



# TRADITIONAL FOOD REGULATORY SYSTEMS

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FOR *THE GREAT LAKES INDIAN FISH AND WILDLIFE COMMISSION*

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## 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.



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## 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.



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## 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.



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## 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.



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## 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.).



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## 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.

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## 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

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### 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

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- 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)

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- 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	5) Tree nuts
2) Eggs	6) Peanuts
3) Fish	7) Wheat
4) Crustacean shellfish	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.



## SMALL SCALE PROCESSORS' EXEMPTION FROM PREVENTIVE CONTROLS

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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
<ul style="list-style-type: none"> <li>• Food facility registration</li> <li>• Current good manufacturing practices</li> <li>• Hazard preventive controls</li> <li>• Sanitary transportation rule</li> <li>• HACCP plan (fish, wild game, juice)</li> <li>• Produce rule (fruits/vegetables)</li> <li>• Inspections (processing, manufacturing)</li> <li>• Labeling</li> </ul>	<ul style="list-style-type: none"> <li>• Food processing licenses</li> <li>• Food handling licenses</li> <li>• Retail food establishment licenses</li> <li>• Inspections (processing, manufacturing)</li> </ul>	<ul style="list-style-type: none"> <li>• Retail food establishment licenses</li> <li>• HACCP plan (retail food establishments)</li> <li>• Inspections (retail food establishments)</li> <li>• Perform the ministerial function of inspection and licensing.</li> </ul>



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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.



**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

