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Great Lakes Indian Fish & Wildlife Commission
Traditional Food Regulatory System Project
2020 Supplement to the
2019 Second Food Code Guidance Report

I. Introduction.

In this report, we analyze food safety regulations related to labeling, packaging, and sales of Treaty-harvested wild foods. This report adds to our Food Code Guidance Report submitted as part of the first year of the Great Lakes Indian Fish & Wildlife Commission's ("GLIFWC") Chippewa Ceded Territory Traditional Food Regulatory System Project ("Project"). In particular, we discuss the requirements for labeling, packaging, and ultimately selling products of Treaty-harvested wild foods.

In our first Food Code Guidance Report ("Year 1 Report"), we found that the U.S. Food and Drug Administration ("FDA") is the principal agency with regulatory jurisdiction over wild foods relevant to the Project.[1] Our Year 1 Report outlined the federal regulatory system that governs most food sales in the United States under the Federal Food, Drug, and Cosmetic Act ("FDCA").[2] We found that Treaty-harvested wild foods are regulated under the FDCA. Likewise, we found for this report that the FDCA's requirements for labeling, packaging, and sales apply in most instances to Treaty-harvested wild foods intended for sale.

For labeling, the FDA requires each label of a consumer food product to be appropriately labeled to prevent the product from being deemed misbranded in violation of the FDCA. At a minimum, each label must include the food product's name, net quantity of contents, the nutrition facts, the ingredient and allergen list, and the name and address of the manufacturer, packer, or distributor.

The FDA's packaging requirements address concerns related to the possibility that packaging materials can adulterate food and render it unfit for human consumption. Food packaging operations must ensure they use packaging materials that are safe and suitable. The FDA requires that packaging operations follow current good manufacturing practices and use appropriate quality control operations. Food packaging operations must also ensure they obtain materials from reputable suppliers of FDA-approved packaging materials.

Finally, sales requirements include compliance with the FDCA as a predicate to a lawful sale in most situations. In other words, a food product must be harvested, processed, transported, packaged, and labeled in compliance with the FDCA's requirements and FDA's regulations. Many of these requirements are discussed in our Year 1 Report and are further noted below.

Below, Part II discusses the FDA's labeling requirements for food products; Part III discusses the FDA's packaging requirements; and Part IV discusses sales requirements.

[1] We understand that the Project has identified 14 traditional wild foods, including white-tailed deer, rabbit/hare, duck, wild turkey, whitefish, walleye, fresh berries, wild leeks (ramps), wild beach pea, hazelnut, morel mushroom, wild rice, berry jams/jellies, maple syrup, animal fat, venison jerky. These foods are subject to the FDA's jurisdiction under the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. § 321(f).
[2] 21 U.S.C. § 301 *et seq.*

2020 Supplement: As part of the Project's third year, we reviewed and updated this Report to account for regulatory and other changes since July 2019. This supplemental information is identified and discussed as the 2020 Supplement where relevant throughout the Report.

II. Labeling requirements.

A. Labeling requirements for food primarily seek to ensure that the consumer is adequately informed about a food product in order for the consumer to make an educated food choice. To that end, the FDCA prohibits the sale of misbranded food products in interstate commerce.[3] A food product is deemed misbranded if its labeling is false or misleading, it is offered for sale under the name of another food, or its label does not have the required information.[4]

Based on the FDCA's prohibition against misbranded food, federal requirements comprise the vast majority of labeling requirements that apply to food sold throughout the United States. The FDA has jurisdiction to promulgate and enforce labeling requirements to prevent the sale of misbranded food. We note that the United States Department of Agriculture ("USDA") has separate authority to regulate labeling of meat and poultry products under the Federal Meat Inspection Act[5] and the Poultry Products Inspection Act.[6] The USDA's labeling requirements share many characteristics as the FDA's, but there are some differences.[7] However, the USDA's labeling requirements do not apply to the Treaty-harvested wild foods relevant to the Project, because the USDA does not have jurisdiction over wild game, as discussed in more detail in our Year 1 Report.[8] Consequently, wild foods relevant to the Project are subject to the FDA's labeling requirements under the FDCA if they are intended for sale in interstate commerce and not otherwise exempt from the requirements.[9]

B. FDA's general labeling requirements.

The FDA requires each food product to include specific information on the label. Specifically, a label must include 5 categories of information: (1) the food's statement of identity; (2) the net quantity of contents; (3) the nutrition facts; (4) the ingredient and allergen list; and (5) the name and address of the manufacturer, packer, or distributor. The FDA then requires that this information be located on certain areas of the package. The FDA has published a guidance document for food labeling called *Guidance for Industry: Food Labeling Guide* ("Food Labeling Guide"), which we include in the appendix to this report. We recommend you refer to the Food

[3] 21 U.S.C. §§ 331, 343.
[4] *Id.* § 343.
[5] 21 U.S.C. §§ 601-695.
[6] 21 U.S.C. §§ 451-472.
[7] For example, the FDA and USDA have different labeling requirements for added colors. If a food product contains added coloring, the USDA requires a statement next to the product name, whereas the FDA requires the color to be disclosed in the ingredient statement.
[8] *See* Year 1 Report at 17-19.
[9] *See* 21 C.F.R. § 101.100 (exemptions from labeling).

Labeling Guide for its various depictions of labeling requirements. We summarize here the FDA's general requirements for labels.

1. Principal Display Panel

The Principal Display Panel ("PDP") is the regulatory term for the front label of a food product.[10] The PDP is the label that is most readily observed by the consumer at the time of purchase.[11] The FDA requires PDPs to include the following components:

- Statement of identity: The common name of the food (e.g., wild rice).[12]
- Net quantity of contents: The amount of food in the appropriate measurement (e.g., weight, fluid measurement, number of items).[13]

The lettering on the PDP must be easily readable. Other information or artwork on the PDP must not hide or detract from the visibility of the statement of identity and the net quantity.[14]

2. Information Fact Panel

The information fact panel ("IFP") must be located to the right of the PDP, as seen by consumer facing the product.[15] The IFP is not required if the information can fit on the PDP. The IFP includes the following information:[16]

- Nutrition facts: The food manufacturer is responsible for determining appropriate values for the product's nutrition facts. We note that the USDA Agricultural Research Service maintains an online Food Composition Database, which could be referenced for nutritional information of various wild game meat.[17] Raw seafood, fruits, and vegetables are exempt from nutrition labeling. The FDA has voluntary nutrition labeling guidelines for these products.[18]

2020 Supplement: The FDA has issued guidance on sugar labeling for maple syrup.[19] The FDA states it will exempt single-ingredient packages of pure maple syrup from the requirement to include the words "Includes Xg Added Sugars" on the label for nutrition facts.[20]

[10] 21 C.F.R. § 101.1.
[11] *Id.*
[12] *Id.* § 101.3(a)
[13] *Id.* § 101.7(a).
[14] *Id.* §§ 1.21(a)(1); 101.3(a); 101.105(h).
[15] *Id.* § 101.2(a).
[16] *Id.* § 101.2(b).
[17] USDA Food Composition Databases, https://ndb.nal.usda.gov/ndb/search/list?format=&count=&max=25&sort=&fg=&man=&lfacet=&qlookup=game+meat&offset=25 (search "game meat").
[18] *See* 21 C.F.R. § 101.42.
[19] *The Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups, and Certain Cranberry Products: Guidance for Industry* (2019), *available at* https://www.fda.gov/media/127928/download.
[20] *Id.* at 3.

However, packages of pure maple syrup must still be labeled with the percent daily value for added sugar on the label.[21] Under the FDA's labeling requirements, the percent daily value refers to the amount of nutrients in one serving of food expressed as a percentage of the amount of that nutrient you need each day. The FDA's guidance responds to concerns that labeling sugar in a container of maple syrup as "added" would mistakenly imply that table sugar had been added to the product.

- Ingredient and allergen list: The package must list the ingredients by their common name in descending order by weight.[22] There are special rules for certain types of ingredients, such as preservatives, which must include the name and its function.[23] As for allergens, federal law identifies eight foods that must be clearly identified on a label if it is present as an ingredient in the food.[24] The eight foods subject to mandatory allergen labeling are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.

FDA guidance provides alternative approaches for labeling of allergens.[25] First, a label's ingredient list may include the allergen in parenthesis following the common or usual name of the major food allergen, e.g., "lecithin (soy), flour (wheat), whey (milk)." Second, a label may include a "contain" statement with the name of the major food allergen placed immediately after or adjacent to the ingredient list, e.g., "Contains: Wheat, Milk, Egg, and Soy."

Under federal law, we note that supplemental disclosures regarding whether a product is manufactured in a facility that also processes other products that contain allergens are voluntary. As such, the FDA does not require labeling such as: "may contain [allergen]" or "produced in a facility that also uses [allergen]."[26] In fact, the FDA states that these supplemental disclosures should not be used as a substitute for properly identifying major food allergens present in a food product.[27] Nevertheless, many food manufacturers include these supplemental disclosures in an attempt to be transparent to the consumer and to comply with labeling requirements in state and local jurisdictions throughout the United States that require these disclosures.[28]

- Signature line: The signature line is simply the name and address of the product's manufacturer, packer, or distributor.[29] This requirement is important to identify the source of a

[21] *Id.*
[22] *Id.* § 101.4(a).
[23] *See, e.g., id.* § 101.22(j).
[24] 21 U.S.C. § 343(w).
[25] Food Labeling Guide at 23.
[26] *See* What You Need to Know about Food Allergies, U.S. Food & Drug Admin. ("Food Allergen 'Advisory' Labeling"), *available at* https://www.fda.gov/food/buy-store-serve-safe-food/what-you-need-know-about-food-allergies.
[27] *See id.* (general disclosures "should not be used as a substitute for adhering to current good manufacturing practices and must be truthful and not misleading").
[28] For example, Wisconsin's DATCP provides criteria for determining whether to include a supplemental allergen statement, *see* Labeling Language, Wisconsin Food Allergen Fact Sheet #5, *available at* https://datcp.wi.gov/Documents/AllergenLabelLanguage.pdf.
[29] 21 C.F.R. § 101.5.

food product in the event that there is a food safety issue. This information provides consumers and regulators with information to track the source of the food product.

- Leech Lake's wild rice is an example of a packaged wild food that adheres to the FDA's labeling requirements:

Principal Display Panel

1. Statement of identity
2. Net quantity of contents

Information Fact Panel

1. Nutrition Facts
2. Signature Line

* Note: This information fact panel does not have an ingredient list. Ingredients may be listed on the principal display panel (21 C.F.R. §101.4 (a)(1)).

3.

Warning and safe handling statements for specific foods.

Certain foods must be labeled with an appropriate warning or safe handling statement.[30] Examples of FDA warning and safe handling requirements for relevant foods include:

- Shell eggs: "SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly."[31]
- Unpasteurized juices: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."[32]

[30] *See* 21 C.F.R. § 101.17.
[31] *Id.* § 101.17(h)(1).
[32] 21 C.F.R. § 101.17(g)(2)(ii).

- Fish products: We note that the FDA suggests that processors of frozen fish products implement a control strategy for labeling that seeks to prevent the formation of the *C. botulinum* toxin. The FDA's control strategy for frozen fish products provides that all finished product labels contain a "keep frozen" statement, such as: "Important, keep frozen until used, thaw under refrigeration immediately before use."[33] In order to further reduce the possibility of the formation of *C. botulinum*, additional labeling should be placed on packaging to instruct the consumer or end user to cut or otherwise break the vacuum seal of the packaging during the thawing process.

C. Tribal and state labeling requirements.

The FDA's labeling requirements are widely incorporated by tribal and state governments. Indeed, tribal or state labeling requirements would be preempted if in conflict with federal requirements. For example, the Tribal Model Fish Processing Code, which we include in the appendix, reflects the FDA's labeling requirements.[34] Likewise, the Wisconsin Department of Agriculture, Trade and Consumer Protection's regulations are consistent with the FDCA's labeling requirements.[35]

The Tribal Model Fish Processing Code contains a labeling requirement for fish fillets, smoked fish, or roe that are packaged in vacuum packed jars or plastic bags. The Tribal Model Fish Processing Code requires these packages to have a label that states:

"KEEP REFRIGERATED AT 38º F (3.33º C) OR LESS."

Similarly, the Project may want to consider a model labeling requirement for wild game. The FDA's general labeling requirements do not specifically address safe handling concerns regarding wild game. The Project could consider the USDA's safe handling instructions for labels of meat and poultry products, which address similar food safety concerns.[36]

In some cases, tribes and states have additional labeling requirements directed at consumer protection concerns related to marketing. These types of labeling requirements do not address food safety, but seek to prevent false or misleading claims about a food product. Member Tribes may want to consider regulating marketing claims on labels for products made from Treaty-harvested wild foods to prevent false or misleading claims. For example, Wisconsin has special labeling requirements for wild rice, which prohibits suppliers from selling any rice labeled as "100 percent natural wild rice," unless that rice is actually wild rice and not blended with any other rice.[37] A supplier must include a qualifying label if the product contains paddy-grown rice, which

[33] *Fish and Fishery Products Hazards and Controls Guidance*, U.S. Food & Drug Admin., Chapter 13: Clostridium botulinum Toxin Formation, at 282 (4th ed. 2011), https://www.fda.gov/media/80637/download.
[34] *See* Draft Tribal Model Fish Processing Code, chapter 5.
[35] Wis. Stat. § 97.10(1); *see* ATCP 90.02 (declaration of product identity), 90.03 (declaration of responsibility), 90.04 (declaration of net quantity).
[36] *See* 9 C.F.R. § 317.2(l) (meat); 9 C.F.R. § 381.125(b) (poultry).
[37] Wis. Stat. § 97.57(3).

is rice that is mechanically planted, harvested, or cultivated with the use of chemical fertilizers or herbicides.[38] By definition, wild rice is rice that is not mechanically harvested and is cultivated without the use of any chemical fertilizer or herbicides.[39]

III. Packaging requirements.

Packaging requirements seek to prevent adulteration of the food contained in a package. Food packaging may adulterate food by making the food unsafe, unfit for human consumption, or qualifying as an unapproved food additive.[40] Packaging can be a food additive because it contains substances that can reasonably be expected to become a component of the food or otherwise affect the characteristic of the food. The FDA generally must give prior approval to a food additive to recognize its safety before it can be used.[41] Use of an unapproved food additive constitutes per se adulteration and is prohibited.[42]

Most packaging materials fall under an exception for substances classified as "generally recognized as safe" ("GRAS") or are approved as a "food contact substance" ("FCS"). Substances classified as GRAS achieve this status if grandfathered in as safe for use prior to 1958 or subsequently accorded the status through a scientific determination by the FDA or a manufacturer's self-determination.[43] Substances in packaging are more commonly approved as FCSs, which include materials such as plastics, paper, adhesives, and coatings that are used for packaging food but are not intended to have any technical effect on the food.[44] An FCS receives approval through the FDA's Food Contact Notification Program administered by the Center for Food Safety and Applied Nutrition's Office of Food Additive Safety.[45]

In practice, the FDA's regulations place a significant burden for complying with packaging requirements on the manufacturers of food packaging materials. Indeed, a typical food packaging operation is not in the business of manufacturing the materials used to package the food nor the scientific regulatory approval processes. Instead, food packaging operations must ensure they obtain their materials from a reputable supplier such that they can be assured that the materials have been approved for use.

Food packaging operations must then adhere to the FDA's current good manufacturing practices, which generally require that packaging operations use appropriate quality control operations to ensure that food packaging materials are safe and suitable.[46] The FDA's current

[38] *Id.* § 97.57(2).
[39] *Id.* § 97.57(1)(b).
[40] *See* 21 U.S.C. §§ 342(a)(1) (adulterated food); 321(s) (definition of "food additive").
[41] *Id.* § 321(a)(1).
[42] *See id.* § 342(a)(1).
[43] 21 C.F.R. § 170.30(
[44] 21 U.S.C. § 348(h)(6).
[45] *See* Anna P. Shanklin & Elizabeth R. Sanchez, *Regulatory Report: FDA's Food Contact Substance Notification Program*, Food Safety Magazine (Oct./Nov. 2005), *available at* https://www.foodsafetymagazine.com/magazine-archive1/octobernovember-2005/fdas-food-contact-substance-notification-program/.
[46] 21 C.F.R. § 110.80, (13)(iii).

good manufacturing practices include requirements such as employee hygiene,[47] pest control,[48] sanitation of food-contact surfaces,[49] cleanable equipment and utensils,[50] and sanitary practices for handling and preparing food.[51] The current good manufacturing practices also provide general processes and controls for packaging that seek to ensure adequate sanitation principles are applied to packaging operations.[52] We include the current version of the FDA's current good manufacturing practices in the appendix to this report.

In addition to the general standards in the current good manufacturing practices, the FDA's regulations provide specific processes and controls for thermally processed[53] low-acid foods that are packaged in airtight containers,[54] acidified foods,[55] and canned fruits[56] and vegetables.[57] A food packaging operation needs to comply with these standards if it engages in these packaging activities.

The FDA also has requirements for specific types of food products and to address food safety concerns associated with packaging such as botulism. For most fruits and vegetables, the FDA's produce rule requires that packagers use food packing material that is adequate for its intended use, cleanable or designed for single use, and unlikely to support growth or transfer of bacteria.[58] The produce rule requires produce to be packaged in a manner that prevents the formation of *Clostridium botulinum* ("*C. botulinum*") toxin if the toxin is a known or reasonably foreseeable hazard, such as in the case of mushrooms.[59]

For fish products, the fish processor's HACCP plan[60] must list controls to prevent food safety hazards associated with the formation of *C. botulinum* toxin in the finished, packaged product.[61] The FDA has published guidance for preparation and packaging of fish products to prohibit the formation of *C. botulinum* toxin.[62] We attach this guidance in the appendix to this

[47] *Id.* § 110.10.
[48] *Id.* § 110.35(c).
[49] *Id.* § 110.35(d).
[50] *Id.* § 110.40(a).
[51] *Id.* § 110.80(b), (c).
[52] *See* 21 C.F.R. 110.80.
[53] Thermal processing is a food sterilization technique through which the food is heated to destroy microorganisms.
[54] 21 C.F.R. pt. 113.
[55] 21 C.F.R. pt. 114.
[56] 21 C.F.R. pt. 145.
[57] 21 C.F.R. pt. 155.
[58] 21 C.F.R. § 112.116(a).
[59] *Id.* § 112.115.
[60] As discussed in our Year 1 Report at 13, the FDA requires processors of fish to adopt and implement a HACCP plan. *See* 21 C.F.R. § 123.6.
[61] 21 C.F.R. § 123.6(e).
[62] *Fish and Fishery Products Hazards and Controls Guidance*, U.S. Food & Drug Admin., Chapter 13: Clostridium botulinum Toxin Formation, at 245-291 (4th ed. 2011), https://www.fda.gov/media/80637/download.

report. This guidance can be used by processors to develop relevant controls in their HACCP plans to ensure consistency with FDA requirements for packaged fish products. We also note and attach in the appendix Wisconsin's regulations for processing smoked fish, which provide suggested procedures for preparing smoked fish products to address botulism risks.[63]

IV. Sales requirements.

The sale of food is governed by all sorts of regulation that apply in various contexts and seek to achieve different regulatory goals. The sale of food is regulated in contexts as diverse as zoning, business licensing, and taxation. Not all of this regulation concerns food safety and is outside the scope of this report. Indeed, the principal impediment to broader sales of wild foods concerns the need for regulation to ensure the safety of wild food for human consumption. We discussed the regulatory framework that governs food safety in our Year 1 Report. In this report, we seek to further delineate the jurisdictional scope of food sales requirements under the FDCA. We also discuss regulatory approaches that seek to promote food sovereignty and local control for small-scale sales of food.

A. Sales in interstate commerce.

As discussed in our Year 1 Report, the FDCA governs food sales in interstate commerce, which is defined as "commerce between any State or Territory and any place outside thereof" and "commerce . . . within any other Territory not organized with a legislative body."[64] The FDA has taken a very broad view of its jurisdiction to enforce the FDCA within an Indian reservation, concluding that it has "complete jurisdiction over products . . . that are manufactured on an Indian reservation," because the agency considers the food products to be in interstate commerce "at all times."[65] The FDA has also stated that it is "rare" for food products intended for sale to fall outside its jurisdiction under the FDCA, because "at least some of [the] ingredients or packaging most likely originate from out of state and it is foreseeable that [the] products will leave the state."[66]

Consequently, the FDCA applies to most food sales and compliance with these federal requirements is a predicate to a lawful sale. This compliance includes, unless exempted, the requirements discussed in our Year 1 Report and the packaging and labeling requirement discussed above. The FDA also provides an overview of the basics to starting a food business that can assist Treaty harvesters with understanding the scope of the FDCA's requirements and exemptions.[67] In order to facilitate broader sales of wild foods, Member Tribes need to ensure they implement regulatory systems with requirements that fill the role that state and local governments play within

[63] ATCP ch. 70, Appendix A.
[64] 21 U.S.C. § 321(b).
[65] FDA Jurisdiction on Indian Reservations, Compliance Policy Guides, U.S. Food & Drug Admin., *available at*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-100350-fda-jurisdiction-indian-reservations.
[66] What the FD&C Act Means by "Interstate Commerce," U.S. Food & Drug Admin., *available at* https://www.fda.gov/cosmetics/cosmetics-laws-regulations/key-legal-concepts-cosmetics-industry-interstate-commerce-adulterated-and-misbranded.
[67] How to Start a Food Business, U.S. Food & Drug Admin., https://www.fda.gov/food/food-industry/how-start-food-business.

the FDCA's food safety regulatory regime. These concepts are discussed at further length in our Year 1 Report, but the general functions by jurisdiction are listed in the table below.

Sales Requirements Related to Food Safety		
FDA	**Tribal/State**	**Tribal/Local**
• Food facility registration • Current good manufacturing practices • Hazard preventive controls • Sanitary transportation rule • HACCP plan (fish, wild game,[68] juice) • Produce rule (fruits/vegetables) • Inspections (processing, manufacturing)[69] • Labeling	• Food processing licenses • Food handling licenses • Retail food establishment licenses • Inspections (processing, manufacturing)	• Retail food establishment licenses • HACCP plan (retail food establishments) • Inspections (retail food establishments)

B. Exemptions from the FDCA and Food Sovereignty laws.

The FDCA's extensive requirements do not govern all food sales within an Indian reservation or within a state. As discussed in our Year 1 Report, a Member Tribe may appropriately exclude certain intra-tribal transactions of food from the scope of formal regulation.[70] In addition, direct-to-consumer sales may also be exempt from certain FDA and other requirements. Specifically, the FDA provides an exemption from food facility registration requirements for establishments that sell food directly to consumers and if their annual direct sales exceed annual sales to all other buyers (e.g., businesses).[71] As discussed in our Year 1 Report, the FDA also excludes small-scale processors from the full FDA preventive controls rule if the processor has more average sales to consumers within the same Indian reservation than to all other purchasers.

[68] A HACCP plan is not technically required for processing wild game by FDA regulation. However, the Model FDA Food Code suggests that wild game should be processed according to laws governing meat and poultry, as discussed in our Year 1 Report at 25. The USDA's regulations for processing meat and poultry require HACCP plans. *See* 9 C.F.R. parts 416, 417.

[69] In practice, the FDA often relies on relationships with state and local regulators, as the majority of inspections in food facilities are conducted by state and local agencies under contract with the FDA. On Indian reservations, the Indian Health Service's Division of Environmental Health Services can contract with tribes to perform inspections of tribal food operations, though tribes may assert this authority if they have the capacity to do so.

[70] *See* Year 1 Report at 10, 35.

[71] 21 C.F.R. § 1.227; *see also* Retail Food Establishment Exemption Flowchart, U.S. Food & Drug Admin. (May 2018), *available at* https://www.fda.gov/media/112967/download.

Tribal and state governments also often enact "cottage food" exemptions for home-based operations that exclude them from licensing and inspection requirements.[72] "Cottage food" exemptions are typically limited to direct-to-consumer sales of products made from fruits and vegetables and exclude potentially hazardous food, such as animal food products.[73] However, we note that the Pokagon Band of Potawatomi Indians in Michigan has adopted a provision that is essentially a cottage food law for wild game. This provision allows food establishments to sell wild game from uninspected sources in limited circumstances. We discussed this provision in our Year 1 Report,[74] but it is unclear whether it has been successfully implemented by the Pokagon Band such that sales of uninspected wild game food products occur without objection by the FDA.

2020 Supplement: In 2019, the Bay Mills Indian Community enacted its Jiibaakwaan Production Ordinance ("Jiibaakwaan Ordinance") for cottage foods sold at the Bay Mills Farmers' Market.[75] The Jiibaakwaan Ordinance provides for the sale of homemade food at the Bay Mills Farmers' Market that is "non-potentially hazardous."[76] This includes foods such as baked goods without cream or meat fillings; candies; dried fruits, pastas, and spices; maple syrup; and granola, cereals, and nuts.[77] Similar to many other cottage food laws, the Jiibaakwaan Ordinance does not permit the sale of "potentially hazardous food," which is defined as food "that has generally been shown to support the growth of pathogenic bacteria or other foodborne pathogens without a time and temperature control."[78] This effectively includes animal food products that are typically excluded from sale under cottage food laws.

The Jiibaakwaan Ordinance provides that "non-potentially hazardous" food may be sold if it is "prepared in a traditionally safe manner."[79] A food is prepared in a "traditionally safe manner" if it is produced "using cultural practices specific to the Bay Mills Indian Community peoples that have proved to be safe over past generations."[80] The Jiibaakwaan Ordinance also requires annual licenses for vendors and enforcement by an appointed "Market Master."[81]

The Jiibaakwaan Ordinance has labeling requirements to indicate that the food product is homemade and uninspected:

[72] *See, e.g.*, Wis. Stat § 97.29(b); Minn. Stat. § 28A.152.
[73] Wis. Stat. § 92.29(b); Minn. Stat. § 28A.152(1)(a)(1).
[74] *See* Year 1 Report at 31.
[75] Jiibaakwaan Production Ordinance (July 23, 2019), *available at* https://baymillstribalcourt.org/wp-content/uploads/2019/08/JiibaakwaanProductionOrdinance.pdf.
[76] *Id.* § 104(A)(1).
[77] *Id.* § 103(H).
[78] *Id.* § 103(G).
[79] *Id.* § 104(A)(2).
[80] *Id.* § 103(J).
[81] *See id.* § 105.

"Made in a home kitchen not inspected by the Bay Mills Indian Community and processed in a traditional manner."

"Not for resale beyond the Bay Mills Indian Community boundaries."

"Made in a home kitchen not inspected by the Bay Mills Indian Community."[82]

The Jiibaakwaan Ordinance is notable for its incorporation of Anishinaabe practices into a system of food safety regulation. Nevertheless, the Jiibaakwaan Ordinance has a limited scope in terms of geographic sales and the types of food permitted for sale. This is another example of the limits imposed on sales by federal food laws.

The State of Maine has gone further than "cottage food" laws by enacting a food sovereignty law in 2017 to encourage local control over food systems for sales of locally-produced food.[83] The Maine Food Sovereignty Act ("MFSA") declares Maine's policy on food sovereignty, including the policies to "encourage food self-sufficiency for its citizens"; "[e]nsure the preservation of family farms and traditional foodways through small-scale farming and food production"; to "[i]mprove the health and well-being of citizens of this State by reducing hunger and increasing food security through improved access to wholesome, nutritious foods supporting family farms and encouraging sustainable farming and fishing"; to "[p]romote self-reliance and personal responsibility by ensuring the ability of individuals, families and other entities to prepare, process, advertise and sell foods directly to customers intended solely for consumption by the customers or their families"; and to "[e]nhance rural economic development and the environmental and social wealth of rural communities."[84]

The MFSA provides that Maine will not enforce state food laws for direct-to-consumer transactions if a municipality has enacted an ordinance to govern those transactions.[85] In turn, municipalities enact ordinances to implement the MFSA within the local jurisdiction. Because most licensing and inspection requirements are carried out by state authorities,[86] the MFSA effectively exempts local food producers from licensing and inspection requirements for food sales between the producers and customer for the customer's personal consumption. It also forces the FDA to enforce federal food laws itself, because the State does not undertake its role of enforcing federal requirements that form the basis of state food regulation.

[82] *Id.* § 106.
[83] Me. Rev. Stat. tit. 7, §§ 281-286.
[84] *Id.* § 283.
[85] *Id.* § 284.
[86] This arrangement is not entirely analogous to an Indian reservation because not all tribes have assumed primary responsibility for licensing and inspecting food operations within their jurisdiction.

However, the MFSA does not exempt licensing and inspection requirements for meat and poultry products.[87] This exclusion was in direct response to the USDA's objection to the original MFSA, which applied to meat and poultry products. The USDA objected to the original MFSA as falling below federal requirements for meat and poultry in the Federal Meat Inspection Act and Poultry Products Inspection Act. This is an example of how federal authorities take issue with attempts to sell food products from potentially hazardous food. This would likely be the response from the FDA if Member Tribes attempt to encourage the sale of unregulated food products made from fish and wild game.

C. Sales into state and local jurisdictions.

Finally, we note the particular problem of sales into, or within state and local jurisdictions. Treaty harvesters that sell or serve food in a state or local jurisdiction are subject to nondiscriminatory state and local laws.[88] As discussed in our Year 1 Report, retail food establishments that sell or serve food to consumers (e.g., grocery stores, restaurants) are generally regulated by food codes modeled off the FDA's Model Food Code. Under the Model Food Code, retail food establishments must obtain food only from approved sources. Moreover, some states, such as Wisconsin and Minnesota, have amended the model provisions to effectively prohibit retail food establishments from receiving products made from field-dressed wild game for sale or service to consumers.[89] In these cases, it is very unlikely that retail food establishments will be willing to purchase wild game food products for sale or service in their establishments.

However, there may be more of an opportunity for direct-to-consumer sales in state and local jurisdictions. It is critical that Treaty harvesters comply with the FDCA's requirements if they intend to sell their products directly to consumers in jurisdictions outside an Indian reservation. This is due to the preemptive force of the FDCA for food products being sold in interstate commerce. A Treaty harvesters' compliance with the FDCA makes it more difficult for state and local jurisdictions to take issue with a food product made from wild foods. Nevertheless, the ability to market food products made from wild game throughout the United States is largely untested and certain to draw attention from federal, state, and local regulators. This presents the opportunity for Member Tribes to adopt their own standards to facilitate broader marketing of wild foods if they demonstrate food safety and the standards become accepted more broadly.

[87] *Id.* § 285.
[88] *See, e.g.*, *Mescalero Apache Tribe v. Jones*, 411 U.S. 145, 148-49 (1973). The extent to which the off-reservation Treaty rights would provide a basis to exempt sales of wild foods occurring outside a reservation from state law is unclear. The ability of Treaty harvesters to sell wild foods into a state or local jurisdiction would likely depend on acceptance by the state or local government of tribal standards.
[89] *See* Minn. R. 46260160(C); Wis. Admin Code § ATCP 75, App. § 3-201.17(B).

V. Conclusion

A product of Treaty-harvested wild food needs to comply with the FDCA's labeling, packaging, and sales requirements if intended to be marketed in interstate commerce. Only certain types of sales may be properly exempted from the FDCA's requirements and these are generally limited to intra-tribal transactions and small-scale producer-to-consumer sales of non-hazardous foods (i.e., fruits, vegetables, and wild rice). Tribes and state often reference federal requirements for labeling, packaging, and sales, as the federal requirements preempt conflicting requirements and govern sales throughout the United States in any event. A model code for Treaty-harvested wild foods may likewise reference the federal requirements and then address specific food safety concerns for wild game.

Respectfully submitted,

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Appendix to
Great Lakes Indian Fish & Wildlife Commission
Chippewa Ceded Territory Traditional Food Regulatory System Project
Second Food Code Guidance Report

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1. Model Tribal Model Fish Processing Code
    - See “Table of Contents” in Training Manual

2. FDA’s Current Good Manufacturing Practices, 21 C.F.R. part 110
    - https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/current-good-manufacturing-practices-cgmps-food-and-dietary-supplements

3. ATCP ch. 70, Appendix A, Smoked Fish Processing (Wisconsin)
    - https://docs.legis.wisconsin.gov/code/admin_code/atcp/055/70_a

4. *Guidance for Industry: Food Labeling Guide*, U.S. Food & Drug Admin.
    - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide

5. *Fish and Fishery Products Hazards and Controls Guidance*, U.S. Food & Drug Admin.
    - https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls (most recent edition March 2020)