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August 13, 2020

**Great Lakes Indian Fish & Wildlife Commission**  
**Traditional Food Regulatory System Project**  
**2020 Supplement to the**  
**2018 First Food Code Guidance Report**

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## **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<sup>1</sup> 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

<sup>1</sup> 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,<sup>2</sup> the *Mille Lacs* decision,<sup>3</sup> and the

<sup>2</sup> *Lac Courte Oreilles Band of Lake Superior Chippewa Indians v. Voigt*, 700 F.2d 341 (7th Cir. 1983).

<sup>3</sup> *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*.<sup>4</sup> 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.<sup>5</sup> These decisions held that the Tribes retain their hunting, fishing, and gathering rights in the ceded territories.<sup>6</sup>

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.”<sup>7</sup> Likewise, the federal district court in *Mille Lacs* found the Tribes retained “the right to harvest the resources for commercial purposes.”<sup>8</sup> 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.<sup>9</sup> 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”).<sup>10</sup> 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.<sup>11</sup>

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

<sup>4</sup> *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).

<sup>5</sup> *Voigt*, 700 F.2d at 343; *Mille Lacs*, 124 F.3d at 910; *Carlson*, 68 F.3d at 254-55.

<sup>6</sup> *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).

<sup>7</sup> 653 F. Supp. 1420, 1435 (W.D. Wis. 1987).

<sup>8</sup> 861 F. Supp. 784, 838 (D. Minn. 1994).

<sup>9</sup> *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).

<sup>10</sup> *Lac Courte Oreilles Band of Lake Superior Chippewa v. Wisconsin*, No. 74-C-313 (W.D. Wis. 1989) (Deer Trial Stipulation).

<sup>11</sup> 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.”<sup>12</sup> 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.”<sup>13</sup> The Deer Trial Stipulation applies only to “wild game,”<sup>14</sup> 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.<sup>15</sup> 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.<sup>16</sup> 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

<sup>12</sup> *Id.* at 18.

<sup>13</sup> *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.

<sup>14</sup> 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.

<sup>15</sup> See Part III.B *infra*.

<sup>16</sup> 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.<sup>17</sup> 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”).<sup>18</sup>

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”).<sup>19</sup> 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.<sup>20</sup> 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

<sup>17</sup> 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.

<sup>18</sup> 21 U.S.C. § 301 *et seq.*

<sup>19</sup> Pub. L. No. 111-353 (Jan. 4, 2011).

<sup>20</sup> 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.<sup>21</sup> 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.<sup>22</sup> 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.”<sup>23</sup> 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,<sup>24</sup> the FDCA’s methods of regulation are relevant to all levels of the food distribution system.

<sup>21</sup> 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”).

<sup>22</sup> 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/LawsRegulations/ucm074248.htm>.

<sup>23</sup> 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.*

<sup>24</sup> 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.<sup>25</sup> The FDCA makes it unlawful for adulterated food to be received in, or enter interstate commerce for human consumption.<sup>26</sup> 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.<sup>27</sup>

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,<sup>28</sup> hazard preventive controls,<sup>29</sup> standards for produce,<sup>30</sup> and sanitary transportation requirements,<sup>31</sup> among others. There are requirements that apply to food generally, as well as to specific types of foods, such as fish.<sup>32</sup> A food processing operation is subject to both the general requirements and those applicable to the type of food it processes, stores, or distributes.<sup>33</sup>

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.

<sup>25</sup> 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.

<sup>26</sup> 21 U.S.C. § 331(a), (c).

<sup>27</sup> *Food Law* at 82-83.

<sup>28</sup> *See* 21 C.F.R. part 110.

<sup>29</sup> *See* 21 C.F.R. part 117.

<sup>30</sup> *See* 21 C.F.R. part 112.

<sup>31</sup> *See* 21 C.F.R. §§ 1.900-1.934.

<sup>32</sup> *See* 21 C.F.R. part 123 (fish and fishery products).

<sup>33</sup> 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.<sup>34</sup> 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.<sup>35</sup> 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.<sup>36</sup>

## 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.<sup>37</sup> 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,<sup>38</sup> pest control,<sup>39</sup> sanitation of food-contact surfaces,<sup>40</sup> cleanable equipment and utensils,<sup>41</sup> and practices for handling and preparing food.<sup>42</sup> 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.<sup>43</sup> Current good manufacturing practices do not apply to operations that only

<sup>34</sup> 21 U.S.C. §§ 374; 350j.

<sup>35</sup> *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.*

<sup>36</sup> See Food Safety, Div. of Env'tl. Health Servs., Indian Health Serv., available at [https://www.ihs.gov/dehs/includes/themes/responsive2017/display\\_objects/documents/priorities/FoodSafety.pdf](https://www.ihs.gov/dehs/includes/themes/responsive2017/display_objects/documents/priorities/FoodSafety.pdf).

<sup>37</sup> 21 C.F.R. part 110; *id.* § 110.3 (definition of "plant").

<sup>38</sup> 21 C.F.R. § 110.10.

<sup>39</sup> 21 C.F.R. § 110.35(c).

<sup>40</sup> 21 C.F.R. § 110.35(d).

<sup>41</sup> 21 C.F.R. § 110.40(a).

<sup>42</sup> 21 C.F.R. § 110.80(b), (c).

<sup>43</sup> 21 C.F.R. § 110.6(a).

harvest, store, or distribute food in its raw or natural state, such as unprocessed fruits and vegetables.<sup>44</sup>

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.<sup>45</sup> 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).<sup>46</sup>

## 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.<sup>47</sup> 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.<sup>48</sup> 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.<sup>49</sup> 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.<sup>50</sup>

<sup>44</sup> 21 C.F.R. § 110.19; *see also* 21 U.S.C. § 321(r).

<sup>45</sup> 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>.

<sup>46</sup> 21 C.F.R. § 123.3(k)(2).

<sup>47</sup> 21 C.F.R. § 123.6.

<sup>48</sup> *Food Law* at 141.

<sup>49</sup> *Food Law* at 141.

<sup>50</sup> 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.<sup>51</sup> 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."<sup>52</sup> A food facility includes any facility that manufactures, processes, packs, or holds food for human consumption.<sup>53</sup> A food safety plan is very similar to the HACCP method of regulation, though the FDA contends the FSMA's requirements are not identical.<sup>54</sup> The FDA's regulations require food facilities to adopt and implement food safety plans even if their products do not enter interstate commerce.<sup>55</sup> 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.<sup>56</sup> 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.<sup>57</sup>

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).<sup>58</sup> This qualified exemption allows a small-scale processor to submit an attestation to the FDA that it has incorporated HACCP principles into

<sup>51</sup> See 9 C.F.R. part 417.

<sup>52</sup> 21 C.F.R. § 117.126; *id.* § 117.3 (definitions of "facility" and "you").

<sup>53</sup> 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>.

<sup>54</sup> 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 . . .").

<sup>55</sup> 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).

<sup>56</sup> 21 C.F.R. § 1.226(c).

<sup>57</sup> See 21 C.F.R. § 1.227 (definition of "farm").

<sup>58</sup> 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.<sup>59</sup>

#### 4. Food Facility Registration

Food facilities must also register with the FDA and renew such registration biennially.<sup>60</sup> 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.<sup>61</sup> 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).<sup>62</sup> 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.<sup>63</sup> 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.<sup>64</sup> 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.<sup>65</sup> 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.<sup>66</sup> In this circumstance, the producer’s private residence is not a “facility” and is not required to register.<sup>67</sup>

#### 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.<sup>68</sup> As a result, the FDA issued its produce rule in 2015 to govern

<sup>59</sup> 21 C.F.R. § 117.201(2).

<sup>60</sup> 21 U.S.C. § 350d(a)(2); 21 C.F.R. § 1.230.

<sup>61</sup> 21 C.F.R. § 1.225(b).

<sup>62</sup> 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>.

<sup>63</sup> *Questions & Answers Regarding Food Facility Registration (7th ed.): Guidance for Industry* (Aug. 2018), available at <https://www.fda.gov/media/85043/download>.

<sup>64</sup> *Id.* at 9 (FAQ B.1.13).

<sup>65</sup> *Id.*

<sup>66</sup> *Id.* at 22 (FAQ C.1.5).

<sup>67</sup> *Id.*

<sup>68</sup> 21 U.S.C. § 350h.

growing, harvesting, packing, and holding produce for human consumption.<sup>69</sup> The produce rule applies to most fruits and vegetables,<sup>70</sup> except for certain types that are rarely consumed raw, such as potatoes, squash, cranberries, hazelnuts, and many types of beans.<sup>71</sup>

Harvesters of wild fruits and vegetables do not grow them and are therefore exempt from the produce rule's requirements applicable to growers.<sup>72</sup> 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.<sup>73</sup> 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.<sup>74</sup> 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.<sup>75</sup> 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.<sup>76</sup> 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).<sup>77</sup>

<sup>69</sup> 21 C.F.R. part 112.

<sup>70</sup> 21 C.F.R. § 112.1(b)(1). Examples include blueberries, gooseberries, cucumbers, and herbs such as basil. *See id.*

<sup>71</sup> *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.

<sup>72</sup> 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).

<sup>73</sup> 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>.

<sup>74</sup> 21 C.F.R. § 112.112.

<sup>75</sup> 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.

<sup>76</sup> 21 C.F.R. § 112.4(a).

<sup>77</sup> 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.<sup>78</sup> The USDA's Food Safety and Inspection Service ("FSIS") is required to inspect meat under the Federal Meat Inspection Act<sup>79</sup> ("FMIA") and poultry under the Poultry Products Inspection Act ("PPIA").<sup>80</sup> 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,<sup>81</sup> 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.<sup>82</sup>

The FMIA and PPIA do not apply to wild game.<sup>83</sup> 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.<sup>84</sup> The carcasses of exotic animals that are inspected and passed under the voluntary inspection program receive a triangular mark of approval from the USDA,

<sup>78</sup> 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").

<sup>79</sup> 21 U.S.C. §§ 601-695.

<sup>80</sup> 21 U.S.C. §§ 451-472.

<sup>81</sup> 21 U.S.C. §§ 603(a) (FMIA ante mortem inspection); 604 (FMIA post mortem inspections); 455(a), (b) (PPIA ante and post mortem inspections).

<sup>82</sup> 21 U.S.C. §§ 606(a), 607(a); 9 C.F.R. § 381.96.

<sup>83</sup> 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").

<sup>84</sup> 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.<sup>85</sup> Similar to inspections under the FMIA and PPIA, the voluntary inspection program requires ante and post mortem inspections.<sup>86</sup> 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.<sup>87</sup>

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.<sup>88</sup> 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,<sup>89</sup> 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

<sup>85</sup> 9 C.F.R. § 352.5.

<sup>86</sup> 9 C.F.R. §§ 352.10, 352.11.

<sup>87</sup> 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).

<sup>88</sup> 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”).

<sup>89</sup> 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.<sup>90</sup> 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.<sup>91</sup> 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.<sup>92</sup> 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.<sup>93</sup> 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.<sup>94</sup> 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."<sup>95</sup> 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

<sup>90</sup> See 7 C.F.R. part 210.

<sup>91</sup> 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](https://foodbuyingguide.fns.usda.gov/Content/TablesFBG/USDA_FBG_Section1_MeatsAndMeatAlternates.pdf).

<sup>92</sup> 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).

<sup>93</sup> See *id.* § 4033(c)(1)-(8). We have included the criteria in the Appendix to this report.

<sup>94</sup> 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](http://www.slate.com/articles/health_and_science/medical_examiner/2017/10/the_fight_for_the_right_to_eat_seal_blubber.html).

<sup>95</sup> 42 C.F.R. § 483.60(i)(1).

of Environmental Conservation (“DEC”), which has authority over food establishments under Alaska’s food code.<sup>96</sup>

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.<sup>97</sup> 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.<sup>98</sup> Maniilaq has continued to work with Alaska’s DEC to develop safety standards for other types of traditional foods.<sup>99</sup>

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.<sup>100</sup> 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.<sup>101</sup> The demonstration project will also require an additional appropriation of \$5 million by Congress.<sup>102</sup> The 2018 Farm Bill provides that food purchased by tribes will need to “meet any other criteria” established by the Secretary of Agriculture.<sup>103</sup> As such, it remains to be seen whether the demonstration project will offer any

<sup>96</sup> See Sigluaq, Maniilaq Ass’n (Dec. 15, 2015), available at <https://www.maniilaq.org/sigluaq/>; see also 18 AAC ch. 31 (Alaska food code).

<sup>97</sup> 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.

<sup>98</sup> See Sigluaq, *supra* n.88.

<sup>99</sup> 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).

<sup>100</sup> Pub. L. No. 115-334 (Dec. 20, 2018).

<sup>101</sup> See 84 Fed. Reg. 67,424 (Dec. 10, 2019) (request for information on the criteria for the self-determination demonstration project).

<sup>102</sup> Pub. L. No. 115-334, § 4003(b)(6).

<sup>103</sup> *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.<sup>104</sup> 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.<sup>105</sup>

Finally, the 2018 Farm Bill expanded the liability protections for the donation and service of traditional foods in federal food programs.<sup>106</sup> 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.”<sup>107</sup> 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.<sup>108</sup> The Food Code does not have the status of federal law, nor is it preemptive of tribal, state, or local law.<sup>109</sup> 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.<sup>110</sup>

<sup>104</sup> *Id.* § 3312(a).

<sup>105</sup> *Id.* § 3312(b)(1).

<sup>106</sup> *Id.* § 4203.

<sup>107</sup> *Id.*

<sup>108</sup> Food Code, U.S. Food & Drug Admin. (“2017 Food Code”), *available at* <https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM595140.pdf>.

<sup>109</sup> 2017 Food Code preface iii (“The model Food Code is neither federal law nor federal regulation and is not preemptive.”).

<sup>110</sup> 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.<sup>111</sup> 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.<sup>112</sup> 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.<sup>113</sup> 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.<sup>114</sup> 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.<sup>115</sup> The Food Code also encourages food establishments to implement HACCP principles,<sup>116</sup> including requirements for HACCP plans for certain types of activities.<sup>117</sup> The requirements apply to wild foods just as they would any other food sold or served in a food establishment.<sup>118</sup> 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

<sup>111</sup> 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.

<sup>112</sup> 2017 Food Code § 1-201.10 (definition of “food establishment”).

<sup>113</sup> 2017 Food Code § 3-201-11(B).

<sup>114</sup> *See* 2017 Food Code § 1-201.10 (exclusions from definition of “food establishment”).

<sup>115</sup> *See generally* 2017 Food Code Chapters 2-7.

<sup>116</sup> *See* 2017 Food Code at 320-21 (Annex 2 – References).

<sup>117</sup> 2017 Food Code § 8-201.13.1.

<sup>118</sup> *See* 2017 Food Code § 1-201.10 (definition of “food”).

law, and they must ensure that they receive food from approved sources.<sup>119</sup> 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."<sup>120</sup> 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.<sup>121</sup> 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.<sup>122</sup> The Food Code specifically includes game animals such as elk, deer, rabbit, opossum, and nonaquatic reptiles.<sup>123</sup> The Food Code allows a food establishment to sell or serve meat from a field-dressed wild game animal under a routine inspection program<sup>124</sup> 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.<sup>125</sup>

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

<sup>119</sup> 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").

<sup>120</sup> 2017 Food Code at 412 (Annex 3 – Public Health Reasons/Administrative Guidelines).

<sup>121</sup> 2017 Food Code § 1-201.10 (definition of "regulatory authority").

<sup>122</sup> 2017 Food Code §§ 3-201.17; 1-201.10 (definition of "game animal").

<sup>123</sup> 2017 Food Code § 1-201.10.

<sup>124</sup> 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).

<sup>125</sup> 2017 Food Code § 3-201.17(4).

of wild game, including requirements for HACCP plans and sanitation standards.<sup>126</sup> 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.<sup>127</sup> 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.<sup>128</sup>

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.<sup>129</sup> Wisconsin and Minnesota also have “cottage food” exemptions, which exclude home-based operations from licensing and inspection requirements.<sup>130</sup> 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.<sup>131</sup> Cottage food operations are also limited to selling their products directly to consumers and may not sell their products outside the state.<sup>132</sup> A cottage food operation must appropriately label their products

<sup>126</sup> See, e.g., 9 C.F.R. parts 416 (sanitation), 417 (HACCP).

<sup>127</sup> See 2017 Food Code preface iii (stating that the model provisions are “designed to be consistent with federal food laws and regulations”).

<sup>128</sup> 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.

<sup>129</sup> 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.

<sup>130</sup> See Wis. Stat. § 97.29(b); Minn. Stat. § 28A.152.

<sup>131</sup> Wis. Stat. § 92.29(b); Minn. Stat. § 28A.152(1)(a)(1).

<sup>132</sup> 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.<sup>133</sup>

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.<sup>134</sup>

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.<sup>135</sup> The ATCP may designate a local health department as its agent for the purposes of licensing and inspecting food establishments.<sup>136</sup> 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.<sup>137</sup> 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.<sup>138</sup>

<sup>133</sup> 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.").

<sup>134</sup> 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.

<sup>135</sup> Wis. Stat. §§ 97.29 (food processing plants); 97.30 (retail food establishments).

<sup>136</sup> Wis. Stat. § 97.41.

<sup>137</sup> *See* Sawyer Cnty. Health & Human Servs., available at <https://www.sawyercountygov.org/DocumentCenter/View/1163/HHS-Ordinance-Public-Notice>.

<sup>138</sup> *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.<sup>139</sup> 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.<sup>140</sup> The food establishment needs a permit from the Department of Natural Resources,<sup>141</sup> and it must be closed to the general public while the wild game is served.<sup>142</sup> The wild game must be stored and prepared separately from other food,<sup>143</sup> and cooked to 145°F.<sup>144</sup>

Michigan has maintained the model provision in its food code for field-dressed wild game received for sale,<sup>145</sup> but only private processing of wild game and service at charitable functions are actually permitted.<sup>146</sup> 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.<sup>147</sup>

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.<sup>148</sup> Although Congress granted Wisconsin and Minnesota criminal and civil adjudicatory jurisdiction

<sup>139</sup> Minn. R. 4626.0160(C). These requirements are somewhat similar to Section 4033 of the 2014 Farm Bill.

<sup>140</sup> Wis. Admin. Code § ATCP 75, App. § 3-201.17(B).

<sup>141</sup> *Id.* § 3-201.17(B)(2).

<sup>142</sup> *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).

<sup>143</sup> *Id.* § 3-201.17(B)(8).

<sup>144</sup> *Id.* 3-401.11(A)(1)(b).

<sup>145</sup> *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](https://www.michigan.gov/documents/mdard/MI_Modified_2009_Food_Code_396675_7.pdf).

<sup>146</sup> *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](https://www.michigan.gov/documents/MDA_FSPR_VP_Deer_Processing_K_49407_7.pdf).

<sup>147</sup> *Id.* (Checklist for Processing Venison in a Retail Food Establishment).

<sup>148</sup> *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,<sup>149</sup> this grant of jurisdiction does not extend to civil regulatory laws.<sup>150</sup> 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.<sup>151</sup>

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.<sup>152</sup> 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.

<sup>149</sup> 18 U.S.C. § 1162(b); 25 U.S.C. §§ 1321(b); 1322(b); 28 U.S.C. § 1360(b).

<sup>150</sup> 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).

<sup>151</sup> 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.

<sup>152</sup> 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.<sup>153</sup> 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.<sup>154</sup> 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.”<sup>155</sup> 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.<sup>156</sup> 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 HACCP [sic] management training regulations.”<sup>157</sup>

<sup>153</sup> 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>.

<sup>154</sup> *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>.

<sup>155</sup> *Id.* § 2.02(e)(2).

<sup>156</sup> 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>.

<sup>157</sup> 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.<sup>158</sup>

### 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.<sup>159</sup> 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."<sup>160</sup> 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."<sup>161</sup>

### 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.<sup>162</sup> 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.<sup>163</sup>

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

<sup>158</sup> See Food Quality Guidelines, Columbia River Inter-Tribal Fish Comm'n, available at <http://www.critfc.org/for-tribal-fishers/food-quality-guidelines/>.

<sup>159</sup> 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.

<sup>160</sup> *Id.* § 24.1.2.

<sup>161</sup> *Id.* § 24.1.3.

<sup>162</sup> See Purchase Leech Lake Wild Rice Today!, Leech Lake Band of Ojibwe, available at <https://www.llwildrice.com/wild-rice-products.html>.

<sup>163</sup> 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.<sup>164</sup> 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).

<sup>164</sup> 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.

Respectfully submitted,

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