment's Address	123 Wiigwaas Ave. Odanah, WI 54861

Product Name	Wild Harvested, Duck
Brief Description	Raw, Refrigerated, Duck, Breast Meat
Ingredients	Duck (*Anas platyrhynchos*)
Allergens	None
Packaging	Food safe tray, moisture absorbent pad, plastic wrap
Distribution	Refrigerator truck delivery to retail outlets
Intended Use	To be cooked
Target Consumer	General Public

Date: 02/25/2019

HACCP Team Member(s)	Position	Signature
John Doe	Owner	John Doe

Process Flow Diagram



Hazard Analysis Worksheet	
Establishment's Name: Mino Wiisinidaa	**Intended Use to Consumer:** To be cooked
Establishment's Address: 123 Wiigwaas Ave. Odanah, WI 54861	**Product Description:** Raw, Refrigerated, Wild Harvested Poultry, Breast Meat
	Method of Storage & Distribution: Refrigerated truck delivery to retail outlets

(1) Processing Step	(2) List all potential biological, chemical, & physical food safety hazards that could be associated with this product & Process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Receiving Packaging Materials	**B:** Contamination with biological material and pathogens	No	Materials are purchased from approved sources. Proper receiving procedures.	Proper receiving procedures (SOP). Letter of guarantee for materials purchased.	No
	C: Non-food grade materials or allergens	No	Materials are purchased from approved sources. Proper receiving procedures.	Proper receiving procedures (SOP). Letter of guarantee for materials purchased.	No
	P: Foreign material	No	Materials are purchased from approved sources. Proper receiving procedures.	Proper receiving procedures (SOP). Letter of guarantee for materials purchased.	No
Storage of Packing Materials	**B:** Contamination with biological material and pathogens	No	Storage area kept clean	Proper storage procedures (SOP)	No
	C: Non-food grade materials or allergens	No	Storage area kept clean	Proper storage procedures (SOP)	No
	P: Foreign material	No	Storage area kept clean	Proper storage procedures (SOP)	No

Receiving and Weighing Carcass	**B:** Pathogens: Salmonella, Campylobacter spp.	No	Raw meat and animal feathers are known sources of pathogens. Carcass is received from an approved Harvester.	Letter of guaranty from Harvester documenting animal health at time of harvest and transport makes hazard unlikely to occur.	No
	C: Lead	No	Poultry harvested with lead ammunition is likely to contain lead (GLIFWC Addendum on file). Poultry harvested with lead ammunition will be rejected.	none	No
	P: Shot Pellets	Yes	Poultry harvested with shot is likely to contain shot pellets.	Hazard will be controlled by later CCP that removes shot pellets that pose a physical risk.	No

Refrigerated Holding	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Pathogen introduction and growth is not reasonably likely at this step.	Time and temperature control (SOP for temperature controlled storage). Correct clean up and sanitizing procedures (SSOP).	No
	C: none				No
	P: none				No
Head and Feet Removal	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	Yes (Introduction) No (Growth)	Skin opening and removal of head or feet may introduce pathogens onto the carcass. Head and feet are processed rapidly enough to next step to prevent pathogen growth.	Correct practices for production and processing controls (SOP) control growth. Introduction pathogens controlled at CCP 2-B. Correct clean up and sanitizing procedures (SSOP).	No
	C: none				No
	P: none				No
Sanitary Dressing	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	Yes (Introduction) No (Growth)	Skin opening and removal of head or feet may introduce pathogens onto the carcass. Sanitary dressing practices incorporate a quick skin	Correct practices for production and processing controls (SOP) control growth.	No

Sanitary Dressing (cont.)			removal and carcasses are moved rapidly enough to next step to prevent pathogen growth.	Introduction pathogens controlled at CCP 2-B. Correct clean up and sanitizing procedures (SSOP).	
	C: none				No
	P: none				No
Oil Gland Removal	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	Yes (Introduction) No (Growth)	Skin opening and removal of head or feet may introduce pathogens onto the carcass. Oil gland remove is done quickly and carcasses are moved rapidly enough to next step to prevent pathogen growth.	Correct practices for production and processing controls (SOP) control growth. Introduction pathogens controlled at CCP 2-B. Correct clean up and sanitizing procedures (SSOP).	No
	C: none				No
	P: none				No
Trim Zero Tolerance	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Pathogen introduction is not reasonably likely to occur at this step. Carcass are moved rapidly enough to next step to prevent pathogen growth during this step.	All visible fecal material, ingesta, and visible contaminants are trimmed off carcasses and organ meats as required by insert model code section. Correct	**Yes CCP 1-B**

Trim Zero Tolerance (cont.)				clean up and sanitizing procedures (SSOP).	
	C: none				No
	P: bullet fragment	Yes	Animals harvested with a shot ammunition may contain shot in the meat.	Meat will be inspected for visible shot. All visible shot will be removed.	**Yes CCP 1-P**
Final wash	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Pathogen introduction is not reasonably likely to occur at this step. Carcass are moved rapidly enough to next step to prevent pathogen growth during this step.	Correct clean up and sanitizing procedures (SSOP).	No
	C: none				No
	P: none				No
Organic Acid Dip	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Pathogen introduction and growth are not reasonably likely to occur at this step.	Organic Acid Dip treatments are well known to reduce pathogen numbers. Organic acid Dip prepared and applied according to the Organic Acid Dip SOP will reduce pathogen	**Yes CCP 2-B**

Organic Acid Dip (cont.)				numbers to non-detectable level. Correct clean up and sanitizing procedures (SSOP).	
	C: Excessive organic acid	No	SOP for preparing organic acid rinse solution makes hazard unlikely. Organic acid used is food-grade	Organic Acid Dip preparation and application procedures in accordance with manufacturer's instruction (Organic Acid Dip SOP)	No
	P: none				No
Cutting/ Fabrication	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Pathogen introduction and growth are not reasonably likely to occur at this step. Carcasses are moved rapidly enough to next step to prevent pathogen growth during this step.	**(1)** Correct clean up and sanitizing procedures (SSOP). Temperature control of product (Product Temperature Control SOP)	No
	C: none				No
	P: none				No

Packaging and Labeling	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) Yes (Growth)	Pathogen growth may occur if product is not handled properly.	Correct clean up and sanitizing procedures (SSOP). Temperature control of product (Product Temperature Control SOP) Label includes proper handling and cooking instructions.	**Yes CCP 3-B**
	C: none				No
	P: none				No
Finish Product Refrigerated Storage	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Pathogen introduction and growth is not reasonably likely at this step.	Time and temperature control (SOP for temperature controlled storage) Product is handled according to SOP for Finished Product Storage	No
	C: none				No
	P: none				No

Distribution	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Pathogen introduction and growth is not reasonably likely at this step.	Time and temperature control (SOP for temperature controlled storage)	No
	C: none				No
	P: none				No
Returned Product	**B:** Pathogen introduction and growth (Salmonella and Campylobacter spp.)	No (Introduction) No (Growth)	Product has been outside of the control of the establishment.	Product will be disposed of according to disposal SOP.	No
	C: Presence of contaminant and/ or allergen	No	Product has been outside of the control of the establishment.	Product will be disposed of according to disposal SOP.	No
	P: Foreign Material	No	Product has been outside of the control of the establishment.	Product will be disposed of according to disposal SOP.	No

HACCP Plan	
Establishment's Name: Mino Wiisinidaa	**Intended Use to Consumer:** To be cooked
Establishment's Address: 123 Wiigwaas Ave. Odanah, WI 54861	**Product Description:** Raw, Refrigerated, Wild Harvested Poultry, Breast Meat
	Method of Storage & Distribution: Refrigerated truck delivery to retail outlets

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Trim Zero Tolerance 1-B	Pathogens: Salmonella; E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Zero visible fecal material, or ingesta, present	visible fecal material, or ingesta present	visual inspection	Each carcass	Shift Leader or other trained designee	Fecal material, or ingesta will be trimmed away until Trim Zero Tolerance is achieved or the carcass is rejected and disposed. Shift Leader will retrain Trim employee to prevent recurrence or adjust process.	Daily review of trim log by Facility Manager or designee	• Training log • Trim log • Rejection and Disposal log • Corrective action log • Verification reports

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Trim Zero Tolerance 1-P	Shot Pellets	Zero visible pellets	Number of visible pellets	visual inspection	Each carcass and	Shift Leader or other trained designee	Visible pellets will be removed. Shift Leader will retrain Trim employee employee to prevent recurrence or adjust process.	Daily review of trim log by Facility Manager or designee	• Training log • Trim log • Rejection and Disposal log • Corrective action log • Verification reports
Organic Acid Dip 2-B	Pathogens: Salmonella, Campyl-obacter spp.	Each carcass is dipped thoroughly in accordance with the Organic Acid Dip SOP.	Pathogen reduced to a non-detectable level	Organic acid application is prepared and applied to carcass according to the Organic Acid Dip SOP.	Each carcass	Trained Dip Applicator other trained designee	The cause of misapplication will be identified and eliminated. Affected carcasses will be washed and receive a second application. Any meat suspected of misapplication that cannot be reconditioned will be disposed of.	Daily review of organic acid dip log by Shift Leader or designee	• Training log • Organic acid dip log • Corrective action log • Verification reports • Purchasing records and Safety Data Sheet • Organic Acid Dip SOP

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Labeling 3-B	Pathogen growth due to unsafe handling and improper cooking	Correct label affixed to each finished product package	Label containing safe handling instructions and "cook through to 165°F internal temperature"	Visual inspection	Each package	Trained packing employee	Remove and replace labels from mislabeled product prior to storing in refrigerator	Daily review of labelling logs by Shift Leader or designee	• Training logs • Labelling inspection log • Corrective action reports • Verification reports • Purchasing records including copy of label purchased
Signature:					**Print Name:**				

Harvester Model HACCP Plan

Deer Harvest

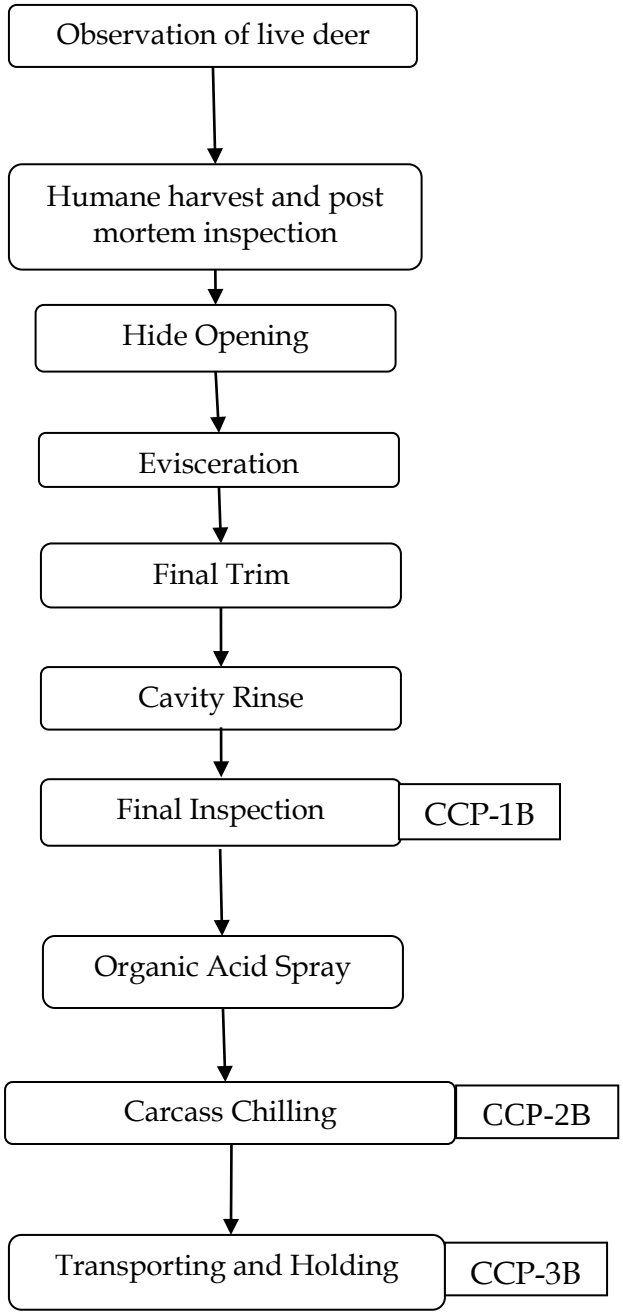
PRODUCT DESCRIPTION

Establishment's Name	Mino Wiisinidaa
Establishment's Address	123 Wiigwaas Ave. Odanah, WI 54861

Common Name	Whitetail Deer Carcass or Venison Carcass (*Odocoileus virginianus*)
How is it to be Used	As whole carcass. Further fabrication and processing to be done by consumer.
Allergens	None
Packaging	Carcass- Not applicable
Length of Shelf-life	14-21 days at 32°F-36°F
Distribution Needs	Maintain below 40°F
Where Will it be Sold	Wholesale

Date: 02/25/2019		
HACCP Team Member(s)	**Position**	**Signature**
John Doe	Owner	John Doe

Process Flow Diagram



HAZARD ANALYSIS DEER HARVEST

Establishment's Name: Mino Wiisinidaa	**Intended Use:** Further fabrication and processing
Establishment's Address: 123 Wiigwass Ave. Odanah, WI 54861	**Product:** Deer/Venison Carcass
	Target Consumer: Wholesale

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Observation of live deer	B: none	No	Animals showing signs of disease are not accepted for harvest per, Chapter 5.01 of the Model Food Code.		No
	C: none	No	Animals showing signs of disease are not accepted for harvest per, Chapter 5.01 of the Model Food Code.		No
	P: none	No	Animals showing signs of disease are not accepted for harvest per, Chapter 5.01 of the Model Food Code.		No

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Humane harvest	**B:** Introduction or growth Pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Yes (Introduction) No (growth)	Pathogens maybe introduced into animal's circulatory system by harvest instrument.	GMP for production and process controls. Correct sanitation and operational procedures for slaughter environment. Potential pathogen introduction and growth will be addressed at a later step: CCP-1B	1) No
	C: None	No			No
	P: Bullet fragments	Yes	Deer harvested with ammunition is likely to contain bullet fragmentation.	Utilizing ammunition with lower fragmentation rates. Bullet and fragments are removed by processor during processing.	No
Post Mortem Inspection	B: 1) Introduction or growth Pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC) 2) Evidence of zoonotic disease.	1) No (Introduction) Yes (growth) 2) No (zoonotic disease)	1) Potential pathogen growth at this step can occur if proper procedures are not followed 2) Animals showing signs of disease will be deemed unfit for human consumption and properly disposed.	Post Mortem Inspection SOP Diseased animal disposal SOP	1) No 2) No

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Post Mortem Inspection (cont.)	C: none	No	Animals showing signs of chemical contamination are not accepted for harvest per, Chapter 5.01 of the Model Food Code.		No
	P: none	No	Animals showing signs of previous injury where a physical hazard may remain (e.g. shot pellets) are not accepted for harvest per, Chapter 5.01 of the Model Food Code.		No
Hide Opening	**B:** Introduction or growth of pathogens: : Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Yes (Introduction) No (Growth) No	Potential fecal contamination during this step can occur.	GMP for production and process controls. Correct sanitation and operational procedures (SSOP) for slaughter environment. Potential pathogen introduction and growth will be addressed at a later step: CCP-1B	No

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Hide Opening (cont.)	**C:** Residues from cleaners or sanitizer	No	Residues from cleaners or sanitizers may remain if proper procedures are not followed or completed.	SSOP includes correct cleaning and sanitizing procedures.	No
	P: None	No			No
Evisceration	**B:** Introduction or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Yes (Introduction) No (Growth) No	Potential fecal contamination during this step can occur.	GMP for production and process controls. Correct sanitation and operational procedures (SSOP) for slaughter environment. Potential pathogen introduction and growth will be addressed at a later step: CCP-1B	No
	C: Residues from cleaners or sanitizer	No	Residues from cleaners or sanitizers may remain if proper procedures are not followed	SSOP includes correct cleaning and sanitizing procedures.	No
	P: None	No			No

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Final Trim	**B:** Introduction or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	No (Introduction) No (Growth) No	Potential fecal contamination during this step can occur.	Final Trim procedure (SOP) Final Inspection performed GMP for production and processing controls Correct sanitation and operational procedures (SSOP) for slaughter environment. Potential pathogen introduction and growth will be and growth will be addressed at a later step: CCP-1B	No
	C: Residues from cleaners or sanitizer	No	Residues from cleaners or sanitizers may remain if proper procedures are not followed	SSOP includes correct cleaning and sanitizing procedures.	No
	P: None.	No			No
Cavity Rinse	**B:** Introduction or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Yes (Introduction) No (Growth)	Potential fecal contamination during this step can occur.	GMP for production and process controls. Correct sanitation and operational procedures (SSOP) for slaughter environment.	No

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Cavity Rinse (cont.)	**B:** (continued)			Potential pathogen introduction and growth will be addressed at a later step: CCP-1B	
	C: Residues from cleaners or sanitizer	No	Residues from cleaners or sanitizers may remain if proper procedures are not followed	SSOP includes correct cleaning and sanitizing procedures.	No
	P: None	No			No
Final Inspection	**B:** Introduction or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Yes (Introduction) Yes (Growth) No	Potential pathogen introduction and growth from previous processes must be addressed here	Final inspection is performed according to Final Inspection SOP GMP for production and process controls. Correct sanitation and operational procedures (SSOP) for slaughter environment.	Yes – CCP 1B
	C: Residues from cleaners or sanitizer	No	Residues from cleaners or sanitizers may remain if proper procedures are not followed	SSOP includes correct cleaning and sanitizing procedures.	No
	P: None	No			No

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Organic Acid Spray	**B:** Introduction or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	No (Introduction) No (Growth)	Pathogen introduction and growth is not a potential during this process	Proper preparation and application of Organic Acid Spray (SOP) GMP for production and processing controls Correct sanitation and operational procedures (SSOP) for slaughter environment.	No
	C: Residue from organic acid spray	No	Organic acid spray have the potential of being left behind if correct procedures are not followed	Proper preparation and mixing of Organic Acid Spray (SOP) Proper application of Organic Acid Spray procedures (SOP)	No
	P: None	No			No
Carcass Chilling	**B:** Introduction or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 (STEC)	No (Introduction) Yes (Growth)	Pathogen growth is a potential during this processing step	Carcass Chilling SOP GMP for production and processing controls	Yes- CCP 2B
	C: Residues from cleaners or sanitizer	No	Residues from cleaners or sanitizers may remain if proper procedures are not followed	SSOP includes correct cleaning and sanitizing procedures.	No
	P: None	No			No

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Transporting and Holding	**B:** Introduction or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	No (Introduction) Yes (Growth)	Pathogen growth is a potential during this processing step	Cooler Temperature SOP GMP for production and processing controls	Yes- CCP 3B
	C: Residues from cleaners or sanitizer	No	Residues from cleaners or sanitizers may remain if proper procedures are not followed	SSOP includes correct cleaning and sanitizing procedures.	No
	P: None	No			No

HACCP PLAN DEER HARVEST

Establishment's Name: Mino Wiisinidaa	**Intended Use:** Further fabrication and processing
Establishment's Address: 123 Wiigwass Ave. Odanah, WI 54861	**Product:** Deer/Venison Carcass **Target Consumer:** Wholesale

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Final Inspection 1-B	Pathogens: Salmonella; E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Zero visible fecal material, ingesta, milk, or debris present	visible fecal material, ingesta, milk, or debris present	visual inspection	Each carcass cavity	Harvester or other trained designee	Fecal material, ingesta, milk, or debris will be trimmed or rinsed away until zero fecal material, ingesta, milk, or debris remains in the carcass cavity. Harvester will retrain designee to prevent recurrence or adjust process.	Review of Final Inspection log by Receiving Staff at Processing Facility	• Training log • Final Inspection log • Disposal log • Corrective Action log • Verification reports

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Carcass Chilling 2B	Pathogens: Salmonella; E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Temperature of carcass will be less than 40°F within 24 hours of Humane Harvest	Internal Temperature of Carcass	Hand Held Probe Thermometer	Each Carcass	Harvester or other trained designee	Carcass is deemed unfit for human consumption and disposed.	Review of Carcass Chilling Temperature log and Disposal Log by Receiving Staff at Processing Facility	• Training log • Carcass Chilling Temperature log • Disposal log • Corrective Action log • Verification reports • Ice receipt (if used)

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Transport and Holding 3B	Pathogens: Salmonella; E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Temperature of cooler will be less than 40°F	Internal temperature of cooler	Refrigerator thermometer	Every 4 hours	Harvester or other trained designee	Internal temperature of carcass is checked and recorded. Ice is add. Cooler temperature and internal carcass temperature are cooled to 40°F or less, within 1 hour. Carcasses remaining above 40°F after 1 hour will be disposed.	Review of Cooler log by Receiving Staff at Processing Facility	• Training log • Cooler log • Disposal log • Corrective Action log • Verification reports • Ice receipt (if used)
Signature:					Print Name:				

Harvester Model HACCP Plan

Rabbit or Snowshoe Hare Harvest

PRODUCT DESCRIPTION

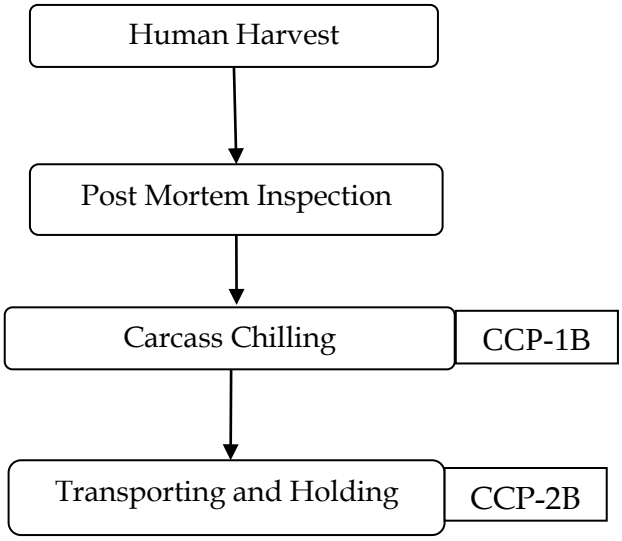
Establishment's Name	Mino Wiisinidaa
Establishment's Address	123 Wiigwaas Ave. Odanah, WI 54861

Common Name	Wild Rabbit (*Sylvilagus floridanus*) or Snowshoe Hare Carcass (*Lepus americanus*)
How is it to be Used	As whole carcass. Further fabrication and processing to be done by consumer.
Allergens	None
Packaging	Carcass- Not applicable
Length of Shelf-life	14-21 days at 32°F-36°F
Distribution Needs	Maintain below 40°F
Where Will it be Sold	Wholesale

Date: 02/25/2019

HACCP Team Member(s)	Position	Signature
John Doe	Owner	John Doe

Process Flow Diagram



HAZARD ANALYSIS RABBIT OR SNOWSHOE HARE HARVEST

Establishment's Name: Mino Wiisinidaa	**Intended Use:** Further fabrication and processing
Establishment's Address: 123 Wiigwass Ave. Odanah, WI 54861	**Product:** Rabbit or Snowshoe Hare
	Target Consumer: Wholesale

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Humane harvest	B: 1) Introduction or growth pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC) 2) Evidence of zoonotic disease.	1) No (Introduction) Yes (growth) 2) No (zoonotic disease)	1)Pathogen growth is a potential during this processing step 2) Animals showing signs of disease will be deemed unfit for human consumption and properly disposed.	Snaring SOP GMP for production and process controls. Potential pathogen introduction and growth will be addressed at a later step: CCP-1B Diseased animal disposal SOP	1) No 2) No
	C: None	No			No
	P: None	No	Animal is harvested by snare.		No

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Post Mortem Inspection	B: none	No	Animals showing signs of disease are not accepted for harvest per, Chapter 5.01 of the Model Food Code.	Post Mortem Inspection SOP Correct sanitation and operational procedures for slaughter environment.	No
	C: none	No	Animals showing signs of chemical contamination are not accepted for harvest per, Chapter 5.01 of the Model Food Code.		No
	P: none	No	Animals showing signs of previous injury where a physical hazard may remain (e.g. shot pellets) are not accepted for harvest per, Chapter 5.01 of the Model Food Code.		No

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Carcass Chilling	**B:** Introduction or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 (STEC)	No (Introduction) Yes (Growth)	Pathogen growth is a potential during this processing step	Carcass Chilling SOP GMP for production and processing controls	Yes- CCP 1B
	C: Residues from cleaners or sanitizer	No	Residues from cleaners or sanitizers may remain if proper procedures are not followed	SSOP includes correct cleaning and sanitizing procedures.	No
	P: None	No			No
Transporting and Holding	**B:** Introduction or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	No (Introduction) Yes (Growth)	Pathogen growth is a potential during this processing step	Cooler Temperature SOP GMP for production and processing controls	Yes- CCP 2B
	C: Residues from cleaners or sanitizer	No	Residues from cleaners or sanitizers may remain if proper procedures are not followed	SSOP includes correct cleaning and sanitizing procedures.	No
	P: None	No			No

HACCP PLAN RABBIT OR SNOWSHOE HARE HARVEST

Establishment's Name: Mino Wiisinidaa	**Intended Use:** Further fabrication and processing
Establishment's Address: 123 Wiigwass Ave. Odanah, WI 54861	**Product:** Rabbit or Snowshoe Hare Carcass **Target Consumer:** Wholesale

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Carcass Chilling 1B	Pathogens: Salmonella; E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Temperature of carcass will be less than 40°F within 24 hours of Humane Harvest	Internal Temperature of Carcass	Hand Held Probe Thermometer	Each Carcass	Harvester or other trained designee	Carcass is deemed unfit for human consumption and disposed.	Review of Carcass Chilling Temperature log and Disposal Log by Receiving Staff at Processing Facility	• Training log • Carcass Chilling Temperature log • Disposal log • Corrective Action log • Verification reports • Ice receipt (if used)

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Transport and Holding 2B	Pathogens: Salmonella; E. coli 0157:H7, non-O157 Shiga-toxigenic E. coli (STEC)	Temperature of cooler will be less than 40°F	Internal temperature of cooler	Refrigerator thermometer	Every 4 hours	Harvester or other trained designee	Internal temperature of carcass is checked and recorded. Ice is add. Cooler temperature and internal carcass temperature are cooled to 40°F or less, within 1 hour. Carcasses remaining above 40°F after 1 hour will be disposed.	Review of Cooler log by Receiving Staff at Processing Facility	• Training log • Cooler log • Disposal log • Corrective Action log • Verification reports • Ice receipt (if used)
Signature:					Print Name:				

Harvester Model HACCP Plan

Wild Poultry Harvest

PRODUCT DESCRIPTION

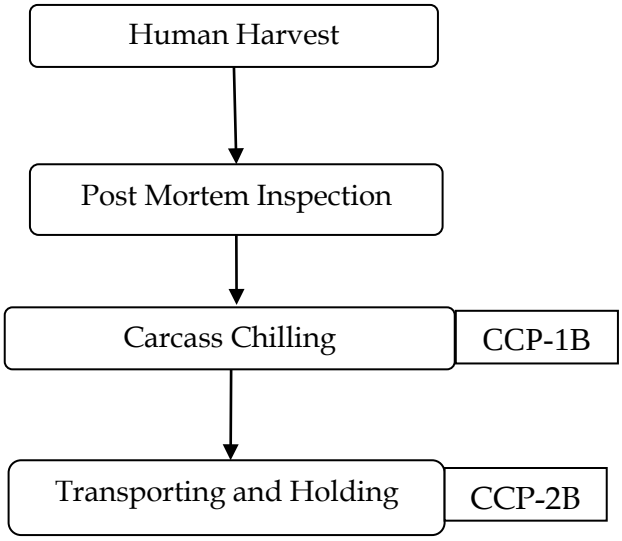
Establishment's Name	Mino Wiisinidaa
Establishment's Address	123 Wiigwaas Ave. Odanah, WI 54861

Common Name	Wild Poultry e.g. Turkey (*Meleagris gallopavo*) or Duck (*Anas platyrhynchos*)
How is it to be Used	As whole carcass. Further fabrication and processing to be done by consumer.
Allergens	None
Packaging	Carcass- Not applicable
Length of Shelf-life	14-21 days at 32°F-36°F
Distribution Needs	Maintain below 40°F
Where Will it be Sold	Wholesale

Date: 02/25/2019

HACCP Team Member(s)	Position	Signature
John Doe	Owner	John Doe

Process Flow Diagram



HAZARD ANALYSIS WILD POULTRY HARVEST

Establishment's Name: Mino Wiisinidaa	**Intended Use:** Further fabrication and processing
Establishment's Address: 123 Wiigwass Ave. Odanah, WI 54861	**Product:** Wild Poultry e.g. Turkey or Duck
	Target Consumer: Wholesale

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Observation of live bird	**B:** none	No	Animals showing signs of disease are not accepted for harvest per, Chapter 5.01 of the Model Food Code.		No
	C: none	No	Animals showing signs of disease are not accepted for harvest per, Chapter 5.01 of the Model Food Code.		No
	P: none	No	Animals showing signs of disease are not accepted for harvest per, Chapter 5.01 of the Model Food Code.		No

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Humane harvest	**B:** Introduction or growth pathogens: Salmonella and Campylobacter	Yes (Introduction) No (growth)	Pathogens maybe introduced into animal's circulatory system by harvest instrument.	GMP for production and process controls. Potential pathogen introduction and growth will be addressed at a later step: CCP-1B	No
	C: None	No			No
	P: Shot pellets	Yes	Poultry harvested with ammunition is likely to contain bullet fragmentation.	Utilizing ammunition with lower fragmentation rates. Bullet and fragments are removed by processor during processing.	No
Post Mortem Inspection	**B:** 1) Introduction or growth Pathogens: Salmonella and Campylobacter 2) Evidence of zoonotic disease.	1) No (Introduction) Yes (growth) 2) No (zoonotic disease)	1) Potential pathogen growth at this step can occur if proper procedures are not followed 2) Animals showing signs of disease will be deemed unfit for human consumption and properly disposed.	Post Mortem Inspection SOP Diseased animal disposal SOP	1) No 2) No

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Post Mortem Inspection (cont.)	**C:** none	No	Animals showing signs of chemical contamination are not accepted for harvest per, Chapter 5.01 of the Model Food Code.		No
	P: Bullet fragment or shot pellet	No	Animals showing signs of previous injury where a physical hazard may remain will be documented for removal during processing.		No
Carcass Chilling	**B:** Introduction or growth of pathogens: Salmonella and E. coli 0157:H7, non-O157 (STEC)	No (Introduction) Yes (Growth)	Pathogen growth is a potential during this processing step	Carcass Chilling SOP GMP for production and processing controls	Yes- CCP 1B
	C: Residues from cleaners or sanitizer	No	Residues from cleaners or sanitizers may remain if proper procedures are not followed	SSOP includes correct cleaning and sanitizing procedures.	No
	P: None	No			No

(1) Processing Step	(2) List all potential Biological, Chemical, & Physical food safety hazards that could be associated with this product & process	(3) Is this potential food safety hazard significant (introduced, enhanced, or eliminated) at this step? (Yes or No)	(4) Justify the decision that you made in column 3	(5) What control measure(s) can be applied to prevent, eliminate, or reduce this significant hazard?	(6) Is this step a Critical Control Point (Yes or No)?
Transporting and Holding	**B:** Introduction or growth of pathogens: Salmonella and and Campylobacter	No (Introduction) Yes (Growth)	Pathogen growth is a potential during this processing step	Cooler Temperature SOP GMP for production and processing controls	Yes- CCP 2B
	C: Residues from cleaners or sanitizer	No	Residues from cleaners or sanitizers may remain if proper procedures are not followed	SSOP includes correct cleaning and sanitizing procedures.	No
	P: None	No			No

HACCP PLAN WILD POULTRY HARVEST

Establishment's Name: Mino Wiisinidaa	**Intended Use:** Further fabrication and processing
Establishment's Address: 123 Wiigwass Ave. Odanah, WI 54861	**Product:** Wild Poultry e.g. Turkey or Duck **Target Consumer:** Wholesale

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Carcass Chilling 1B	Pathogens: Salmonella and Campylobacter	Temperature of carcass will be less than 40°F within 24 hours of Humane Harvest	Internal Temperature of Carcass	Hand Held Probe Thermometer	Each Carcass	Harvester or other trained designee	Carcass is deemed unfit for human consumption and disposed.	Review of Carcass Chilling Temperature log and Disposal Log by Receiving Staff at Processing Facility	• Training log • Carcass Chilling Temperature log • Disposal log • Corrective Action log • Verification reports • Ice receipt (if used)

(1) Critical Control Point (CCP)	(2) Hazard(s)	(3) Critical Limits for each Control Measure	Monitoring				(8) Corrective Action(s)	(9) Verification	(10) Records
			(4) What	(5) How	(6) Frequency	(7) Who			
Transport and Holding 2B	Pathogens: Salmonella and Campylobacter	Temperature of cooler will be less than 40°F	Internal temperature of cooler	Refrigerator thermometer	Every 4 hours	Harvester or other trained designee	Internal temperature of carcass is checked and recorded. Ice is add. Cooler temperature and internal carcass temperature are cooled to 40°F or less, within 1 hour. Carcasses remaining above 40°F after 1 hour will be disposed.	Review of Cooler log by Receiving Staff at Processing Facility	• Training log • Cooler log • Disposal log • Corrective Action log • Verification reports • Ice receipt (if used)
Signature:					Print Name:				

Model Standard Sanitation Operating Procedures

Administrative Structure as follows:

President/Owner: _____ Signature:_____

Manager:_____ Signature:_____

The manager is responsible for implementing and daily monitoring of the Sanitation SOP, and recording the findings and any corrective actions. All records pertaining to this SSOP will be maintained on file and made available to [Establistment's Name and Department] personnel.

Establishment's Name:	Establishment's Address:
Sample Traditional Food Co.	*123 Name Rd.* *Odanah, WI 54861*

Tools and Equipment Standard Sanitation Operation Procedure

SCOPE

Steps for cleaning and sanitizing all food contact tools and surfaces used for harvesting and/ or field dressing wild game for human consumption.

FREQUENCY

- To be performed at the start of each harvest season, within 24 hours of planned harvest activity (e.g. preformed the night prior to a morning hunt).
- After every animal harvested and/or field dressed. For example, if several snares are set and two rabbits are caught, tools must be cleaned twice: 1) after field dressing the first rabbit and 2) after field dressing the second.
- As needed.

PERSONAL PROTECTIVE EQUIPMENT

Wear appropriate personal protective equipment such as gloves, eye protection, apron, etc.

CLEANING

Necessary step to remove dirt, debris, oils, liquids or other materials that may contain or cover pathogens.

1. Wipe tools clean of visible debris and fluids with paper or cloth towels.
2. Rinse all tools with clean water.
3. Wash with warm water and soap. A sponge, brush, towel and/or similar cleaning applicator may be used.
4. Be sure to wash every part of each tool, disassembling tools if necessary. Include handles, hinges, grooves, spouts, lids, and any additional features.
5. Rinse thoroughly with clean, potable water.
6. On a clean, stable surface, allow to air dry completely or dry with a clean, lint free towel.
7. Visually inspect for damage, remaining debris, or residue. Clean again or discard as necessary.

SANITIZING

Option 1: Commercial Sanitizer

1. Follow all manufacturer's instructions and safety procedures.
2. Sanitize in a well-ventilated space and avoid inhaling sanitizer.
3. Mix sanitizer according to manufacturer's instructions, use or other indicator to identify correct solution.
4. Apply sanitizer to each tool per sanitizer manufacturer's instructions. Be sure to apply sanitizer to all parts of each tool, to include handles, grooves, and other features.
5. Allow to dry in accordance with manufacturer's instructions.

Option 2: Chlorine Bleach Solution (Hypochlorite)

1. Use only fragrance free, coloring free, chlorine bleach and room temperature, clean, potable water. Hot water will decrease effectiveness.
2. Never add additional cleaners such as soap or other cleaning agents.
3. Sanitize in a well-ventilated space and avoid inhaling chlorine.
4. Add 1 tablespoon/15 mL/0.5 liquid ounces of bleach to 1 gallon of water to obtain 200 ppm chlorine solution. Chlorine test strips can be used to verify ppm.
5. Use immediately. Solution loses effectiveness within XX hours.
6. Using a clean dry sponge, or similar applicator, apply solution to all parts of each tool, including but not limited to handles, grooves, and other features.
7. Alternatively, smaller tools can be fully submerged in solution for a minimum of one second and then removed. If using this method, test concentration as needed.
8. On a clean, stable surface, allow to air dry completely.
9. Use remaining solution immediately or discard according to chlorine manufacture's directions.

RECORD KEEPING

- The results from testing the concentrations of cleaning solutions are recorded on the Sanitation Test Log immediately following the test.
- Cleaning and sanitizing of cooler is recorded on Daily Sanitation Checklist.

The following individual is responsible for implementation of SSOP:

Name: _____ Date:_____

Position Title: _____

Transport Cooler Standard Sanitation Operation Procedure

SCOPE

Steps for cleaning and sanitizing all transport coolers used for transporting wild game, intact or in quarters, for human consumption.

FREQUENCY

- To be performed at the start of each harvest season, within 24 hours of planned harvest activity (e.g. preformed the night prior to a morning hunt).
- After each use and additionally as needed.

PERSONAL PROTECTIVE EQUIPMENT

Wear appropriate personal protective equipment such as gloves, eye protection, apron, etc.

CLEANING

Necessary step to remove dirt, debris, oils, liquids or other materials that may contain or cover pathogens.

1. Empty cooler(s) of all items.
2. If possible, separate cooler and lid.
3. Rinse inside and outside of cooler and lid with clean potable water.
4. Wash inside and outside of cooler, with warm water and soap, to remove any visible fluids and debris. A sponge, towel or similar cleaning applicator may be used.
5. Be sure to wash every part of the cooler, to include handles, hinges, grooves, spouts, lid, and any additional features. If necessary, use a brush to remove debris from grooves, etc.
6. Rinse thoroughly with clean, potable water.
7. On a clean, stable surface, allow to air dry completely or dry with a clean, lint free towel.
8. Visually inspect for damage, remaining debris, or residue. Clean again or discard as necessary.

SANITIZING

Option 1: Commercial Sanitizer

1. Follow all manufacturer's instructions and safety procedures.
2. Sanitize in a well-ventilated space and avoid inhaling sanitizer.
3. Mix sanitizer according to manufacturer's instructions, use or other indicator to identify correct solution.
4. Apply sanitizer to inside and outside of cooler and lid per sanitizer manufacturer's instructions. Be sure to apply sanitizer to every part of the cooler, to include handles, hinges, grooves, spouts, lid, and any additional features.
5. Allow to dry in accordance with manufacturer's instructions.

Option 2: Chlorine Bleach Solution (Hypochlorite)

1. Use only fragrance free, coloring free, chlorine bleach and room temperature, clean, potable water. Hot water will decrease effectiveness.
2. Never add additional cleaners such as soap or other cleaning agents.
3. Sanitize in a well-ventilated space and avoid inhaling chlorine.
4. Add 1 tablespoon/15 mL/0.5 liquid ounces of bleach to 1 gallon of water to obtain 200 ppm chlorine solution. Use chlorine test strips to verify ppm.
5. Use immediately, do not store for later use. Solution loses effectiveness within XX hours.
6. Using a clean dry sponge, towel, or similar applicator, apply solution to all parts of the cooler, including handles, hinges, grooves, spouts, lid, and any additional features.
7. On a clean, stable surface, allow to air dry completely.
8. Use remaining solution immediately or discard according to chlorine manufacture's directions.

RECORD KEEPING

- The results from testing the concentrations of cleaning solutions are recorded on the Sanitation Test Log immediately following the test.
- Cleaning and sanitizing of cooler is recorded on Daily Sanitation Checklist.

The following individual is responsible for implementation of SSOP:

Name: _____ Date:_____

Position Title: _____

Sanitation Standard Operating Procedures

(Lox)

(Ken Hilderbrand, Oregon State University)

Date: February 22, 1996

To: Employees of Brand Lox Company

From: Kenneth S. Hilderbrand Jr., President

Subject: Sanitation Standard Operating Procedure

Effective immediately, Brand Lox Company is adopting a Sanitation Standard Operating Procedure (SSOP) as described in the Food and Drug Administration's new regulation Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products.

A copy of this SSOP is available in the office, and employees who need a copy will be provided one.

The SSOP does not change the way we will practice sanitation in our plant; it simply documents what we've been doing successfully for some time. So although the FDA regulations do not go into effect until December 18, 1997, the SSOP will be a useful tool for us and there is no reason to wait to adopt it. The SSOP itself is not required by the law, but monitoring sanitation procedures and keeping records is. The SSOP will make it easier to meet these requirements.

BRAND LOX COMPANY

SANITATION STANDARD OPERATING PROCEDURE

EMPLOYEES MUST WASH HANDS BEFORE RETURNING TO WORK	THIS IS A FINISHED PRODUCT AREA ---------- NO RAW PRODUCTS PASSAGEWAY	WASH HANDS BEFORE RETURNING TO WORK
LEAVE SMOCKS AND GLOVES IN PRODUCTION ROOM	WEAR CUT-PROOF GLOVE WHEN TRIMMING DID YOU OPEN/CLOSE THE STRIP DOOR	CORDS ONLY

BRAND LOX

SANITATION STANDARD OPERATING PROCEDURE

drafted 2/8/96 revised 2/22/96

FDA Conformance Requirement:

Sec. 123.11--Sanitation control procedures. (a) Sanitation SOP. Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section. (b) Sanitation monitoring. Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

Company Policy/Procedures:

Although not mandated by the regulations, Brand has written and adopted this Sanitation Standard Operating Procedure (SSOP) believing that it will be a useful document and that it will assist the

company in producing safe products. It will be a "living" document to be revised as needed, based on new technology or production procedures.

Brand's sanitation program will conform, at a minimum with the conditions and practices specified in part 110 (sanitation) of the regulations. Part 110 is attached as Appendix III of this SSOP.

SAFE WATER--SSOP item 1

FDA Conformance Requirement:

(1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice; Existing Conditions:

Brand Lox processing water comes from the Southbeach Utility Board (SUB), a reliable municipal system serving Southbeach, Oregon, meeting all state and federal standards, and complies with the Oregon Drinking Quality Act (ORS 448.119 to 448.285). If a treatment failure occurs, we will be notified by public media, but such a failure is a very remote possibility. SUB has 30 wells spread over several power grids, so only a massive regional power failure could shut down the source of water. There is a 2- to 3-day supply of treated water in the reservoirs most of the time. During peak demand periods, there is a 1- day supply.

Company Policy/Procedures:

In the event of water treatment failure, Brand will immediately stop production, determine when the failure occurred, embargo all product produced during the failure until the nature of the problem is known and products are tested for pathogens if necessary. Only wholesome product will be shipped. Monitoring:

(Semiannual testing) Twice each year, water samples will be submitted to a private testing laboratory for pathogen screening in case some local or in-plant water service line problem should develop. If a water purity problem is discovered, Brand management will stop production and determine the nature and

extent of the problem prior to restarting production or shipping products. Only wholesome product will be shipped.

Record Keeping:

All records and test data pertaining to safety of water will be kept in Brand's SSOP files for 2 years.

CLEAN FOOD CONTACT SURFACES: SSOP item 2

FDA Conformance Requirement:

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

Existing Conditions:

Built in 1991, the Brand facility is a modern processing plant meeting all applicable state codes. It is located in a modern industrial park and is surrounded by paved parking. It complies with part 603-25-020 (General Standards) of Chapter 603, Division 25, Oregon Administrative Rules.

Company Policy/Procedures:

Sanitation procedures at Brand will comply with part 603-25-150 (Food Processing Establishments) of Chapter 603, Division 25, Oregon Administrative Rules.

- Daily
    - All finished product workers are required to wear hair/beard nets, smock, and disposable gloves. Raw product workers also wear waterproof aprons.
    - Food contact surfaces, with the exception of smokehouses, carts, and racks, are cleaned twice each day--once at the midday break, and again at the finish of the shift.
    - Pick up and remove major solid wastes. Tear down slicers.

    - Rinse all surfaces with cold water. Degrease and scrub all surfaces with degreaser. (See Appendix I, List of Approved Sanitizing Chemicals.)
    - Rinse all surfaces with hot water (190 degrees F).
    - Sanitize with Quaternary Ammonia. This food contact-approved sanitizer is squeegeed from surfaces prior to resuming production after the midday break. It is left on overnight at the end of shift cleaning.
    - Floors are freed of solid waste, then rinsed twice each day with hot water (190 degrees F) and sprayed with Quaternary sanitizer.
    - Utensils are cleaned twice each day, once at the midday break and again at the finish of the shift.
    - Clean in deep sink with degreaser (and abrasive cleaner if necessary)
    - Rinse in hot water (190 degrees F) Soak in Quaternary sanitizer
    - Rinse in hot water (190 degrees F) prior to use
    - Outer garments (smocks) for finished-product workers are laundered in-house as needed. In some workspaces, this will be twice per week. Disposable gloves are replaced as needed, normally at each lunch break and at the end of the shift. Raw-product workers wash and sanitize their aprons and gloves twice each day, at midday break and at the end of the shift.
- Weekly
    - Smokehouse and accessory dollies and racks are cleaned on the first day following the end of weekly production (normally a Saturday).
    - Smokehouses and accessories are sprayed with degreaser (see list)
    - Rinse with hot water (190 degrees F).
    - All food contact surfaces are rinsed with Sodium Hypochlorite (100 ppm).
- Bi-weekly
    - Smokehouses and accessories are heated to 200 degrees F for 30 minutes.
- Periodically

- At least once per year, the evaporators in the cooler are cleaned to prevent buildup of biofilms. Monitoring: A cleanup crew and supervisor are identified for daily sanitation. A special crew is employed for weekly (Saturday) cleanup and sanitizing contact surfaces. A post-sanitation cleanup inspection is performed by the supervisor after each cleanup period, and a form is checked off with the supervisor's initials (noting any problems or deviation from company policy) and the date, and is then given to the plant manager for signature and filing.
- Record Keeping: All sanitation inspection sheets and other records are kept in the company SSOP file for 2 years.

Monitoring:

A cleanup crew and supervisor are identified for daily sanitation. A special crew is employed for weekly (Saturday) cleanup and sanitizing contact surfaces. A post sanitation cleanup inspection is performed by the supervisor after each cleanup period and a form is checked off with the supervisors initials (noting any problems or deviation from company policy), dated, and given to the plant manager for signature and filing.

Record Keeping:

All sanitation inspection sheets and others records are kept in the company SSOP file for two years.

PREVENT CROSS-CONTAMINATION - SSOP item 3

FDA Conformance Requirement:

(3) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments; and from raw product to cooked product;

Existing Conditions:

The layout of Brand's processing facility does not lend itself to complete isolation of finished product from raw materials. The facility is, however, designed for ease in cleaning, sanitation, and traffic control.

Company Policy/Procedures:

Brand uses an aggressive sanitation program to remove potentially harmful microorganisms from raw materials prior to their exposure to the plant in unprocessed form. As recommended by Dr. Mel Eklund, National Marine Fisheries Service Utilization Research Division (NMFS), frozen raw materials are thawed in chlorine and isolated in the thaw/fillet rooms until they are ready for brining. By preventing microorganisms from entering the plant environment, sanitation programs become an effective method of eliminating contamination of finished product from raw materials, thereby ensuring complete product safety.

Brand policy does not allow employees from raw-product processing areas to pass through finished-product areas on their way to toilets or lunch rooms. Appropriate signage is in place outside the entrance to finished product areas. Each process area is provided with hand washing and sanitizing facilities.

Monitoring:

The success of Brand's sanitation program is monitored by periodic microbiological evaluation. Several times per year, swab samples from the skin of thawed and rinsed fish are screened for total aerobic plate count and Listeria species. If a Listeria test is ever positive, then species identification will be conducted. Finished products are also screened for total plate count. Numerous tests for the presence of Listeria in the finished product conducted prior to 1996 have all been negative.

Record Keeping:

All microbiological test results will be kept on file for 2 years.

EMPLOYEE HYGIENE - SSOP item 4

FDA Conformance Requirement:

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;

Existing Conditions:

Employee toilet facilities are located off the lunch room. Appropriate signage warns employees to wash hands before returning to work.

Company Policy/Procedures:

Brand company policy is that all employees will wash and sanitize their hands with company-approved antiseptic hand cleaner. In addition, disposable gloves are required. Supervisors are instructed to enforce these policies.

Monitoring:

Supervisors are instructed to enforce hand washing policies, but more important, employees are taught the importance of sanitation to their job.

Record Keeping:

All records related to hand washing and toilet facilities are kept on file for 2 years.

ADULTERATION - SSOP item 5

FDA Conformance Requirement:

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

Company Policy/Procedures:

Bulk quantities of chemicals that are not food grade are stored separate from those that are food grade, and are accessed only by authorized employees. Properly labeled 5-gallon containers of food contact sanitizing chemicals are stored in processing areas at their point of use. Food-grade lubricants are stored outside processing areas and separated from non-food-grade lubricants. Only chemicals listed in Appendix I of this document may be purchased or used at Brand. Only authorized employees may handle these substances.

All packaging materials are stored in the shipping/receiving room and are not exposed to stored chemicals or lubricants.

Monitoring/Record Keeping:

All records pertaining to purchase and use of chemicals will be kept on file for 2 years.

TOXIC COMPOUNDS - SSOP item 6

FDA Conformance Requirement

(6) Proper labeling, storage, and use of toxic compounds.

Existing Conditions:

All bulk quantities of toxic and non-toxic compounds are properly labeled (an OSHA requirement), segregated by food/non-food contact category, and stored outside the process areas. They are accessible to authorized employees only. Bulk quantities of cleaning/sanitizing chemicals are kept in the smoker room with appropriate drip protection. Smaller day-use quantities are kept in the production room, the cooler, and the thaw/fillet room. Lubricants are separated by food/non-food categories and stored in the supply room. Ingredients (salt, sugar, etc.) are stored in a separate storage room off the smoking room.

Company Policy/Procedures:

Only authorized employees are allowed to handle or use toxic compounds.

Monitoring/Record Keeping:

Supervisors are required to be knowledgeable about chemicals used in Brand processes. All records pertaining to chemical use will be kept on file for 2 years.

EMPLOYEE HEALTH - SSOP item 7

FDA Conformance Requirement:

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces.

Existing Conditions:

Brand is a small company with a normal complement of 35 employees (45 maximum) and cannot justify the cost of a nurse.

Company Policy/Procedures:

Employees are instructed to report any health condition that might result in contamination of food or food-contact surfaces. Immediate supervisors are instructed to report suspected health problems to the Plant Manager, who then makes a case-by-case decision about the potential of food contamination. Employees who represent a risk are sent home or reassigned to non-food contact jobs if appropriate.

Monitoring/Record Keeping:

The Plant Manager is responsible for monitoring employee health. All appropriate records will be kept on file for 2 years.

FDA Conformance Requirement:

(8) Exclusion of pests from the food plant.

Existing Conditions:

Brand is located in a relatively vermin-free environment with few outside doors. Plastic curtains screen all processing areas, and bug-killing devices are located outside the entrance to these areas.

Company Policy/Procedures:

Brand contracts with a pest management firm to treat the exterior plant areas once per month in warm weather and every other month in cool weather. They also inspect the interior of the plant and treat as necessary with appropriate chemicals.

Monitoring/Record Keeping:

All supervisory personnel are required to report all pest management problems. Records of pest treatment procedures will be kept on file for 2 years. .

TIMELY ACTION

FDA Conformance Requirement:

The processor shall correct in a timely manner, those conditions and practices that are not met.

Company Policy:

Brand policy is that this SSOP is to be followed and any deviations to be reported to the Plant Manager. The Plant Manager is instructed to correct, in a timely manner, any such deviations from the plan.

RECORD KEEPING

FDA Conformance Requirement:

(c) Sanitation control records. Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of Sec. 123.9.

Company Policy:

A special section of hard-copy files is reserved for all SSOP records, which will be kept for 2 years. The general and minimum requirements of Sec. 123.9 (which is part of this SSOP) will be followed.

HACCP PLAN

FDA Conformance Requirement:

(d) Relationship to HACCP plan. Sanitation controls may be included in the HACCP plan, required by Sec. 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section, they need not be included in the HACCP plan, and vice versa.

Company Policy:

Brand Lox Company chooses not to include sanitation controls as part of its HACCP plan, but instead intends to monitor sanitation in accordance with paragraph (b) of the regulations.

BRAND LOX COMPANY

SANITATION CHECK LIST

Instructions: 1. Place initials by each item OKAYED by inspection/observation (meets SSOP standard)

2. date and sign form
3. return form to Plant Manager
4. keep form on file for 2 years

	Butcher Room	Finish Room	Operations	Ship/Receive
Daily - food contact surfaces, utensils, floors, toilets				
Condition at startup				
Hand-wash facilities				
Midday cleanup				
End-of day-cleanup				
Employee hygiene				
Toilets				
Weekly				
Smokehouse cleaning				
Chlorine rinse				
Bi-weekly				
Smokehouse heating				
Monthly or Bi-monthly				
Pest management				
Periodically				
Cooler evaporators				
Deviations from SSOP and corrective action:				
Reviewed by (Plant Manager):				
Date:				

Appendix I

Chemicals Approved for Use in Brand Lox Facilities

Revised 2/22/96

Sodium Hypochlorite Sanitizer

Brand:	All Pure Nugget Brand 5.25%	
Usage:	Weekly sanitation rinse	100 ppm
	Thaw tanks	30 ppm

Quaternary Ammonium Sanitizer

Brand:	Spartan Sani-T-10	
Usage:	Food contact surfaces, floors	200 ppm
	Disinfecting dip for scrubbers, sponges, utensils	400 ppm

Degreaser/detergent

Brand:	Spartan Inspector's Choice	
Usage:	Food contact surfaces, utensils	1:20 dilution

Smokehouse Cleaner

Brand:	Spartan SC-200	
Usage:	Smokehouse interior surfaces, racks, and screens	1:10 dilution

Hand Cleaner

Brand: Spartan Antiseptic Hand Cleaner
Usage: Toilets and hand cleaning stations in all process areas

Lubricants

Brand: Kasco Lubricoat
Usage: Slicers

Brand: Lyondell Ideal FG HT2 grease (H1)
Brand: Bettcher Ins. Special Whizard grease (H1)
Usage: Slicers

Brand: Terand White Grease Lithium base
Usage: General purpose

Additional Appendices available from Ken Hilderbrand:

APPENDIX III: CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING HUMAN FOOD, PART 110 - SANITATION

APPENDIX IV: PROCEDURES FOR THE SAFE AND SANITARY PROCESSING AND IMPORTING OF FISH AND FISHERY PRODUCTS

APPENDIX V: CROSS REFERENCES

Note: There may be some charges for postage & handling.

Return to Seafood NIC Home Page

Return to Oregon Sea Grant Home Page

Publication No. ORESU-I-97-003

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Sea Grant combines basic research, education, and technology transfer to serve the public. This national network of universities works with others in the private and public sectors to meet the changing environmental, economic, and social needs of people in the coastal, ocean, and Great Lakes regions of the U.S.

Record Templates

Cooler Temperature Log

Name of operation:_____

Cooler number: _____**Thermometer number:**

Please see the Cooler SOP for overall temperature control procedures and thermometer calibration instructions.

Date	Thermometer calibrated date	Recorded temperature		Corrective actions if necessary:	Result of corrective actions and date accomplished	Initials
		AM	PM			

Reviewed by: _____ **Title:** _____ **Date:**_____

*Daily review for meat and meat products.
*Weekly review for fish and fishery products.

Company:
Address:
Daily Sanitation Audit Form p. 1

Sanitation Condition	Start-up Time __:____ Pass/Fail	4 hours Time __:____ Pass/Fail	8 hours Time __:___ Pass/Fail	Observations after 12 hours or Comments/ Corrections
1. Equipment cleaning and sanitizing				
a. Equipment cleaned and sanitized before start-up.				
b. Concentration of sanitizer used for the sanitizing equipment (type/ppm).				
c. Product residue removed during breaks.				
d. Picking utensils (knives, plastic containers) cleaned and sanitized at each weigh-up.				
2. Employee attire				
a. Gloves, hair restraints and aprons clean and in good repair.				
3. Cross contamination				
a. Employees' hands, gloves, equipment and utensils that contact unsanitary objects are washed and sanitized before contacting products.				
b. Employees from raw crab areas do not contact cooked crab surfaces unless hands, gloves and aprons are washed and sanitized; red gloves = cooked.				
4. Handwashing and sanitizing facilities.				
a. Adequate supplies				
b. Conc. of chlorine in hand dips (record ppm).				
Picking room at handwashing station				
Picking room #1, hand dips				
Picking room #2, hand dips				
Packing room				

Daily Sanitation Audit Form

Sanitation Condition	Start-up Time _____ Pass/Fail	4 hours Time _____ Pass/Fail	8 hours Time _____ Pass/Fail	Observations after 12 hours or Comments/ Corrections
5. Protection from adulterants				
a. Cleaning compounds labeled and stored properly. Water chlorinator functioning.				
b. Lubricants labeled and stored properly				
c. Pesticides labeled and stored properly				
d. Product protected from condensate				
e. Product protected from floor splash				
6. Cooler storage				
a. Unpackaged, cooked crab separated from raw product. No significant condensate.				
7. Employee health				
a. Employees do not show signs of medical problems that could compromise product				
8. Toilet facilities				
a. Toilets are clean, supplied with toilet paper and functioning properly				
9. Pests				
a. Pests controlled as required by contract				

Firm Name:_____ Address:_____

Date:_____ Supervisor/Technician:_____

Fresh Ground Venison Production on Log/ Tracking List

Employee Name: _____ Today's Date: _____

Grind Log							Tracking List			
Time of Grind	Lot/ Batch Number (lot = same source material)	Exact Name/ Type of Product Produced	Package Size of Product Produced	Amount (in pounds) of Product Produced	Production Code of Product Produced	Manufacturer, Name of Source Material Used for Product Produced	Supplier Lot Numbers, Product Code and/or Pack Date of Source Material Used	Establishment Information from Label of Source Product Used (Est. #, pH #, contact info)	Grinder Cleaned and Sanitized Between Source Materials? If Yes, Date and Time	Comments

_____ _____

Signature of Store Management Reviewer Date

Finished Product:	Production Lot Number(s):
Production Date/ Time:	Quantity (Pounds) Produced:
Production Operator:	Packing Operator:
Quantity (Cases and Packages) Produced:	UPC/ SKU Number:

Ingredients Used in Batch

Ingredient Name/ Supplier:	Non Venison Weight	Venison Weight	Supplier Lot or Product ID Number/ Est Fed or State

Column Totals: 6 pounds 2 ounces + 10 pounds = Final Weight: 16 pounds 4 ounces

Equipment Sanitation: Note complete prior to start of daily operations. If a further cleaning nd sanitizing is done immediately prior to this batch enter that cleaning and sanitizing event.

Date/ Time Grinder Cleaned/ Sanitized	By Who	Comments	Date/ Time Pack Equipment Cleaned	By Who	Comments

Illness/Injury Report Form

(Completed forms will be collected and kept on file by the supervisor)

Worker Name: _____

Today's Date: _____

Person completing report:_____

Date and Time of First Symptoms:_____

Symptoms: (check all that apply)

_____Fever _____Vomiting _____Diarrhea

_____Respiratory _____Jaundice _____Nausea

_____Sore Throat w/ Fever _____Lesions (on exposed skin)

_____Other (explain below)

Did the employee see a doctor? _____Yes _____No
(If yes, explain diagnosis if relevant and not confidential)

Date employee expects to return to work (or returned to work, if same, and document if employee is assigned to fruit/vegetable handling job or another non-handling job, and for how long.):

_____

Pest/Rodent Control Log

Name of operation:_____

Please see the food safety plan for overall Pest/Rodent control procedures.

Company Used* or self	Date of Service or action taken	Type of Pest	Type of Control**	Location of Traps	Traps Checked (date)	Checked by (name)	Disposal means

*If using a company for service, attach report or receipt of service for each of their visits.
**List type of control methods used such as exclusion, traps, poison, repellants, etc.

Reviewed by:_____ **Title:**_____ **Date:**_____

Establishment Name
Establishment Address
Establishment City, State, Zip Code

Date
Establishment Number

Pre-requisite Program
For Antimicrobial Preparation and Application (*Beef Carcasses and Edible Offal*)

Frequency: Operational Days of Beef Slaughter

Person Responsible: HACCP Coordinator, Production Manager, or Plant Designee

Procedure:

In response to addressing potential *E. coli* O157:H7, and non-O157 adulterant STECs (*i.e.*, O26, O45, O103, O111, O121, and O145) contamination of beef carcasses and edible offal, establishment has developed this program for proper antimicrobial preparation and application.

Antimicrobial Preparation

Establishment purchases food grade lactic acid from a commercial distributor which has an initial concentration of 88% lactic acid.

Water Temperature: Warm water should be used in preparation the lactic acid solution so that the ending solution temperature can be achieved: 55°C (131°F).

Antimicrobial Formulation: Since the initial concentration of the lactic acid is 88%, it must be diluted to achieve the desired 2% lactic acid solution.

Starting concentration = 88% Final volume = 5 liters Final concentration = 2%

Starting volume (liters) × 88% = 5 liters × 2%

$$\text{Starting volume} = \frac{5 \text{ liters} \times 2\%}{88\%}$$

Starting volume = 10 ÷ 88

Starting volume = 0.1136 liters (113.6 ml) concentrated acid

Measure 0.1136 liters (113.6 ml) of the 88% concentrated lactic acid into a plastic container. Then add enough water to make 5 liters of solution.

5 liter – 0.1136 liters = 4.8864 liters tap water

Conversion:

1 liter of water = 0.264 gallons of water

$$\frac{1 \text{ liter of water}}{0.264 \text{ gallons of water}} \times \frac{4.8864 \text{ liters of water}}{1.290 \text{ gallons of water}}$$

1 gallon of water = 8.33 pounds

$$\frac{1 \text{ gallon of water}}{8.33 \text{ pounds}} \times \frac{1.290 \text{ gallons of water}}{10.75 \text{ pounds of water}}$$

Utilizing a 2.0% lactic acid solution, mix the following

- 0.1136 liters (113.6 ml) liters of 88% concentrated lactic acid
- 10.75 pounds of water

Date: _____ Approved by: _____

Use a titration kit to measure acidity (% acid) after preparing a solution of 2% lactic acid. Follow the manufacturer's instructions closely to get a valid measurement. Record the acidity of each batch of 2% lactic acid solution on a record sheet.

Antimicrobial Application

Beef carcass and edible should be rinsed with water.

- Wash carcass/edible offal from top to bottom
- Wash carcass/edible offal with warm water (150°F to 180°F) for 2 minutes
- Nozzle distance from carcass: No more than 12 inches from the carcass/edible offal surface
- Carcasses/edible offal spaced to avoid coming in contact with other carcasses/edible, nearby walls, and other surfaces
- Allow excess water to drip from the carcass/edible offal for at least 5 minutes

After the beef carcasses/edible offal have been allowed to drip for at least 5 minutes, the 2% lactic acid solution can be applied.

- Solution temperature: 55°C (131°F)
- Solution application time: Sufficient application amount sprayed on the carcass/edible offal such that some of it drips off – spray each beef carcass side/edible offal for at least 1 minute
- Nozzle distance from carcass/edible offal: No more than 12 inches from the carcass/edible offal surface
- Spray carcass/edible offal from top to bottom
- Solution application device: Heavy duty, stainless steel spray tank - tank fitted with a 100 psi pressure gauge, 100 psi pressure relief valve, a spray wand with a flat, fan-spray nozzle, and a quick connect plug for rapid pressurization with an air compressor
- Solution application pressure: No pressure indicated in scientific supporting documentation

Using a gentle sweeping motion, apply the lactic acid solution to all surfaces of the beef carcass/edible offal.

Log:

- Pre-requisite Program Log: Antimicrobial Preparation and Application Log (*Beef Carcasses and Edible Offal*)

Reference:

- Antimicrobial Spray Treatments for Red Meat Carcasses Processed in Very Small Meat Establishments. 2005. Author: The Pennsylvania State University.

Sanitation Audit Form

Form used for both daily and monthly sanitation activities

Firm Name: _____ Address:_____

Date:_____ Supervisor/Technician:_____

Sanitation Conditions & Practices	Time Pre-Op Pass/Fail	Time Pass/Fail	Time Pass/Fail	Time Pass/Fail	Comments
1. Safety of water					
A. City water: annual verification (on file)					
B. No cross-connections between potable and wastewater systems					
2. Condition and cleanliness of food-contact surface					
A. Processing equipment and utensils in suitable condition					
B. Equipment cleaned and sanitized before start-up					
1. Concentration of chlorine used for sanitizing equipment (ppm)					
C. Product residue removed from equipment during breaks					
D. Ready-to-eat-product equipment cleaned and sanitized during breaks					
E. Gloves and aprons in good repair					
3. Cross contamination					
A. Physical condition of plant and layout of equipment suitable to minimize risk of contamination					
B. Employees' hands, gloves, equipment and utensils that contact unsanitary objects are washed and sanitized before contacting product					
C. Employee in raw-product area wash and sanitize hands, gloves and aprons before moving to cooked-product area					

Sanitation Conditions & Practices	Time Pre-Op Pass/Fail	Time Pass/Fail	Time Pass/Fail	Time Pass/Fail	Comments
4. Maintenance of hand-washing, hand-sanitizing and toilet facilities					
A. Adequate supplies					
B. Concentration of iodine in hand dips (ppm)					
1. Front entrance					
2. Rear entrance					
3. Side entrance					
4. Start of line 1					
5. End of line 1					
6. Start of line 2					
7. End of line 2					
C. Toilets are clean and properly functioning					
5. Protection from adulterants (lubricants, fuel, pesticides, cleaning and sanitizing agents, condensates, floor splash, etc.)					
A. Food product					
B. Food-packaging material					
C. Food-contact surfaces					
6. Labeling, storage and use of toxic compounds					
A. Cleaning compounds labeled and stored properly					
B. Lubricants labeled and stored properly					
C. Pesticides labeled and stored properly					
7. Employee health condition					
A. Employees show no signs of medical problems that could compromise product safety					
8. Exclusion of pests					
A. No evidence of pests in plant					

Worker Training Log

Name of operation:_____ **Date:**_____

Trainer:_____ **Training Time:**_____

Location: _____

Training material (Please attach any written materials to this log with a staple):
Please see the food safety plan for overall Worker Training procedures.

Employee Name (please print)	**Employee Signature**
1._____	_____
2._____	_____
3._____	_____
4._____	_____
5._____	_____
6._____	_____
7._____	_____
8._____	_____
9._____	_____

10._____ _____

11._____ _____

12._____ _____

13._____ _____

14._____ _____

15._____ _____

Reviewed by:_____ **Title:**_____ **Date:**_____

HARVESTER CERTIFICATE OF GUARANTEE (VENISON)

Commercial Tag No._____
Tribal Disease Management Area Tag No. _____
Only applicable to deer harvested in Tribal Disease Management Areas
Name of the Tribal Member Harvester: _____
NAGFA Id. No.: _____

Pre-mortem Inspection Information Record
Required for Class 2 and 3 Sales Only
Condition and behavior of animal at rest, and in motion:
Overall condition of the animal, especially the head, eyes, leg and body:
(normal, or describe) _____

Alertness, mobility and breathing (normal, or describe): _____

Presence of any unusual swelling, signs of injury or other abnormalities?
(N/A, or describe) _____

Displaying any abnormal behavior? _____ If so, describe: _____
_____

Normal gait, normal grazing activity, alert to danger: yes/no (circle one)

Alive, when harvested: yes/no (circle one)

□ Unable to walk due to broken appendages, severed tendons or ligaments, nerve paralysis or fractured spine (circle as applicable).

Time of Kill Information
Required for All Classes of Sale

Date: _____

Time: _____

DMU: _____

Air temp: _____

Manner of killing:

Bow/arrow __

Crossbow __

Rifle __

Type of shot used (if applicable): _____

Nontoxic shot is required.

□ Was harvested within a Tribal Disease Management Area for Chronic Wasting Disease (CWD) or Bovine Tuberculosis (TB).

Humane Handling Certification
Required for All Classes of Sale
□ The animal was killed in a swift and efficient manner consistent with the methods approved by my Tribe's conservation codes.
□ The animal was not shackled, hoisted, thrown or cast until the animal was stunned or killed in a manner that caused permanent unconsciousness or death.

Field Dressing Certification:
Required for All Classes of Sale
□ All personnel engaged in field dressing the animal wore clean, washable outer clothing and food handling gloves, with any long hair covered or tied back; and all personnel washed and rinsed their hands sufficiently during the operations to prevent contamination of the carcass.
□ Equipment and utensils used for field dressing were made of sanitary design and construction, and were kept clean and sanitary (free from contamination by soil, vermin, insects, vermin and waste products) prior to, and during, field dressing.
□ Prior to making any incisions into the carcass, loose dirt and debris was cleaned from the carcass, and the carcass was placed on a non-permeable, clean and sanitized surface (i.e. clean and sanitized tarp, game processing table, etc.).

□ While field-dressing, care was taken to avoid contaminating the meat with fluids contained within the intestinal tract and bladder. An examination of the abdominal cavity and the heart, lungs, liver, stomach and intestines, through sight and smell, was performed. Any organs or parts from the carcass that exhibited physical deformation or signs of disease (i.e. cysts, unusual growth, abnormal colors, etc.), were collected, and stored at or below 38° Fahrenheit, for further inspection.
□ At least one individual performing field-dressing has satisfactorily completed the required tribal training program on field-dressing and that/those individual(s) supervised all field-dressing activities.

Transportation and Storage Certification
Required for All Classes of Sale
□ Transportation of the carcass was conducted in a manner consistent with Sec. 5.04 of the Tribal Traditional Food Processing Code. Describe the measures taken to protect the carcass from contamination during transportation from the field: _____

_____

_____

If carcass was not taken directly from the field to a food processing plant, describe the manner in which the carcass was stored, including how continuous cooling of the carcass occurred, and was monitored:
_____

_____

_____

For Class 2 and 3 Sales Only
Enter time and date that carcass was presented for inspection by a tribally-certified meat processor:
_____

This form must be signed by the tribal member harvester who killed the deer using his/her tribal deer hunting license to kill the animal. By signing this form, the harvester certifies that all of the information displayed on this form is true and complete. The harvester further certifies that she/he complied with applicable tribal law when hunting for, killing, tagging and registering the animal.

Tribal Harvester Signature: _____ Dated: _____

This form must also be signed by each individual who participated in field-dressing, certifying that the information and certifications listed on this form regarding field-dressing are true and accurate.

Individual(s) field-dressing the carcass:

Name: _____ Signature: _____ Dated: _____
Name: _____ Signature: _____ Dated: _____
Name: _____ Signature: _____ Dated: _____

Examples of GLIFWC Harvesting Permits

Great Lakes Indian Fish & Wildlife Commission
PO. Box 9 • Odanah, WI 54861
(715) 682-6619 • www.glifwc.org

2020-2021 Season

NAGFA ID #: 7600 **Tribe**: BRV
Name: JOHN D DOE 3
Address: ashland ashland, WI 54806
Phone: 715 685 5555 **Hunter Safety #:**
Remote Registration (deer, bear, turkey, crane): 1-844-234-5439 or glifwc.nagfa.net/online/
More Information: data.glifwc.org/regulations/

GATHERING
Wild Rice
Stamp# 248871

Please submit all harvest reports in a timely manner!

I will not conduct wasteful, unsafe or inhumane practices while exercising my treaty rights and will abide by the regulations set forth by my tribe's conservation code.

Signature of Applicant: _____ Date: _____

In recognition of those who reserved the rights and to ensure harvest opportunities for the 7th generation, harvesters are encouraged to honor the traditions of the Anishinaabeg, which include the offering of asemaa (tobacco) to the manidoog (spirits) prior to harvesting.

Da-manaaji'indwaa gete-anishinaabebaneg gaa-ganawendangig i'iw akeyaa wenji-bimaadiziyang, inga-asemaakawaag nanaandomindwaa ingiw manidoog naa gaye wiindamaageyaan dabwaa-mamooyaan gegoo gemaa gaye giiwosaadamaan gegoo. Gaawiin inga-banaajitoosiin naa gaye gaawiin inga-nishwanaajitoosiin gegoo babaa-mamooyaan gemaa gaye babaa-giiwoseyaan. Inga-degwetawaag ingiw gaa-onaakonigejig eni-mamooyaan gegoo gemaa geye eni-giiwoseyaan.

Great Lakes Indian Fish & Wildlife Commission
PO. Box 9 • Odanah, WI 54861
(715) 682-6619 • www.glifwc.org

2020-2021 Season

NAGFA ID #: 7600 **Tribe**: BRV
Name: JOHN D DOE 3
Address: ashland ashland, WI 54806
Phone: 715 685 5555 **Hunter Safety #:**
Remote Registration (deer, bear, turkey, crane): 1-844-234-5439 or glifwc.nagfa.net/online/
More Information: data.glifwc.org/regulations/

GATHERING
Wild Rice
Stamp# 248871

Please submit all harvest reports in a timely manner!

I will not conduct wasteful, unsafe or inhumane practices while exercising my treaty rights and will abide by the regulations set forth by my tribe's conservation code.

Signature of Applicant: _____ Date: _____

In recognition of those who reserved the rights and to ensure harvest opportunities for the 7th generation, harvesters are encouraged to honor the traditions of the Anishinaabeg, which include the offering of asemaa (tobacco) to the manidoog (spirits) prior to harvesting.

Da-manaaji'indwaa gete-anishinaabebaneg gaa-ganawendangig i'iw akeyaa wenji-bimaadiziyang, inga-asemaakawaag nanaandomindwaa ingiw manidoog naa gaye wiindamaageyaan dabwaa-mamooyaan gegoo gemaa gaye giiwosaadamaan gegoo. Gaawiin inga-banaajitoosiin naa gaye gaawiin inga-nishwanaajitoosiin gegoo babaa-mamooyaan gemaa gaye babaa-giiwoseyaan. Inga-degwetawaag ingiw gaa-onaakonigejig eni-mamooyaan gegoo gemaa geye eni-giiwoseyaan.

SAMPLE

Great Lakes Indian Fish & Wildlife Commission

PO. Box 9 • Odanah, WI 54861
(715) 682-6619 • www.glifwc.org

2017-2018 Season

NAGFA ID #: 7599 **Tribe**: BRV
Name: JOHN D DOE 2
Address: bad river odaanah, WI 54861
Phone: 715-682-5611 **Hunter Safety #:**445-458-698
Remote Registration (deer, bear, turkey, crane): 1-844-234-5439 or glifwc.nagfa.net/online/
More Information: data.glifwc.org/regulations/

HUNTING/DEER
Any Deer
Stamp# 171087

Please submit all harvest reports in a timely manner!

I will not conduct wasteful, unsafe or inhumane practices while exercising my treaty rights and will abide by the regulations set forth by my tribe's conservation code.

Signature of Applicant: _____ Date: _____

In recognition of those who reserved the rights and to ensure harvest opportunities for the 7th generation, harvesters are encouraged to honor the traditions of the Anishinaabeg, which include the offering of asemaa (tobacco) to the manidoog (spirits) prior to harvesting.

Da-manaaji'indwaa gete-anishinaabemaneg gaa-ganawendangig i'iw akeyaa wenji-bimaadiziyang, inga-asemaakawaag nanaandomindwaa ingiw manidoog naa gaye wiindamaageyaan dabwaa-mamooyaan gegoo gemaa gaye giiwosaadamaan gegoo. Gaawiin inga-banaajitoosiin naa gaye gaawiin inga-nishwanaajitoosiin gegoo babaa-mamooyaan gemaa gaye babaa-giiwoseyaan. Inga-degwetawaag ingiw gaa-onaakonigejig eni-mamooyaan gegoo gemaa geye eni-giiwoseyaan.

"GLIFWC Chippewa Ceded Territory Traditional Food Regulatory Project"

Food Harvester & Handler Training

PowerPoint Slides

September 21, 2020

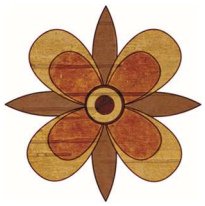
Welcome to GLIFWC's Food Harvester & Handler Training

We are glad you could join us!
We will get started soon.

Introductions

2

- Name
- Tribal Affiliation
- What are you hoping learn?
- What is your favorite traditionally harvested food?



Training Objectives & Expectations

3

- To provide information in support of food harvesters and food handlers effectively processing, selling and distributing safe, wholesome treaty harvested foods within the scope of the project.
- Provide contaminant and food safety information for maple syrup, wild rice, walleye, whitefish, venison, and wild turkey.

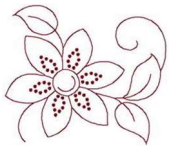
To be eligible receive a certificate of completion, attendees will need to:

- Attend the full training as provided (estimated to be 4 hours)
- Participate in class exercises, to the best of your abilities
- Complete and return the course survey

Training Agenda

4

- Project Background and Outcomes
- Food Safety Basic
- Food Safety Systems
- Model Food Code-General Provisions
- Fish, Food Safety and the Model Food Code
- Meat, Food Safety and the Model Food Code
- Low-Risk Foods, Food Safety and the Model Food Code



About GLIFWC

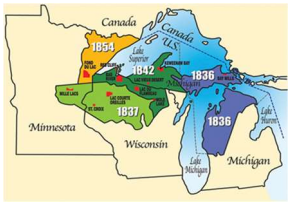
5

- Conservation Enforcement
- Division of Intergovernmental Affairs
- Planning and Development
- Public Information Office
- Administration
- Biological Services Division
  - Inland Fisheries Section
  - Great Lakes Section
  - Wildlife Section
  - Environmental Section
  - Climate Change

About the project

6

- **GLIFWC Chippewa Ceded Territory Traditional Food Regulatory System Project**
  - 3 Year Project
  - Currently in Year 3
  - Funded by the Administration for Native Americans
- **Project Aim**
  - Create regulatory tools around treaty-reserved traditional foods to assist tribes in expanding sovereignty over food systems



Project Impact

7

- **Important Note**
  - Only applies if your tribal council approves and implements the specific Model Food Code
  - Will not impact:
    - Cultural and community feasts
    - Home use of traditional foods
    - Informal commercial sale
      - *Examples:*
        - Fundraisers
        - Powwow Stands

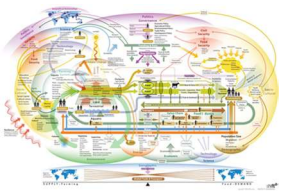
Project Timeline and Outcomes

8

- Traditional Food Interest List
  - ~326 participants
- "2018 Traditional Food Contaminant and Food Safety Report" page 7 and Addendum page 157
- "Guidance Reports": page 488
  - Small scale food production of wild foods harvested off-reservation
  - Packaging, labeling, and sales of wild foods harvested off-reservation
- Community Roundtables and Workshops

Food Systems

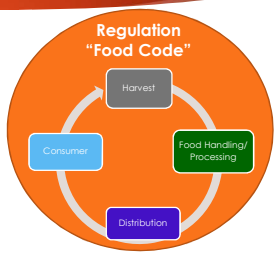
9



What is a Food Regulatory System?

10

- A legal system made of policies, guidelines, and regulations with the purpose of **protecting the health and safety of food consumers**
  - Managing food safety risks in three broad categories: biological, chemical, and physical contaminants



Why contaminant information is important

11

- Information on contaminant risks are used in several ways:
  - To guide the development of safety standards that apply to the entire food system, and with respect to specific foods
  - Used by the individuals and entities who produce, store and transport food to manage risks associated with the foods they are producing, and to reduce potential liability

Food Safety Basics

12

OBJECTIVES:
- WHAT IS FOODBORNE ILLNESS
- WHAT ARE CONTAMINANTS

Foodborne Illness and Unsafe Food

13

- Foodborne illness is a disease transmitted to people by ingesting unsafe foods
- Most commonly from bacteria
- Common bacteria causing foodborne illness:
  - *E. Coli*
  - *Listeria monocytogenes*
  - *Salmonella spp.*

Impacts of Foodborne Illness-US

14

- The Centers of Disease Control estimates each year[1]:
  - 1 in 6 Americans (48 million) become sick with foodborne illness
  - 128,000 hospitalizations
  - 3,000 death
- US Department of Agriculture (USDA) estimates foodborne illness cost $15.6 billion each year[2]

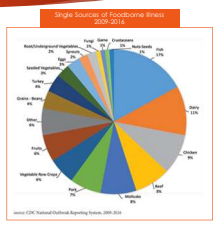


Photo Credit: AgriMarketing.com

[1] Centers of Disease Control. "Burden of Foodborne Illness: Findings" https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html
[2] Centers of Disease Control. "CDC and Food Safety". https://www.cdc.gov/foodsafety/cdc-and-food-safety.html#:~:text=Foodborne%20Illness%20is%20a%20common,than%20%2415.6%20billion%20each%20year.

Causes of Foodborne Illness

15

- Biological hazard
- Chemical hazard
- Physical hazard
- Hazards are unsafe levels of contaminants which can cause illness or injury
- Common ways foods become unsafe:
  - Time and Temperature Abuse
  - Cross contamination
  - Poor personal hygiene
  - Poor cleaning and sanitizing
  - Purchasing from unapproved sources

Biological Hazards-brief

16

- There are 5 types of biological hazards:
  - Bacteria
  - Viruses
  - Parasites
  - Fungi
  - Biological toxins
- Biological hazards are often referred to as pathogens
- Pathogens = microorganisms that make people sick

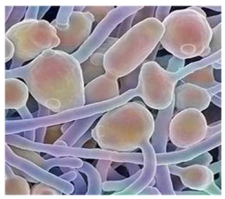


Photo Credit: MicroBiology Society

Bacteria

17

- Microorganisms
- Bacteria need certain conditions to grow:
  - **F**ood
  - **A**cid
  - **T**emperature
  - **T**ime
  - **O**xygen
  - **M**oisture

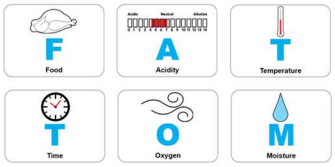


Photo Credit: ServSafe Food Manager 6th edition

Bacteria: Food and Acidity

18

- Food
  - Bacteria needs food (nutrients) to grow and survive
- Acidity
  - Acidity is measured in pH
    - 1 is most acidic
    - 7 is neutral
    - 14 is most alkaline (basic)
  - Bacteria grows best in foods that are neutral to mildly acidic (7.5 - 4.6pH)

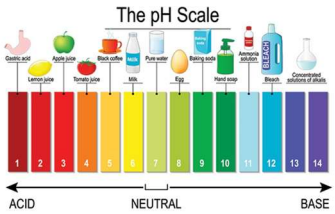


Photo Credit: Science News for Students.org

Bacteria: Temperature and Time

19

- Temperature
  - Bacteria grows well when the temperature of the food is between:
    - 41°F – 135°F (5°C – 57°C)
    - Known as the "Danger Zone"
  - Bacteria can grow very quickly between:
    - 70°F – 120°F (21°C – 52°C)
- Time
  - It takes time for bacteria to multiply, even in prime conditions
  - Example:
    - In food held at **42°F – 50°F**, it takes *Listeria* **24 hours** to grow to unsafe levels
    - The same food held **above 86°F,** *Listeria* can grow to unsafe levels in **1 hour**[1]

1 Food and Drug Administration. *Fish and Fishery Products Hazard Guide*. 2020. Page 421

Bacteria: Oxygen and Moisture

20

- Oxygen
  - Some bacteria require oxygen to survive
  - Some bacteria require the absence of oxygen to survive or become dangerous

Photo Credit: SciencePhotoLibrary

- Moisture
  - Water activity is the amount of water available to react with bacteria
    - Water activity = a_w
  - Water activity is not moisture content
  - Water activity is measure on a scale of 0 - 1:
    - 0 = low water activity
    - 1 = high water activity
  - Bacteria prefer a water activity of 0.85 and higher

Common Bacteria Species

21

- *Bacillus cereus*
- *Listeria monocytogenes*
- Shiga toxin-producing *E. coli*
- *Campylobacter jejuni*
- *Clostridium perfringens*
- *Clostridium botulinum*
- Nontyphoidal *Salmonella*
- *Salmonella* Typhi
- *Shigella* spp.
- *Staphylococcus aureus*

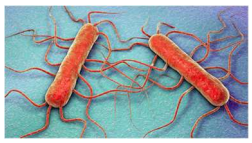


Photo Credit: BioCote

Viruses and Parasites

22

- **Viruses:**
  - Needs a host to survive
  - Does not need food
- Virus Sources:
  - Humans and animals
  - Contaminated water
  - Contaminated surfaces
- Common Food Related Viruses:
  - Hepatitis A
  - Norovirus
- **Parasites:**
  - Needs a host to survive
  - Typically associated with the food or water, not the food handler
- Parasite sources:
  - Fish (seafood), wild game, and contaminated water
- Common Parasites:
  - *Anisakis simplex*
  - *Cryptosporidium parvum*
  - *Giardia duodenalis*
  - *Cyclospora cayetanensis*

Fungi

23

- Mold or yeast
  - Can make people sick
    - Toxins or allergic reactions
  - Most often associated with food spoilage
  - Refrigerator or freezer temperatures may slow but do not destroy molds and yeast
  - Prefers acidic and low water activity foods (i.e. jams and jellies)

Photo Credit: HealthyCanning

Biological Toxins

24

- Naturally forming chemicals within foods which can make people sick
- Sources:
  - Seafood (typically ocean fish)
  - Plants
  - Mushrooms

Photo Credit: Purdue University

- Underscores the importance of plant identification and understanding of proper preparation.

Chemical Hazards

25

- The inclusion of chemicals at levels unsafe to human health
- Sources:
  - Allergens
  - Processing equipment
  - Machine lubricants
  - Misuse of sanitizers and cleaning agents
  - Pesticides or environmental contaminants (e.g. mercury in fish)
  - Health and beauty products from anyone handling food

Photo Credit: Safetyskills.com

Physical Hazards-brief

26

- Physical objects in food which can cause harm
- Common Sources:
  - Rocks
  - Wood
  - Bones
  - Fruit pits
  - Glass
  - Jewelry

Additional Food Safety Education

27

Indian Health Service:

- Offers free online Food Handler Training https://www.ihs.gov/foodhandler/
- Training is 1 hour and includes a 20 question quiz

ServSafe

- Nationally recognized food safety training
- Food Handler course ($15 online course)
- Food Manager course ($179 online course)
- https://www.servsafe.com/

Purpose of a Food Regulatory System & Food Safety

To provide safe and wholesome foods for consumption

This is done through regulation and implementation of food safety systems

- Food is made or kept safe for consumption by managing risk through reducing food related hazards

IDENTIFIED TRADITIONAL FOODS LIST

Food	*Classification*
White-Tail Deer	Large Game
Rabbit/Hare	Small Game
Duck	Migratory Birds
Turkey	Upland Game Birds
Whitefish	Great Lake Fish
Walleye	Inland Fish
Fresh Berries	Fruit
Wild Leeks/Ramps	Bulb Vegetable
Wild Beach Pea	Legume
Hazelnut	Tree nut
Morel Mushroom	Fungi
Wild Rice	Grain
Berry Jams/Jellies	Value Added
Maple Syrup	Value Added
Animal Fat	Value Added
Venison Jerky	Value Added

Traditional Food Focused Contaminant Information

29

Biological Hazard Overview

- 2018: project staff completed a review of scientific literature to identify known and unknown contaminant and food safety risks of the traditional foods from the Interest List. (page 16 of Training Manual)
- Traditional foods carry many of the same risks as conventional foods (e.g. bacteria, disease, etc.)
  - from "2018 Traditional Food Contaminant and Food Safety Report"

TABLE 2: THIS MATRIX OUTLINES BIOLOGICAL, CHEMICAL, AND PHYSICAL HAZARDS ASSOCIATED WITH IDENTIFIED TRADITIONAL FOODS.

		HAZARDS				
		BIOLOGICAL				
Common Name	**Scientific Name**	**Pathogen**	**Disease / Virus**	**Parasite**	**Prions (CWD)**	**Allergen**
Large/Small Game						
White-tailed Deer	*Odocoileus virginianus*	X	X	X	X	
Snowshoe Hare	*Lepus americanus*	X	X	X		
Cottontail Rabbit	*Sylvilagus floridanus*	X	X	X		
Birds						
Ducks/Divers						
Scaup/Bluebill	*Aythya affinis/ A. marila*	X	X	X		
Ring-necked Duck	*Aythya collaris*	X	X	X		
Duck/diver						
Blue-winged Teal	*Anas cyanoptera*	X	X	X		
Green-winged Teal	*Anas discors*	X	X	X		
Mallard	*Anas platyrhynchos*	X	X	X		
Wood Duck	*Aix sponsa*	X	X	X		
Upland						
Wild Turkey	*Meleagris gallopavo*	X	X			
Fish						
Walleye	*Sander vitreus*	X		X		X
Whitefish	*Coregonus clupeaformis*	X		X		X
Flowing Fungi						
Wild Strawberry	*Fragaria ovesca*	X				
Wild Raspberry	*Rubus idaeus*	X				
Wild Blueberry	*Vaccinium angustifolium*	X				
Wild Blackberry	*Rubus allegheniensis*	X				
Highbush Cranberry	*Viburnum opulus*	X				
Wintergreen	*Gaultheria procumbens*	X				
Elderberry	*Sambucus canadensis*	X				
Wild Ramps/Leeks	*Allium tricoccum*	X				
Hazelnuts	*Corylus americana*	X				X
Beach Pea	*Lathyrus japonicus*	X				
Wild Rice	*Zizania palustris*	X				
Morel Mushroom	*Morchella esculenta*	X				
Value Added						
Maple Syrup	*Acer saccharum*	X				
Jams/Jellies	Various species	X				
Venison Jerky	*Odocoileus virginianus*	X	X	X	X	X
Animal Fat (duck)	*Anas spp*	X				
		Pathogen	**Disease / Virus**	**Parasite**	**Prions (CWD)**	**Allergen**

Chemical & Physical Hazard Overview

- Page 17 from "2018 Traditional Food Contaminant and Food Safety Report"

Exercise: Look over Table 2 on pages 16-17 in training manual. Using your microphone or the chat please answer the following:

1. Please list the biological, chemical, and physical hazards associated with Wild Turkey?
2. Look over the list and find one food's hazard that you want to know more about (i.e. Deer & heavy metal)

TABLE 2: THIS MATRIX OUTLINES BIOLOGICAL, CHEMICAL, AND PHYSICAL HAZARDS ASSOCIATED WITH IDENTIFIED TRADITIONAL FOODS. (CONTINUED FROM PREVIOUS PAGE)

		HAZARDS				
		CHEMICAL			PHYSICAL	
Common Name	Scientific Name	Heavy Metal	Chemical / Pesticide	Natural Toxin	Bullet Fragment	Shot Pellet
Large/Small Game						
White-tailed Deer	*Odocoileus virginianus*	X	X		X	
Snowshoe Hare	*Lepus americanus*	X	X		X	X
Cottontail Rabbit	*Sylvilagus floridanus*	X	X		X	X
Birds						
Dabbyfeathers						
Scaup/ Bluebill	*Aythya affinis, A. marila*	X	X			X
Ring-necked Duck	*Aythya collaris*	X	X			X
Duck/dabbyfeathers						
Blue-winged Teal	*Anas cornifimmis*		X			X
Green-winged Teal	*Anas discors*		X			X
Mallard	*Anas platyrhynchos*		X			X
Wood Duck	*Aix sponsa*		X			X
Upland						
Wild Turkey	*Meleagris gallopavo*	X				X
Fish						
Walleye	*Sander vitreus*		X			
Whitefish	*Coregonus clupeaformis*		X			
Plants						
Wild Strawberry	*Fragaria vesca*		X			
Wild Raspberry	*Rubus idaeus*	X				
Wild Blueberry	*Vaccinium angustifolium*	X	X			
Wild Blackberry	*Rubus allegheniensis*	X				
Highbush Cranberry	*Viburnum opulus*					
Wintergreen	*Gaultheria procumbens*					
Elderberry	*Sambucus canadensis*			X		
Wild Ramps/Leeks	*Allium tricoccum*					
Ginseng	*Panax americanus*					
Beach Pea	*Lathyrus japonicus*	X		X		
Wild Rice	*Zizania palustris*	X				
Morel Mushroom	*Morchella esculentoides*	X				
Value Added						
Maple Syrup	*Acer saccharum*	X				
Jams/Jellies	Various species					
Venison Jerky	*Odocoileus virginianus*	X			X	
Animal Fat (duck)	*Anas spp.*	X	X	X		
		Heavy Metals	Chemical / Pesticide	Natural Toxin	Bullet Fragment	Shot Pellet

Diving Deeper

- During the literature review for the "2018 Traditional Food Contaminant and Food Safety Report" project staff identified 3 major gaps in scientific knowledge and data:
  - Wild rice and arsenic
  - Tribally harvested maple syrup and lead from equipment
  - Lead exposure from ammunition used to harvest wild turkey
- These gaps lead to a 2019 study
  - Study results are available in the "Addendum" document

2019 Study Results - Wild Rice

- Wild Rice:
  - 40 samples
  - Finished wild rice seeds harvested and processed by Ojibwe tribal members **do not contain** lead, zinc, cadmium, total mercury, copper, magnesium, total chromium, selenium, or total and inorganic arsenic concentrations in any amount that would be of negative impact to human health, in either cooked or dry form

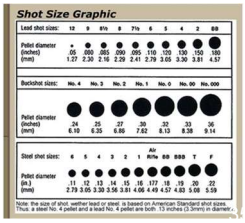
Figure 2. Wild rice samples for heavy metals testing were collected from natural beds located in the 1842, and 1854 treaty territories. However, three sample were collected outside ceded territory boundaries.

2019 Study Results - Maple Syrup

- Maple Syrup:
  - 29 samples
  - Maple sap harvested and processed by Ojibwe tribal members into syrup **does not contain** lead concentrations that would be harmful to human health using the Canadian Maximum Residue Limit of (0.5 ppm) for lead in maple syrup
    - The US does not have an action level for lead in maple syrup
  - Processing equipment can impact lead concentrations in maple syrup and other foods
    - Lead and lead solder are not recommended for food contact surfaces

2019 Study Results - Wild Turkey

- Wild Turkey:
  - 30 birds sampled
  - Harvesting with smaller size No. 8 and No. 6 shot increased lead content found in the breast meat
  - Larger shot reduces lead contamination risk
  - Turkey harvested with larger size No. 5 copper coated lead shot were found to test below laboratory detection limits



Food Safety Systems

36

OBJECTIVES:

- Understand Good Manufacturing Practices (GMP)
- Understand Standard Sanitation Operating Procedures (SSOP)
- Understand Hazard Analysis and Critical Control Point (HACCP)
- Understand the difference between GMPs, SSOPs, and HACCP
- Identify where these systems are required within the Model Food Code

Model Food Code Food Safety System Requirements

37

	GMP	SSOP	HACCP
Tribally Licensed Food Facility	Required	Required	Required
Retail Food Establishment	Required	Required	x
Class 1 Meat Vendor	Required	Required	Required
Class 1 Fish Vendor	Required	Required	Required
Low-Risk Food Vendor*	modified	modified	x

*Low-Risk Foods produced within a tribally licensed food facility must comply with the requirements of the food facility, which include GMPs, SSOPs, HACCP.

Food Safety Terminology

38

- **Food contact surface(s):** any surface that comes into contact with food
  - Examples: work table, utensils, food service gloves, food containers
- **Ready to Eat (RTE):** refers to foods that ready to consume as is and do not need any additional cooking
  - Examples: fresh berries, cooked meat, bread
- **Cross Contamination:** the process of transferring microorganisms from one surface to another with a harmful effect
  - Example: Using tongs to move raw turkey to a baking pan, then using the same tongs to move muffins to a platter without cleaning and sanitizing tongs

Food Safety Terminology continued

39

- **Adulterant:** poisonous or deleterious substances, either naturally occurring or added to food. To include added substance, unapproved substances, handling or holding food in ways that could make the food unsafe. *May include substances from food contact surfaces and packaging
  - Examples: Lead ammunition can fragment within a deer carcass. These fragments would be considered adulterants
- **Kill Step:** a process within the production of food where pathogens are eliminated or reduced to an acceptable level
  - Example: boiling, baking, smoking, etc.

Components of Safe Food Processing

40

HACCP Plan:
Management plan to analyze critical hazardous factors set Critical Control Point, establish limitations, set-up monitoring method, set-up improvement plan, set-up verification process, maintain record and control documents.

SSOP (Sanitation Standard Operating Procedures):
Operating procedures for general sanitation management operation standard, office management, water control, storage and transportation supervision, inspection, recalls.

GMP (Good Manufacturing Practice)
Operating procedures for general sanitation management operation standard, office management, water control, storage and transportation supervision, inspection, recalls.

Good Manufacturing Practices (GMPs)

41

- Focus of GMPs is the sanitary environment of food production or manufacturing

Requirements:
- General maintenance of physical facilities
- Cleaning and sanitizing of equipment and utensils
- Storage and handling of clean equipment and utensils
- Pest control
- Proper use and storage of cleaning compounds, sanitizers, and pesticides
- Employee training
- Plant design
- Quality assurance assessment

Model Food Code - Chapters 3.06 & 3.11 parts 4-8 which can be found in the training manual

Current Good Manufacturing Practices (cGMP)

42

- Focus on reducing cross contamination and employee hygiene
- Includes:
  - Employee food handling and personal hygiene training
  - Inspection of employee hygiene and work habits
  - Proper maintained sanitary facilities and supplies
  - Care taken during the handling of allergens

Model Food Code - Chapter 3.04 part 1 which can be found in the training manual

Standard Sanitation Operating Procedures (SSOP)

43

- SSOPs are the specific, **written procedures** necessary to ensure sanitary conditions in the establishment, before, during, and after operations
- Used to meet the requirements of GMPs
- Address processing environments and employee practices

8 Areas of Sanitation

44

1. Safety of water which comes into contact with food or food surfaces
2. Condition and cleanliness of food contact surfaces
3. Prevention of cross-contamination and cross-contact of allergenic foods
4. Maintenance of hand washing stations, hand sanitizing, and toilet facilities
5. Protecting food and food contact surface from adulterants
6. Proper use and storage of toxic chemicals used in the facility
7. Pest control measures
8. Where employee health may be a biological risk to food, controlling access to food and food surfaces

Model Food Code - Chapter 3.11 parts 4-8 which can be found in the training manual

SSOPs and the Model Food Code

45

Chapter 3.08

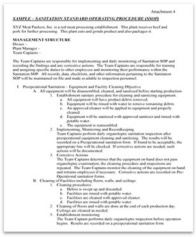
- Required for:
  - Tribally Licensed food facility
  - Retail food establishment
  - Class 1 Meat Vendor
  - Class 1 Fish Vendor

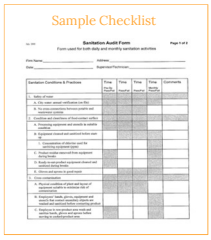
SSOPs:

- Must be written
- Must be monitored
- Specific to the location
- Specific to the establishment
- Must be signed by the establishment authority
- Requires monitoring activities
- Recordkeeping is required
- Must be routinely evaluated for effectiveness

Template SSOP (training manual page 730)

46





Hazard Analysis Critical Control Points (HACCP)

47

- A management tool used to monitor and protect a food product, before, during, and after, processing
- Addresses food safety issues around **a specific food product or processing line**
- Monitors food safety in 3 main areas
  - Biological
  - Chemical
  - Physical
- Designed to minimize the risk of food hazards but may not reduce the hazards to zero
- Documents the active protection of food from contaminants

HACCP in 7 Steps

48

1. Conduct a hazard analysis
2. If hazards are identified, determine critical control points in the process
3. Establish critical limits
4. Establish monitoring procedures
5. Establish corrective actions
6. Establish verification procedures
7. Establish recordkeeping procedures

The plan itself is a written, signed, and dated document that is periodically updated

HACCP and the Model Food Code

49

- **All food processing plants, retail food establishments, and class 1 fish/meat vendors must:**
  - Conduct a **hazard analysis** for each raw and finished food product processed by the facility
  - Identify **preventive control measure** to control **hazards identified** in the hazard analysis
  - GLIFWC has developed model HACCP plans that can be used by tribal entities
- Training: Training on HACCP, or equivalent job experience, is required to develop or amend a HACCP plan, and to conduct a records review required for HACCP implementation. Currently, GLIFWC offers an annual fish HACCP training course each fall

HACCP and the Model Food Code

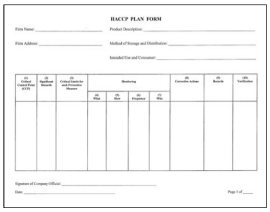
50

- HACCP plans are required when a hazard is identified through the Hazard Analysis
- HACCP Records include:
  - Written hazard analysis
  - Written HACCP plans
  - Critical control point and critical limit supporting documents
  - Monitoring records of critical control points
  - Corrective action plans (optional)
  - Documentation of corrective actions taken

Model Food Code - Chapter 4 which can be found in the training manual

HACCP Form Examples (training manual page 562)

51



52

"Let's take a short break!"

K.

53

General Provisions Summary & Labeling

Objectives:
- Understand what General Provisions are and where to find them
- Understand the aspects of labeling

Model Food Code Structure

54

Please turn to the Model Food Code Chapters - page 400 in the training manual

- Chapter 1 - Purpose and Powers
- Chapter 2 - Food Code Definitions
- Chapter 3 - General Provisions
- Chapter 4 - HACCP
- Chapter 5 - Meat
- Chapter 6 - Fish
- Chapter 7 - Produce
- Chapter 8 - Low-Risk Foods

General Provisions

55

- **Chapter 3**
  - Chapter 3.01 - Zhawenindiwag: Respect for Traditional Foods and Consumers
  - Chapter 3.02 - 3.02 Debwenin: Truth in Labeling
  - Chapter 3.03 - Food Additives
  - Chapter 3.04 - *Personnel*
  - Chapter 3.05 - Food Transportation and Storage
  - Chapter 3.06 - *Equipment and Utensils*
  - Chapter 3.07 - Handling of Inedible Food Bi-Products
  - Chapter 3.08 - *Sanitation Control Procedures & GMPs*
  - Chapter 3.09 - Variance
  - Chapter 3.10 - Recordkeeping
  - Chapter 3.11 - *Food Processing Plants*
  - Chapter 3.12 - Retail Food Establishments
  - Chapter 3.13 - Enforcement
  - Chapter 3.14 - Prohibited Practices

Chapter 3 - General Provisions

Licensing Classes

56

Classes are based on location of sale, the customer and the risk level of the product being sold

- **Class 1 =** sales from tribal member to tribal member, on reservation
- **Class 2 =** sales to tribal institutions and programs
- **Class 3 =** retail sales, on and off reservations, to both tribal and non-tribal members
- *All commercial harvesters must comply with applicable Off-Reservation Conservation Code requirements regarding records of commercial transactions*

Class 1 meat vendor license is required to sell cuts of meat.

Class 1 fish vendor license is required to sell fresh fish filets.

These licenses allow for the processing of meat or fish in facilities which are not licensed as food processing plants (home kitchens), an inspection of the facilities and a licensing fee may apply.

Foundations of the Model Food Code

57

- 3.01 Zhawenindiwag: Respect for Traditional Foods and Consumers:
  - All foods are to be handled in a respectful manner and in order to prevent adulteration
  - All foods sold or donated must be amenable* foods
  - No adulterated food may be donated or sold

*Amenable - food that may be sold or donated to institutions or individuals

Labeling - General

58

- 3.02 Debwenin: Truth in Labeling:
  - All foods must be labeled in a truthful manner, not misleading
  - Information on label must be in a readable format
    - Letters and numbers must be a minimum of 1/16th of an inch

Wild rice (manoomin), **maple syrup** (zhiiwaagamizigan), **fish** (giigoohn), and **mushrooms** (wazhashkwedoons) have special labeling requirements.

*Meat has additional inspection labeling requirements

- Terminology:
  - **Principal Display Panel (PDP)** - the part of the food label most likely to be displayed to the customer when the product is offered for sale
  - **Information Fact Panel (IFP)** - a label with required information that appears on a location on the product other than the front of the product

Labeling Standards - Specialized

59

Food processed outside of a License Food Processing Plant:

- *Most Low-Risk Food licenses, Class 1 meat/fish license*
- Including foods prepared, processed, or packaged
- If ingredients contain an allergen, it must be listed
- Must include, in 12-point font

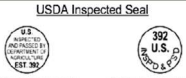
"Processed and packaged in a home facility"

Meat:

- Inspected meat requires an inspection legend
- Legends will be developed by tribes during the implementation process

Sample Inspection Label:

USDA Inspected Seal



USDA Inspection Legend Used on raw meat | USDA Inspection Legend Used on processed meat

Photo Credit: South Dakota Animal Industry Board

Labeling Standards - Additional

60

- If an allergen is present, it must be clearly stated on the label
  - In the ingredient list [Example: Walleye (fish)] OR
  - As a "Contains: …." Statement

The Big-8

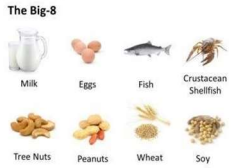


Photo Credit: University of Nebraska Lincoln

Food Additives

61

- Ingredients or additives must be listed by weight from largest to smallest
- Any ingredients or items added to food must be declared
  - including water, vegetables, or salt
  - includes items such as garlic powder
- Only food safe colors and preservatives may be used
  - Must include declaration of purpose
    - Example: Red #40 (coloring)
  - Packaging must be made of food safe materials

Personnel, Training, and Records

62

- Each person engaged in processing, packaging, or holding of food for donation or sale should:
  - Should be trained for the duties they are assigned and food safety
  - Must maintain good personal hygiene
  - Be free of contagious disease
  - Clothing should be cleanable or single use and adhere to food contact surface standards and SSOPs
  - Records of staff training should be maintained in accordance with recordkeeping regulations (Sec. 3.10)

*Mushroom harvesters must complete training on mushroom identification and harvesting and maintain records of this training

Food Transportation and Storage

63

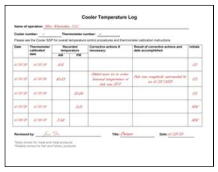
- Food should be transported and stored in a manner to protect it from contamination and deterioration:
  - Made of food grade material
  - Cleanable or single use
  - Clean and sanitary prior to use
  - Prior to use with another food, containers, or vehicle or food trailer must be cleaned and sanitized to prevent cross contamination
    - E.g. fish boxes should be cleaned and sanitized before holding fresh fruit
- Food storage areas should be cleaned regularly

Transportation Temperature Controlled Food

64

- Time and Temperature Control for Safety (TCS) foods are foods where bacteria grow more readily. Strict control of temperature or reduction of time foods are in the danger zone.
- When Transporting or Storing TCS Foods:
  - Temperature should be:
    - at or below 45°F

      OR
    - at or above 140°F (unless exempt)
  - Adequately monitor temperature
  - Monitoring creates records which should be kept in accordance with RecordKeeping Ch. 3.10
  - Meats must be continuously cooled
  - Must be loaded in a manner that allows proper refrigerated air circulation


Cooler Temperature Log

Name of operation: Mike Rotondo, LLC

Cooler number: _____ Thermometer number: _____

Please see the Cooler SOP for overall temperature control procedures and thermometer calibration instructions.

Date	Thermometer calibrated (yes)	Recorded temperature (at 8 – 12)	Corrective actions if necessary	Result of corrective actions and date accomplished	Initials
01/01/20	01/01/20	38.0F			JT
01/02/20	01/01/20	45.0F	Moved meat into 35 cooler. Removed temperature at 2PM, now 38.0F	Met new compliant temperature at 01/01/2020	JT
01/03/20	01/01/20		23.0F		JT
01/04/20	01/01/20	34.0F			JKW
01/05/20	01/06/20	37.0F			JKW

Reviewed by: _____ Title: Owner Date: 01/08/20

*Daily review by target and critical products.
*Weekly review for TCS and critical products.

Equipment and Utensils

65

- All equipment and utensils should be:
  - Designed to be cleanable and to be sanitized according to SSOP, HACCP plans, or Harvest Safety Plans, as applicable
  - Made of food safe or food grade material
  - All storage equipment for tools must not create adulteration or unsanitary conditions
- Receptacles used for storing inedible material cannot be used for storing edible product and must be conspicuous marked with intended use i.e. "Trash"
- Instruments used to measure, regulate, or record critical controls must be:
  - Accurate and precise (in most instances, calibrated before use)
  - Maintained in working order
  - Appropriate quantity for designated uses (i.e. enough recording thermometers to record temperature at each fish smoker)

Standard Sanitation Operating Procedures (SSOPs)

66

- Required for:
  - Food Processing Plants
  - Retail Food Establishments
  - Facilities used by Class 1 Meat Processors
  - Facilities used by Class 1 Fish Processors
- The SSOP should specify how the establishment will meet required sanitation conditions and practices
- Records document sanitation monitoring and corrections
- Shall be signed and dated by the person with overall authority for the facility

Recordkeeping

67

Record Types	Duration
Sanitation Records	6 months
Refrigerated meat, fish, and other HACCP required product records	1 year
Frozen, shelf-stable, or preserved meat, fish, and other HACCP required product	2 years
Equipment records or scientific study based process records	2 years
Training records of all workers (paid, unpaid, permanent, and temporary personnel)	3 years
Tribally Licensed facilities: Harvester education or training records and harvester processing records	3 years

Record Locations

68

- For seasonal facilities, records may be located in a reasonably accessible location at the end of the season
  - Records must be returned to the facility within 24 hours, if requested
- Records may be kept electronically if appropriate controls are implemented to ensure the integrity of the data and signatures
- **All records and plans required by Model Food Code Chapter 3.10 [Recordkeeping] must be available, at reasonable times, for official review and copying by the tribal licensing authority**

Food Processing Plant - Summary

69

Chapter 3.11

- Must be licensed and registered
  - Licensing requires an inspection and certification
- Annual inspection
- Compliance with standards on the following required:
  - Water quality and plumbing (complies with CFR 141)
  - Construction and sanitary design
  - Toilet facilities for personnel
  - Controlled access and pest exclusion
  - Waste disposal

Covered in the Food Manager and Regulator training

Retail Food Establishments

70

- Chapter 3.13
- Retail food establishments are required for entities selling class 3 foods (sales to non-Anishinaabeg)
  - Covered in the Food Manager and Regulator training

Licensing and Enforcement

71

- The following operations require licensing with the tribal licensing authority:
  - Food processing plant
  - Retail food establishment
  - Class 1 Meat vendor
  - Class 1 Fish vendor
  - Produce packer
  - Low risk food vendor
- Type of enforcement actions:
  - Penalties
  - Suspension of license
  - Revocation of license
- Examples of reasons for enforcement actions:
  - Evidence of serious health or safety threat
  - Reasonable grounds to suspect food is adulterated
  - Non-compliance with regulations
  - Failure to pass inspection

72

“Let’s take a short break!”

K.

73

Traditional Foods Harvest to Kitchen

OBJECTIVES:

- Review processing and labeling requirements for:
  - Low Risk Foods
  - Fish
  - Venison
  - Turkey

74

Summary of Standards for Traditional Foods and Processing

The following applies to All Licensing Classes & All Foods:

- All food contact surface should be made of only food grade materials
  - This includes food packaging material, utensils, equipment, etc.
- All food contact surfaces should be cleaned and sanitary prior to use and cleaned and sanitized as needed
  - Single use, disposable items should arrive clean and sanitary prior to use and do not need cleaning and cannot be reused
- Clothes should be made of cleanable material or single use and should be cleaned prior to use and as needed
- Good personal hygiene and frequent hand washing is required
- All water used in food or on food contact surfaces should be potable
- Persons handling or packing food should be free of contagious disease

75

Model Food Codes for Treaty-Harvested Foods

In recognition of the Tribes' civil regulatory authority, the Model Food Code requires varying degrees of regulation per class

- Class 1 = sales from tribal member to tribal member, on reservation (minimal regulation; limited to lower risk products)
- Class 2 = sales to tribal institutions and programs (more involved regulation; includes products that involve a higher degree of risk)
- Class 3 = retail sales, on and off reservations, to both tribal and non-tribal members (most regulated; for products that must be carefully produced to remain safe)

Labeling standards vary depending on the class of the food

76

State/Federal Food Safety Standards

State/Federal Standard	Every-day meaning
Adulteration	Food needs to be clean, wholesome & safe
Misbranding	Food label needs to be accurate
Food Processing Plants	Food needs to be prepared in a facility that is safe, sanitary and secure
Meat Inspection (not applicable for fish)	Food from animals needs to be checked for potential disease or spoilage to make sure its safe for human consumption
Preservatives, artificial colors, food additives	Food processors can only use certain additives to foods and they must be safe

77

Fish:

Adikameg (Whitefish)

Ogaa (Walleye)

OBJECTIVES:

- CONTAMINANT INFORMATION
  - Harvester
  - Food Processor/Handler
- PROCESSING REQUIREMENTS
- MODEL FOOD CODE CHAPTER SUMMARY

78

Overview of Harvester Responsibilities

- For off-reservation, inland harvesting, use GLIFWC website for information on fish harvesting regulations
- Tribal codes address commercial harvesting in Lake Superior
- Hazards from water to freezer
- Hazards in the Food Facility and Kitchen

Food Safety Considerations

79

- *Biological*
  - *Bacteria (E. Coli, Listeria, Salmonella)*
  - *Parasites*
- *Chemical*
  - *Ogaa:*
    - *Mercury*
  - *Adikameg:*
    - *Low in chemical contaminants*
- Physical
  - Low likelihood of physical hazards from harvest to processor

Biological Contaminants - Location Selection

80

- Bacteria is found in the water and the body of fish
- During large water events, the amount of bacteria can increase

Risk Reduction:

- Check with tribal and state natural resource departments about areas closed to fishing
- Consider the impact of flooding or other water related natural
- Always use potable water for processing, handwashing, etc.

Food Safety – Bacterial Pathogens

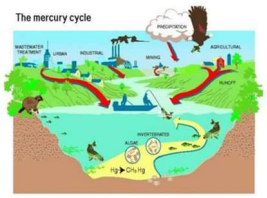
81

Reduce Risk

- Cool rapidly and keep cool (below 38°F)
- Potable water must be used for processing and any ice used for cooling must be made of potable water
- Treat ice as food
- Gut, process, and handle using clean and sanitized surface, equipment, and hands
- Transport at or below 38°F

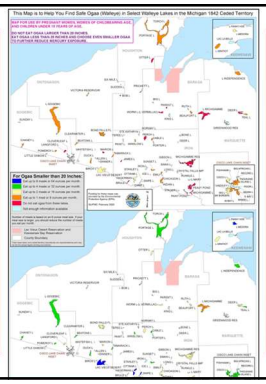
Chemical Contaminant - Methylmercury

82



Mercury (Walleye)

- Fish consumption is the primary route of exposure
- Can pass from mother to fetus
- Can impair neurodevelopment in children
- In adults, impacts the central nervous system and cardiovascular health
- Possible Sources:
  - Mining and metals processing
  - Burning of fossil fuels
  - Forest Fires and volcanoes



Chemical: Methylmercury

83

Inland Lakes:

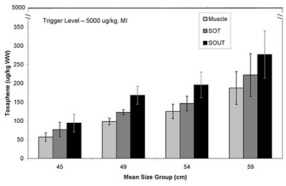
- Since 1989, GLIFWC has tested nearly 9,000 walleye from inland waters for mercury
- Annual testing provides information on mercury concentration walleye from inland Ceded Territory lakes

Consuming Fish:

- Found in the muscle or meat of the fish
- Cannot be removed by cooking or trimming fat
- Body of water, fish species, and fish age and size can impact mercury exposure
- Walleye are large, long-lived, and sit high on the food chain

Adikameg Chemical Contaminants

84



- Studies performed on Great Lakes Whitefish have shown it to be low in contaminants of concern:
  - Polychlorinated Biphenyls (PCBs)
  - Dioxin
  - Toxaphene
- Trimming fat can reduce but not eliminate these particular contaminants

Food Safety Considerations Harvest to Kitchen

85

Fish & Food Safety - Snapshot

86

Fish is a TCS Food (Time and Temperature Control for Safety)

- Biological
  - Botulism for Reduced Oxygen Packaging
  - Bacteria
  - Parasites & Viruses
- Physical
  - Metal
- Chemical
  - Allergens (industry and labeling)
  - Methylmercury

Keweenaw Bay Tribal Judge by day, fish processor by night Brad Dakota fillets a lean lake trout. Brother and Tribal Police Chief Dale Dakota shares responsibility at their fish shop near L'Anse, Michigan.

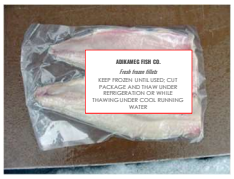
Food Safety – Botulism *Clostridium botulinum*

87

- Creates a spore which can survive both cooking and freezing
- Spores can release a powerful neurotoxin
- A LITTLE CAN BE LETHAL TO ALL AGES
- A concern when fish is stored in environments without air (e.g. vacuum packed)

Reduce Risk

- Vacuum Packed Frozen:
  - Reduce the time that the product is subject to temperature abuse during transportation, storage and processing
  - These products must be labeled with safe handling instructions



"KEEP FROZEN UNTIL USED; CUT PACKAGE AND THAW UNDER REFRIGERATION OR WHILE THAWING UNDER COOL RUNNING WATER."

Food Safety – About *E. Coli*

88

Reduce Risk

- Cool rapidly and keep cool (below 38°F)
- Check fish when receiving, fish should be completely surrounded by ice. If using another form of cooling, internal temperature should be 38°F or below
- Fish should look healthy and fresh
- Keep processing times short
- Reduce opportunities for cross contamination

HACCP Plan in place

- **HACCP Plan includes the concepts for Food Handlers and Consumers but on a larger, more formal scale**

Food Safety- Parasites, Viruses, & Physical Hazards

89

General

- Naturally occurring in the fish and water
- Both need a living host to survive

Food Handler or Consumer

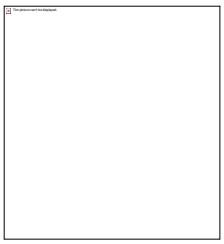
- Keeping fish 38°F or lower
- Prevent cross contamination
- Cook thoroughly to internal temp of 145°F
  - If smoking, opt for hot smoking and bring the internal temperature of the fish to 145°F for 30 full minutes

Physical Concerns

- Metal inclusion
  - Rare, but can happen, risk may depend on harvest tool or previous experience

Fish and the Model Food Code

90



All Licensing Class Processing

91

- Appropriate quality control must be used:
  - Examples:
    - Time and Temperature control: refrigeration or freezing (below 40°F)
    - Cross contamination prevention: SSOP
    - Food safe materials: food safe plastics, stainless steel
    - Sanitation control: good hygiene, clean, and sanitary surfaces
    - Using potable water for processing fish, ice, cleaning hands, and other surfaces
- Packaging materials must be food safe, kept clean and dry prior to using
- SSOPs in place for the processing facility
- HACCP to manage risks associated with the products being produced

Prior to Processing Fresh Fish

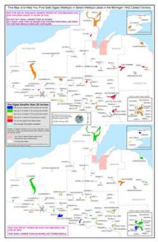
92

- To be processed for sale, (evisceration/gutting is not considered processing) fish must be:
  - Fresh and wholesome
  - Proof that the fish was held at or below 38°F (ambient or internal temperature)
    - Transportation records (i.e. recording thermometer records, temperature check records, etc.)
    - Fish is completely surrounded by ice
    - Chemical cooling media (i.e. ice blocks) remain frozen and the product's internal temperature at delivery is 38°F or below
    - Delivered refrigerated with transit time of 4 hours or less, transportation records, and the product's internal temperature at deliver is 38°F or below

Prior to Processing Fresh Fish continued

93

- Proof of legal harvest
  - All fish received by a food facility or Class 1 processor must be accompanied by proof of legal harvest
  - Records of the proof of harvest must be maintained in accordance with Chapter 3
- All fish, sold or donated, must be accompanied by a Harvester Certificate of Guarantee. To include:
  - Waterbody(ies) of harvest
- The following inland fish cannot be sold or donated: Inland fish harvested from lakes which are labeled on GLIFWC Mercury maps as "Do Not Eat" for pregnant women, children, and women childbearing age



Class 1 Regulations

94

- Sales to tribal members only, on reservation

  Fresh filets only

  - Must be stored in a refrigerated container at or below 38° F or in contact with ice
  - Containers holding fish must be sanitary
  - Allergen label required

Can be processed outside of a tribally licensed food processing plant in a facility such as a home kitchen.

Class 2 Regulations

95

- Sales to tribal programs

  Fresh and frozen fish only (whole, gutted, or filets)

  - Labeling for Class 2 & Class 3 apply
    - Standard labeling (identity of food, net contents, nutrition facts, etc.)

Must be processed in a tribally licensed food processing plant

Fisherman finds street corner success

Class 3 Regulations

96

- Retail sales to anyone, anywhere

  Fresh, frozen vacuum packed, smoked, and roe

  - Same food safety standards as Class 1 & 2, plus additional safety requirements for specialty products
  - Class 2 and 3 Labeling applies

Processed in a tribally licensed food processing plant (facility requirements and HACCP apply)

97

Class 3: Smoked Fish Products

- All fish intended for smoking must be eviscerated in a food safe manner
- Brining and pickling loads are single species and similarly sized (liquid must be changed as frequently as necessary to reduce harmful microbial load)

Hot smoking fish:

- During process:
  - Fish internal temperature must be maintained **at or above 145°F for a minimum of 30 minutes**
  - Smoked fish products which are cooked should be rapidly cooled:
    - Example:
      - Less than 70°F within 2 hours
      - Cool to less than 41°F in 48 hours
  - Refrigerated smoked fish products muse have a minimum of **3.5% water phase salt** content or a minimum of **100 ppm nitrate and 3% water phase salt** content

98

Class 3: Smoked Fish Standards, cont.

Packaging

- Refrigerated smoked fish product packaged in reduced oxygen packaging (e.g. vacuum sealing) must have a minimum of 3.5% wps (water phase salt)
- Otherwise, smoked fish is contained in air permeable membranes (i.e. film or butcher paper wrapped) and must have a minimum of 3% wps

Labeling

- Smoked fish must be labeled with handing instructions: "PERISHABLE" and/or "KEEP REFRIGERATED AT 38° F (3.33° C) OR LESS."
- If additives are used (nitrites), they must be included in the ingredient list, along with its function (preservative)
- Allergen labeling required for fish products

For information on fish egg products please see Chapter 6.04 of the Model Food Code.

99

Class 3 Only: Fish Egg Products

- Refrigerated or frozen fish egg products
  - After skeins are removed, salt must be added to produce a ratio of 1 pound salt to 33 pounds of roe
  - Only use canning salt (other forms of salt contain anti-caking chemicals which produce a bad flavor)
  - Strict refrigeration control is necessary (most roe products are kept frozen for export to European nations)
  - Labeled with handling instructions and allergen statement

100

Labeling: Fish Products

Class 1 Fish Products

- If processed outside of a food processing plant, must be labeled "PROCESSED AND PACKAGED IN A HOME FACILITY"

Labeling requirement:

- Allergen name (Fish), along with the name of the food source (i.e. walleye) is included on the label:
  - In the ingredient list OR
  - "Contains: …." Statement

Class 2 & 3 Fish Products

- Standard labeling requirement (similar to federal labeling)
- Handling instructions
- Allergen name (Fish), along with the name of the food source (i.e. walleye) is included on the label:
  - In the ingredient list OR
  - "Contains: …." Statement

101

"Let's take a short break!"

If you have questions feel free to unmute and ask.

102

Meat:

Venison

Wild Turkey

OBJECTIVES:

- MODEL FOOD CODE CHAPTER SUMMARY
- CONTAMINANT INFORMATION
- PROCESSING REQUIREMENTS

Food Processing & LCO v. Wisconsin

103

- In the 1980s, the parties the *Lac Courte Oreilles v. Wisconsin* (Voigt) case made agreements or stipulations on many issues
- Commercial sale of venison agreement
  - The Tribes agreed to hold off on selling any processed venison products (i.e. any cuts of venison, ground venison, venison jerky, etc.) until they created a food regulatory system similar to state and federal models
  - The Tribes also agreed to give the state notice and provide a copy of their regulations to the federal court
- Currently, the only opportunity for tribal members to sell venison is by selling a whole carcass

For more information about this, please join us for our Food Manager and Regulator trainings

State/Federal Food Safety Standards

104

State/Federal Standard	Every-day meaning
Adulteration	Food needs to be clean, wholesome & safe
Misbranding	Food label needs to be accurate
Food Processing Plants	Food needs to be prepared in a facility that is safe, sanitary and secure
Meat Inspection (not applicable for fish)	Food from animals needs to be checked for potential disease or spoilage to make sure its safe for human consumption
Preservatives, artificial colors, food additives	Food processors can only use certain additives to foods and they must be safe

Meat - General

105

- Meats are a TCS food
  - Animals carry in their intestinal tract and on their fur or feathers, bacteria which could make consumers sick if not controlled
- Like fish, meat requires more care and regulation due to the higher risk nature of meat
- Terms:
  - **Game Animal -** individual of a wildlife species of animal used by the Anishinaabe for food that has not been raised domestically

*All references to meat, animal, or game animal in this section specifically refer to wild, undomesticated animals

Harvesting Under the Model Food Code

106

- Harvesters must comply with applicable tribal conservation codes including tagging and registering
- Ambient air temperature must be **41°F or below** when the animal is slaughtered
- Only non-toxic ammunition may be used
- Only small game may be harvested with projectile shot (pellets)
  - Pellet sizes may be smaller than size 6

Harvesting Documentation

107

- All harvested game animals, including wild poultry, should include assurances in writing that:
  - The animal was healthy when harvested
  - Was field dressed using clean clothes and cleanable equipment
  - Transported and stored in accordance with Transportation and Storage regulation (Sec. 3.06)
- Harvesters will need to successfully complete field-dressing education or equivalent training approved by the regulating tribe. Training number will need to be indicated on form

Class 2 & Class 3

- Inspected within 24 hours of kill
- Documentation must be provided to a tribally-certified meat inspector regarding the measures taken during and after field-dressing

Harvester Certificate of Guarantee

108

- Harvester Certificate of Guarantee includes:
  - Harvest/Carcass tag number (or equivalent information)
  - Date, time, and location of harvest
  - Ambient air temperature information at the location and time of harvest
  - Manner of kill (i.e. "killed by gunshot wound to the upper right shoulder")
  - Type of ammunition or killing instrument

HARVESTER CERTIFICATE OF GUARANTEE (VENISON)

Commercial Tag No.: _____
Tribal Disease Management Area Tag No.: _____
Only applicable to deer harvested in Tribal Disease Management Areas:
Name of the Tribal Member Harvester: _____
NAGPA M. No.: _____

Pre-mortem Inspection Information Record
Required for Class 2 and 3 Sales Only
Condition and behavior of animal at rest, and in motion:
Overall condition of the animal, especially the head, eyes, leg and body: (normal, or describe) _____

Alertness, mobility and breathing (normal, or describe): _____

Presence of any unusual swelling, signs of injury or other abnormalities? (N/A, or describe) _____

Displaying any abnormal behavior? _____ If so, describe: _____

Normal gait, normal grazing activity, alert to danger: yes/no (circle one)

Alive, when harvested: yes/no (circle one)

□ Unable to walk due to broken appendages, severed tendons or ligaments, nerve paralysis or fractured spine (circle as applicable).

Time of Kill Information
Required for All Classes of Sale

Date: _____
Time: _____
DMC: _____
Air temp: _____
Manner of killing:
Bow/arrow __
Crossbow __
Rifle __
Type of shot used (if applicable): _____
Neuteric shot is required.
□ Was harvested within a Tribal Disease Management Area for Chronic Wasting Disease (CWD) or Bovine Tuberculosis (TB).

Class 1 Regulations

109

Sales to tribal members only, on reservation
Fresh and frozen cuts of meat only

- Can be processed in a non-licensed facility such as a home kitchen or shed
- Must have a valid Class 1 meat vendor license
- Annual inspection is required

Photo Credit: The News-Gazette

Class 2 Regulations

110

Sales to tribal programs such as Head Start and Elderly Nutrition Programs
Limited to cuts of meat or ground meat which are fresh or frozen

- All butchering is done in a tribally licensed food processing facility
- Standard labeling requirements apply (i.e. nutrition content, weight of package, facility name & address, etc.)

Class 3 Regulations

111

Retail sales both on and off reservation, to anyone
Fresh/frozen cuts of meat/ground meat and dried meat products (jerky)

- All butchering/packaging is done in a tribally licensed food facility
- Standard labeling requirements apply (i.e. nutrition content, weight of package, facility name & address, etc.)

Photo Credit: The National Provisioner

Harvester to Processing in a Food Plant

112

Class 2 & 3:

- No animal carcass enters the food processing plant until it has passed inspection
- Harvester must document steps taken to protect carcass from contamination and continuously cool it
- The harvester must be present documentation (Harvester Certificate of Guarantee) and the carcass for inspection
- Inspection must take place within 24 hours of the kill
  - A tribally-certified meat inspector can reject carcass or request a second inspection by a licensed veterinarian
- Food Processing Plant must keep on file the Harvester Certificate of Guarantee and accompanying documents for each carcass it accepts

Tribal Disease Management Areas

113

- Harvests from a Tribal Disease Management Area are presumed be diseased must undergo a post-mortem inspection with 24 hours of harvest
  - Transport carcass to Tribal Natural Resource department or designee for sample collection
- Until results of testing are provided, the carcass must be stored in compliance with Transportation and Storage regulation (Sec. 3.06), below 38°F, without contacting other carcasses or food and records kept.
- Test Results:

Tribal Disease Management Areas continued

114

- Until results of testing are provided, the carcass must be stored in compliance with Transportation and Storage regulation (Sec. 3.06), below 38°F, without contacting other carcasses or food and records kept
- Test Results:
  - No detectable disease = carcass may be released to food processing facility or may be processed by a Class 1 Meat vendor
  - Disease detected = carcass is condemned and may not be used for human consumption

Food Safety for Venison & Turkey-Harvester

116

- *Biological concerns:*

  Venison
  - *Chronic Wasting Disease (CWD)*
  - *Bovine Tuberculosis (bTB)*

  Turkey
  - *West Nile Virus*

  Both
  - *Bacteria: E. Coli, Salmonella, Listeria*
- Chemical
  - Lead
- Physical
  - Bullet fragments

Before the Hunt (Ceded Territory)

117

- Read through relevant hunting regulations at https://data.glifwc.org/regulations/
- GLIFWC Wardens are available to answer your questions

Hunter must:
- Complete Hunter's Education & Firearm Safety
  - Unless born before January 1, 1977
  - Or have completed an Armed Forces basic training
  - Or hunt with a qualified mentor
  - http://data.glifwc.org/archive.bio/hunter.safety.mentor.hunter.summary.2020-04-03.pdf
- Contact tribal registration station for updates and to obtain required permits

Protecting Hunter's Health

118

- Tick and mosquito-borne diseases carry the risk of serious infection
  - Wear long sleeves and pants
  - If possible, wear tick and mosquito repellants and apply according to manufacturer's instructions
  - Perform daily tick checks following time in the woods

Photo Credit: Missouri Department of Conservation

Photo Credit: Cleveland Clinic

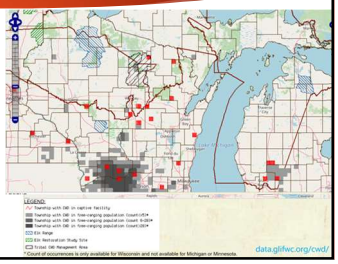
Photo Credit: The Conversation.com

Deer Related Disease - CWD

119

- Chronic Wasting Disease (CWD)
  - A protein based disease which infects deer, moose, and elk
  - Unknown risk to humans
  - There is no cure
  - The disease is always fatal to deer
  - May be transmitted through many different vectors (i.e. urine, feces, carcasses and potentially other animals, vegetation, and tools)

CWD has been found in MI, WI, and MN



Deer Related Diseases - bTB

120

- Bovine Tuberculosis
  - According to the CDC, bTB represents about 2% of tuberculosis cases annually or about 130 people[1]
  - Can be passed from cattle to deer
  - Can transmit to humans through bodily fluid contact & inhaling bacteria exhaled from infected lungs[1]
  - Monitored by state natural resource departments and GLIFWC

1 Centers for Disease Control "Table 18 Reported Tuberculosis 2018" September 2019. (see handout)

Deer Disease Monitoring in the Ceded Territories

121

- CWD and Bovine Tuberculosis
  - GLIFWC Biological Services Division is engaged on efforts to monitor the spread of these diseases in the Ceded Territories, in conjunction with tribal, state, and federal partners
  - The Voigt Intertribal Task Force and Tribes have processes in place to manage wildlife diseases (Tribal Wildlife Disease and Invasive Species Management Areas) within the Wisconsin portion of the 1837 and 1842 Ceded Territories

MAINGWAGAN PAGE 4 • CWD • SUMMER 2018

Chronic wasting disease taking hold in Wisconsin Ceded Territory

Captive deer rules fail to halt spread

By Travis Bartnick, GLIFWC Wildlife Biologist

Parasite - *Toxoplasma gondii*

122

- Common parasite found in mammals and contaminated water throughout US
- Persons infected may not show signs of illness
- Venison = top 3 sources of *T. gondii* in food (CDC) as deer may show no signs of infection or disease
- Use hygienic practices during field dressing and processing to reduce the risk of cross-contamination with cooking being the best known way to reduce risk to consumer
  - Whole cuts: minimum 145°F and rested for several minutes
  - Ground meat: minimum internal 160°F

Protecting Consumer Health

123

- Chronic Wasting Disease
  - Refrain from harvesting deer that exhibit strange characteristics (abnormally thin, irregular gait, etc.)
  - Have harvest tested for deer harvested in CWD Management Areas
- Bovine Tuberculosis
  - Check for signs of tuberculosis when harvesting in bTB Management Areas
  - Signs of disease include white spots on the lung and/or lung cavity

Photo Credit Michigan DNR

Clean and sanitize all surfaces and equipment

rom deer that test positive for CWD or bTB CANNOT BE SOLD OR DONATED

Protecting Hunter's Health-Field Dressing

124

When Field Dressing:

- Wear gloves when field dressing **any animal** and change as needed
- For **Bovine Tuberculosis** (in areas where TB is present)
  - Cover nose and mouth with breathing mask when working with the lungs, throat, and mouth of deer
  - Inspect lungs for signs of disease, retain a tissue sample of lungs which appear diseased for testing

After Field Dressing:

- Wash hands, especially before eating or drinking
- For **Chronic Wasting Disease** (CWD) have deer tested
  - Decontaminate all equipment between harvests (50% bleach/water solution for 5 min. is an effective decontaminant)

Protecting Hunter's Health - West Nile Virus

125

- Mosquito disease which can infect both birds and humans. Needs blood to blood transmission
- Limited incidences of West Nile Virus have been seen in turkey
- Harvesters should:
  - Wearing gloves when handling turkey can reduce likelihood of transmission
  - Examine harvest for signs of disease

Animals exhibiting signs of disease cannot be sold or donated under the model food code

Comparison of breast meat of grouse suffering from west nile virus (left) and healthy grouse breast meat (right).
Photo credit: Milwaukee Journal Sentinel

General Bacterial Hazards

126

- Animals carry a variety of bacterial in their intestines which, if allowed to grow, could cause illness and disease
- Most Likely:
  - *E. Coli* - Both Venison and Turkey
  - *Salmonella* - Turkey
  - *Listeria* - Turkey

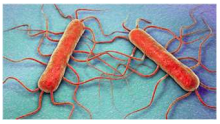


Photo Credit: BioCote

- Incidences of reported foodborne illness related to these foods is very low

Food Safety – Bacteria in the Field

127

- Harvesters
  - Process harvest in clean, sanitary environment
  - Process with clean, sanitized equipment
  - Avoid nicking the intestines or allowing fecal matter to come into contact with meat
- Process and cool carcass quickly:
  - Example:
    - Less than 70°F within **2 hours**
    - Cool to less than 41°F in 48 hours

Continuous cooling is required

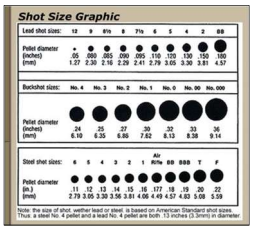
Optional Techniques:
- Shot placement
- Bung tying
- Antimicrobial rinse

Photo Credit & M. Scholz

Keeping Turkey Safe

128

- Turkey is naturally low in heavy metals
- 2019 study conducted by GLIFWC found that ammunition pellet size and metal type can impact the amount of lead in found in harvested turkey breast meat
  - The following lead shot increased lead content of the breast meat in the study:
    - No. 6
    - No. 8
  - Pellet size must be larger than size 6



Shot Size Graphic

Lead shot sizes:	12	9	8½	8	7½	6	5	4	2	BB
Pellet diameter (inches) (mm)	.05 1.27	.080 2.30	.085 2.16	.090 2.29	.095 2.41	.110 2.79	.120 3.05	.130 3.30	.150 3.81	.180 4.57

Buckshot sizes:	No. 4	No. 3	No. 2	No. 1	No. 0	No. 00	No. 000
Pellet diameter (inches) (mm)	.24 6.10	.25 6.35	.27 6.86	.30 7.62	.32 8.13	.33 8.38	.36 9.14

Steel shot sizes:	6	5	4	3	2	1	Air Rifle	BB	BBB	T	F
Pellet diameter (in.) (mm)	.11 2.79	.12 3.05	.13 3.30	.14 3.56	.15 3.81	.16 4.06	.177 4.49	.18 4.57	.15 4.83	.20 5.08	.22 5.59

Note: the size of shot, neither lead or steel, is based on American Standard shot sizes. Thus a steel No. 4 pellet and a lead No. 4 pellet are both .13 inches (3.3mm) in diameter.

Photo Credit: Shot Gun World.com

Waawaashkeshi & Mizise wiiyas in the Facility or Kitchen

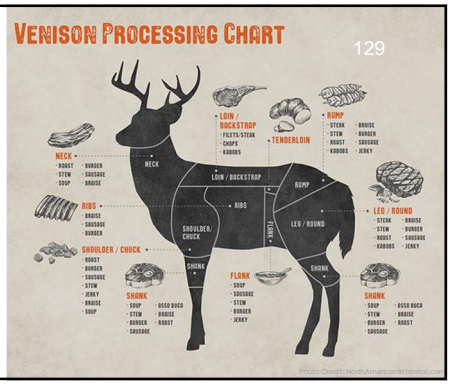


Photo Credit: NorthAmericanWildlife.com

Reminder: Receiving Food from Harvesters

130

- All harvested game animals, including wild poultry must be accompanied by a complete Harvester Certificate of Guarantee, documenting
  - That the animal was healthy when harvested
  - Examined by the hunter before and after harvest
  - Was field dressed using clean clothes and cleanable equipment
  - Transported and stored in accordance with standards

HARVESTER CERTIFICATE OF QUARANTINE (SAMPLE)

Commercial Tag No. _____
Tribal Disease Management Area Tag No. _____
Only applicable to deer harvested in Tribal Disease Management Areas
Harvester's Name _____
Tribal Id. No. _____

Pre-mortem Inspection Information Record
Required for Class 2 and Class 3 kills
Condition and behavior of animal at rest, and in motion.
Any abnormalities observed, separately by body zone, leg and body; (normal, or describe)

Alertness, mobility, and breathing (normal, or describe) _____

Presence of any unusual swelling, signs of injury or other abnormalities? (N/A, or describe) _____

Displaying any abnormal behavior? _____ If so, describe _____

Normal gait, normal grazing activity, alert to danger (not to kills only)

Alive, when last seen? (not to kills only)

☐ Unable to walk due to broken appendages, or avoid motion or ligaments, torn muscles or fractured spine (noted as applicable)

Humane Handling Certification
Required for Class 2 and Class 3 kills
☐ The animal was killed in a swift and efficient manner consistent with the methods approved by my Tribe's Game Code.
☐ The animal was not skinned, bound, thrown or cast until the animal was stunned or killed in a manner that caused permanent unconsciousness or death.

Field Dressing Certification:
Required for Class 2 and Class 3 kills
☐ All personnel engaged in field dressing the animal wear clean, washable outer clothing and food handling gloves, with any long hair covered or tied back, and all processed washed and treated their hands sufficiently to prevent the spread of contaminants and pathogens.
☐ Equipment and utensils used for field dressing were made of sanitary design and construction, and were kept clean and sanitary (free from contamination by soil, venison, viscera, venison and waste products) prior to, and during use.
☐ Prior to washing any viscerous into the carcass, from dirt and debris was cleaned from the carcass, and the carcass was placed in a non-permeable, clean and sanitized surface (i.e. clean and sanitized tray, game processing table, etc.)

Time of Kill
Required for All Classes of Take
Date _____
Time _____
AM/PM _____
Location of Kill _____
Method of Killing _____
Bow hunter _____
Crossbow _____
Rifle _____
Type of shot used (if applicable) _____
Nontoxic shot is required
Tribal Disease Management Area for Chronic Wasting Disease (CWD) or Bovine Tuberculosis (TB)

Food Safety

131

Animals exhibiting signs of disease cannot be sold or donated under the model food code

- Consumers, Food Handlers & Processors
  - Ask for:
    - Harvest location or county
    - CWD test results (required for deer from CWD Management Areas)
    - Temperature logs from transportation
      - Food code requires deer from CWD Management Areas held under refrigeration and not

T. gondii

132

- ***Toxoplasmosis gondii***
  - Cannot be seen with the naked eye
  - Assume all venison contains *T. gondii*
  - Prevent cross-contamination
    - All equipment and utensils should be cleaned and sanitized after use on venison
  - Consider wearing gloves to protect food handlers
  - **Cook thoroughly:**
    - Whole cuts of venison to 145°F and let rest for several minutes
    - Cook ground venison products to 160°F

Photo Credit:Cooking NY Times.com

Food Safety – Bullet Fragments & Shot Pellets

133

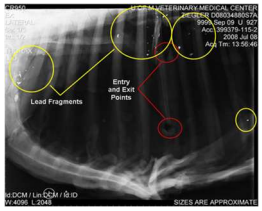


Photo Credit: NY Department of Environmental Conservation

Bullets Fragments and Shot Pellets

- Only non-toxic (lead free) ammunition is allowed for harvesting
- Inspect meat for bullet fragments or pellets. Remove found fragments or pellets

Food Safety – Bacteria in the Kitchen

134

- All
  - Keep meat or carcasses refrigerated or frozen until ready to use
  - Ask hunter about food safety practices
  - Use good hygiene and sanitary practices
- Processors and Food Handlers
  - Clean and sanitize equipment often
- Consumers
  - Cook meat thoroughly

Low-Risk Foods

135

OBJECTIVES:

- WHAT ARE LOW-RISK FOODS
- CONTAMINANT INFORMATION
- PROCESSING REQUIREMENTS
- MODEL FOOD CODE CHAPTER SUMMARY

Low-Risk Foods (LRF)

136

- Low-Risk Foods are foods that do not require a time and temperature control or refrigeration to remain safe

AND

- Which have been shown to not support the grown of pathogens

Chapter 8 of the Model Food Code

Photo Credit: North Wind Organic Farm

Example of Low-Risk Foods

137

- Maple Syrup
- Maple Sugar
- Wild Rice (manoomin)
- Jams and Jellies (low acid preserved foods)
- Pickles (low acid preserved foods)
- Dried fruits/teas (not including melons)
- Candy

Low-Risk Food Licensing

138

- Low-Risk Food Vendor license is required for Class 1, Class 2 & Class 3 if Low-Risk Food is produced **anywhere other than** a tribally licensed food processing plant (i.e. home kitchen)

- Licenses are:
  - Issued by the tribe
  - Annual
  - Location specific
  - Not required for the production of Class 1 manoomin or Class 1 sugar and syrup
- Obtain a license:
  - Submit an application
  - Participate in an Inspection
  - Pay any required fees

Categories of Low Risk Foods

139

Less than $50,000* annual sales

- Outside of a tribally licensed food processing plant
- Exempt from HACCP
- Must comply with portions of Chapter 3
- Must comply with simplified processing regulations in Chapter 8.01(3)

$50,000* and above in annual sales

- INSIDE a tribally licensed food processing plant
- HACCP required
- Must comply with ALL of Chapters 3, 4, and 8

*excluding any revenue from manoomin or syrup/sugar sales

LRF General Requirements

140

Less than $50,000* annual sales

- **Vendors must demonstrate an understanding of the applicable food safety standards**
- **Foods are prepared consistent with traditionally safe methods**
- **Any produce used is appropriately cleaned and inspected (by vendor)**
- Water must be safe to drink (potable)
- Persons preparing/packaging foods are not sick with a contagious disease

LRF Processing Requirements

141

Less than $50,000* annual sales

Preparing and Packaging Specific:

- Wear clean, cleanable clothing and washes hands sufficiently
- Keep premises, tools, equipment clean and sanitary in compliance with traditionally safe methods
- **No animals are allowed in the workspace while in use**
- **No other domestic activities are to be conducted during use (i.e. preparing your own meal)**
- Materials used for packaging will be clean and dry prior to use if single use. Other containers should be clean and sanitized prior to use

Class Exercise

142

- Using the training manual starting on page 480:
  - **Please list in the chat the 6 portions of Chapter 3 which Low-Risk Food Vendors with annual sales less than $50,000 must comply.**
    - 3.01 Respect for Traditional Foods and Consumers
    - 3.02 Truth in Labeling
    - 3.03 Food Additives
    - 3.05 Food Transportation and Storage
    - 3.06 Equipment and Utensils
    - 3.10 Recordkeeping

LRF Sale Requirements

143

- Low-Risk Foods must be sold from processor directly to the consumer with the exception of:
  - Maple syrup
  - Maple sugar
  - Manoomin
- If sales take place off-reservation, vendors may have to comply with state law (i.e. cottage food laws), which may differ from this regulation

LRF Labeling Requirements

144

- Sec. 3.02 Truth in Labeling:
- All food, except for manomin and maple syrup/sugar, produced outside of a tribally licensed food processing plant must be labeled

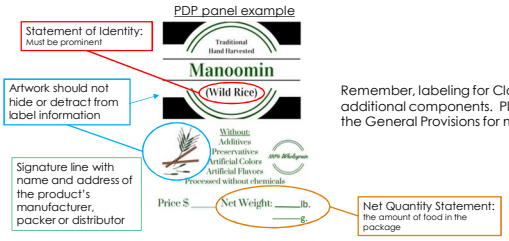
"PROCESSED AND PACKAGED IN A HOME FACILITY"

- Specialized terminology and labeling is required for certain processing practices for wild rice and maple syrup

Class 2 & 3 LRF Labeling Standards

145

PDP panel example



Remember, labeling for Class 2 & 3 require additional components. Please refer back to the General Provisions for more information

Zhiiwaagamizigan (Maple Syrup)

146

Zhiiwaagamizigan Contaminant Overview

147

Maple syrup is a safe, low contaminant food

- Maple sap is low in chemical contamination including:
  - Heavy metals
  - Lead
- Food Safety Risks
  - Process related chemical risks:
    - Lead from food contact surfaces
    - Misuse of chemical cleaners

Maple Syrup & the Model Food Code

148

- Maple Syrup and Sugar
  - Syrup is defined as "liquid derived from sugar-rich tree sap, which is not less than 66 degrees brix"
  - Sugar is defined as "a solid, grainy or viscous substance derived from sugar-rich tree sap, which was boiled beyond 66 degrees Brix and stirred"
  - Sugar content of finished syrup must be measured by a properly calibrated refractometer or equivalent device, with a record made and kept by producer

Photo Credit: Cook's Maple Farm

Photo Credit: Aliexpress.com

Photo Credit: Ohio State University Extension

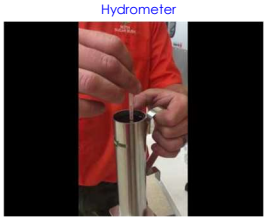
How to use

149

Refractometer

Video credit: Roth Sugar Bush and CDL Wisconsin

Hydrometer



Video credit: Roth Sugar Bush and CDL Wisconsin

Maple Syrup Processing Requirements

150

- Sap must be covered and care taken to avoid spoilage
- Only nontoxic defoaming/filtering agents may be used
- Equipment and facilities
  - Food contact surfaces used for syrup/sugar production must be cleaned and sanitized prior to use and
  - when there's break in boiling sap
    OR
  - at least every 40 days
- All producers need to employ practices to keep maple syrup products safe

Photo credit: University of Maine

Canning and Labeling Maple Syrup

151

- Jars or bottles used for packaging maple syrup must be cleaned and sanitized prior to their use
- Maple syrup may not be labeled "traditionally processed Ojibwe maple syrup" unless the syrup was produced by boiling sap over a wood-burning fire
  - Reminder: Food contact surfaces which come into contact with maple sap, syrup, or sugar should be free of lead and lead solder and resistant to corrosion.

Licensing Classes and Maple Syrup

152

- For Class 1 food:
  - Low-risk vendor license not needed
- For Class 2 and Class 3 food:
  - Low risk vendor license needed; inspection requirement
  - The final boiling and packaging of the product occurs in a tribally licensed food processing plant or premises exempt from 21 CFR 1.225. *Residences are exempt*

Manoomin

Wild Rice

Manoomin Food Safety - General

154

Manoomin is a low-risk food

- Low in heavy metals including:
  - Methylmercury
  - Lead
  - Arsenic (both organic and inorganic)
- Food safety risks:
  - Mold
  - Sand and Rocks
  - Bacteria – Bacillus Cereus -- cooked rice only

Food safety risks are effectively managed with traditional processing techniques

Traditional Practices for Reducing Risk

155

- **Mold**
  - Lay rice out to dry as soon as possible
  - Dry rice efficiently, turning often throughout the day
  - Parch rice soon after drying
  - Store rice in cool, dry locations both during and after the processing

- **Sand and Rocks**
  - Reasonable efforts should be made to remove or prevent sand, rocks, or other inedible materials from commingling with the rice
- **Efforts may include:**
  - Cleaning or rinsing canoe well immediately before harvesting
  - Removing sand, rocks, and debris from shoes prior to entering canoe every time you enter the canoe
  - Any items entering the canoe should be checked and cleaned of sand, rocks, and debris (i.e. dry bags, water bottles, etc.)

Manoomin Processing Standards

156

Manoomin for Sale or Donation:

- Processed in line with cultural practices of the regulating tribe, which may include machines
- Does not contain inedible materials larger than 7mm, with reasonable efforts to remove all inedible materials prior to packaging

4 quarters stacked is about 7 mm

Manoomin Packaging Standards

157

Make sure to keep packaging materials clean and dry prior to their use

Only use clean, single-use containers (i.e. plastic bags) or containers which were cleaned and sanitized prior to use (i.e. glass jars)

- Wild rice may not be labeled as "natural wild rice" or "hand-harvested wild rice" unless the contents **consist entirely of hand-harvested wild rice** and **contains no mechanically-harvested wild rice**, or **wild rice grown with the use of chemical fertilizers or herbicides**

Jams, Jellies and Pickles

158

- Are considered low risk foods if they are "acidified" fruit preserves or vegetable pickles
- The pH of the finished product needs to be measured with a pH meter or equivalent device to ensure that the **pH is 4.6 or lower**
- Producers need to make and keep a record for each batch, documenting the pH measurement
- Jars used to package need to be cleaned and sterilized

Photo Credit: The Fruit Guys

Questions

159

Miigwetch for your time!

160

- Project Staff:
  - Owen Schwartz
    - Community Dietitian
  - Madelyn Wiggins
    - Community Food Project Outreach Coordinator Assistant
  - LaTisha Coffin
    - Project Coordinator
- Other Project Staff: James Thannum (Planning and Development Director), Philomena Kebec (GLIFWC Policy Analyst), and Zoongee Mayotte (Planning and Development Assistant)

More Questions or Concerns?

Contact LaTisha at 715-685-2128 or

lcoffin@glifwc.org

GLIFWC Chippewa Ceded Territory Traditional Food Regulatory System Project

"GLIFWC Chippewa Ceded Territory Traditional Food Regulatory Project"

Food Manager & Regulator Training

PowerPoint Slides

September 21, 2020

Food Manager and Regulator Training

"GLIFWC's Chippewa Ceded Territory Traditional Food Regulatory System Project"
Funded by the Administration of Native Americans and Great Lakes Indian Fish & Wildlife Commission

Great Lakes Indian Fish and Wildlife Commission

GLIFWC is an intertribal natural resource agency of its member tribes, operating through a specific delegation of tribal sovereignty to provide **conservation enforcement**, **intertribal coordination**, **technical assistance** (scientific and legal) and **assistance on resource development** within and pertaining to the tribes' off-reservation rights and incorporating Ojibwe culture.

- Conservation Enforcement
- Division of Intergovernmental Affairs
- Planning and Development
- Public Information Office
- Administration
- Biological Services

2

Welcome and Course Objectives

Provide participants with information on:

- Model Food Processing Code
- Equipment and methods
- HACCP and SSOPs
- Contamination risks
- Food safety overview

Discussions will be framed in a practical context to make it more engaging, with your participation encouraged!

3

Training Schedule

Session 1: Project Background & Model Food Code History and Jurisdiction

Session 2: Introduction to the Model Food Code and Overview of Food Contaminants

Session 3: Fish Processing

Session 4:Meat Processing

Session 5: Produce Harvesting and Packaging

Session 6: Low Risk Foods

Session 7: Additional Resources and Implementation Discussion

Session 8: Wrap up, Final Review, & Final Quiz

4

Course Expectations

- Attendance
  - Participate in the live sessions
  - Engage in discussions
- What happens if I miss a course?
  - Contact course instructor
- Final Survey
  - Must provide codes
- Certificates will be mailed to address on file
- CLE credit will be requested for MN and/or WI, let us know if you need one or the other

5

Session Overview for Today's Session

- Overview of the project, project details
- Background on Anishinaabe governance, economy and foodways
- Treaties with the United States and court cases involving treaty rights and tribal sovereignty
- Tribal jurisdiction -- where does the tribe's power to regulate extend
- First look into the Model Food Processing Code -- Definitions

6

Project Background

- GLIFWC member tribes have affirmed their treaty rights, which include commercial sale of treaty harvested foods
- 2014 Farm Bill
- 2015 Meetings with tribal leadership and the Wisconsin's Department of Agriculture, Trade, and Consumer Protection (DATCP)
- May 2016, GLIFWC's Board of Commissioners held a Model Food Code Listening Session

7

Project Overview and Goals

- Three year project funded through the Administration of Native Americans (currently in Year 3)
- Overall project goals
  - Provide tribal programs and communities with increased access to traditional wild-harvested foods
  - Provide economic opportunities for tribal harvesters to sell value-added products made from wild-harvested foods
- Objectives and outcomes
  - Model food processing code for traditional foods
  - Reports on research into food safety, HACCP plans, SSOPS on traditional food processing
  - Training for harvesters and governmental staff

Goal: "Expand the utilization of treaty harvested fish, game and plants by increasing tribal self-regulatory capacity and sovereign control over activities governing the use of treaty resources"

8

Food Regulatory System Project Impact

Many Ojibwe treaty harvested foods are not regularly served in Federally-funded programs, even on reservation, or available in restaurants, grocery stores, etc.

- Represents technical assistance to tribal governments
  - This food system must be implemented through official action of a tribal governing body
- The 2014 Farm Bill authorizes the use of traditional foods in certain federal food programs by donation
  - This project will assist tribes in implementing that provision of the 2014 Farm Bill to immediately expand the amount of traditional foods in tribal programs, with a transition to purchasing possible

9

Tribes' Treaty Rights Vindicated in Suits Against States

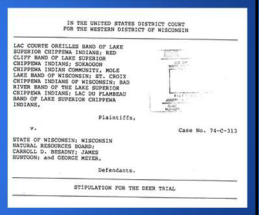
Photo: Drum ceremony at the Seventh Circuit during proceedings in the *LCO v. Wisconsin* case. Ojibwe cultural traditions continue to be critical to tribal sovereignty

- "Treaty rights" are those pre-existing rights that the tribes reserved in treaties
- Tribes are in charge of regulating "treaty rights" related activities
  - As long as they **effectively** regulate their people and **protect** legitimate State conservation, health and safety interests.
- Tribes retain civil regulatory jurisdiction over on-reservation activities
- Issues of food production have not been entirely resolved

10

LCO Case Stipulations on Food Processing

- Stipulations are agreements made by litigants to avoid trial
- In the *Lac Courte Oreilles v. Wisconsin* case (off-reservation treaty rights case) the Tribes and the State of Wisconsin made agreements about the regulation of food processing for commercial sale of treaty-harvested venison and inland fish.



IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

LAC COURTE OREILLES BAND OF LAKE SUPERIOR CHIPPEWA INDIANS; RED CLIFF BAND OF LAKE SUPERIOR CHIPPEWA INDIANS; SOKAOGON CHIPPEWA INDIAN COMMUNITY; MOLE LAKE BAND OF LAKE SUPERIOR CHIPPEWA INDIANS OF WISCONSIN; BAD RIVER BAND OF THE LAKE SUPERIOR CHIPPEWA INDIANS; LAC DU FLAMBEAU BAND OF LAKE SUPERIOR CHIPPEWA INDIANS,

Plaintiffs,

v.

Case No. 74-C-313

STATE OF WISCONSIN; WISCONSIN NATURAL RESOURCES BOARD; CARROLL D. BESADNY; JAMES HUNTOON; and GEORGE MEYER,

Defendants.

STIPULATION FOR THE DEER TRIAL

The Stipulation for the Deer Trial was submitted to the Court in 1989

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LCO Case Stipulations on Food Processing, cont.

- The parties agreed that ***state regulation would apply*** "both on- and off-reservation, in the interest of public health" ***if*** the products would be meant for ***consumption by nonmembers***.
- The state's regulations would ***not*** apply, however, ***if*** the Tribes adopted "***corollary regulations***" and "employ[ed] ***trained and qualified personnel*** to enforce such regulations."
- This means that the ***adoption of tribal food processing regulations*** and ***tribal enforcement (i.e. licensing, inspections, etc.) of those regulations*** is key to move forward on commercial sale of treaty-harvested meat and fish.

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Foundations for Tribal Food Regulations

Legal/Regulatory
- How are various types of foods regulated by tribal, state and federal agencies?
- What is the current status of wild-harvested foods?

Tribal customary practices
- How do tribal members harvest/process their foods?
- What food safety practices are already in place?
- What is the tribal law around specific foods?

Environmental/Biological
- What food safety risks are associated with traditional foods: chemical, biological and physical?
- What has been published?
- What research is needed?

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Sonosky law firm research on food regulation in the U.S.

- Year One Report focused on the current ways in which Ojibwe traditional foods are regulated by federal, tribal, state and local governments.
- Year Two Report looked at packaging, labeling and sales requirements for Ojibwe traditional foods
- In year three, Sonosky created a summary report for tribal councils

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Summary of findings

- Licensing and inspections are key elements. Food producers, transporters and vendors are accustomed to paying upfront fees to operate food businesses. These fees fund staff time for inspections and other administrative duties.
- Standards on sanitation (SSOP, GMP), training, food safety hazards (HACCP) or something similar, and accurate labeling are required.
- Food-related businesses are required to create and maintain records related to their compliance with regulations.

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Anishinaabe Inakonigewin (Law)

Photo: Midewewin ceremony near Whitefish, LCO; taken by an anthropologist in 1910.

All aspects of creation (including humans) received original instructions from the Creator.

As long as the people continue to adhere to those original instructions (i.e. responsibilities), they will maintain their cultural distinctiveness, inherent sovereignty and rights to their traditional territories.

These fundamental teachings are considered the original treaties.

"Mino bimaadiziwin"

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Aadizokaanag on Traditional Foods

Food is prominently featured in Anishinaabe inaakonigewin

Example: Wenaboozhoo story on maple syrup production (many others!)

Maple syrup and sugar are indigenous foods, and knowledge about their production derives from indigenous TEK food science

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Photo: Bad River Tribal Member Jerome Powless hauling maple sap

Incorporation of Tribal Law (Aadizokaanag)

Patience and hard work are values associated with processing maple syrup

- Labeling standards
  - 3.02 Debwewin; Truth in Labeling
    Maple syrup shall not be labeled "traditionally processed Ojibwe maple syrup" unless the contents of the package **consist entirely of maple sap that was condensed into syrup by the heating of the sap over a wood-burning fire**, however a **final boil of the sap may occur using a heating element other than a wood-burning fire.**

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Model Treaty-Harvested Food Codes

- Created "corollary" food safety standards for the processing of 16 Ojibwe foods:
  - White-tailed deer (venison)
  - Rabbit
  - Duck
  - Turkey
  - Whitefish
  - Walleye
  - Fresh berries/berry jams and jellies
  - Wild leeks, beach peas, hazelnuts, morel mushrooms
  - Wild rice
  - Maple syrup
  - Animal fat and jerky
- Addresses risks identified in scientific research; tailored to Ojibwe practices; no more restrictive than federal or state regulations.

Organizational Structure
Chapter 1: Purpose and Powers
Chapter 2: Definitions
Chapter 3: General Provisions
Chapter 4: HACCP
Chapter 5: Meat
Chapter 6: Fish
Chapter 7: Produce
Chapter 8: Low-Risk Foods


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Tribal Jurisdiction

- Tribes maintain civil regulatory jurisdiction
  - Over tribal members, tribal governmental activities, **where tribal law exists**
- In general, tribes' civil jurisdiction is more limited:
  - Off reservation
  - On reservation on lands owned by others
  - Where non-Natives are involved (as consumers or producers)
- Tribes' reserved rights include commercial harvesting
  - 3 major commercially-available foods

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Jurisdiction in the Model Food Processing Code

- Applies to all individuals and facilities involved in the production of treaty-harvested foods for commercial sale, **but not:**
  - Informal commercial and community feasts
  - Home use
  - Sale of whole deer and elk carcasses
- Territorial jurisdiction extends to the Ceded Territories (excluding Menominee Reservation) and any other area as permitted by law.

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Group Exercise: Definitions (Chapter 2)

Model Food Code Definitions (Chapter 2)

Please look over Chapter 2 (Definitions)

- Find one word/definition that you're already familiar with
- Find one word/definition that surprised you
- Find one word/definition that you'd like to know more about

Share with us one or more of these definitions

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Summary of Session One

- The overall goal : provide Ojibwe governments tools to make traditional foods more accessible
- The adoption of law governing food production is key
- These laws need to address food safety risks and be consistent with Ojibwe customs
- The GLIFWC Model Food Processing Code applies to important Ojibwe foods
- Chapter 2 of the Code contains definitions, which include words and ideas that are Ojibwe and words and ideas that are commonly used in the U.S. by food regulators

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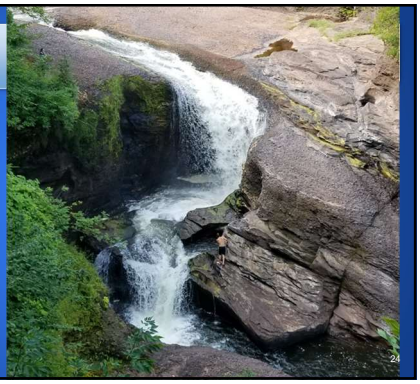
Questions?



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Session 2:
Contaminants & Food Safety

Course Objectives

- Overview of food safety and contaminant risks related to traditional foods from the Interest List
- Understand components of a food safety system and how they work together
  - Good Manufacturing Practices (GMP)
  - Standard Sanitation Operating Procedures (SSOP)
  - Hazard Analysis Critical Control Point (HACCP)

2

Purpose of a Food Regulatory System & Food Safety

- To provide safe and wholesome foods for consumption

This is done through regulation and implementation of food safety systems.

- Food is made or kept safe for consumption by managing risk through reducing food related hazards

IDENTIFIED TRADITIONAL FOODS LIST

Food	*Classification*
White-Tail Deer	Large Game
Rabbit/Hare	Small Game
Duck	Migratory Birds
Turkey	Upland Game Birds
Whitefish	Great Lake Fish
Walleye	Inland Fish
Fresh Berries	Fruit
Wild Leeks/Ramps	Bulb Vegetable
Wild Beach Pea	Legume
Hazelnut	Tree nut
Morel Mushroom	Fungi
Wild Rice	Grain
Berry Jams/Jellies	Value Added
Maple Syrup	Value Added
Animal Fat	Value Added
Venison Jerky	Value Added

3

Food Safety Risks

- Foods inherently carry risk
  - Both raw food and processed foods have associated risks
- Risks can be broadly categorized as:
  - **Biological:** bacteria, viruses, etc.
  - **Chemical:** natural toxins, added toxic chemicals, allergens, etc.
  - **Physical:** metal inclusion, glass inclusion, etc.
- Reducing risk is a large part of food preparation and processing

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Biological Hazard Overview

- 2018: project staff completed a review of scientific literature to identify known and unknown contaminant and food safety risks of the traditional foods from the Interest List.
- Traditional foods carry many of the same risks as conventional foods (e.g. bacteria, disease, etc.)
  - Training Manual page 11 – "2018 Traditional Food Contaminant and Food Safety Report"

TABLE 2: THIS MATRIX OUTLINES BIOLOGICAL, CHEMICAL, AND PHYSICAL HAZARDS ASSOCIATED WITH IDENTIFIED TRADITIONAL FOODS.

		HAZARDS				
		BIOLOGICAL				
Common Name	Scientific Name	Pathogen	Disease / Virus	Parasite	Prion (CWD)	Allergen
Large/Small Game						
White-tailed Deer	*Odocoileus virginianus*	X	X	X	X	
Snowshoe Hare	*Lepus americanus*	X	X	X		
Cottontail Rabbit	*Sylvilagus floridanus*	X	X	X		
Birds						
Duck/diVers						
Scaup/Bluebill	*Aythya affinis/ A. marila*	X	X	X		
Ring-necked Duck	*Aythya collaris*	X	X	X		
Duck/diVers						
Blue-winged Teal	*Anas cyanoptera*	X	X	X		
Green-winged Teal	*Anas discors*	X	X	X		
Mallard	*Anas platyrhynchos*	X	X	X		
Wood Duck	*Aix sponsa*	X	X	X		
Upland						
Wild Turkey	*Meleagris gallopavo*	X	X			
Fish						
Walleye	*Sander vitreus*	X		X		X
Whitefish	*Coregonus clupeaformis*	X		X		X
Plants/Fungi						
Wild Strawberry	*Fragaria vesca*	X				
Wild Raspberry	*Rubus idaeus*	X				
Wild Blueberry	*Vaccinium angustifolium*	X				
Wild Blackberry	*Rubus allegheniensis*	X				
Highbush Cranberry	*Viburnum opulus*	X				
Wintergreen	*Gaultheria procumbens*	X				
Elderberry	*Sambucus canadensis*	X				
Wild Ramps/Leeks	*Allium tricoccum*	X				
Hazelnuts	*Corylus americana*	X				X
Beach Pea	*Lathyrus japonicus*	X				
Wild Rice	*Zizania palustris*	X				
Morel Mushroom	*Morchella esculenta*	X				
Value Added						
Maple Syrup	*Acer saccharum*	X				
Jams/Jellies	Various species	X				
Venison Jerky	*Odocoileus virginianus*	X	X	X	X	X
Animal Fat (duck)	*Anas spp.*	X				
		Pathogen	Disease / Virus	Parasite	Prion (CWD)	Allergen

Chemical & Physical Hazard Overview

- Training Manual Page 12 – "2018 Traditional Food Contaminant and Food Safety Report"

Exercise: Look over Table 2 on pages 11-12 in training manual. Using your microphone or the chat please answer the following:

1. Please list the biological, chemical, and physical hazards associated with Cottontail Rabbit?
2. Use your manual to find *Tularemia*. Please read provide one fact on *Tularemia*.

TABLE 2: THIS MATRIX OUTLINES BIOLOGICAL, CHEMICAL, AND PHYSICAL HAZARDS ASSOCIATED WITH IDENTIFIED TRADITIONAL FOODS. (CONTINUED FROM PREVIOUS PAGE)

		HAZARDS				
		CHEMICAL			PHYSICAL	
Common Name	Scientific Name	Heavy Metal	Chemical / Pesticide	Natural Toxin	Bullet Fragment	Shot Pellet
Large/Small Game						
White-tailed Deer	*Odocoileus virginianus*	X	X		X	
Snowshoe Hare	*Lepus americanus*	X	X		X	X
Cottontail Rabbit	*Sylvilagus floridanus*	X	X		X	X
Birds						
Duck/diVers						
Scaup/Bluebill	*Aythya affinis/ A. marila*	X	X			X
Ring-necked Duck	*Aythya collaris*	X	X			X
Duck/diVers						
Blue-winged Teal	*Anas cyanoptera*		X			X
Green-winged Teal	*Anas discors*		X			X
Mallard	*Anas platyrhynchos*		X			X
Wood Duck	*Aix sponsa*		X			X
Upland						
Wild Turkey	*Meleagris gallopavo*	X				X
Fish						
Walleye	*Sander vitreus*		X			
Whitefish	*Coregonus clupeaformis*		X			
Plants						
Wild Strawberry	*Fragaria vesca*		X			
Wild Raspberry	*Rubus idaeus*	X				
Wild Blueberry	*Vaccinium angustifolium*	X	X			
Wild Blackberry	*Rubus allegheniensis*	X				
Highbush Cranberry	*Viburnum opulus*					
Wintergreen	*Gaultheria procumbens*					
Elderberry	*Sambucus canadensis*			X		
Wild Ramps/Leeks	*Allium tricoccum*					
Hazelnuts	*Corylus americana*					
Beach Pea	*Lathyrus japonicus*	X		X		
Wild Rice	*Zizania palustris*	X				
Morel Mushroom	*Morchella esculenta/elata*	X				
Value Added						
Maple Syrup	*Acer saccharum*	X				
Jams/Jellies	Various species				X	
Venison Jerky	*Odocoileus virginianus*	X				
Animal Fat (duck)	*Anas spp.*	X	X	X		
		Heavy Metals	Chemical / Pesticide	Natural Toxin	Bullet Fragment	Shot Pellet

Diving Deeper

- During the literature review for the "2018 Traditional Food Contaminant and Food Safety Report" project staff identified 3 major gaps in scientific knowledge and data.
  - Wild rice and inorganic arsenic
  - Tribally harvested maple syrup and lead from equipment
  - Lead exposure from ammunition used to harvest wild turkey
- These gaps lead to a 2019 study
  - Study results are available in the "Addendum" document

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2019 Study Results - Wild Rice

- Wild Rice:
  - 40 samples
  - Finished wild rice seeds harvested and processed by Ojibwe tribal members do not contain lead, zinc, cadmium, total mercury, copper, magnesium, total chromium, selenium, and total and inorganic arsenic concentrations in any amount that would be of negative impact to human health, in either cooked or dry form

Figure 2: Wild rice samples for heavy metals testing were collected from natural beds located in the 1842, and 1854 treaty territories. However, three sample were collected outside ceded territory boundaries.

8

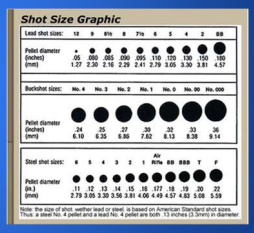
2019 Study Results - Maple Syrup

- Maple Syrup:
  - 29 samples
  - Maple sap harvested and processed by Ojibwe tribal members into syrup does not contain lead concentrations that would be harmful to human health using the Canadian Maximum Residue Limit of (0.5 ppm) for lead in maple syrup.
    - The US does not have an action level for lead in maple syrup
  - Processing equipment can impact lead concentrations in maple syrup and other foods.
    - Lead and lead solder are not recommended for food contact surfaces

9

2019 Study Results - Wild Turkey

- Wild Turkey:
  - 30 birds sampled
  - Harvesting with smaller size No. 8 and No. 6 shot increased lead content found in the breast meat.
  - Larger shot reduces lead contamination risk
  - Turkey harvested with larger size No. 5 copper coated lead shot were found to test below laboratory detection limits.



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Regulatory Impact Contaminant Information

Example:

- Harvest tools
  - Lead free ammunition (required)
  - Food contact surfaces and implements made out of food-grade or nontoxic materials (required)
- Air temperature at time of harvest (cooler temps required for harvesting meat animals)
- Inspection within 24 hours of kill (if required)
  - Deer harvested in Chronic Wasting Disease Management Areas will need to be tested

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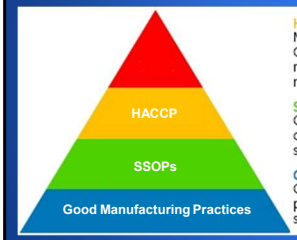
Components of Food Safety Processing



HACCP Plan
Management plan to analyze critical hazardous factors set Critical Control Point, establish limitations, set-up monitoring method, set-up improvement plan, set-up verification process, maintain record and control documents.

SSOP (Sanitation standard operating procedures)
Operating procedures for general sanitation management operation standard, office management, water control, storage and transportation supervision, inspection, recalls.

GMP (Good Manufacturing Practice)
Operating procedures for general sanitation management peration standard, office management, water control, storage and transportation supervision, inspection, recalls.

Closer look at Components of a Food Safety System

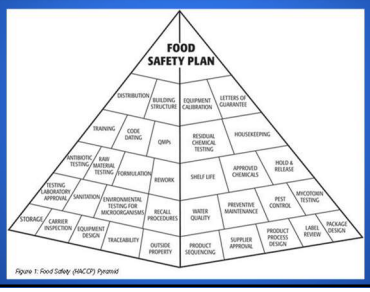


Figure 1: Food Safety (HACCP) Pyramid

Definitions

- **Food contact surface(s)**: any surface that comes into contact with food, and those surfaces from which drainage may leak onto food or food contact surfaces.
  - Examples: work table, utensils, food service gloves, food containers, shelving in cooler unit
- **Ready to Eat (RTE)**: refers to foods that ready to consume as is and do not need any additional cooking.
  - Examples: fresh berries, cooked meat, bread, jerky
- **Cross Contamination**: the process of transferring pathogens from one surface to another.
  - Example: Using tongs to move raw turkey to a baking pan, then using the same tongs to move muffins to a platter without cleaning and sanitizing tongs

Definitions, continued

- **Adulteration**: bears or contains poisonous or deleterious substances, either naturally occurring or added to food. Adulteration also includes the addition of unapproved substances to food and handling or holding food in ways that could make the food unsafe.
  - Examples: lead bullet fragments, storing raw meat at room temperature, using unclean hands or utensils to handle food.

GMP Requirements

Facility-wide requirements to design and maintain a food safe environment

Chapter 3.08 & 3.11 (6)

- General maintenance of physical facilities
- Cleaning and sanitizing of equipment and utensils
- Storage and handling of clean equipment and utensils
- Pest control
- Proper use and storage of cleaning compounds, sanitizers, and pesticides
- Employee training
- Plant design
- Quality assurance assessment

Photo Credit: San Antonio Food Bank

Photo Credit: Spoon University

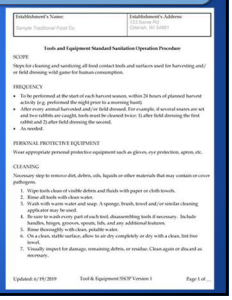
Current Good Manufacturing Practices

Current Good Manufacturing Practices (cGMP)

- Focus on reducing cross contamination and employee hygiene
- Includes:
  - Employee food handling and personal hygiene training
  - Inspection of employee hygiene and work habits
  - Proper maintained sanitary facilities and supplies

Standard Sanitation Operating Procedures

- SSOPS are the specific, written procedures necessary to ensure sanitary conditions in the establishment, before, during, and after operations
- Are used to meet the requirements of GMPs
- They address the details of maintaining sanitary processing environments and employee practices



Establishment's Name:	Establishment's Address:
Sample Traditional Food Co.	123 Anywhere St. Ontario, MI 55887

Tools and Equipment Standard Sanitation Operation Procedure

SCOPE

Steps for cleaning and sanitizing all food contact tools and surfaces used for harvesting and/or field dressing wild game for human consumption.

FREQUENCY

- To be performed at the start of each harvest season, within 24 hours of planned harvest activity (e.g. performed the night prior to a morning hunt).
- After every animal harvested and/or field dressed. For example, if several snares are set and two rabbits are caught, tools must be cleaned twice: 1) after field dressing the first rabbit and 2) after field dressing the second.
- As needed.

PERSONAL PROTECTIVE EQUIPMENT

Wear appropriate personal protective equipment such as gloves, eye protection, apron, etc.

CLEANING

Necessary step to remove dirt, debris, oils, liquids or other materials that may contain or cover pathogens.

1. Wipe tools clean of visible debris and fluids with paper or cloth towels.
2. Rinse with clean water.
3. Wash with hot water and soap. A sponge, brush, towel and/or similar cleaning applicator may be used.
4. Be sure to wash every part of each tool, disassembling tools if necessary. Include handles, hinges, grooves, spouts, lids, and any additional features.
5. Rinse thoroughly with clean, potable water.
6. On a clean, stable surface, allow to air dry completely or dry with a clean, lint free towel.
7. Visually inspect for damage, remaining debris, or residue. Clean again or discard as necessary.

Updated 6/19/2019 Tool & Equipment SSOP Version 1 Page 1 of ...

8 Areas of Sanitation

8 Areas for Sanitation in GLIFWC Model Code

1. Safety of water which comes into contact with food or food surfaces
2. Condition and cleanliness of food contact surfaces
3. Prevention of cross contamination
4. Maintenance of hand washing stations, hand sanitizing, and toilet facilities
5. Protecting food and food contact surface from adulterants
6. Proper use and storage of toxic chemicals used in the facility
7. Pest control measures
8. Where employee health may be a biological risk to food, controlling access to food and food surfaces

SSOPs and the Model Food Code

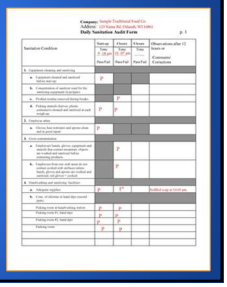
Chapter 3.08

- Required for:
  - Tribally Licensed food facility
  - Retail food establishment
  - Class 1 meat or fish processor
- Must be written
- Must be monitored
- Sanitation control records must be kept as facility records or monitored and documented as part of HACCP plan implementation

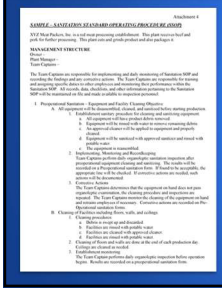
SSOP Specification

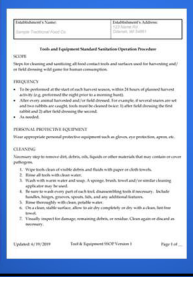
SSOPs are:

- Specific to the location
- Specific to the establishment
- Must be signed by the establishment authority
- Requires monitoring activities
- Recordkeeping is required
- Must be routinely evaluated for effectiveness

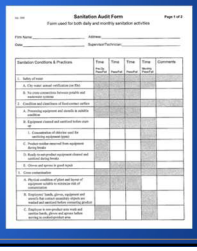


SSOP Examples





Sample Checklist



Hazard Analysis Critical Control Points (HACCP)

- A management tool used to monitor and protect a food product, before, during and after, processing.
- Addresses food safety issues around **a specific food product or processing line**
- Monitors food safety in 3 main areas
  - Biological
  - Chemical
  - Physical
- Designed to minimize the risk of food hazards but may not reduce the hazards to zero
- Documents the active protect of food from contaminants

HACCP teaches processors to look critically at their food process through the lens of science and investigation

HACCP include 7 Principles

1. Conduct a hazard analysis
2. If hazards are identified, determine critical control points in the process
3. Establish critical limits
4. Establish monitoring procedures
5. Establish corrective actions
6. Establish verification procedures
7. Establish recordkeeping procedures

HACCP and the Model Food Code

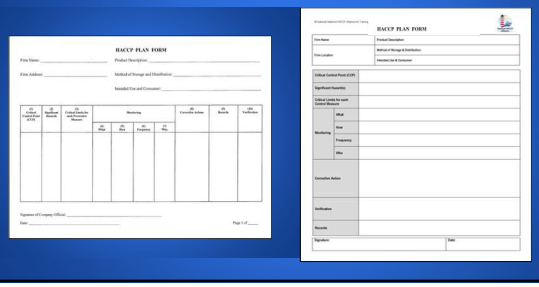
Chapter 4

- HACCP plans are required when a hazard is identified through the Hazard Analysis
- HACCP Records include:
  - Written hazard analysis
  - Written HACCP plans
  - Critical control point and critical limit supporting documents
  - Monitoring records of critical control points
  - Corrective action plans (optional)
  - Documentation of corrective actions taken (required)

HACCP and the Model Food Code

- All food processing plants and class 1 meat/fish vendors must:
  - Conduct a hazard analysis for each raw and finished food product processed by the plant
  - Identify preventive control measure to control hazards identified in the hazard analysis
- Training: Training on HACCP, or equivalent job experience, is required to develop or amend a HACCP plan, and to conduct a records review required for HACCP implementation. Currently, GLIFWC offers an annual fish HACCP training course each fall.

Blank HACCP Plan Form Examples


HACCP PLAN FORM

Firm Name: _____ Product Description: _____

Firm Address: _____ Method of Storage and Distribution: _____

Intended Use and Consumer: _____

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for Each Control Measure	Monitoring				(8) Corrective Actions	(9) Records	(10) Verification
			(4) What	(5) How	(6) Frequency	(7) Who			

Signature of Company Official: _____

Date: _____ Page 1 of ____

© Science-based HACCP Planning & Training

HACCP PLAN FORM

Firm Name	Product Description
Firm Location	Method of Storage & Distribution
	Intended Use & Consumer

Critical Control Point (CCP)		
Significant Hazard(s)		
Critical Limits for each Control Measure		
Monitoring	What	
	How	
	Frequency	
	Who	
Corrective Action		
Verification		
Records		

Signature	Date

Group Activity - Breakout Rooms

In a moment you will be put into a breakout group to discuss the following.

How do Good Manufacturing Practices (GMPs), Standard Sanitation Operating Procedures (SSOPs), and Hazard Analysis and Critical Control Point (HACCP) work together to help create safe foods?

Break

Let's take a short break!

We'll be talking about generally applicable procedures next.

Philomena Kebec
Policy Analyst
pkebec@glifwc.org

Owen Schwartz
Community Dietitian
ohschwartz@glifwc.org

Class Exercise

Use the training manual and what you learned during this session to answer the following 3 questions:

1. **What are differences between Standard Sanitation Operating Procedures (SSOPs) and Hazard Analysis Critical Control Points (HACCP)?**
2. **Which Model Food Code chapter refers to SSOPs? Which for HACCP?**
3. **Using the training manual, list the hazards identified in the "cold storage of Fish" Processing Step and "Weigh, Pack, & Label" Processing Step of Whitefish Model HACCP Plan for Frozen Fillet-Reduced Oxygen Packaging" (starts on pg 475).**

Session 3:
General Provisions

1

Unit Objectives

- Understand the basic components of the Model Food Code related to:
  - General food safety
  - Labeling requirements
  - Facility standards
  - Licensing and Enforcement

2

Model Food Code Structure

- Chapter 1- Purpose and Power
- Chapter 2- Food Code Definitions
- Chapter 3- General Provisions
- Chapter 4- HACCP
- Chapter 5- Meat
- Chapter 6- Fish
- Chapter 7- Produce
- Chapter 8- Low-Risk Foods

Foundations of the Model Food Code

- 3.01 Zhawenindiwag: Respect for Traditional Foods and Consumers:
  - All foods are to be handled in a respectful manner and in order to prevent adulteration and remain consistent with our cultural traditions
  - All foods sold or donated must be amenable wild-harvest foods
  - No adulterated food may be donated or sold

Amenable wild-harvest food - Ojibwe food that is safe, wholesome and unspoiled.

State/Federal Food Safety Standards

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State/Federal Standard	Every-day meaning
Adulteration	Food needs to be clean, wholesome & safe
Misbranding	Food label needs to be accurate
Food Processing Plants	Food needs to be prepared in a facility that is safe, sanitary and secure
Meat Inspection (not applicable to fish)	Food from animals needs to be checked for potential disease or spoilage to make sure its safe for human consumption
Preservatives, artificial colors, food additives	Food processors can only use certain additives to foods and they must be safe

Regulations vary based on food safety risk of product and market served

- **Class 1** = sales from tribal member to tribal member, on reservation
- **Class 2** = sales to tribal institutions and programs
- **Class 3** = retail sales, on and off reservations, to both tribal and non-tribal members

*All commercial harvesters must comply with Off-Reservation Conservation Code requirements regarding Records of Commercial Transactions

Some meat and fish products may be produced outside of tribally-licensed food processing plants. The types of products that can be produced in informal facilities are limited to those that carry lower food safety risks.

MN Rules of Professional Professional Conduct

- **Class 1** = sales from tribal member to tribal member, on reservation
  - ALTERNATIVE 1
- Class 1 = sales from tribal member to tribal member (any tribe), on (or off) reservation
  - ALTERNATIVE 2
- Class 1 = direct sales to individuals (anyone), on reservation

Rule 1.2 Scope of Representation and Allocation of Authority Between Client and Lawyer

(a)Subject to paragraphs (c) and (d), a lawyer shall abide by a client's decisions concerning the objectives of representation and as required by Rule 1.4, shall consult with the client as to the means by which they are to be pursued. A lawyer may take such action on behalf of the client as is impliedly authorized to carry out the representation.

Labeling - General

- 3.02 Debwenin: Truth in Labeling:
  - All foods must be labeled in a truthful manner, not misleading
  - Information on label must be in a readable format
    - Letters and numbers must be a minimum of 1/16th of an inch.

Wild rice (Manomin), maple syrup, fish, meat, mushrooms and any foods produced in home kitchens have special labeling requirements.

*Meat has additional inspection labeling requirements

- Terminology:
  - **Principal Display Panel (PDP)**- the part of the food label most likely to be displayed to the customer when the product is offered for sale.
  - **Information Fact Panel (IFP)**- a label with required information that appears on a location on the product other than the front of the product

Labeling Standard PDP

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Class 2 & 3 Label Example

Statement of Identity: Must be prominent

Artwork should not hide or detract from label information

Statement of Identity - common name of the food

Net Quantity Statement - a measurement of the food contained within the package

Net Quantity Statement: the amount of food in the package

Labeling Standards- IFP

The following information must be included in IFP if not on PDP:

- Nutrition Facts
- Ingredients (if containing 2 or more)
  - All artificial flavoring, Coloring, or chemical preservatives should be listed:
    - Name **and** function
    - Example: Calcium Propionate [Preservative]
- Signature line with name and address of the product's manufacturer, packer or distributor
- Allergen information (if containing one of the 8 major allergens)
  - Could be in ingredients list

Photo is rendered from Leech Lake Band of Ojibwe Wild Rice package

Labeling: Allergens

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- The presence of a major allergens in the food should be clearly and prominently articulated on the label
- Allergen name (Fish), along with the name of the food source (i.e. walleye) is included on the label:
  - Example: Walleye (fish)
- Can be:
  - In the ingredient list OR
  - As a "Contains: ...." Statement

Photo Credit: University of Nebraska Lincoln

Labeling Standards- IFP continued

The following information must be included in IFP if not on PDP:

- Production sales date, or code, or lot number identifying the specific product batch
- Special handling instructions to maintain the wholesomeness of the food (e.g. fish, meat)
- If date label is used it must be in accordance with the following:
  - Food safety related: "USE by" or "USE by or FREEZE by"
  - Food quality related: "BEST if Used by" or "BEST if Used or Frozen by"
  - Sell by dates may only be used for five years from the adoption of the code (being phased out at the federal level)

Labeling Standards- Specialized

Food processed outside of a Licensed Food Processing Plant:

- Including foods prepared, processed or packaged outside of a licensed food processing plant
- Must include, in 12-point font

"**Processed and packaged in a home facility**"

Meat:

- Inspected meat requires an inspection legend
- Legends will be developed by tribes during the implementation process

Produce:

- Most produce is exempt from labeling requirements
- Exception: mushrooms are required to be labeled with the common name, scientific name, harvester name and address, date of harvest and consumer advisory "WILD MUSHROOMS: CLEAN WELL AND COOK THOROUGHLY BEFORE CONSUMING"

Labels Available

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Contact Owen Schwartz at GLIFWC at **(715) 685-2147**

- Labels for manoomin are available at GLIFWC
  - 25 bags and labels per request
  - Only available to tribal members of GLIFWC member tribes
  - Available at no cost
- For larger producers
  - Electronic copies of the label or nutrition facts are also available
  - Available at no cost

Food Additives

- Added flavors:
  - Must be declared
  - Declared in order of weight; largest first
  - Spices: common name or as "spices"
  - Vegetables which are processed are considered foods and should be declared by common name
    - E.g. garlic powder
  - Any salt (sodium chloride) should be list as "salt"
  - Water added to food is an ingredient and should be listed
- Colors and preservatives:
  - Only food-safe colors, and preservatives may be used
  - Only in amounts which are safe for human consumption
  - Purpose must be declared
  - List in order of weight; largest to smallest

Packaging:

- Must be made of food safe materials
- Must be appropriate to the type of food it contains

Personnel- General

- Each person engaged in processing, packaging, or holding of food for donation or sale should:
  - **Possess the education, training and experience** necessary to manufacture process, pack or hold clean and safe food as appropriate to the person's assigned duties
  - **Receive training** on the principles of personal hygiene and food safety, as appropriate to the food, facility, operation, and assigned tasks
  - **Records of staff training** should be maintained in accordance with recordkeeping standard

Personnel, cont.

- All persons in contact with food, food contact surfaces, and product packaging materials must adhere to hygienic practices while on duty
- All outer clothing worn by persons handling food must be made of material that is disposable or readily cleaned
  - Garments must be clean at the start of each work day and changed as necessary to prevent adulteration and unsanitary conditions
- Any person who has or appears to have an infectious disease, open lesions or any other abnormal source of microbial contamination, must be excluded from any operation which could result in adulteration or unsanitary conditions
- Tribal mushroom harvesters must:
  - complete training on mushroom identification and harvesting and keep a records of completion

Food Transportation and Storage

- Food should be transported and stored in a manner to protect it from contamination and deterioration
- All containers shall be made of food grade materials and are either cleanable or single use
- Containers must be clean and sanitary prior to the additions of food and be suitable to the food being contained
- Vehicles, food trailers, or containers used for should be cleaned and sanitized prior to use with a different type of food or item when there's a risk of foodborne illness due to cross-contamination
  - E.g. fish boxes should be cleaned and sanitized before holding fresh fruit
- Food storage areas should be cleaned regularly

Food Transportation and Storage

- Temperature controlled food transportation should:
  - Have adequate monitoring of temperature during transport and storage.
  - This monitoring should create reports documenting monitoring and kept in accordance with Recordkeeping regulations
  - Temperature of TCS foods should be at or below 45°F or 140°F or above unless otherwise except for limited circumstances provided for in the model code:
    - For example, wildlife carcasses may be transported from the field immediately after the animal has been killed (and may still be warm) as long as the carcass is being continuously cooled
  - Must be loaded in a manner that allows proper refrigerated air circulation

Equipment and Utensils

All equipment and utensils should be:

- Designed to be cleanable
- Designed to be sanitized according to SSOP, HACCP plans, or Harvest Safety Plans, as applicable
- Made of food safe or food grade material (or nontoxic material, in some instances)
- All storage equipment for tool must not create adulteration or unsanitary conditions

Receptacles used for storing inedible material cannot be used for storing any edible product and must bear a conspicuous markings identifying the permitted uses, i.e. "Trash"

Instruments used to measure, regulate, or record critical controls must be:

- Accurate and precise (in most instances, calibrated before use)
- Maintained in working order
- Appropriate quantity for designated uses (i.e. enough recording thermometers to record temperature at each fish smoking unit)

SSOP's

Required for:

- Food Processing Plants
- Retail Food Establishments
- Facilities used by Class 1 Meat Processors
- Facilities used by Class 1 Fish Processor

- The SSOP should specify how the establishment will meet required sanitation conditions and practices
- Records document sanitation monitoring and corrections
- Shall be signed and dated by the person with overall authority for the facility

Variance

A variance is a written, approved deviation from the standard regulations

- Harvesters and anyone operating, owning or in charge of a food producing facility may request a variance *in writing*
- Variance request must specify the following:
  - The specific provisions that require a variance
  - Reasons for the variance
  - Alternative procedures
- Licencing authority must consider the types of food and risks involved in processing these foods → <u>are the alternative procedures adequate to protect health and safety?</u>
- Procedures that are consistent with cultural practices that have proven safe over generations are eligible for variance

Records

- Personnel Records (education/training) -- maintained for 3 years
- Sanitation Records:
  - Must be maintained for at least **<u>6 months</u>** (but may be longer if they pertain to the following products)
- HACCP, Meat, & Fish Records:
  - Refrigerated product records must be maintained for 1 year after their creation
  - Frozen products must be maintained for 2 years after their creation
- Low Risk Food Records -- maintained for 3 years after their creation
- Covered Produce Records -- maintained for 2 years after sale of product

Recordkeeping-

Record Types	Duration
Sanitation Records	6 months
Refrigerated meat, fish, and other HACCP required product records	1 year
Frozen, shelf-stable, or preserved meat, fish, and other HACCP required product	2 years
Equipment records or scientific study based process records	2 years
Training records of all workers (paid, unpaid, permanent, and temporary personnel)	3 years
Licensed facilities: Harvester education or training records and harvester processing records	3 years

Record Locations

- For seasonal facilities, records may be located in a reasonably accessible location at the end of the season.
  - Records must be returned to the facility within 24 hours, if requested.
- Records may be kept electronically if appropriate controls are implemented to ensure the integrity of the data and signatures
- **All records and plans required by Model Food Code Chapter 3.10 [Recordkeeping] must be available, at reasonable times, for official review and copying by the tribal licensing authority**

Food Processing Plant- Summary

Chapter 3.11

- Must be licensed and registered with the tribal authority
  - Licensing requires and inspection and certification
- Annual inspection and for cause inspection if reasonable belief of a serious safety issue
- Requirements Include:
  - Water quality and plumbing
  - Construction and sanitary design
  - Toilet facilities for personnel
  - Controlled access and pest exclusion
  - Waste disposal
  - Storage of toxic materials
  - Sanitary operations

Food Processing Plant- Water

- Requirements:
  - Potable water source (complies with CFR 141)
    - Private water users (own well) will need to regularly test their water for potability
    - Must have record to this effect on file and updated 2 times a year
  - Water amount, pressure, and temperature suitable for to the processing and sanitation needs within the facility

Retail Food Establishments

Retail food establishments are businesses licensed to sell class 3 foods.

- A retail food establishment license is required to sell class 3 foods to non-Indians, except for:
  - Manomin
  - Maple syrup/sugar
- Current FDA Food Code, or equivalent, applies
- License and inspection required (annual and for cause)

Licensing and Enforcement

- The following operations are licensed with the tribal licensing authority:
  - Food processing plant
  - Retail food establishment
  - Class 1 meat or fish processor
  - Class 2/3 produce harvester
  - Low risk food vendor
- Type of enforcement actions:
  - Penalties
  - Suspension or revocation of license
  - Condemnation of food product
- Examples of reasons for enforcement actions:
  - Evidence of serious health or safety threat
  - Reasonable grounds to suspect food is adulterated
  - Non-compliance with regulations
  - Failure to pass inspection

Questions and Feedback on Chapter 3

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We'll be talking about fish next.

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Session 4:
Fish

1

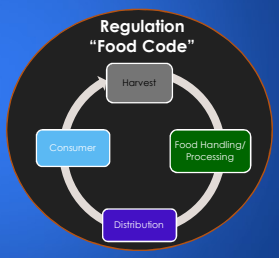
Unit Objectives

- Understand the Model Food Code regulations for fish
- Able to differentiate the between licensing class
- Understand the food safety and contaminant risks related to whitefish and walleye and fish processing
- Review food safety systems related to fish processing

2

Reminder: Food Regulatory System

A legal and economic system made of policies, guidelines, and regulations with the purpose of **protecting the health and safety** of food consumers



3

State/Federal Food Safety Standards

State/Federal Standard	Every-day meaning
Adulteration	Food needs to be clean, wholesome & safe
Misbranding	Food label needs to be accurate
Food Processing Plants	Food needs to be prepared in a facility that is safe, sanitary and secure
Preservatives, artificial colors, food additives	Food processors can only use certain additives to foods and they must be safe

4

Model Food Codes for Treaty-Harvested Foods

In recognition of the Tribes' civil regulatory authority, the model food code requires varying degrees of regulation per class.

- Class 1= sales from tribal member to tribal member, on reservation (minimal regulation; limited to lower risk products)
- Class 2= sales to tribal institutions and programs (more involved regulation; includes products that involve a higher degree of risk)
- Class 3= retail sales, on and off reservations, to both tribal and non-tribal members (most regulated; for products that must be carefully produced to remain safe)

Labeling standards vary depending on the class of the food.

5

All Licensing Class Processing

- Appropriate quality control must be used:
  - Examples:
    - Time and Temperature control: refrigeration or freezing (below 40°F)
    - Cross contamination prevention: SSOP
    - Food safe materials: food safe plastics, stainless steel
    - Sanitation control: good hygiene, clean and sanitary surfaces
    - Using potable water for processing fish, ice, cleaning hands and other surfaces
- Packaging materials must be food safe, kept clean and dry prior to using
- SSOPs in place for the processing facility
- HACCP to manage risks associated with the products being produced

6

Prior to Processing Fresh Fish continued

- To be processed for sale, (evisceration/gutting is not considered processing) fish must be:
  - Fresh and wholesome
  - Proof that the fish was held at or below 38°F (ambient or internal temperature)
    - Transportation records (i.e. recording thermometer records, temperature check records, etc.)
    - Fish is completely surrounded by ice
    - Chemical cooling media (i.e. ice blocks) remain frozen and the product's internal temperature at delivery is 38°F or below
    - Delivered refrigerated with transit time of 4 hours or less, transportation records, and the product's internal temperature at deliver is 38°F or below

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Prior to Processing Fresh Fish continued

- Proof of legal harvest
  - All fish received by a food facility or Class 1 processor must be accompanied by proof of legal harvest
  - Records of the proof of harvest must be maintained in accordance with Chapter 3
- All fish, sold or donated, must be accompanied by a Harvester Certificate of Guarantee. To include:
  - Waterbody(ies) of harvest
- The following inland fish cannot be sold or donated: Inland fish harvested from lakes which are labeled on GLIFWC Mercury maps as "Do Not Eat" for pregnant women, children and women childbearing age

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Class 1 Regulation

- Sales to tribal members only, on reservation
  - Fresh filets only
  - Must be stored in a refrigerated container at or below 38° F or in contact with ice
  - Containers holding fish must be sanitary
  - Allergen label required

Can be processed outside of a tribally licensed food processing plant in a facility such as a home kitchen

9

Class 2 Regulations

- Sales to tribal programs
  - Fresh and vacuum packed frozen fish
  - Same food safety requirements of Class 1 sales
  - Frozen fish must be kept frozen
  - Standard labeling requirements

Fisherman finds street corner success

Must be processed in a tribally-licensed food processing plant

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Class 3 Regulations

- Retail sales
  - Fresh, frozen vacuum packed, smoked and roe
  - Same food safety standards as Class 1 & 2, plus additional safety requirements for specialty products
  - Standard labeling requirements

Cathy Newago mans the family fish shop, Newago Fish Market, spring through fall, selling fresh and smoke Lake Superior fish as well as a variety of fish spreads.

Must be processed in a tribally-licensed food processing plant

11

Labeling: Allergen

- Fish is one of the FDA's 8 major allergens

Labeling requirement:

- Allergen name (Fish), along with the name of the food source (i.e. walleye) is included on the label:
  - In the ingredient list OR
  - "Contains: ...." Statement

Photo Credit: University of Nebraska Lincoln

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Fish and Food Safety

13

Food Safety Snapshot -- Food Safety Risks

Types of risks involved with fish processing:

- Biological
  - Pathogens: Bacteria, Parasites, Viruses
  - Botulism from reduced oxygen packaging (e.g. vacuum pack)
- Physical
  - Metal fragments
- Chemical
  - Allergens (industry and labeling)
  - Methylmercury (walleye)

Keweenaw Bay Tribal Judge by day, fish processor by night Brad Dakota fillets a lean lake trout. Brother and Tribal Police Chief Dale Dakota shares responsibility at their fish shop near L'Anse, Michigan.

Fish is a TCS Food (Time and Temperature Control for Safety)

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Food Safety - Pathogens

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Pathogens are present on the fish at time of harvest.

- **Common bacteria:**
  - ***Escherichia coli***
  - ***Listeria monocytogenes***
  - ***Clostridium botulinum***
- **Common freshwater parasites:**
  - ***Diphyllobothrium latum*** (tapeworms)
- **Viruses are typically associated with mollusk or humans**
  - Hepatitis A and Norovirus

Food Safety - Botulism

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- A concern when fish or products are stored in environments without air, specifically mechanically removed or altered packaging environments (e.g. vacuum sealing)

Clostridium botulinum

- Creates spores which can survive both cooking and freezing
- Spores can release a powerful neurotoxin
- A LITTLE CAN BE LETHAL TO ALL AGES
- Frozen fish must be kept frozen until use
- Open package while thawing is recommended

Food Safety - Physical Risks

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Physical Concerns

- Metal inclusion
  - Typically concerns are knife tips
  - Metal to metal contact (industry)

Food Safety -- Chemical Risk (Allergen)

- Allergens are a chemical component which causes an immune response in the body
- Fish is one of the 8 major allergens
- Allergens can contaminate non-allergen containing food through **cross contact**
- Allergen cross-contact may result in the unintentional introduction of allergens into foods that do not properly declare the allergens on the labels[1]

[1]Food and Drug Administration. "Fish and Fisheries Products Hazards and Control Guidance". April 2019. Pg A9-1

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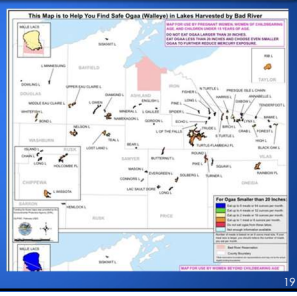
Food Safety -- Chemical Risk (Mercury)

- Methylmercury is a neurotoxin, especially dangerous for children and babies
- GLIFWC has been sampling and analyzing the methylmercury levels in off-reservation inland walleye and other fish for decades and has produced maps of lakes describing the relative levels of mercury in various types of fish based on the studies



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Adikameg Consumption Recommendations

- Studies performed on Great Lakes adikameg (whitefish) have shown it to be low in chemical contaminants
- State based fish consumption recommendations for sensitive populations (children and women of childbearing age):
  - 2 times a month, any size, untrimmed and skin on
  - 4 times a month, any size, fat and skin removed

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Hazard Controls

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Required Food Safety Documents

Harvester:

- Certificate of Guarantee ID'ing waterbody
- Temperature log (if applicable)

Food Processor:

- SSOPs
- HACCP plan & records
- License to operate facility

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Group Exercise

What can and should harvesters do on board, and before fish enter a processing facility to preserve the integrity of the fish they've harvested?

Hint: Look in the definitions and in Sec. 6.01

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HACCP Notes

HACCP is required for:

- Food Processing Plants
- Class 1 Fish Vendor License

- HACCP plans are product specific and facility specific
- Must be reevaluated and signed annually

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Hazards: All Fish Products

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Fish and Fish Products

- ***Pathogens***
  - Control: Time and Temperature
    - Cool rapidly and keep cool (below 38°F)
    - Cooked products should be cooked thoroughly (e.g. 145°F)
    - Prevent cross contamination
    - Water, including ice, used for processing or cooling must potable water

Photo credit: EUFIC

Hazards: All Fish Products continued

Fish and Fish Products

- ***Allergens***
  - Control: Labeling or Spacing & Scheduling
    - Adequately label foods containing allergens or coming into contact with allergen containing ingredients
    - Store allergen containing ingredients and non-allergen containing in a physically separated manner (i.e. in separate boxes, etc.)
    - Store allergen containing ingredients below non-allergen containing ingredients
    - Process non-allergen ingredients prior to allergen containing ingredients
    - Color code specific tools and ingredient containers for allergen free foods

Photo credit: Central Restaurant Products

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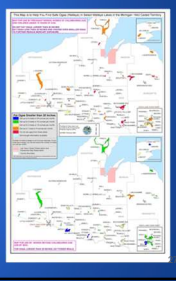
Hazards: Fresh and Frozen Fish

Fresh or Frozen with Oxygen

- ***Pathogens***
  - Control: Time and Temperature
    - Store fish under refrigeration, appropriate ice, or freezing
    - Time out of refrigeration should be kept short to reduce pathogen growth
    - All ice must be made from potable water
- ***Methylmercury (walleye)***
  - Control: Size of Fish and Harvest Location
    - Fish less than 20 inches, harvested from lakes approved for vulnerable populations



Hazards: Reduced Oxygen Packaging

Reduced Oxygen Packaging (ROP)

Typically raw, frozen fillets

- ***Clostridium botulinum***
  - Control: Time and Temperature
    - Maintaining freezer storage
  - Control: Proper Thawing Instructions (Label)
    - Label on package should state "Keep frozen until ready to use. To thaw, cut bag open **and** thaw under refrigeration or cool running water"

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Hazards: Smoked Fish Processing

Risk: Clostridium botulinum

- Control: Water Activity
  - Brine with a solution to reach a water phase salt of 3.5% or 3.0% (depending on the packaging used) within the flesh of the fish
- Control: Preservative Content
  - Finished smoked fish sausage must have a minimum of 100 ppm nitrite
- Control: Time and Temperature
  - Smoked fish should be cooked to 145°F (internal temperature of the fish) and maintain this temperature or above for a minimum of 30 minutes.
  - Other method proven by a scientific study for the process and equipment used

Photo by The Black Peppercorn

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Hazards: Smoked Fish Processing, continued

Smoked Fish

Risk: Pathogen formation/growth after Hot Smoking

- Control: Time and Temperature
  - Smoked fish should be cooled quickly
  - Smoked fish should be kept at or below refrigerated temperatures (40°F)
- Control: Packaging
  - Vacuum packed smoked fish may not have less than 3.5% water phase salt (wps)
  - Otherwise, smoked fish must be wrapped in air permeable membranes, with a minimum wps of 3%

Photo by HAGC

Photo by Politico

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Hazards: Fish Eggs

Fish Eggs

- ***Clostridium botulinum***
  - Control: Salinity
    - Salt should be added to the fish eggs (roe) to achieve a ratio of 1 pound salt to 33 pounds roe (skeins removed)
    - The salt should be carefully added and combined to achieve uniformity
  - Control: Time and Temperature
    - Fish eggs should be kept at or below refrigerated temperatures (38°F)

Photo credit: Solex Catsmo.com

Photo credit: Great Lakes Gazette

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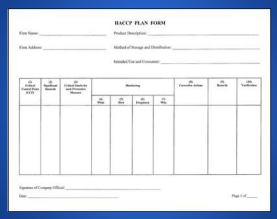
Blank HACCP Plan Form Examples



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What Documents are Required?

Harvester Certificate of Guarantee

Sample

Used to verify that the fish is not subject to a fish consumption advisory for mercury levels (fish that are subject to "do not eat" advisories for pregnant women, women of childbearing age and children may not be sold, donated or received by a food processing plant.

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Resources

Great Lakes Indian Fish and Wildlife Commission

- Great Lakes Fish (Whitefish)
  - http://glifwc.org/lakesuperiorwhitefish/Sustainable.html
  - Whitefish contaminant studies, HACCP forms, whitefish marketing materials
  - Seafood HACCP Training
- Mercury Maps
  - http://glifwc.org/Mercury/
  - Guidance for safe consumption of walleye from inland lakes in ceded territory

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Resources

State-based Sea Grant programs:

- Michigan:
  https://www.michiganseagrant.org/
- Wisconsin:
  https://www.seagrant.wisc.edu/
- Minnesota:
  http://www.seagrant.umn.edu/
- Florida:
  https://www.flseagrant.org/seafood/haccp/
  - Seafood HACCP tools and education

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HACCP Resources

US Food and Drug Administration

- *Fish and Fisheries Products Hazards and Control Guidance (March 2020)*
  - https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls
  - Excellent resource on fish and fish product hazards and controls. Fish HACCP plans are difficult to write without this book. Free download and supplemental material

Association of Food and Drug Officials

- www.afdo.org
- HACCP training information and industry updates

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Questions and Feedback

Summary:

- Fish harvesting regulations may be different from tribe to tribe and year to year. Check with your local tribal Natural Resources for information on harvesting regulations.
- Fish are an allergen and must be have an allergen label on all fish containing products.
- Walleye harvested from low mercury containing lakes are safer. Consuming walleye under 20" in length is safest for children, pregnant women, and women of child bearing age.

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Miigwetch gaa-bizindaawiyeg!

Thank you for listening!

Owen Schwartz
Community Dietitian
ohschwartz@glifwc.org

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Session 5:
Meat

1

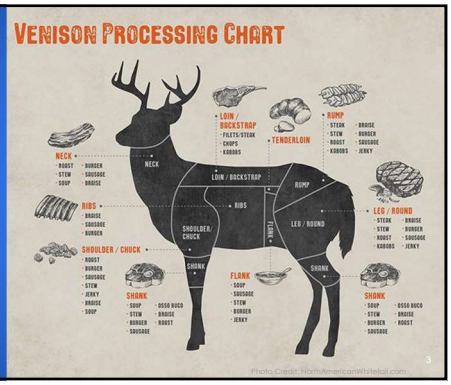
Before the Hunt (Off-Reservation)

- Read through relevant hunting regulations at https://data.glifwc.org/regulations/
- GLIFWC Wardens are available to answer your questions

- Hunter must:
  - Complete Hunter's Education & Firearm Safety
    - Unless, born before January 1, 1977
    - Or have completed an Armed Forces basic training
    - Or hunt with a qualified mentor
    - https://data.glifwc.org/archive.bio/hunter.safety.course.hunter_summary.2020-04-30.html
- Contact tribal registration station for updates and to obtain required permits

2

Waawaashkeshi-wiiyas & Model Food Code



3

Food Processing & LCO v. Wisconsin

- In the 1980s, the parties the *Lac Courte Oreilles v. Wisconsin* (Voigt) case made agreements or stipulations on many issues.
- Commercial sale of venison agreement
  - The Tribes agreed to hold off on selling any processed venison products (i.e. any cuts of venison, ground venison, venison jerky, etc.) until they created a food regulatory system similar to state and federal models
  - The Tribes also agreed to give the state notice and provide a copy of their regulations to the federal court
- Currently, the only opportunity for tribal members to sell venison is by selling a whole carcass.

4

State/ Federal Food Safety Standards

State/Federal Standard	Every-day meaning
Adulteration	Food needs to be clean, wholesome & safe
Misbranding	Food label needs to be accurate
Food Processing Plants	Food needs to be prepared in a facility that is safe, sanitary and secure
Meat Inspection	Food from animals needs to be checked for potential disease **before and after they are killed** to make sure the meat is safe for human consumption
Preservatives, artificial colors, food additives	Food processors can only use certain additives to foods and they must be safe

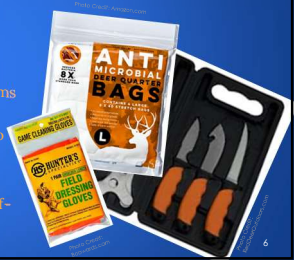
5

GLIFWC Model Food Code

In recognition of the Tribes' civil regulatory authority, the model food code requires varying degrees of regulation per class.

- Class 1= sales from tribal member to tribal member, on reservation (minimal)
- Class 2= sales to tribal institutions and programs (more)
- Class 3= retail sales, on and off reservations, to both tribal and non-tribal members (highest)

*All commercial harvesters must comply with Off-Reservation Conservation Code requirements regarding Records of Commercial Transactions



6

Class 1 Regulation

Sales to tribal members only, on reservation

- Products: fresh and frozen cuts of meat, not including ground meat
- Includes assurances in writing that
  - The deer was healthy when harvested
  - Was field dressed using clean clothes and cleanable equipment, etc.
- Allergen label required (if applicable)

Can be processed in a non-licensed facility such as a home kitchen or other residential location.

Photo Credit: The News-Gazette

7

Class 2 Regulations

Sales to tribal programs such as Head Start & Elderly Nutrition Programs

- Includes assurances in writing that
  - The deer was healthy when harvested
  - Was field dressed using clean clothes and cleanable equipment etc.
- All butchering/packaging is done in a tribally-licensed food processing facility
- Standard labeling requirements apply
- Products include: fresh/frozen cuts of meat and ground meat

8

Class 3 Regulations

Retail sales both on and off reservation, to anyone

- Products: fresh/frozen cuts of meat, ground meat **and jerky**
- Same processing and labeling standards as Class 2

Photo Credit: The National Provisioner

Photo Credit: PheasantForDinner.com

9

Venison and Food Safety

10

Venison Food Safety Snapshot

- Biological concerns:
  - Chronic Wasting Disease (CWD)
  - Bovine Tuberculosis (bTB)
  - *Toxoplasma gondii*
  - E. Coli
- Chemical
  - Lead
- Physical
  - Bullet fragments

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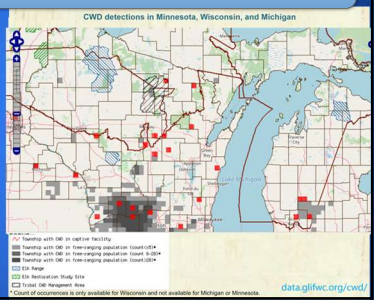
Deer Related Diseases- CWD

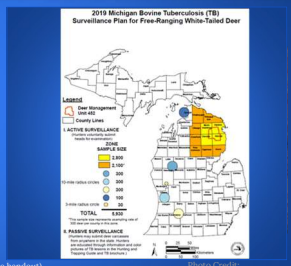
- Chronic Wasting Disease (CWD)
  - A protein based disease which infects deer, moose and elk
  - Unknown risk to humans
  - There is no cure
  - The disease is always fatal to deer
  - May be transmitted through many different vectors (i.e. urine, feces, carcasses and potentially other animals, vegetation and tools)

CWD has been found in MI, WI, and MN



Deer Related Diseases - bTB

- Bovine Tuberculosis
  - According to the CDC, bTB represents about 2% of tuberculosis cases annually or about 130 people[1]
  - Can be passed from cattle to deer
  - Can transmit to humans through bodily fluid contact & inhaling bacteria exhaled from infected lungs[1]
  - Monitored by state natural resource departments and GLIFWC



[1] Centers for Disease Control "Table 18 Reported Tuberculosis 2018" September 2019. (see handout)

Photo Credit: MI DNR

Toxoplasma gondii

- Common parasite infecting warm-blooded animals.
  - Causes Toxoplasmosis which typically presents flu-like symptoms and enlarged lymph nodes. Though rare, it can cause damage to the eyes
  - Vulnerable populations include pregnant women and immunocompromised individuals
    - Can pass from mother to fetus, leading to eye and brain issues in some, later in life
    - In immunocompromised individuals, it may cause a severe infection, and possibly seizures
  - The CDC estimates that 40 million americans carry the parasite, often without symptoms.

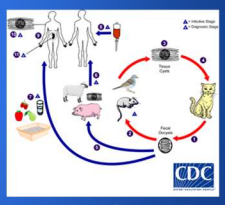


Photo credit: Centers for Disease Control

Toxoplasma gondii continued

- Humans can become sick when they consume the cyst from undercooked game meat or pork, unpaztuazed goat milk, unwashed fruits of vegetables, contaminated soil, or water.
  - According to the CDC, about 50% of infections come from food
- The prevalence of *T. gondii* in wildlife is believed to be widespread.
  - A report release in June 2020 found that 36% of samples from white tailed deer across the U.S. tested positive for *T. gondii*[1]

[1] Dubey, J., Cerqueira-Cézar, C., Murata, F., Verma, S., Kwok, O., Pedersen, K., . . . Su, C. (2020). White-tailed deer (Odocoileus virginianus) are a reservoir of a diversity of Toxoplasma gondii strains in the USA and pose a risk to consumers of undercooked venison. Parasitology, 147(7), 775–781. doi:10.1017/S0031182020000451

Escherichia Coli

- Bacteria found in the intestinal tracts of animals (e.g. humans, deer, cattle)
- Also found in fecal matter, which can be found on animal fur
- Can cause nausea, vomiting, bloody diarrhea, fever, stomach cramps
- Young children and elders = higher risk of more serious complications

Photo Credit: Washington University

Lead in Venison

Table 1. Summary of lead content analysis in Wisconsin hunter-killed deer.

Sample group	*Number of samples**	*Mean lead conc., lead-positive samples mg/kg ±std. dev.*	*Mean lead conc., all samples mg/kg ±std. dev.*	*Prevalence of lead-positive samples*
Commercial processor	*199*	*15.9 ± 32.5*	*2.4 mg/kg ± 13.8*	*15%*
Hunter processed	*98*	*21.8 ± 67.1*	*1.8 mg/kg ± 19.8*	*8%*

*Each sample represents a nominal 1 pound package.

- Results
  - Consuming venison with as little as 1.8 mg/kg once a month can increase blood lead levels.
  - Consuming more lead can increase the amount of lead in the blood
  - According to the CDC, "No safe blood level in children has been identified"[2]

[1] U.S. Department of Health and Human Services, Agency of Toxic Substances and Disease Registry. *Health Consultation: The Potential for Ingestion Exposure to Lead Fragments in Venison in Wisconsin.* November 4th, 2008. (handout)
[2] Centers for Disease Control. Blood Lead Levels in Children. July 30, 2019. https://www.cdc.gov/nceh/lead/data/index.htm

Chemical Contamination Risk Lead in Venison

How does it get into venison

- Bullets often fragment into small pieces which are invisible to the human eye
- Lead fragments can contaminate equipment such as meat grinders, which can effectively mix any lead present in one area or carcass, throughout a processing lot

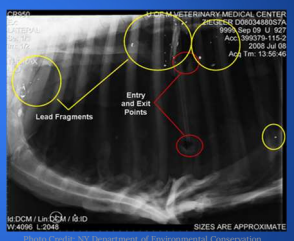


Photo Credit: NY Department of Environmental Conservation

Chemical Contamination Risk Lead in Venison

Lead ammunition contaminates meat with lead, a known neurotoxin

- Lead ammunition fragments into particles that are too small to locate without expensive equipment, and can travel away from the exit and entry wound
- Nontoxic ammunition is made with a metal other than lead, such as copper that doesn't fragment in the same manner as lead ammunition
- Because lead is a chemical contaminant that is considered dangerous to human health, lead shot shouldn't be used for meat intended for donation or sale

Photo Credit: University of Minnesota Food Policy

Bullet fragments are physical hazards; any visible bullet fragments must be removed during processing.

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Hazard Controls

20

During the Hunt

Group Exercise

- What do hunters need to do during the hunt (before killing an animal)?
- What do hunters need to do during field dressing?
- What do hunters need to do during transportation?

Hint: answers will be found in Sec. 5.01-5.06

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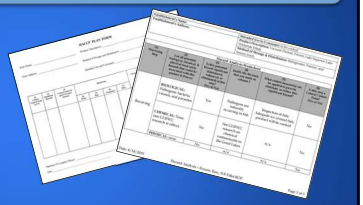
HACCP Notes

Hazard Analysis is required for:

- Food Processing Plants
- Class 1 license
- Class 2 license
- Class 3 license



- HACCP plans are product specific and facility specific
- Must be reevaluated and signed annually

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Hazards: Deer Diseases

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All Venison Products

- ***Deer Disease: Chronic Wasting Disease & Bovine Tuberculosis***
  - Control: Inspection
    - Tribal Inspectors/class 1 meat vendors must condemn harvest exhibiting signs of disease or harvested from Tribal Disease Management Areas that have not been cleared through testing
    - All condemned harvest must be disposed of in accordance with the tribe's regulations

Deer exhibiting signs of disease are not allowed for sale or donation under the Model Food Code.

For CWD: Stainless steel equipment can be cleaned first with warm soap and water. Then, decontaminated with a 5 minute soak in a solution which is 50% bleach and 50% water. Followed by air drying

Hazard: Chronic Wasting Disease continued

All Venison Products

- ***Deer Disease: Chronic Wasting Disease***
  - Control: Exclusion
    Currently, the only way to control for CWD is to have the harvest tested and excluding harvest which test positive for CWD.
- Class 1 Meat Vendors and Food Processing Plants are required to:
  - Maintain a copy of the Certificate of Guarantee and CWD test results
  - Maintain records of processing and distribution

CWD positive deer are not allowed for sale or donation under the Model Food Code.

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Hazard: *E. coli* in the field

All Venison Products

Pathogen: E. coli

- Control: Environment & Time and Temperature
  - Hunt in cool weather
  - Shot placement can reduce *E.coli* leaving the intestines
  - Process harvest in clean environment, with clean and sanitary equipment and clothes
  - Avoid nicking the intestines or allow fecal matter to come into contact with the meat
  - Process and cool carcass quickly

Continuous cooling is required

Photo Credit: L & M Supply

Photo Credit: Texas Parks and Wildlife

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Hazards: Fresh and Frozen

Fresh or Frozen

- ***Pathogens***
  - Control: Time and Temperature
    - Store under refrigeration or freezing
    - Time out of refrigeration should be kept short to reduce pathogen growth
    - Grinding equipment and other equipment should be frequently taken apart and sanitized completely
- ***Lead***
  - Control: Harvest Ammunition Selection
    - Lead ammunition is not allowed under the Model Food Code
- ***Bullet Fragments***
  - Control: Harvest Ammunition Selection & Product Inspection
    - Bullet fragments should be inspected for and removed
    - Fragments larger than 7 mm must be removed

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Resources

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GLIFWC staff are available to assist tribal members in testing their deer for CWD. CWD testing is free for tribal members. Please contact Wildlife Biologist Travis Bartnick for more information: tbartnick@glifwc.org

Hazards: Dehydration (making jerky)

Dehydration

- ***Pathogens***
  - Control: Time and Temperature/Humidity

  - Store under refrigeration or freezing until processed
  - Time out of refrigeration should be kept short to reduce pathogen growth
  - Employ GMPs to minimize contamination
  - **Lethality treatment** involving heat & humidity, or extra interventions to achieve the same result (e.g. subjecting meat to hot marinade to raise internal temp. To 165°F)

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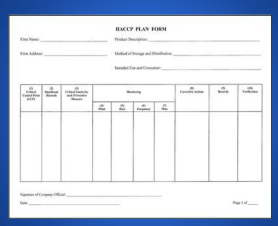
Blank HACCP Plan Form Examples



HACCP PLAN FORM

Firm Name: _____ Product Description: _____

Firm Address: _____ Method of Storage and Distribution: _____

Intended Use and Consumer: _____

CCP Critical Control Point (CCP)	Hazard Hazard	CL Critical Limits for each Control Measure	Monitoring					CA Corrective Action	VR Records	RR Verification
			WH What	HW How	FR Frequency	WO Who				

Signature of Company Official: _____

Date: _____ Page 1 of ____

Evidence-based HACCP Materials Training

HACCP PLAN FORM

Firm Name	Product Description	
Firm Location	Method of Storage & Distribution	
	Intended Use & Consumer	

Critical Control Point (CCP)		
Significant Hazard(s)		
Critical Limits for each Control Measure		
Monitoring	What	
	How	
	Frequency	
	Who	
Corrective Action		
Verification		
Records		
Signature		Date

29

What Documents are Required?

30

Harvester Certificate of Guarantee

Sample

HARVESTER CERTIFICATE OF GUARANTEE (VENISON)

Commercial Tag No.: _____
Tribal Wildlife Management Area Tag No.: _____
(*NA applicable to deer harvested on Tribal/Ceasar Management Areas.*
Name of the Tribal Member Harvester: _____
NAGPA Id. No: _____

Pre-mortem Inspection Information Record
Required for Class 2 and 3 Sales Only
Condition and behavior of animal at rest, and in motion:
Overall condition of the animal, especially the head, eyes, leg and body: (normal, or described) _____

Alertness, mobility and breathing (normal, or describe) _____

Presence of any unusual swelling, signs of injury or other abnormalities? (N/A, or described) _____

Displaying any abnormal behavior? _____ If so, describe _____

Normal gait, normal grazing activity, alert to danger: yes/no (circle one)

Alive, when harvested: yes/no (circle one)

☐ Unable to walk due to broken appendages, severed tendons or ligaments, nerve paralysis or fractured spine (circle as applicable)

Humane Handling Certification
Required for All Classes of Sale
☐ Animal was killed in a swift and efficient manner consistent with the methods approved by my Tribe's conservation codes.
☐ The animal was not shackled, hoisted, thrown or cast until the animal was stunned or killed in a manner that caused permanent unconsciousness or death.

Field Dressing Certification:
Required for All Classes of Sale
☐ All personnel engaged in field dressing the animal wore clean, washable outer clothing and food handling gloves, with any long hair covered or tied back, and all personnel washed and rinsed their hands sufficiently during the operations to prevent contamination of the carcass.
☐ Equipment used in the field dressing of the carcass met the standards of sanitary design and construction, and were kept clean and sanitary (Free from contamination by soil, vermin, insects, vermin and waste products) prior to, and during, field dressing.
☐ Prior to making any incisions into the carcass, loose dirt and debris was cleaned from the carcass, and the carcass was placed on a non-permeable, clean and sanitized surface (i.e. clean and sanitized tarp, game processing table, etc.).

Time of Kill Information
Required for All Classes of Sale
Date: _____
Time: _____
EMD: _____
Air temp: _____
Manner of Killing: _____
Bow/arrow: ___
Crossbow: ___
Rifle: ___
Type of shot used (if applicable): _____
Notescan shot is required: _____
☐ Kill Harvested within a Tribal Wildlife Management Area for Chronic Wasting Disease (CWD) or Bovine Tuberculosis (TB).

Next Unit

31

PRODUCE

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Session 6:
Produce

Unit Objectives

- Become familiar with the terms used in Chapter 7 (Produce)
- Understand which standards apply to various types of harvesters
- Compare food safety standards applicable to produce vs. other products

2

Produce Chapter -- Background

- The Food Safety Modernization Act (FMSA) is a federal law that was passed in 2011
- One objective of FMSA was to create food safety standards for fresh produce in order to prevent widespread sickness associated with shipments of contaminated produce
- For the first time, many farms and produce packing facilities are subject to safety standards and inspections
- Smaller producers, and those that serve local markets are exempted from the highest standards created in the FSMA

3

Produce Chapter -- Background

Chapter 7 of the GLIFWC Model Code is equivalent to the FMSA, but adapted to Ojibwe foods and the manners in which they are harvested

4

Produce Chapter -- Terms

- **Produce** is any fruit, vegetable or mushroom and includes tree nuts and herbs. DOES NOT include grains (i.e. manomin)
- **Covered produce** is produce which is consumed raw, **not subject to processing** (i.e. cooking) that adequately reduces the presence of microorganisms of public health significance. Does not include:
  - Beach peas
  - Cranberries
  - Hazelnuts
  - Wild mushrooms
  - Fiddlehead ferns

5

Produce Chapter -- Types of Harvesters

- Qualified small and very small business
  - Average monetary value of **produce** sold is no more than $500,000 and majority of sales are direct sales located in same rez/state or no more than 275 miles away
- Harvester earning less than $25,000 per year on **covered produce** for 3 years (rolling basis)
- All others ("non-exempt harvester")

6

Produce Chapter -- Food Safety Concerns

- Mold and fungus
  - May be present in overripe produce
- *E. coli*, Hepatitis A
  - Bacteria/virus that causes illness in humans, and can lead to death.
  - Biological pathogens contaminate crops through a variety of vectors:
    - Irrigation and flooding
    - Improper use of manure within fields
    - Animal excreta (wild animals & pets) and soil
    - Unclean hands, equipment or storage compartments

7

Produce Chapter -- FSMA Exempted Harvester

When harvesting plants and mushrooms, the people harvesting must:

- Wear clean clothes, wash and rinse hands as frequently as necessary to keep them clean
- Have access to toilet facilities, including off-site
- Have training on proper hand cleaning, hygienic practices, etc.
- Not harvesting when sick with a communicable disease that could transfer to food (i.e. Hepatitis A)
- Have access to clean potable water for drinking

8

Produce Chapter -- FMSA Exempt Harvester

- Equipment, tools, vehicles, bins, etc. used must be **appropriate for harvesting**, be **clean before their use**
- Contaminated produce may not be sold
  - Upland plants in areas that have been recently flooded
  - Any plant contaminated by animal poop
  - Dropped produce (except for root plants)
- Packaging
  - Clean packaging materials must be used
  - Packaging must inhibit growth of pathogens
  - Mushrooms, if enclosed, must be wrapped in anerobic packaging (i.e. breathable film or paper packaging

9

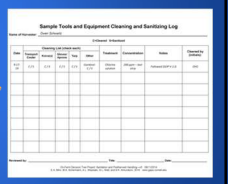
Produce Chapter -- Mushroom Picking

- Some wild mushrooms can carry chemical or biological risk to humans, which can lead to illness or death
- Prior to selling wild mushrooms, tribal mushroom harvesters must successfully **complete training on mushroom identification**, as required by the tribe
- Mushrooms are the only produce product that must be labeled, with the following information on the label:
  - Common name and scientific name of mushroom
  - Harvester name and address
  - Date of harvest
  - "WILD MUSHROOMS: CLEAN WELL AND COOK THOROUGHLY BEFORE CONSUMING"

10

Produce Chapter -- Non-Exempt Produce Harvester

- FMSA approach to regulating covered produce involves elements of SSOPs/GMPs and HACCP
  - Detailed requirements for personnel, protecting covered produce from contamination by animals, maintenance and cleaning of tools and equipment, standards for packing sheds, documentation and records
  - These standards apply to harvesting, holding and packing **covered produce**



Sample Tools and Equipment Cleaning and Sanitizing Log

Name of Harvester: _____ Week Beginning: _____

☐ Cleaned ☐ Sanitized

Date	Cleaning Log (check each)												
	Transport Totes	Harvest	Stems/ Harvest	Tools	Other	Treatment	Concentration	Notes	Cleaned by (initials)
M	T	W	Th	F	Sa	Su							

Reviewed by: _____ Title: _____ Date: _____

Grower Harvest Tool Check Sanitized and Maintained Handling - JF - 06/13/14
S.S. Ann Sch. Kalamazoo, Inc. Website: 11 Mail: 6470 Kalamazoo, 2014 - www.gapp.com.au

11

Produce Chapter -- Non-Exempt Produce Harvester

- Non-Exempt Produce Harvesters are licensed through the tribal licensing authority
- Submission of an application, payment of fees and an inspection is required

- No license or inspection is required for FMSA exempt produce harvesters

12

Group Exercise

Identify one difference between FMSA exempt plant harvest requirements and non-exempt produce harvester requirements

13

Produce Chapter -- Applicability of General Standards

- Except for mushrooms, produce is exempted from labeling requirements
- Food transportation and storage requirements apply: produce must be protected from contamination during storage and transportation and held in conditions that preserves its integrity
- Inedible food byproducts (i.e. dropped produce, spoiled produce) must be separated from produce meant for sale and placed into waste receptacles

14

Produce Chapter -- Applicability of HACCP and SSOPs

- Chapter 4 (HACCP) applies to food processing plants and class 1 meat/fish vendors
- Sec. 3.08 (SSOPs) apply to the above, plus retail food establishments
- Locations **dedicated only to packing produce** do not need to create HACCP or SSOP documents

Watch out for multi-use facilities
if covered produce is being packed in the same location as raw fish or meat is processed or stored, there is a risk of cross-contamination that will likely require a HACCP plan.

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Next Unit

LOW RISK FOODS

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Session 7:
Low-Risk Foods

OBJECTIVES:

-WHAT ARE LOW-RISK FOODS

-CONTAMINANT INFORMATION

-PROCESSING REQUIREMENTS

-MODEL FOOD CODE CHAPTER SUMMARY

2

Unit Objectives

- Understand what foods are considered Low-Risk Foods
- Understand the standards and processing requirements
- Identify contaminant and food safety risks related to Low-Risk Foods

3

Low-Risk Foods (LRF)

- Low-Risk Foods are foods that do not require a time and temperature control or refrigeration to remain safe

AND

- Foods which have been shown to not support the grown of pathogens.

Chapter 8 of the Model Food Code

Example of Low Risk Foods

- Maple Syrup
- Maple Sugar
- Wild Rice (manoomin)
- Jams and Jellies (low acid preserved foods)
- Pickles (low acid preserved foods)
- Dried fruits/teas (not including melons)
- Candy

Low Risk Food Licensing

- Low-Risk Food Vendor license is required if low-risk food is produced **anywhere other than** a licensed food processing plant (i.e. home kitchen).
- Licenses are:
  - Issued by the tribe
  - Annual
  - Location specific
  - Not required for the production of class 1 manoomin or class 1 sugar and syrup
- Obtain a license:
  - Submit an application
  - Participate in an inspection
  - Pay any required fees

Additional Considerations

Moderate to high risk foods are not covered by the low-risk foods regulations. High and moderate risk foods include:

- Meat products
- Fish products
- Produce: foods which are consumed raw or without a step to reduce pathogens to adequate levels
- Dairy products
- Non-food items

For vendors who produce a variety of food, including Low-Risk Foods:

- Low-Risk Food regulations only apply to the Low-Risk Foods which meet the definition of Low-Risk Food
- Other types of food should not be processed at the same time

Categories of Low- Risk Food Vendors

- Less than $50,000* in annual sales
  - Not required to be produced in a tribally-licensed food processing plant
  - Qualifies for specific exemptions namely
    - Portions of Chapter 3
    - Chapter 4 (HACCP)
    - Instead, simplified regulations for processing (Sec. 8.01(3)) apply.
- $50,000* or more in annual sales
  - Food must be produced in a tribally-licensed food processing plant
  - Must comply with the entirety of the following Model Food Code Chapters:
    - Chapter 3
    - Chapter 4 (HACCP)
    - Chapter 8 (applicable portions acc'd to food being produced)

*excluding any revenue from manoomin or syrup/sugar sales

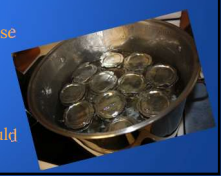
LRF General Requirements (under $50,000 in annual sales)

- Vendors must demonstrate an understanding of the applicable food safety standards
- Foods are prepared consistent with traditionally safe methods
- Water must be safe to drink (potable)
- Any produce used is appropriately cleaned and inspected (by vendor)
- Persons preparing/packaging foods are not sick with a contagious disease

LRF Processing Requirements

Preparing and Packaging Specific:

- No other domestic activities are to be conducted during use (i.e. preparing your own meal)
- Keep premises, tools, equipment clean and sanitary in compliance with traditionally safe methods
- No animals are allowed in the workspace while in use
- Wear clean, cleanable clothing and wash hands sufficiently
- Materials used for packaging will be clean and dry prior to use if single use. Other containers should be clean and sanitized prior to use.



LRF Sale Requirements

- Low-Risk Foods, processed outside of food processing plants must be sold from processor directly to the consumer with the exception of:
  - Maple syrup
  - Maple sugar
  - Manoomin
- If sales take place off-reservation, vendors may be requested to comply with state law (i.e. cottage food laws), which differ from this regulation

LRF Labeling Requirements

Sec. 3.02 Truth in Labeling:

- All statements listed on the label must be true and not misleading
- All food, except for manomin and maple syrup/sugar, produced outside of a tribally-licensed food processing plant must be labeled "PROCESSED AND PACKAGED IN A HOME FACILITY"

Wild rice may not be labeled as "natural wild rice" or "hand-harvested wild rice" unless the contents **consist entirely of hand-harvested wild rice** and **contains no mechanically-harvested wild rice**, or **wild rice grown with the use of chemical fertilizers or herbicides**

Maple syrup may not be labeled "traditionally processed Ojibwe maple syrup" unless **the syrup was produced by boiling sap over a wood-burning fire**

Zhiiwaagamizigan Contaminant Overview

Maple syrup is a safe, low contaminant food

- Maple sap is low in chemical contamination.
- High sugar content = less water available for bacteria to grow
- Syrup is low in contaminants when processed in the absence of lead food contact surfaces
- Chemical residues can be found in maple syrup if cleaning chemicals are not properly used and removed before
- Production includes boiling, which is a "kill step"
  - Kill steps are processes or steps within food production where pathogens are eliminated or reduced to an acceptable level

Maple Syrup and the Model Food Code

- For Class 1 food (for on-reservation sales to tribal members):
  - Low-risk vendor license not needed
- For Class 2 and Class 3 food:
  - Low risk vendor license needed; inspection requirement
  - The final boiling and packaging of the product occurs in a licensed food processing plant or premises exempt from 21 CFR 1.225. *Residences are exempt.*
- All producers need to employ practices to keep maple syrup products safe

Photo of tribal harvester, Jerome Powless, boiling maple sap over a wood burning evaporation pan.

Maple Syrup & the Model Code

- Maple Syrup and Sugar
  - Sugar content of finished syrup must be measured
  - FCS used for syrup/sugar production must be cleaned and sanitized prior to use, when there's break in boiling sap, or at least every 40 days
  - All equipment which comes into contact with maple sap, syrup or product should be food grade

Definitions:

"Syrup" means a liquid derived from sugar-rich tree sap, which is not less than 66 degrees Brix.

"Sugar" means a solid, grainy or viscous substance derived from sugar-rich tree sap, which was boiled beyond 66 degrees Brix and stirred.

Keeping Maple Syrup Safe

- Sap must be covered and care taken to avoid spoilage
- Only nontoxic defoaming/filtering agents may be used
- Finished syrup needs to be checked for sugar content -- must be no less than 66 degrees brix
- Jars or bottles used for packaging maple syrup must be cleaned and sanitized prior to their use

Remember:

Tools and equipment to measure critical controls (i.e. sugar content) must be maintained in good condition and calibrated before use

Harvesting and Food Safety

Manoomin Food Safety - General

- Manomin is a low-risk food
- Food safety risks:
  - Mold
  - Sand and Rocks
  - Bacteria – Bacillus Cereus

Food safety risks are effectively managed with traditional processing techniques

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Traditional Practices for Reducing Risk- Harvester

- **Mold**
  - Lay rice out to dry as soon as possible
  - Dry rice efficiently, turning often throughout the day
  - Parch rice as soon after drying
  - Store rice in cool, dry locations both during and after the processing

- **Sand and Rocks**
  - Reasonable efforts should be made to remove or prevent sand, rocks or other inedible materials from commingling with the rice.
- **Efforts may include**:
  - Cleaning or rinsing canoe well immediately before harvesting
  - Removing sand, rocks, and debris from shoes prior to entering canoe every time you enter the canoe
  - Any items entering the canoe should be checked and cleaned of sand, rocks, and debris (i.e. dry bags, water bottles, etc.)

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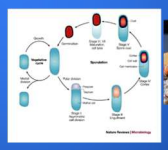
Reducing Risk- Consumer

- Mold
  - Store rice in cool, dry locations
- Bacillus Cereus (Cooked Rice Only)
  - Most commonly associated with cooked, ready to eat rice
  - After cooking rice, keep temperature **above 140 degrees F** or cool to below 41 degrees F within 2 hours.
  - Store cooked rice in temperatures below 41 degrees F
- Sand and Rocks
  - Prior to cooking, check rice for small rocks.



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Manoomin in the food code

FOR SELLING WILD RICE

Manoomin Processing Standards

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Manoomin which is sold pursuant to this Title shall be processed in manner that is consistent with the cultural practices specific to the [tribe], and may include the use of machines for parching, threshing and separating hulls from the finished product.

Wild rice should be processed in line with cultural practices which may include using machines.

Manomin Processing Standards

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Prior to packaging manomin harvested for donation or sale pursuant to this Title, the manomin shall be examined to ensure that it does not contain any fragments of hard, inedible material (i.e. pebbles, mud, metal shavings) exceeding 7 mm in length, with reasonable efforts made to remove all inedible materials.

Check finished manomin for pebbles or other inedible materials.

Manomin Packaging Standards

The materials used to package low-risk foods shall be kept clean and dry prior to their use, and be clean, single-use containers or containers which were cleaned and sterilized prior to their use.

Food safe materials must be used.

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Manoomin Labeling Standards

Class 2/3 Label

Statement of Identity: Must be prominent

Artwork should not hide or detract from label information

Signature line with name and address of the product's manufacturer, packer or distributor

Net Quantity Statement: the amount of food in the package

Sec. 3.02 Truth in Labeling:

- Wild rice may not be labeled as "natural wild rice" or "hand-harvested wild rice" unless the contents consist entirely of hand-harvested wild rice and contains no mechanically-harvested wild rice, or wild rice grown with the use of chemical fertilizers or herbicides.
- Class 3 foods must be labeled with standard statement of identity, nutrition facts, etc.

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Manoomin Labels Available

Contact Owen Schwartz at GLIFWC at **(715) 685-2147**

- Labels are available at GLIFWC
  - 25 bags and labels per request
  - Only available to tribal members of GLIFWC member tribes
  - Available at no cost
- For larger producers
  - Electronic copies of the label or nutrition facts are also available
  - Available at no cost

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Jams, Jellies, and Pickles

- Are considered low risk foods if they are "acidified" fruit preserves or vegetable pickles
- The pH of the finished product needs to be measured with a pH meter or equivalent device to ensure that the **pH is 4.6 or lower**
- Producers need to make and keep a record for each batch, documenting the pH measurement
- Jars used to package need to be cleaned and sterilized

Remember:

Tools and equipment to measure critical controls (i.e. pH) must be maintained in good condition and calibrated before use

Group Exercise

Identify the steps involved in:

(1) becoming a low-risk food vendor (beginning business, starting with no revenue) and

(2) making a batch of pickled ramps for sale.

Questions and Feedback

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Summary:

- Low-risk food vendor licenses are required for those who make low-risk foods in locations other than a tribally licensed food plant (only available for vendors who sell less than $50,000 gross in annual sales)
- The following apply to low-risk foods:
  - If produced out of a licensed food processing plant, must be labeled: " "PROCESSED AND PACKAGED IN A HOME FACILITY"
  - Required records on critical control points should be kept for each batch
- Wild rice and maple syrup/sugar are low-risk foods which qualify for additional exemptions and specialized labeling

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Miigwetch gaa-bizindaawiyeg!
Thank you for listening!

Owen Schwartz
Community Dietitian
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Session 8:
Review and Resources

1

Review

- Treaty-reserved traditional foods are safe for consumption
- Tribes are in charge of regulating "treaty rights" related activities
  - As long as they **effectively** regulate their people and **protect** legitimate State conservation, health and safety interests
- The Model Food Code only applies when it is adopted by the tribe, which may be in part or in whole.

2

Review

- Harvesters, food facilities, and retail establishments must adhere to the standards provided in Chapter 3 – General Provision of the Model Food Code. For example:
  - Sanitation Requirements
  - Personnel training
  - Water quality
  - Licensing and Enforcement
- Specific requirements are outline in the remaining, topic based chapters of the Model Food Code

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Review

- All food carries some level of risk, typically categorized as:
  - Biological risks or hazards
  - Chemical risks or hazards
  - Physical risks or hazards
- Biological hazards can be reduced by time and temperature, proper holding and cooking temperatures, and good hygiene and sanitation practices
- Chemical hazards can be reduced through harvest site or tool selections, size of harvest (fish), and proper use and storage of cleaning solutions
- Physical hazards can be reduce by choice of harvest ammunition and visual inspection

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Resources

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Great Lakes Indian Fish and Wildlife Commission

- GLIFWC website: GLIFWC.org
- Harvesting Regulations: http://data.glifwc.org/regulations/
- Training Manual
- Pre-recorded webinars
- GLIFWC YouTube page:

  https://www.youtube.com/user/glifwc

Fish Resources- GLIFWC

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Great Lakes Indian Fish and Wildlife Commission

- Great Lakes Fish (Whitefish)
  - http://glifwc.org/lakesuperiorwhitefish/Sustainable.html
  - Whitefish contaminant studies, HACCP forms, whitefish marketing materials
  - Seafood HACCP Training
- Mercury Maps
  - http://glifwc.org/Mercury/
  - Guidance for safe consumption of walleye from inland lakes in ceded territory
  - For questions, contact Dr. Sara Moses at smoses@glifwc.org

Fish Resources - Sea Grant programs

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State-based Sea Grant programs:

- Michigan:
  https://www.michiganseagrant.org/
- Wisconsin:
  https://www.seagrant.wisc.edu/
- Minnesota:
  http://www.seagrant.umn.edu/
- Florida:
  https://www.flseagrant.org/seafood/haccp/
  - Seafood HACCP tools and education

Fish Resources - HACCP

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US Food and Drug Administration

- *Fish and Fisheries Products Hazards and Control Guidance (March 2020)*
  - https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls
  - Excellent resource on fish and fish product hazards and controls. Fish HACCP plans are difficult to write without this book. Free download and supplemental material

Association of Food and Drug Officials

- www.afdo.org
- HACCP training information and industry updates

Meat Resources- CWD

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- **GLIFWC**
  - https://data.glifwc.org/cwd/
  - Contact Travis Bartnik with questions at tbartnik@glifwc.org
- **Tribal and State Natural Resource Departments**
- **USGS**- nationwide maps on CWD detections
  https://www.usgs.gov/centers/nwhc/science/chronic-wasting-disease?qt-science_center_objects=0#qt-science_center_objects
- **CWD Alliance**- US wide information on CWD
  - http://cwd-info.org/

Meat Resources- HACCP & Food Safety

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- **Intertribal Agriculture Council**
  - https://www.indianag.org/
- **Association of American Meat Producers-** industry resources and HACCP assistance
  - www.AAMP.com
- **International HACCP Alliance**
  - http://www.haccpalliance.org/sub/index.html
- **USDA Food Safety & Inspection Service**
  - https://www.fsis.usda.gov/wps/portal/fsis/home

Produce and Low-Risk Food Resources-

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- **Indigionous Food and Agriculture Initiative- Produce and additional Model Food Codes**
  - https://indigenousfoodandag.com/
- **Produce Alliance- information and training on produce and new FSMA regulations**
  - https://www.producealliance.com/
- **National Association of Home Food Preservation-** instructions and tested recipes
  - https://nchfp.uga.edu/

Questions and Feedback

Miigwetch gaa-bizindaawiyeg!
Thank you for listening!

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