

GLIFWC Model Food Code

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As developed by the Great Lakes Indian Fish and Wildlife Commission as part of its “Chippewa Ceded Territory Traditional Food Regulatory System Project,” with funding provided by the Administration for Native Americans and the Bureau of Indian Affairs.



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Chapter 1 – Purpose and Applicability

1.01 Purpose

(1) This Title should be applied to promote the purpose of this ordinance described in subsection (3), below, and to promote the health and general welfare of the _____ [Tribe] people, their culture, economy, and natural resources through food and agricultural production using materials hunted, fished and gathered pursuant to the _____ [Tribe’s] rights reserved in the [Treaty of 1836] [Treaty of 1837] [Treaty of 1842] [Treaty of 1854].

(2) It is not the intent of this Title to waive the sovereign immunity of the _____ [Tribe] or any of its agencies or instrumentalities through the passage of this Title or with regards to any provisions contained therein. Nothing in this Title or amendments thereto shall be construed as a waiver of sovereign immunity on the part of the _____ [Tribe] absent a recorded, express waiver of sovereign immunity.

(3) Our traditional foods are derived from the plant, fish, and animal beings living within the Ceded Territories, given as gifts by Gichi-Manidoo, and thus are integral to the spiritual and cultural identity of the Anishinaabeg. Access to these traditional foods, for all Anishinaabeg, is critical for our survival, to decrease incidents of chronic disease and to achieve overall wellness. Without the continued availability of plants, fishes, and animals, the Anishinaabeg would cease to be as Gichi-Manidoo made us.

1.02 Applicability

(1) The provisions contained herein apply to all individuals and facilities involved in the harvesting, processing, transporting, packing and holding of food products derived from wild animals and plants harvested by a member or members of the _____ [Tribe] within the Tribe’s Ceded Territories and/or within the exterior boundaries of the _____ Reservation for processing as food for commercial sale and

donation to Indian Tribal Operations and Child Nutrition Programs and do not apply to the following activities:

- (a) Informal commercial sale, as defined in Sec. 2.01 [Definitions], located within the exterior boundaries of the _____ Reservation;
- (b) Home use of treaty-harvested foods, including informal distribution of treaty-harvested foods among tribal families;
- (c) Community feasts, as defined in Sec. 2.01 [Definitions]; and
- (d) Sale of whole deer and elk carcasses pursuant to the tribes' applicable off reservation conservation codes.

(2) This Title applies to the processing and production of food derived from treaty-harvested animals, plants and fungi hunted, fished and gathered on-reservation and off-reservation within the _____ Tribe's Ceded Territories, consistent with permits and authorizations of the _____ [Tribe], pursuant to the applicable tribal regulations pertaining to those activities, but does not apply to foods derived from species considered endangered, threatened or protected under applicable tribal laws.

1.03 Territorial Applicability and Jurisdiction

(1) This Title shall apply within the exterior boundaries of the _____ Reservation, and areas outside of the exterior boundaries of the _____ Reservation within the Ceded Territories subject to rights reserved by the [Treaty of 1836] [Treaty of 1837, Treaty of 1842, Treaty of 1854], but not including any part of the Menominee Nation Reservation. The _____ [Tribe] assumes and retains jurisdiction over all lands and waters not within the exterior boundaries of the _____ Reservation as permitted by any law, convention, charter, compact and/or agreement.

(2) The Tribal Court of the _____ [Tribe] shall have exclusive jurisdiction to prosecute violations of this Title.

1.04 Rights Reserved

Nothing in this title, or any regulations adopted pursuant hereto, shall diminish the rights reserved by the _____ [Tribe] and its members by the [Treaty of 1836] [Treaty of 1837, Treaty of 1842, Treaty of 1854] or deprive the [governing body] of the _____ [Tribe] of the right to modify, amend or repeal this title.

Chapter 2 – Definitions

2.01 Definitions

The words in quotations shall be defined within this Title as follows:

(1) **“Adequate”** means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(2) **“Adequately reduce microorganisms of public health significance”** means reduce the presence of such microorganisms to an extent sufficient to prevent illness.

(3) **“Adulteration” or “Adulterated”** means food that:

(a) Bears or contains any poisonous or deleterious substance in a quantity which may render it injurious to human health, including containing any hard, inedible fragments of material measuring 7 mm or larger in any direction; or

(b) Bears or contains any poisonous or deleterious substance for which no safe tolerance has been established by law; or

(c) Consists in whole or in part of any filthy, putrid or decomposed substance, or is otherwise unfit for human consumption; or

(c) Has been processed, packed or held in unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have become injurious to human health; or

(d) Has been processed, prepared, packed or held under any insanitary conditions whereby there is a reasonable probability that it might have been contaminated with filth or rendered injurious to health; or

(e) Is in whole or in part the product of a diseased animal or an animal which has died otherwise than by slaughter or lawful harvest in the wild with the application of appropriate field-dressing techniques; or

(f) Is packaged within a container comprised in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health.

(4) **“Amenable wild-harvest food”** means safe, wholesome and unspoiled foods derived from free-ranging animals, plants and fungus available for harvest by Anishinaabeg of the _____ [Tribe] within the _____ Reservation and ceded territories.

(5) **“Animal excreta”** means liquid or solid animal waste.

(6) **“Class 1 food”** means those foods processed pursuant to this Title, available for sale within the exterior boundaries of the _____ Reservation, to individual tribal members only.

(7) **“Class 2 food”** means those foods processed pursuant to this Title, available for sale to Indian Tribal Organizations and Child Nutrition Programs for which a majority of the consumers served are tribal members.

(8) **“Class 3 food”** means those foods processed pursuant to this Title, available for sale to a general consumer base, which includes non-tribal members and retail institutions.

(9) **“Community feast”** means the provision of ready-to-eat food for an Anishinaabe cultural or spiritual purpose by members of the _____, where no monetary exchange is necessary or expected.

(10) **“Corrective action”** means procedures to be followed when a deviation occurs.

(11) **“Covered produce”** means produce (e.g. blueberries, raspberries, blackberries, salad greens, etc.), which is consumed raw and not subject to commercial processing that adequately reduces the presence of microorganism of public health significance. Covered produce does not include produce that is rarely consumed raw, such as: beach peas, cranberries, hazelnuts, wild mushrooms and fiddlehead ferns.

(12) **“Critical Control Point”** means a point, step or procedure in a food process at which a control can be applied, and a food safety hazard can as a result, be prevented, eliminated or reduced to acceptable levels.

(13) **“Critical limit”** means the maximum or minimum value to which a physical, biological or chemical parameter must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level, the occurrence of the identified food safety hazard.

(14) **“Cross-contact”** means unintentional incorporation of a food allergen into another food through accidental transfer.

(15) **“Cross-contamination”** means transfer of pathogens from food or a surface to another food or food contact surface.

(16) **“Field dressing”** means the removal of internal organs of a wildlife carcass, which is performed at or near the point of kill.

(17) **“Fish”** means a limbless cold-blooded vertebrate animal with gills and fins, living wholly in water.

(18) **“Fishery product”** means any human food product in which fish is a characterizing ingredient.

(19) **“Food”** means any raw, cooked, or processed edible substance, or beverage, or ingredient intended for human consumption and includes ice and water.

(20) **“Food contact surface”** means those surfaces that contact human food, including the surfaces of equipment and utensils, and those surfaces from which drainage, or other transfer, onto food or other food surfaces ordinarily occurs during the normal course of operations.

(21) **“Food processing plant”** means any place used primarily for the processing of class 2 and 3 foods. Food processing plant does not include a residential dwelling or any of the following: (1) a retail

food establishment, restaurant, or other similar establishment if the amenable wild-harvest food processing activities at the establishment are authorized by a license; (2) a harvest vessel, if practices are limited to those such as heading, eviscerating or freezing fish for holding on board; (3) a place used solely for washing or packaging fresh or otherwise unprocessed produce; (4) a place solely used for field-dressing wild game prior to further processing; or (5) a place solely used for processing a limited volume of low-risk foods and/or class 1 meat products and/or class 1 fish products.

(22) **“Food safety hazard”** means any biological, chemical or physical property that may cause a food to be unsafe for human consumption.

(23) **“Game animal”** means an individual of a wildlife species of animal used by the Anishinaabe for food that has not been raised in captivity.

(25) **“HACCP system”** means the HACCP plan in operation, including the HACCP plan itself.

(26) **“Hazard or hazardous”** means any biological or chemical agent that has the potential to cause injury in the absence of its control.

(27) **“Harvest”** when used in reference to wildlife animals, means the killing of the animal.

(28) **“Informal commercial sale”** means the provision of ready-to-eat food, in an irregular or non-reoccurring basis, prepared on behalf of the _____ [Tribe] or by members of the _____ [Tribe] for a commercial purpose, where the majority of the consumers are members of the _____ [Tribe].

(29) **“Information fact panel”** or **“IFP”** means a label with required information that appears on a location on the product other than the front of the product.

(30) **“Jerky”** means a ready-to-eat (RTE) dried meat product that is considered shelf stable (i.e. does not require refrigeration after proper processing).

(31) “**Low-acid fruit preserves**” means fruit jelly, fruit jam and fruit preserves with a pH of 4.6 or lower.

(32) “**Low-acid pickled produce**” means produce, which has been pickled or packed in a can or jar for pickling, with a pH of 4.6 or lower.

(33) “**Low-risk food**” means a food item intended for human consumption that does not require a time and temperature control or refrigeration to remain safe, and has been shown to not support the growth of pathogenic bacterial or other foodborne pathogens.

(34) “**Lot**” means the food produced during a period of time indicated by a specific code.

(35) “**Manoomin**” means the ripened seeds of manominagaawanzh (northern wild rice or *Zizania palustris*).

(36) “**Microorganism**” means yeasts, molds, bacteria, viruses, protozoa and microscopic parasites and includes species having public health significance.

(37) “**Monitor**” means to conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement.

(38) “**Package or packaging**” means to contain food within a bottle, can, carton or secure wrapping.

(39) “**Packing**” means placing food into a container other than packaging and also includes activities performed incidental to packing or re-packing a food (e.g. sorting, culling, grading and weighing or conveying incidental to packing or re-packing), but does not include any process that would transform the food from its raw, uncooked state.

(40) “**Plant harvesting**” means the removal of raw wild plant matter or fungi from the place where it grows in order to prepare it for use as human food. Examples of plant harvesting include

brushing off dirt from its surface, cooling, field coring, filtering, gathering, drying, parching, hulling, shelling, threshing, trimming off outer leaves and washing. Plant harvesting does not encompass activities that constitute processing.

(41) **“Preventative measure”** means physical, chemical or other factors that can be used to control an identified food safety hazard.

(42) **“Principal display panel”** or **“PDP”** means the part of the food label most likely to be displayed to the customer when the product is offered for sale, also refers to the front label on a product.

(43) **“Process-monitoring instrument”** means an instrument or device used to indicate conditions during processing at a critical control point.

(44) **“Processing”** means the manufacture or preparation of foods for sale through the process of canning, extracting, fermenting, distilling, pickling, freezing, baking, smoking, grinding, cutting, deboning, mixing, coating, stuffing, bottling, packaging or through any other treatment or preservation process. Processing does not include the following:

- (a) Harvesting, transporting or storing wild foods or wild food products, without otherwise engaging in processing;
- (b) Practices such as heading, eviscerating or freezing fish, and field-dressing animals, solely to prepare that fish or animal for transportation from the water or the field; or
- (c) The operation of a retail food establishment.

(45) **“Processor”** means any person engaged in the processing of food for sale or donation pursuant to this Title.

(46) **“Produce”** means any fruit, vegetable or mushroom and includes tree nuts and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (e.g. blueberry or hazelnut). A vegetable

is the edible part of an herbaceous plant (e.g. fiddlehead fern or wild ramp) or the fleshy fruiting body of a mushroom (e.g. morel mushroom). Produce does not include food grains, such as wild rice and amaranth seeds.

(47) **“Qualified small and very small business”** means a plant harvester that is subject to any of the requirements of Chapter 7 [Produce], and on a rolling basis, the average monetary value of the produce they sold during the last 3 years is no more than \$500,000, and the majority of sales are direct sales to consumers of the food; or restaurants, food service institutions or retail food establishments that are located:

- (a) in the same state or Indian reservation as that the produce was harvested; or
- (b) is located no more than 275 miles from the plant harvester’s residence.

(48) **“Raw plant material”** means an agricultural commodity in its raw or natural state, including all fruits, vegetables and mushrooms that are washed, brushed off or otherwise treated in the uncut natural form, and manoomin that is parched, threshed and sorted.

(49) **“Ready-to-eat foods” or “RTE foods”** means foods that require no further processing prior to consumption.

(50) **“Retail food establishment”** means a permanent unit or location within the exterior boundaries of the _____ Reservation within which food is processed on site, or made available, intended for individual consumption, and where goods may be purchased by individuals or entities who are not members of any federally recognized Indian tribe. The term includes any such place whether consumption is on or off premises, including but not limited to the following:

- (a) A restaurant or eating/drinking establishment;
- (b) A market or grocery;
- (c) A catering business;

(d) A bakery or confectionary; or

(e) A convenience store or gas station.

The following entities are excluded from the definition: _____.

(51) **“Sanitize”** means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(52) **“Sanitization”** means effective treatment by a process that provides enough accumulative heat or concentration of chemicals for enough time to reduce the count of microorganisms of public health significance to a safe level on clean surfaces, utensils and equipment.

(53) **“Smoked or smoke-flavored fishery products”** means the finished food prepared by:

(a) Treating fish with salt (sodium chloride); and/or

(b) Subjecting it to the direct action of smoke from burning wood, sawdust or similar material and/or imparting to it the flavor by a means such as immersing it in a solution of wood smoke.

(54) **“Syrup”** means a liquid derived from sugar-rich tree sap, which is not less than 66 degrees Brix.

(55) **“Sugar”** means a solid, grainy or viscous substance derived from sugar-rich tree sap, which was boiled beyond 66 degrees Brix and stirred.

(56) **“Toxic”** means any substance which may have an adverse physiological effect on a person or persons.

(57) **“Traditional food”** means foods and beverages from pre-colonization times that are or have become part of the Anishinaabe diet and food ways.

(58) **“Traditionally safe methods”** means a way of producing and/or preparing food using cultural practices specific to the _____ [Tribe] that have been proven to be safe over past generations.

(59) **“Tribal mushroom harvester”** means a member of the _____ who harvests, picks or collects wild mushrooms for sale or donation as a class 1, 2 or 3 food.

(60) **“Utensil”** means any implement used in the storage, preparation, transportation or service of food.

(61) **“Vehicle”** means any van, truck, trailer, cab, bus, cycle, automobile, push cart, wagon or any other means of conveying food on land.

(62) **“Wildlife Animal”** means an undomesticated mammal or bird found within free-ranging populations within the _____ Tribe’s [reservation/Ceded Territories].

Chapter 3 – General Provisions

3.01 Zhawenindiwig; Respect for Traditional Foods and Consumers

(1) All individuals and entities

harvesting and processing food pursuant to this Title shall handle that food in a respectful manner in order to prevent their adulteration and to remain consistent with our cultural traditions.

(2) Only food which is amenable wild-harvest food may be donated or sold pursuant to this Title. No adulterated food may be donated or sold pursuant to this Title.

3.02 Debwewin; Truth in Labeling

(1) All foods processed in accordance with this title shall be labeled in a truthful manner and not be labeled in a manner that is false or misleading. The information required to be displayed on labels as described in this subsection shall be prominently displayed in readable format, with letters and numbers measuring no less than one-sixteenth of an inch.

RESPECT IS FOUNDATIONAL

The employment of food safety practices builds upon established cultural norms of the Anishinaabeg that protect both the consumers and the sustainability of the harvest. Wild harvested foods are offered to the Anishinaabeg through a complex network of relationships and obligations: among the Anishinaabeg and their plant and animal relatives; among living Anishinaabeg and past and future generations; and among physical and spiritual beings. “Zhawenindiwig” is the Ojibwe word for the act of reciprocal mercy, compassion and love. Within this Model Code, zhawenindiwig is a reference to the reciprocal generosity that both humans and more-than-humans benefit from in order to strive for Anishinaabe inaadiziwin. In recognition of the interconnected-ness of purposeful existence, respect is a key value.

Section 3.01 sets a general standard related to overall food safety. Keeping food safe requires individuals and entities to respect necessary food safety standards, many of which are contained in this code. Tribes may have specific standards related to the manner in which various foods are harvested or processed. For example, many communities regulate the manner in which manoomin is harvested to ensure that harvesters are engaging in respectful conduct that comports with community standards. Additional protocols can be added to the model code as tribes deem necessary.

In drafting this Model Food Code, attempts have been made to center Anishinaabe traditional customary laws and practices. The production of safe, nutritious food has been essential to achieve and maintain a sovereign and sustainable existence. Food safety and contamination reports produced by GLIFWC as part of the “Chippewa Ceded Territory Traditional Food Regulatory System Project” and other reports produced by GLIFWC and its member Tribes demonstrate that these practices produce consistently safe foods.

(a) Wild rice shall not be labeled “natural wild rice” or “hand-harvested wild rice” unless the contents of the package consist entirely of hand-harvested wild rice and contain no mechanically-harvested wild rice or wild rice grown with the use of chemical fertilizers or herbicides.

(b) Maple syrup shall not be labeled “traditionally processed Ojibwe maple syrup” unless the contents of the package consist entirely of maple sap that was condensed into syrup by the heating of the sap over a wood-burning fire, however a final boil of the sap may occur using a heating element other than a wood-burning fire.

(c) Mushrooms shall be contained within packaging materials consistent with Sec.7.03(2), segregated by mushroom species, bearing a label containing the following information:

(i) Common name of mushroom species (e.g. “black trumpet”), followed by scientific name (e.g. *Craterellus cornucopioides*);

(ii) Harvester name and address;

(iii) The following consumer advisory, “WILD MUSHROOMS: CLEAN WELL AND COOK THOROUGHLY BEFORE CONSUMING”; and

(iv) Date of harvest.

(2) Except for produce, all class 2 and 3 foods shall be labeled according to the following standards.

(a) The following information shall be displayed on the principal display panel (“PDP”) of the label:

(i) Statement of identify, which is the common name for the food contained;

and

(ii) Net quantity of contents, which is the amount of food contained in the package, listed in an appropriate measurement.

(b) The following information must be displayed on an information fact panel (“IFP”) if it is not displayed on the PDP.

(i) Nutrition facts, unless the food is exempt from nutrition labeling pursuant to Sec. 3.02(g);

(ii) An ingredient statement if the product contains two or more ingredients.

(I) The ingredient statement shall contain the word “INGREDIENTS:” followed by a listing of ingredients in order of decreasing predominance by weight;

(II) if any of the ingredients constitute major allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans), the major allergen shall be clearly and prominently listed on the label, along with the name of the food source from which the major allergen is derived (e.g. “FISH (lake trout)”).

(III) if any of the ingredients constitute an added artificial flavoring, coloring or chemical preservative, the name and function of the added flavoring, coloring or chemical preservative shall be listed in the ingredient list;

(iii) Signature line displaying the name and address of the product’s manufacturer, packer or distributor.

(iv) A production sales date, or lot or code number identifying the specific product;

(v) If applicable, special handling instructions required to maintain the wholesomeness of the food. The following products must be labeled with special handling instructions:

(I) Frozen fish and meat products shall be labeled with a "KEEP FROZEN" statement (e.g. "Important, keep frozen until used, thaw under refrigeration immediately before use.")

(II) Smoked fish and fresh, unfrozen fish shall be labeled with the statements "PERISHABLE" and/or "KEEP REFRIGERATED AT 38° F (3.33° C) OR LESS."

(III) Frozen fish that are vacuum sealed shall be labeled: "KEEP FROZEN UNTIL USED; THAW UNDER REFRIGERATION OR CUT PACKAGING WHILE THAWING UNDER COOL RUNNING WATER."

(IV) Uncooked meat products, which are not shelf-stable, shall be labeled: "KEEP REFRIGERATED AND COOK TO A MINIMUM INTERNAL TEMPERATURE OF 160°F."

(vi) If date labels are included on any food product labels, these date labels must be consistent with the following standards:

(I) "BEST if Used by" and "BEST if Used or Frozen by" shall be used to indicate the quality date of a product.

(II) "USE by" or "USE or FREEZE by" shall be used to indicate the safety date of a product.

(III) "SELL by" dates, printed on product labels which are visible to consumers shall be prohibited [five years from the date that the Code is adopted into tribal law].

(3) Labeling standards for products produced outside of a tribally-licensed food processing plant.

(a) Any class 1, 2, or 3 foods, except manoomin, maple syrup and maple sugar, and produce, which are prepared, processed or packaged outside of a licensed food processing plant shall include the following disclosure in 12-point font, "PROCESSED AND PACKAGED IN A HOME FACILITY."

(b) If a class 1 food contains any ingredients that constitute major allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soybeans), the major allergen shall be clearly and prominently listed on the label, along with the name of the food source from which the major allergen is derived (e.g. "FISH (lake trout)").

(4) Inspection Legend.

(a) Meat which has been inspected and passed pursuant to Sec. 5.05 [Post-Mortem Inspection] shall bear a tribal inspection legend. The legend shall be clearly visible to the prospective purchaser on all packages and containers of products.

(b) The legend shall consist of (symbol or shape, as determined by each tribe), enclosing the words, " _____ (tribal licensing authority) INSPECTED" and the tribal food processing plant license number assigned to the facility by the _____ (tribal licensing authority).

(5) Prohibited Labeling Practices.

(a) No person or entity may apply, to any meat or poultry product, any mark, legend or label that is false, deceptive or misleading.

(b) No person or entity may misrepresent that the _____ (tribal licensing authority) has inspected meat products, or misrepresent the _____ (tribal licensing authority)'s inspection findings related to meat products.

(c) No person or entity may misrepresent that any meat products have been processed at a tribally licensed food processing plant, or is derived from meat inspected and passed by the _____ (tribal licensing authority).

(d) No person or entity may wrongfully alter or remove any mark or label applied under this section.

(e) No person or entity may sell, transport or store any class 1, 2 or 3 food that is not marked, labeled or identified according to this section.

3.03 Food Additives

(1) Added Flavors. The label of a Class 2 or 3 food product to which spices or other natural flavors are added shall declare such flavors in the list of ingredients, as required, in order by weight, with the largest quantity listed first.

(a) Spices may be declared either by their specific common or usual name, or declared generally as "spices."

(b) Substances obtained by cutting, grinding, drying, pulping or similar processing of vegetables (e.g. powdered or granulated onions, garlic powder and celery powder) are considered foods rather than spices and shall be declared by their common or usual name.

(c) Any salt (sodium chloride) used as an ingredient shall be declared by its common or usual name "salt."

(d) Water added to food shall be listed as an ingredient.

(2) Added colors and preservatives. Only artificial and natural colors, and preservatives, which are considered food-safe may be added to food products, and may only be added in amounts, and for

purposes, which are safe for human consumption. Added colors and preservatives, and the purpose for which it was added, shall be declared on the list of ingredients, as required, in order by weight, with the largest quantity listed first.

(3) Standard for Packaging. If any Class 1, 2 or 3 food is contained within packaging materials, those packaging material shall be clean, composed of substances that are “generally recognized as safe” or “approved food contact substances” and are appropriate to contain the type of food packaged.

3.04 Personnel

(1) Each individual engaged in the harvesting of plants or animals intended as a class 1, 2 or 3 food, or the processing, packaging, packing, transporting or holding of food donated or sold pursuant to this Title (including temporary and seasonal personnel) or in the supervision thereof must:

(a) Possess the education, training and experience (or a combination thereof) necessary to manufacture, process, pack or hold clean and safe food as appropriate to the individual’s assigned duties and as required by this Title; and

(b) Receive training in the principles of food hygiene and food safety, including the importance of health and personal hygiene, as appropriate to the food, the facility or operation, and the individual’s assigned duties.

(2) All tribal mushroom harvesters shall successfully complete training on mushroom identification and harvesting as required by the _____ [tribal licensing authority]. Evidence of the completion of this training shall be maintained by each tribal mushroom harvester, with these records available upon request of the _____ [tribal licensing authority].

(3) Cleanliness. All persons working in contact with food, food-contact surfaces and product packaging materials must adhere to hygienic practices while on duty to prevent adulteration of foods sold or donated pursuant to this Title and the creation of unsanitary conditions.

(4) Clothing. Aprons, frocks and other outer clothing worn by persons who handle food sold or donated pursuant to this Title must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent the adulteration of product and the creation of unsanitary conditions.

(5) Disease control. Any person who has or appears to have an infectious disease, open lesion, including boils, sores or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in the adulteration of food and the creation of unsanitary conditions until the condition is corrected.

(6) Records pertaining to a facility's personnel shall be retained pursuant to Sec. 3.10 [Recordkeeping].

3.05 Food Transportation and Storage

(1) No one shall transport or store food under conditions which fail to protect the food against biological, chemical (including radiological) and physical contamination, as well as against deterioration of the food and any food container used.

(2) Containers, such as plastic coolers, used for the transportation and storage of food shall be made of food-grade materials that are either cleanable or designed for single use, are clean and sanitary prior to the addition of foods, and suitable for the type of foods being contained.

(3) If a vehicle, food trailer or container is used for the processing or receiving of a certain type of food (e.g. fresh-caught fish), no one shall use that conveyance for the holding, processing or transportation of a different type of food (e.g. ready to eat food) until and unless that conveyance has been sufficiently cleaned and sanitized. In addition, vehicles, food trailers and containers used for the conveyance of garbage, manure or other debris, may not be used for the storage or transportation of food without first being carefully cleaned and sanitized.

(4) Vehicles, food trailers and containers shall be inspected for cleanliness, odors, obvious dirt and debris before beginning the loading process. All food must be loaded for transport in a manner designed to minimize physical damage to the food and reduces the potential for contamination.

(5) Food storage areas shall be cleaned regularly to remove all visible debris, dirt and soil. No one shall store or transport food without taking precautions to prevent the cross-contamination of ready-to-eat foods and raw agricultural commodities by raw food products and the contamination of food from free-floating dust and other airborne contaminants.

(6) Temperature Control During Transport. If transported foods require time and temperature controls for safety, the following applies:

(a) Adequate monitoring of temperature during transport and storage shall be conducted and reports documenting the monitoring shall be created and maintained according to record maintenance schedules set forth in Sec. 3.10 [Recordkeeping].

(b) The temperature of potentially hazardous foods (non-shelf stable meat, fish, cooked manoomin and other foods which require time and temperature controls for safety) shall be kept at 45°F, or below, or at 140°F, or above, at all times, except as otherwise provided in this Title.

(c) Food needing refrigeration must be loaded in a manner that allows proper refrigerated air circulation.

3.06 Equipment and Utensils

(1) All equipment and utensils used in processing, packing or holding food sold or donated pursuant to this Title must be so designed, and of such material and workmanship, as to be adequately cleaned and sterilized through the application of sanitation SSOPs, HACCP plans or Harvest Safety Plans, as applicable.

(2) Receptacles used for storing equipment and tools must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of unsanitary conditions. Receptacles for storing inedible material may never be used for storing any edible product and must bear conspicuous and distinctive markings identifying permitted uses.

(3) Process-monitoring instruments or controls used to measure, regulate or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be:

- (a) accurate and precise as necessary in keeping with their purpose;
- (b) adequately maintained; and
- (c) adequate in their number for their designated uses.

3.07 Handling of Inedible Food Byproducts

(1) All inedible food bi-products shall be immediately separated from wholesome food products and placed into waste bins clearly marked as “CONDEMNED, NOT FOR USE AS FOOD,” which are covered and disposed of at or before the close of the day upon which they were condemned. These waste bins shall not be used for any other purpose. Inedible fish and plant waste may be disposed of in an off-site composting facility, as appropriate.

(2) Waste generated by any licensed facility or vendor must be regularly removed from the facility and grounds by a waste handler licensed to handle those waste products, or transported to a waste handling facility in a sanitary manner, with care taken to avoid the contamination of any food, or object or container that will come into contact with food.

3.08 Sanitation Control Procedures; Good Manufacturing Practices

(1) Sanitation SOP. Each establishment licensed as a food processing plant (Sec. 3.11), retail food establishment (Sec. 3.12), and each facility of a class 1 meat vendor (Sec. 5.09) or class 1 fish vendor (Sec. 6.05), shall have and implement a written sanitation standard operating procedure (herein

referred to as SSOP) or similar document that is specific to each location (including mobile processing station) where treaty harvested food products are produced, stored and/or sold. The SSOP should specify how the establishment will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section. The SSOP shall be signed and dated by the individual with overall authority in the establishment. This signature shall signify that the establishment will implement the SSOPs in accordance with the requirements set forth in subsection (2). The SSOP shall be signed and dated upon initially implementing the SSOP and upon any modification to the SSOP.

(2) Sanitation monitoring. The individual with overall authority in the establishment shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices that are both appropriate to the plant and the food being processed and relate to the following:

(a) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;

(b) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(c) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;

(d) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(e) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(f) Proper labeling, storage, and use of toxic compounds;

(g) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(h) Exclusion of pests from the food processing and storage premises.

The establishment shall correct in a timely manner, those conditions and practices that are not consistent with the SSOP. SSOPs shall be routinely evaluated for effectiveness and shall be revised both as necessary and current with respect to changes in the facilities, equipment, utensils, operations or personnel.

(3) Sanitation control records. Each establishment licensed as a food processing plant (Sec. 3.11) or retail food establishment (Sec. 3.12), and each class 1 meat vendor (Sec. 5.09) or class 1 fish vendor (Sec. 6.05) shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements set forth in Sec. 3.10 [Recordkeeping].

(4) Relationship to Hazard Analysis Critical Control Point (HACCP) plan. If sanitation controls are monitored in accordance with this part, they need not be included in the food plant's HACCP plan.

3.09 Variance

Operators, owners and agents in charge of a food processing plant, retail food establishment and class 1 meat vendors, class 1 fish vendors, low risk food vendors and non-exempt produce harvester may request from the _____ [tribal licensing authority], a variance from requirements set forth in this Title. All variance requests must be written documents specifying: (1) the provisions that require a variance; (2) the reason for the request; and (3) alternative procedures that will be employed in lieu of the standards in this Title. In making decisions on variance requests, the _____ [tribal licensing authority] shall consider: (1) the type of foods that are handled within the food processing plant, retail food establishment or by that vendor; (2) the food safety risks associated with those foods; and (3) whether the alternative procedures proposed are

sufficiently protective of health and safety. Procedures that are consistent with ways of producing and preparing foods using cultural practices specific to the _____ [Tribe] that have proven to be safe over past generations shall be eligible for the issuance of variances. If a variance is approved by the _____ [tribal licensing authority], the decision shall be issued in writing, and dated. The requestor shall maintain a copy of the decision consistent with the schedules contained within Sec. 3.10 [Recordkeeping].

3.10 Recordkeeping

(1) Sanitation Control Records. Each food processor, which is not exempt from Sec. 3.08 [Sanitation Control Procedures], shall create and maintain sanitation control records that, at a minimum, document the sanitation monitoring and corrections prescribed by Sec. 3.08 [Sanitation Control Procedures], as applicable. Standard Sanitation Operating Procedure (SSOP) records must be maintained for at least six months after their creation.

(2) HACCP, fish and meat processing record retention.

(a) All records required by Chapters 4, 5 and 6, including records generated by harvesters, shall be retained at the processing facility for at least 1 year after the date they were prepared in the case of refrigerated products, and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

(b) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility for at least 2 years after their applicability to the product being produced at the facility.

(c) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the

seasonal pack but shall be returned to the facility for official review, within 24 hours, upon demand.

(3) Low-Risk Food Processing Record Retention.

Records related to the processing of low-risk foods shall be maintained by the manufacturer for two years from the time of their creation.

(4) Education and training record retention.

(a) All facilities and vendors licensed pursuant to this Title shall retain records documenting each worker's relevant training and education, including the completion of any required training conducted by the operation. Workers include every individual engaged in the operations: paid and unpaid, permanent and temporary personnel. These records shall be retained for a minimum of three years from the time of their creation.

(b) Any facility licensed pursuant to this Title which receives carcasses, plant material or fungi from a harvester shall not receive that food until and unless the harvester produces records documenting compliance with the education and training requirements required for the foods and processes undertaken (e.g. field dressing). These records shall be maintained for a minimum of three years from the time of their receipt, and updated as necessary.

(4) Records maintained on computers or electronic databases. The maintenance of records on computers or electronic databases is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(5) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying by the _____ [tribal licensing authority] at reasonable times.

3.11 Food Processing Plants

(1) General requirement. Each licensed food processing plant shall be maintained in a manner sufficient to prevent the creation of unsanitary conditions, to ensure that products produced are not adulterated, and consistent with the following standards.

(2) Licensing and Registration. A valid food processing plant license is required to engage in any activities which must be performed within a food processing plant; however, food processing plants in operation at the time of enactment of this title shall have 90 days to obtain the required food processing plant license. Any operator, owner or agent in charge of a food processing plant engaged in the processing, packing or holding of foods pursuant to this Title annually shall submit an application for registration and licensing to the _____ [tribal licensing authority], certifying that the facility complies with all applicable laws, including the general requirements (Chapters 1-4) and specific requirements related to foods that will be processed in the plant (Chapters 5-8, as applicable), agreeing to open the facility and its records to inspections by the _____ [tribal licensing authority], and providing other required information. A license is not transferrable between persons or locations. A food processing plant license may be suspended or revoked by the _____ [tribal licensing authority] for violations of this Title.

(3) Inspection and Certification. A license to operate a food processing plant will be issued upon satisfactory completion of inspection and certification. An annual inspection will include a walk-through of the facilities and review of the records to determine compliance with applicable laws and conditions in the plant. A facility may be certified to process, pack and hold meat, fish, produce and low-risk foods, or any combination thereof. The _____ [tribal licensing authority] may inspect licensed food plants, and records thereof, upon a reasonable belief that the food produced, packed or distributed at the facility is adulterated and presents a serious threat of adverse health consequences or death to humans or animals.

(4) Water and Plumbing.

(a) Each licensed food processing plant shall be supplied with a source of water that complies with the National Primary Drinking Water regulations (40 CFR 141), at a suitable temperature and pressure as needed for all areas where required (e.g. for processing product, for cleaning rooms and equipment, utensils and packaging material, for employee sanitary facilities, etc.). If a food processing plant uses a municipal or tribal water supply, it must make available to tribal or federal inspectors upon request, a water report, issued under the authority of the tribal or municipal agency, certifying or attesting to the potability of the water supply. If a food processing plant uses a private well for its water supply, it must make available to tribal or federal inspectors, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.

(b) Plumbing systems used by food processing plants shall conform to the following standards:

(i) Carry sufficient quantities of hot and cold water for cleaning, waste disposal, processing, drinking and personnel sanitation needs.

(ii) Properly convey sewage and liquid disposable waste from the establishment.

(iii) Prevent adulteration of product, water supplies, equipment and utensils and prevent the creation of unsanitary conditions throughout the facility.

(iv) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(v) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing.

(vi) Prevent the backup of sewer gases.

(c) Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through means sufficient to prevent backup of sewage into areas where product is processed, handled or stored.

(5) Licensed food processing plants must conform to the following design and maintenance standards:

(a) Facility buildings are suitable in size, construction and design, and are kept in good repair for safe, sanitary and orderly operations, and for easy cleaning.

(b) Walls, floors and ceilings are built of durable materials, reasonably impervious to moisture and are cleaned and sanitized as necessary to prevent adulteration of product or creation of unsanitary conditions.

(c) Walls, floors, ceilings, doors, windows and other outside openings shall be constructed and maintained to prevent the entrance of vermin, such as flies, rats and mice.

(d) Dressing rooms, toilet rooms and urinals must be sufficient in number and size, conveniently located and maintained in a sanitary condition, and in good repair, to ensure the cleanliness of all persons handling food. Any such room shall be separate from the rooms and compartments used to process, store or handle food.

(e) Dedicated handwashing stations, including running water, soap and towels, shall be placed in or near the toilet and urinal rooms and at other such places within the facility to ensure the cleanliness of all persons handling any product.

(f) Storage of Waste Materials. Refuse receptacles shall be constructed and maintained in a manner that protects against the creation of unsanitary conditions, the emanation of foul smells or the adulteration of food products.

(g) Storage of Toxic Materials. Cleaning compounds, sanitizing agents, processing aids and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled and stored in a manner that will not adulterate product or create unsanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available during facility inspections.

(h) Controlled Access. The facility must be fully enclosed to prevent access by dogs, cats, wild animals, rodents, birds and insects. Each door, window or other access point, must be secured with a functioning lock or other security device to prevent unauthorized access. While operations are running, access shall be controlled to necessary personnel.

(6) Sanitary Operations/Good Manufacturing Practices

(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of unsanitary conditions and the adulteration of product.

(b) Buildings, fixtures and other physical facilities must be cleaned and sanitized as frequently as possible to prevent food from becoming adulterated.

(c) The cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against contamination of food products, food-contact surfaces, and food packing materials.

(e) Care must be taken to prevent the cross-contact of allergenic foods, with processes in place to prevent cross-contamination of potential allergens in receiving, storage, handling and production, specific cleaning and sanitizing procedures, and the training of personnel.

(7) Pest Control. The grounds about an establishment shall be maintained to prevent conditions that could lead to unsanitary conditions, adulteration of product or interference with a tribal or federal inspection programs. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of unsanitary conditions.

(8) Waste Disposal. Facility waste must be managed in a manner that prevents the creation of unsanitary conditions and in compliance with applicable law. Waste storage areas shall be kept neat and orderly, and any refuse containers located outside the facility shall be fitted with covers to keep them securely closed when unattended. Waste generated by the plant must be regularly removed from the facility and grounds by a waste handler licensed to handle those waste products, or transported to a waste handling facility in a sanitary manner, with care taken to avoid the contamination of any food, or object or container that will come into contact with food.

(9) Annual inspections.

(a) Inspections of food processing plants by the _____ [tribal licensing authority] shall be scheduled twice a year.

(b) At any time during the term of the license, either upon receipt of a complaint or upon its own volition, the _____ [tribal licensing authority] may conduct an unscheduled inspection of a food processing plant. Any reinspection conducted as a

result of a prior violation of applicable law will result in an additional fee to the establishment and satisfactory action must be taken to cure the violation.

3.12 Retail Food Establishments

(1) A retail food vendor license is required for the retail sale of class 3 foods to individuals who are not members of a federally recognized Indian tribe, except that manoomin, maple syrup and maple sugar may be sold to any individual by a vendor who has not obtained a retail food vendor license.

(2) No person or persons, corporation or firm shall operate a retail food establishment within the exterior boundaries of the _____ Reservation either permanent or temporary without a valid, unsuspended, unrevoked retail food vendor license issued by the _____ [tribal licensing authority]. Only a person or persons, corporation or firm that complies with the requirements of this Section, and the applicable food code pertaining to retail food establishments, shall be entitled to receive and retain a retail food vendor license. The valid license shall be prominently displayed in every retail food establishment.

(3) All retail food establishments must meet the general requirements of the [current FDA Food Code].

(4) The _____ [tribal licensing authority] shall issue a retail food vendor license following receipt of any required fees, inspection of the premises and assurances from the tribal inspector that the applicant has met the conditions required for a satisfactory score pursuant to the Federal Food Code Guidelines with the Hazard Analysis Critical Control Point, Techniques of Quality Control.

(5) Retail food vendor licenses shall be issued by the _____ [tribal licensing authority] for a 12-month period beginning at the Tribe's fiscal year [month, day] and ending [month, day] of every year. Applicants who initiate their business after [month, day (beginning of tribe's fiscal year)] of any given year shall have their fees prorated for that year. Retail establishments selling class 3

foods in operation at the time that this Title is enacted, shall have 6 months to obtain a valid retail food establishment license.

(6) Inspections.

(a) Inspections of food service premises by the _____ [tribal licensing authority] shall occur twice a year.

(b) At any time during the term of the license, either upon receipt of a complaint or upon its own volition, the _____ [tribal licensing authority] may conduct an unscheduled inspection of a vendor's food preparation site. Any reinspection conducted as a result of a prior violation of applicable law will result in an additional fee to the establishment and satisfactory action must be taken to cure the violation.

3.13 Enforcement

(1) Strict compliance with the specific laws found in this Title and any other applicable standards are required to protect the public health, safety and welfare.

(2) License Required. Operating a business which engages in the processing, distribution or sale of amenable wild-harvest food, which requires a specific license as listed below, without a valid, unrevoked and unsuspended license issued by the _____ [tribal licensing authority] within the [boundaries of the _____ Reservation and/or _____ ceded territories] is strictly prohibited and will result in a fine and/or suspension of the right to operate, sell or receive amenable wild-harvested food:

- (a) Food processing plant (Sec. 3.11);
- (b) Retail food establishment (Sec. 3.12);
- (c) Class 1 meat vendor (Sec. 5.09);
- (d) Class 1 fish vendor (Sec. 6.05);
- (e) Non-exempt produce harvester (Sec. 7.03); and

(f) Low risk food vendor (Sec. 8.01).

(3) The owner, operator or agent in charge of a facility listed in subs. (2)(a)-(f), above, shall submit a registration application to the _____ [tribal licensing authority] on the prescribed form. The _____ [tribal licensing authority] shall compile and maintain an up-to-date list of facilities and vendors that are registered under this Title.

(4) Each registration form shall contain the information necessary to notify the _____ [tribal licensing authority] of the name and address of each facility at which, and all trade names under which, the registrant conducts business, the email address and phone numbers for the contact person of the facility, and the general food category of the foods processed, packed or held at such facility. The registration form shall contain an assurance that the _____ [tribal licensing authority] will be permitted to inspect such facilities at the times and in the same manner as permitted by Section 704 of the Food, Drug and Cosmetic Act. The registrant shall notify the _____ [tribal licensing authority] in a timely manner of changes to such information.

(5) All facilities required to be registered pursuant to this Section shall have six (6) months from the date of adoption of this Title to become compliant. During the period beginning on October 1 and ending on December 31 of each even-numbered year, a registrant that has submitted a registration form under subsection (4), above, shall submit to the _____ [tribal licensing authority] a renewal registration containing the information described in subsection (3), above.

(6) A food production or distribution license will be suspended by the _____ [tribal licensing authority] and the operation closed down if the licensee is non-compliant with any applicable requirement of this Title, any other applicable law or regulation, or for any other reason related to the protection of the community's public health, safety or welfare.

(7) Failure to pass an inspection conducted by the _____ [tribal licensing authority] will be cause for a penalty, revocation or suspension of the license.

(8) The _____ [tribal licensing authority] may close down an operation immediately on an emergency basis upon evidence of an imminent or serious health or safety threat to the community.

(9) Holding order.

(a) The _____ [tribal licensing authority] may issue a holding order preventing the sale or movement of any food if reasonable grounds exist to suspect that the food is adulterated or misbranded, or otherwise fails to meet the standards set forth in this Title. The _____ [tribal licensing authority] may issue a holding order pending further examination or analysis to determine whether the food is adulterated or misbranded, or otherwise fails to meet the standards set forth in this Title.

(b) The _____ [tribal licensing authority] shall serve a holding order by delivering it to the owner or custodian of the food, or by placing a copy in a conspicuous place on or near the food products.

(c) A holding order remains in effect for 14 days unless it is withdrawn. A holding order may be extended by 14 days by re-issuing and serving the re-issued holding order in subsection (b), above.

(d) No person may sell, move or alter any food under holding order, except with the written permission of the _____ [tribal licensing authority]. The _____ [tribal licensing authority] may authorize the owner or custodian to take corrective action.

(e) The _____ [tribal licensing authority] may release a holding order if the _____ [tribal licensing authority] finds that the suspect product is not adulterated or misbranded, or that the violation has been corrected.

(10) Condemnation Order.

(a) If the _____ [tribal licensing authority] finds that food is adulterated, misbranded, or a class 2 or 3 meat product is not derived from a carcass that passed inspection pursuant to Sec. 5.05 [Post-Mortem Inspection], the _____ [tribal licensing authority] may order the owner or custodian to do any of the following:

(i) Correct the violation within a reasonable time period in a manner specified by the _____ [tribal licensing authority] in writing.

(ii) Dispose of the product, in a manner specified by the _____ [tribal licensing authority] in writing. The product may be ordered disposed if a violation cannot be corrected, or if the owner or custodian fails to correct the violation in the time period specified in subsection (i), above.

(b) The _____ [tribal licensing authority] shall serve an order under subsection (a), above, by delivering a copy of the order to the owner or custodian of the food, or by placing a copy in a conspicuous place on or near the food product. An order takes place when served.

(c) No person may sell, move or alter any food covered by a condemnation order, except as directed by the _____ [tribal licensing authority].

(11) The _____ [tribal licensing authority] may order a person to correct a violation of this Title, and may specify a deadline for correcting the violation.

(12) The _____ [tribal licensing authority] may issue an order prohibiting the use of unsanitary facilities, equipment or utensils that may contaminate class 1, 2 or 3 food. The _____ [tribal licensing authority] may issue an order under this subsection by applying a “REJECTED” tag to the facilities, equipment or utensils. A person may not use those facilities, equipment or utensils until the violation is corrected and the order is withdrawn.

(13) Any food processing plant, retail food establishment, or facility of a class 1 meat vendor, class 1 fish vendor, low risk food vendor or non-exempt produce harvester that has been closed down by the _____ [tribal licensing authority] due to evidence of a serious health or safety threat must provide evidence of satisfactorily corrected compliance to the _____ [tribal licensing authority] prior to being reopened for business.

(a) Any food production or distribution establishment that has been closed due to a violation of the applicable law must be re-inspected by the _____ [tribal licensing authority] at the vendor’s cost with a resulting satisfactory inspection pursuant to the applicable standards contained in this Title and any other standards that apply to the operations.

(b) Any food production or distribution establishment that has been ordered closed, may only receive a probationary license for six months upon evidence of satisfactory compliance with applicable sections of this Title and any other standards that apply to the operations.

(c) After six months of compliance with applicable sections of this Title and any other standards that apply to the operations, as determined by the _____ [tribal licensing authority], the licensee may apply to receive an annual license.

(d) Any food production or distribution establishment operator who violates any provision of this Title, upon conviction, shall forfeit not less than \$5.00 nor more than \$500.00, together with the costs of prosecution. In default of payment of such forfeitures and costs, the

food production or distribution establishment shall be closed down or remain closed until such forfeitures and costs are paid and all other areas of non-compliance with this Title or other applicable standards have been cured.

(10) Appeals.

(a) Parties who disagree with the decisions of the _____ [tribal licensing authority] regarding issues of licensing or inspections may appeal to the _____ [tribal court/tribal health department].

(b) Hearings will be conducted according to [the Rules of Civil Procedure] as established by _____.

3.14 Prohibited Practices

(1) Process or sell, as a class 1, 2 or 3 food, any adulterated or food labeled inconsistent with Sec. 3.02 [Debwewin; Truth in Labeling].

(2) Process, store, handle, transport or sell any class 1, 2, or 3 food under conditions that may render the food adulterated.

(3) Make any false, deceptive or misleading statement, when submitting a Harvester Certificate of Guarantee related to any of the following:

(a) The time, date or location of harvest;

(b) The condition of a wildlife animal prior to being killed; or

(c) The manner in which a wildlife animal carcass, fish, plant or fungus was transported, processed or stored.

(4) Obstruct an official of the _____ [tribal licensing authority] performing their duties. Obstruction includes any of the following:

(a) Physical interference.

(b) Verbal or physical assault or abuse.

(c) Threatening behavior or communications.

(d) Refusal to carry out legitimate directives.

(e) Intentional acts that impede the full, effective and efficient performance of the official's duties.

(f) Concealing records, ingredients, food, labels, packaging materials or other items that may be inspected pursuant to Sec. 3.13 [Enforcement].

(5) Wrongfully alter, deface or remove a tribal tag, legend or mark applied under this Title.

Chapter Four – Hazard Analysis Critical Control Point

4.01 Hazard Analysis Critical Control Point (HACCP) Plan

(1) Every food processing plant, class 1 meat vendor and class 1 fish vendor shall conduct, or have conducted for it or them, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of raw and finished food product processed by that facility and to identify the preventative measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during and after entry into the food processing environment. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness, data, scientific reports or other information provide a basis to conclude that there is a reasonable possibility that the hazard will occur in the particular type of product being processed, in absence of those controls.

(2) The HACCP Plan. Every food processing plant, class 1 meat vendor and class 1 fish vendor shall have, and implement, a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in Sec. 4.01(1). At a minimum, HACCP plans shall be specific to:

- (a) Each location where raw and/or finished fish or meat products are processed by the processor.
- (b) Each kind of raw and finished fish or meat product processed by the processor.
- (c) The following processing categories of foods:
 - (i) Raw product – ground.
 - (ii) Not heat treated – shelf stable.
 - (iii) Heat treated – shelf stable.
 - (iv) Fully cooked – not shelf stable.

(vi) Heat treated but not fully cooked – not shelf stable.

(vii) Product with secondary inhibitors – not shelf stable.

(d) The plan may group kinds of raw and finished food products together, or group kinds of production methods together, if food safety hazards, critical control points, critical limits and procedures required to be identified and performed in Sec. 4.01(3)(d) are identical for all raw and finished food products so grouped, or for all production methods so grouped.

(3) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(a) List the food safety hazards that are reasonably likely to occur, as identified in accordance with of this subsection, and that thus must be controlled for each raw and finished food product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Decomposition in any species where a food safety hazard has been associated with decomposition;

(vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing raw or finished food products which will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels or intends for the product to be so consumed;

(viii) Unapproved use of direct or indirect food or color additives;

(ix) Zoonotic diseases; and

(x) Physical hazards.

(b) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced into the food processing environment; and

(ii) Critical control points designed to control food safety hazards introduced outside of the processing plant environment, including food safety hazards that occur before, during and after entry into the processing plant environment;

(c) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards are met.

(d) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.

(e) Include any corrective action plans that have been developed in accordance with Sec. 4.03(1) [Verification – Overall Verification], to be followed in response to deviations from the critical limits at critical control points.

(f) List the verification procedures, and frequency thereof, that the processors will use in accordance with Sec. 4.03 [Verification].

(g) Provide a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring and shall be made as soon as practically possible after monitoring.

(4) Signing and dating the HACCP plan.

(a) The HACCP plan shall be signed and dated, either by the most responsible individual on-site at the processing facility, or by a higher-level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation.

(b) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification;

(iii) Upon verification of the plan in accordance with Sec. 4.03 [Verification].

(5) Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with Sec. 3.08(2) [Standard Sanitation Operating Procedures - Monitoring], they need not be included in the HACCP plan.

(6) Legal basis. Failure of a food processing plant, class 1 meat vendor or class 1 fish vendor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, may render the food products of that operator adulterated. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processor's overall implementation of its HACCP plan, if one is required.

4.02 Corrective Actions

(1) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

(a) Following a corrective action plan that is appropriate for the particular deviation; or

(b) Following the procedures in Sec. 4.02(3).

(2) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with Sec. 4.01(3)(e) [HACCP Plan – Contents], by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective

action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

- (a) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;
- (b) The cause of the deviation is corrected;
- (c) Measures to prevent recurrence are established; and
- (d) No product that it injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(3) When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

- (a) Segregate and hold the affected product, at least until the requirements of paragraphs (3)(b) and (3)(c) of this subsection are met;
- (b) Perform or obtain a review to determine the acceptability of the affected product for distribution.
- (c) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation.
- (d) Take corrective action, when necessary, to correct the cause of the deviation;
- (e) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Sec. 4.05 [Training on HACCP], to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(4) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Sec. 4.03(1)(c)(ii) [Verification; ongoing verification activities; calibration] and the recordkeeping requirements of Sec. 4.04 [Records].

4.03 Verification.

(1) Overall verification. Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

(a) Reassessment of the HACCP plan. A reassessment of the adequacy of the HACCP plan shall occur annually or whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way. Such changes may include changes in the following: raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 4.05 [Training on HACCP]. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of Sec. 4.01(2).

(b) Ongoing verification activities. Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(ii) The calibration of process-monitoring instruments; and,

(iii) At the option of the processor, the performing of periodic end-product or in-process testing.

(c) Records review. A review, memorialized in a record, including signing and dating, by an individual who has been trained in accordance with Sec. 4.05 [Training on HACCP], of the records that document:

(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;

(ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Sec. 4.02 [Corrective Actions]. This review shall occur within 1 week of the day that the records are made; and

(iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(2) Corrective actions. Processors shall immediately follow the procedures in Sec. 4.02 [Corrective Actions] whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(3) Reassessment of the hazard analysis. Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that

could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 4.05 [Training on HACCP].

(4) Recordkeeping. The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with Sec. 4.03(b) shall be documented in records that are subject to the recordkeeping requirements of Sec. 4.04 [Records].

4.04 Records

(1) General requirements. All records required by this part shall include:

- (a) The name and location of the processor or importer;
- (b) The date and time of the activity that the record reflects;
- (c) The signature or initials of the person performing the operation; and
- (d) Where appropriate, the identity of the product and the production code, if any.

Processing and other information shall be entered on records at the time that they are observed.

(2) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(a) The written hazard analysis prescribed in Sec. 4.01(1), including all supporting documentation.

(b) The written HACCP plan, including decision-making documents associated with the selection and development of critical control points and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(c) Records documenting the monitoring of critical control points and their critical limits, including the recording of actual times, temperatures or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product codes and carcass tag numbers. Each of these records shall include the date the record was made.

(3) Prior to shipping product, or transferring it for direct sale, the establishment shall review the records associated with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of the product. Where practicable, this review shall be conducted, with the review memorialized in a record, dated and signed by an individual who did not produce the record(s), preferably someone trained in accordance with Sec. 4.05 [Training on HACCP], or the responsible establishment official.

(4) All records created pursuant to this Part shall be maintained pursuant to Sec. 3.10 [Recordkeeping].

4.05 Training on HACCP

(1) At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to treaty harvested food product processing at least equivalent to that received under standardized curriculum recognized as adequate by the _____ [tribal licensing authority] or who is otherwise qualified through job experience to perform these functions; the individual need not be an employee of the establishment. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of Sec. 4.01(b);

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Sec. 4.02(3)(e), the HACCP plan in accordance with the verification activities specified in Sec. 4.03(1)(a) and the hazard analysis in accordance with the verification activities specified in Sec. 4.03(3); and

(c) Performing the record review required by Sec. 4.04(3).

Chapter 5 - Meat

5.01 Harvesting Wildlife Animals for Processing as a Class 1, 2, and 3 Foods

(1) Only those wildlife animals who are healthy and alive at the time they are harvested, and whose carcasses do not exhibit any signs of injury or disease which pose a risk to human health, shall be suitable for processing for pursuant to this Title. Compliance with Chapter 4 [Hazard Analysis Critical Control Point] is not required for the harvesting and handling wildlife animals outside of tribally-licensed food processing plants; however, wildlife animal carcasses which are not accompanied by a complete Harvester Certificate of Guarantee, signed by the harvester and certifying compliance with all applicable subsections of Sec. 5.01 to 5.04, may not be sold or donated pursuant to this Title.

(2) No member shall hunt wildlife animals for sale as a class 1, 2 or 3 food unless the outdoor air temperature in the tribal deer management unit within which the animal is killed, is 41° Fahrenheit, or cooler, when the animal is slaughtered and field-dressed.

(4) If a wildlife animal is harvested or killed by the use of a firearm, only nontoxic ammunition may be used. Only small game animals may be harvested or killed with projectile shot (pellets).

(5) Harvesters shall comply with all applicable tribal conservation code provisions, including those on tagging and registration. The Harvester Certificate of Guarantee for each wildlife animal sold or donated pursuant to this Title shall reference the sequence of numbers, symbols and/or letters listed on the commercial harvest tag, carcass tag or other registration document, as applicable. The harvester shall also document the following on the Harvester Certificate of Guarantee:

(a) The date, time of location of the kill;

(b) The ambient air temperature at the time of killing, or the range of temperatures in the 24-hour period between trap checks, as applicable, and the ambient air temperature while field dressing;

(c) The manner of killing (i.e. “killed by gunshot wound to the upper right shoulder.”);

and

(d) Type of ammunition, or type of killing trap, used.

(6) Humane Handling.

(a) No one shall kill an animal for sale or donation as a class 1, 2 or 3 food in a manner that is cruel or abusive. Killing an animal in a swift and efficient manner through hunting and trapping methods authorized by applicable tribal law shall not be considered cruel or abusive.

(b) No one shall shackle, hoist, throw or cast a game animal intended for sale or donation as a class 1, 2 or 3 food, until the animal is stunned or killed in a manner that causes permanent unconsciousness or death.

(7) Pre-Mortem Inspection.

(a) A pre-mortem inspection is required for Class 2 and 3 food products containing meat from wildlife animals.

(b) When pre-mortem inspection is required, the animal shall be inspected for signs of disease and injury prior to its killing, with observations recorded on the Harvester Certificate of Guarantee. The harvester or designee shall observe the animal intended to be killed, recording the following:

(i) The condition and behavior of the animal at rest and/or in motion;

(ii) The overall condition of the animal, especially the head, eyes, legs and body;

(iii) The degree of alertness, mobility and breathing;

(iv) Any unusual swellings or other abnormalities; and

(v) Location of the harvest by tribal deer management unit (DMU) or equivalent

area.

(8) Dead and Diseased Animals. The carcasses of animals which exhibit signs of disease or serious injury, during the pre-mortem inspection, or are dead when discovered by the harvester may not be sold or donated pursuant to this Title. Signs of disease include the following:

(a) Non-ambulatory state, including: broken appendages, severed tendons or ligaments, nerve paralysis, fractured spine or metabolic conditions;

(b) Comatose or semi-comatose;

(c) Clinical signs of central nervous system issue, including unusual excitement or depression, deviation or rotation of the head, droopy lips, eyelids, cheeks or ears, convulsions or tremors, paralysis, sudden onset of fainting, head pressing, aimless walking, loss of balance or uncoordinated gait when walking and blindness;

(d) Clinical signs of injury or infection, including open wounds, the presence of blood or pus on the fur or skin of the animal and bite marks; and

(e) Deer and elk harvested from a Tribal Disease Management Areas for chronic wasting disease and bovine tuberculosis as listed in the tribal administrative document *Tribal Disease Management Areas*, shall be presumed to be diseased, unless the carcass is certified as disease-free following the implementation of procedures specified in Sec. 5.05(3) [Post-Mortem Inspection; deer carcasses presumed to be diseased] and shall be tagged with a TMDA tag supplied by the [tribal natural resource department], or designee.

(9) Harvesters shall comply with any requirement of the _____ [tribal natural resources department] and/or [tribal licensing authority] to collect and submit samples of tissue from the carcass for disease testing.

5.02 Small Game Animal Harvesting

(1) No member shall hunt or trap any small game animals for sale or donation as class 1, 2 or 3 food unless a harvest season is listed for the animal in the _____ [Tribe]’s [applicable conservation codes]; however, food derived from the following species shall not be considered amenable wild-harvest food: bobcat, coyote, grey fox and red fox. Food containing the meat of migratory birds may not be sold.

(2) No member shall trap any game intended for sale as a class 1, 2 or 3 food using kill traps unless the outdoor air temperature of the tribal deer management unit within which the traps are set, is 32° Fahrenheit or less, for the period of time between the trap was last checked and the animal is retrieved from the trap, which may not exceed 24 hours.

(3) Small game which is harvested through the use of a killing trap may be sold or donated as a Class 1 food only.

5.03 Field-Dressing

(1) Field-dressing shall be performed promptly after the animal has been killed, and by an individual(s) certified by the _____ [Tribal licensing authority] to field-dress animals following satisfactory completion of training on field-dressing. The individual’s tribal field-dressing certification number must be documented on the Harvester Certificate of Guarantee. If an individual other than the harvester field-dresses a carcass, that individual shall also sign the Harvester Certificate of Guarantee, certifying compliance with this section.

(2) Personnel engaged in field-dressing shall wear clean, washable outer clothing and food handling gloves, with long hair covered or tied back. All personnel shall wash and rinse their hands sufficiently (a field sink or jug of water is sufficient), and refrain from smoking, during the operations to prevent contamination of the carcass.

(3) Equipment and utensils used for field-dressing shall be of sanitary design and construction, and shall be kept clean and sanitary free from contamination by soil, insects, vermin and waste products. Equipment and utensils used for field-dressing shall be cleaned and sanitized after each use, and more frequently as necessary, to keep them clean and sanitary.

(4) Prior to making any incisions into the carcass, loose dirt and debris shall be cleaned from the carcass; and if placed on a surface during evisceration (the removal of internal organs), that surface shall be a non-permeable, clean and sanitized surface (e.g. cleaned and sanitized tarp or game table).

(5) While field-dressing, care shall be taken to avoid contaminating the meat with fluids contained within the intestinal tract and bladder. An examination of the abdominal cavity and the heart, lungs, liver, stomach and intestines, through sight and smell, shall be made. If any organs or parts from the carcass exhibit physical deformation or signs of disease (e.g. cysts, unusual growth, abnormal colors, etc.), those organs and parts shall be collected, and stored at or below 38° Fahrenheit for examination by a licensed veterinarian prior to processing the carcass for sale or donation pursuant to this Title and shall be presented to the tribally-certified meat inspector during the post-mortem inspection.

5.04 Transportation and Storage of Wildlife Carcasses Prior to Processing

(1) The following provisions, in addition to Sec. 3.05 [Food Transportation and Storage], apply to the transportation and storage of wildlife animal carcasses harvested for processing as class 1, 2 or 3 food.

(2) No one may release a wildlife animal carcass to a food processing plant licensed pursuant to this Title, or class 1 meat vendor, unless that carcass has been carried out of the field and transported to the food processing plant in a manner that prevents the spolioation of the meat. Measures shall be taken to protect the carcass from contact with soil, debris or other materials while removing the carcass from the field (e.g. through use of a game cart, or by carrying the carcass suspended from its feet). Wildlife animal carcasses shall be continuously cooled following harvest. If ice is used in cooling, it shall be made

with potable water, and any implements and containers coming into contact with the ice shall be clean and sanitized, and made from food safe materials. If the carcass is held by the harvester, it must be continuously cooled in a secure location and protected from pests and vermin, and the harvester shall actively monitor the air temperature of the smallest container used to hold the carcass.¹

(3) The harvester shall document the measures taken to protect the carcass during transport from the field to the food processing plant (e.g. “placed carcass in clean game cart and wheeled it to the road; lifted carcass from cart and hoisted it onto the clean truck bed.”) in the Harvester Certificate of Guarantee. If the carcass is not immediately released to a tribally-licensed food processing plant, or class 1 meat vendor, the manner in which the carcass is stored shall also be documented on the Harvester Certificate of Guarantee (e.g. “placed sanitary ice within the abdominal cavity,” “hung the carcass in fully-enclosed, unheated pole barn,” “calibrated thermometer in the shed read 32° F at 17:42 on 10/17/19”).

(4) Wildlife animal carcasses intended to be processed as Class 2 and 3 meat products shall be presented to a tribally-certified meat inspector within 24 hours of the animal’s killing.

5.05 Post-Mortem Inspection

(1) Prior to the acceptance of a wildlife animal carcass by a tribally-licensed food processing plant, the field-dressed carcass, otherwise complete, and related records shall be presented for inspection to a tribally-certified meat inspector. Tribally-certified meat inspectors may not release to a food processing plant, wildlife animal carcasses exhibiting signs of disease or injury, which are unrelated to the killing and pose a risk to human health, unless approved by a licensed veterinarian.

(2) The following procedures shall be performed during the post-mortem inspection:

¹ If the carcass is being held in a refrigerated unit in an outbuilding, the harvester or designee will need to regularly check the interior air temperature of the refrigerated unit, making a record of those monitoring activities.

(a) An examination of the outside of the carcass, noting any physical deformities and signs of disease or injury, including indications of post-mortem injury to the carcass.

(b) An internal examination of the carcass, and organs collected by the harvester, noting any physical deformities, signs of disease or injury.

(c) An examination of the Harvester Certificate of Guarantee for completeness and indications of time and temperature abuse or any other food safety concern.

(3) At the conclusion of the inspection, the tribally-certified meat inspector shall release the carcass to a tribally-licensed food processing plant, certifying the carcass for processing as class 2 and 3 food, or reject the carcass as not amenable wild-harvest food. Carcasses which have been rejected by a tribally-certified meat inspector may only be accepted by a tribally-licensed food processing plant if accompanied by a certificate of food safety issued by a licensed veterinarian. Carcasses which have been certified for processing as class 2 and 3 food, shall be affixed with a tribal meat inspection legend, on the body of the carcass and within documentation accompanying that carcass.

(4) Deer and elk carcasses presumed to be diseased, and not amenable wild-harvest food, due to the location of harvest within Tribal Disease Management Areas for chronic wasting disease and bovine tuberculosis must undergo post-mortem inspection within 24 hours of the animal's killing to be certified for processing as Class 1, 2 or 3 food and the following additional procedures apply:

(a) The field-dressed carcass shall be presented to the _____ [Tribe's natural resource department], or designee, within 24 hours of the killing to collect samples to test for the disease(s) associated with the Tribal Disease Management Area;

(b) Testing for the disease associated with the Tribal Disease Management Area shall be performed pursuant to a quality assurance project plan (QAPP) as specified by the _____ [Tribal Natural Resource Department] or designee, and the

documentation submitted with the test sample shall identify the sample using identification information from the TMDA tag.

(c) In the time between the presentation of the carcass for post-mortem inspection and testing, and the receipt of the results of the testing, the carcass must be stored in compliance with Sec. 3.05 [Food Transportation and Storage] within a clean, safe and secure apparatus, facility or container, with measures employed to prevent cross-contact between the carcass and other carcasses, or foods, food contact surfaces, etc. The apparatus, facility or container used to hold the carcass shall be maintained at 38° F or lower, with regular temperature monitoring performed and records created and maintained pursuant to Sec. 3.10 [Recordkeeping].

(d) Carcasses which test results return no detection of the disease associated with the Tribal Disease Management Area, and which have been stored in a manner that preserved the integrity of the meat, consistent with subsection (c), above and other requirements, may be transferred to a food processing plant and/or processed by a class 1 meat vendor. Carcasses which test results detect the presence of the disease associated with the Tribal Disease Management Area, and/or have not been stored in a manner that preserves the integrity of the meat, shall not be considered amenable wild-harvest food.

(5) Each wildlife animal carcass or part thereof, which has been found, upon final inspection, to be unsound, unhealthful, unwholesome, or otherwise adulterated, shall be conspicuously marked on the surface tissues, as possible “ _____ Tribe Inspected and Condemned.” No person or entity may process, store, transport or sell meat as food for human consumption, from a carcass which has been so condemned.

5.06 Release of a Wildlife Animal Carcass to a Food Processing Plant

(1) Upon releasing a wildlife animal carcass to a food processing plant, the harvester shall provide to the food processing plant or class 1 meat vendor a fully-completed Harvester Certificate of Guarantee, which is a signed certificate affirming that the harvester and all others involved in the harvest, transportation and storage of the carcass, adhered to the standards set forth in Sec. 5.01 to 5.04, as applicable.

(2) Harvester Certificates of Guarantee shall be retained by food processing plants and class 1 meat vendors for each carcass, or part of carcass, which enters their facility. Harvest Certificates of Guarantee shall be retained in accordance with the schedules set forth in Sec. 3.10 [Recordkeeping].

5.07 Meat Processing

(1) Wildlife animal carcasses, or parts of those carcasses, which have been released to a food processing plant shall be held in a refrigerated area, physically separated from areas used for cutting or processing meat, jerky or the storage of processed food, ready-to-eat products, or any food contact surfaces used for these products or processes, and stored consistent with Sec. 3.05 [Food Transportation and Storage]. Prior to moving these carcasses, or parts of carcasses, to the other areas of the plant, the skin and feet from carcasses of mammalian animals, and the feathers of bird animals, shall be removed, and each carcass treated with an antimicrobial wash, adequately formulated and applied to the carcass to reduce the levels of *E. Coli* on the entire surface of the carcass.

(2) Specified risk materials (SRMs).

(a) SRMs defined. The following parts are considered SRMs:

(i) The tonsils and distal ileum from all venison carcasses; and

(ii) The brains, eyes, trigemal ganglia, spinal cord, vertebral column (excluding the transverse processes of the thoracic and lumbar vertebrae and wings of the sacrum)

and the dorsal root ganglia from venison carcasses of cervidae aged 12 months and older.

(b) SRMs are not amenable and any meat contaminated with SRMs are not amenable wild-harvest food. Cheek meat, head meat and tongues from cervidae aged 12 months and older are considered adulterated if they have been contaminated with brain matter. Tools and surfaces used in the removal of SRMs shall be dedicated to that process. Cleaning and sanitizing processes employed for those tools and surfaces must be consistent with practices which effectively eliminate or deactivate infectious prions.

(c) Disposal of SRMs. SRMs must be disposed of consistent with Sec. 3.07 [Handling of Inedible Food Byproducts].

(3) Any meat products procured or obtained by a food processing plant or a retail food establishment licensed pursuant to this Title from suppliers other than harvesters of wildlife carcasses, shall not be received unless the food processing plant has a letter of guarantee on file from the supplying establishment. Raw meat and trim should be received in the same manner as wildlife carcasses are received pursuant to subsection (1), above. Letters of guarantee from outside suppliers of meat products shall be retained pursuant to Sec. 3.10 [Recordkeeping].

(4) Meat grinding.

(a) Food processing plants and retail food establishments that grind meat products shall create and maintain the following meat grinding records:

(i) The identifiers of the individuals or entities that supplied the meat used to prepare each lot of ground meat (i.e. names of harvesters or meat dealer);

(ii) Commercial harvest tag numbers and/or supplier lot numbers, and dates of harvest, production or slaughter;

(iii) The names of the supplied materials, including meat components and any materials carried over from one production lot to the next;

(iv) The date and time each lot of ground meat product is produced; and

(v) The date and time grinding equipment and other related food-contact surfaces are cleaned and sanitized.

(b) Meat grinding records shall be maintained consistent with Sec. 3.10 [Recordkeeping].

(c) Care shall be taken to regularly, and frequently, clean and sanitize meat grinding equipment and related food-contact surfaces pursuant to SSOPs and HACCP plans, as applicable.

5.08 Dehydrated Meat Products

(1) Any non-meat ingredients for marinades and spice mixes used in the preparation of dehydrated meat products shall be prepared under good manufacturing practices (GMPs) designed to minimize contamination and the presence and growth of pathogens of public health concern.

(2) If the heating process employed in the preparation of the product does not deliver an adequate lethality, additional interventions shall be employed, such as the following:

(a) Preheating the jerky strips in the marinade, or water, to a minimum internal temperature of 160°F.

(b) Dipping the product in 5% acetic acid for 10 minutes before placing it the marinade.

(c) Dipping the product in 1:2 or 1:3 mixtures of calcium sulfate and water for 30 seconds or dipping in acidified sodium chlorite at concentrations between 500 and 1,200 ppm.

(3) If the product is heated using a low temperature without the application of humidity, to achieve a surface tackiness, this step shall last 30 minutes or less in total.

(4) Lethality treatment.

(a) During the lethality treatment, which is the process step or steps used to destroy pathogenic microorganisms, the establishment's actual processes shall adhere to scientifically-

sound critical operational parameters with respect to product time-temperature combination and relative humidity levels that have been shown to be effective in compliance guidelines issued by the USDA FSIS, journal articles, challenge studies or in-plant data.

(b) The establishment shall regularly monitor relative humidity levels in the sealed oven, and the internal temperature of the product, during the lethality treatment pursuant to HACCP plans. Accurate records of the critical operational parameters (critical control points) shall be created and retained pursuant to Sec. 3.10 [Recordkeeping] and Sec. 4.04 [Records].

(c) Home-style dehydrators do not maintain the necessary humidity levels and may not be used in the lethality treatment for class 3 dehydrated meat products.

(6) Drying.

(a) The upper limit for water activity for jerky stored in aerobic conditions is 0.85 water phase salt (wps), and the upper limit for jerky stored in anaerobic conditions is 0.90 water phase salt (wps), unless the establishment produces scientific support to support higher critical limits.

(b) The product shall not be dried before the lethality treatment.

(c) The establishment shall regularly monitor or verify the water activity of its dried product using an instrument such as a water activity meter pursuant to its HACCP plan for jerky. Accurate records of the critical operational parameters (critical control points) shall be created and retained pursuant to Sec. 3.10 [Recordkeeping] and Sec. 4.04 [Records].

(d) Vacuum packaged jerky products with a water activity of more than 0.85 water phase salt (wps) should be labeled with a statement such as “Refrigerate After Opening.”

(e) A post-drying heating step may be added.

(7) Following the lethality treatment and drying, care shall be taken to avoid contaminating the product by strict implementation of SSOPs, limited handling, elimination of cross-contamination and, for

products which are not shelf stable, to minimize adverse time and temperature effects in all storage and transportation.

5.09 Class 1 Meat Products

(1) Class 1 meat products are limited to fresh and frozen cuts of meat that have not been ground. Chapter 4 [Hazard Analysis Critical Control Point] apply to the production of all Class 1 meat products.

(2) A valid class 1 meat vendor license issued by the _____ [Tribe] is required to produce class 1 meat products outside of a tribally-licensed food processing plant. Class 1 meat vendor licenses shall be issued upon the submission of complete applications and satisfactory inspections, if inspection is required. Class 1 meat vendor licenses may be revoked or suspended for non-compliance with the standards set forth within this Chapter. The _____ [tribal licensing authority] may refuse to issue a class 1 meat vendor license to an individual with ownership or management interest in an operation which has been subject to any serious, or ongoing or unresolved violations of this Chapter. An application for a class 1 meat vendor permit must be submitted to the _____ [tribal licensing authority] annually, for each physical location and mobile processing unit used to process meat as a Class 1 food, containing the following information:

- (a) The name of the food producer and mailing address;
- (b) Physical address of the facility or residence used to process the meat;
- (c) A statement agreeing to comply with the requirements and standards set forth in this Chapter, including any required inspections required by the _____ [tribal licensing authority]; and
- (d) Payment of required fees.

(3) Inspections

(a) An annual inspection is required for all facilities used to process and package class 1 meat.

(b) The _____ [tribal regulatory agency] may inspect facilities licensed to process and package class 1 meat upon a reasonable belief that the operation is in violation of the requirements contained in this chapter or in response to a public health emergency (e.g. such as a foodborne illness outbreak associated with the consumption of foods produced by the operation).

(c) Inspections may include a walk-through of the premises used for the cleaning and sanitizing of surfaces, tools and equipment, for processing and packaging cuts of meat and storage areas, and review of the facility's records. Additionally, during the inspection, the vendor must demonstrate an understanding of the applicable food safety standards and the capacity to comply with those standards.

5.10 Class 2 and 3 Meat Products

(1) Class 2 meat products are limited to fresh and frozen cuts of meat, and fresh and frozen ground meat. The provisions of Sec. 3.11 [Food Processing Plants] and Chapter 4 [Hazard Analysis Critical Control Point] apply to the production of all Class 2 meat products.

(2) Class 3 meat products are limited to fresh and frozen cuts of meat, fresh and frozen ground meat and dehydrated meat products. The provisions of Sec. 3.11 [Food Processing Plants] and Chapter 4 [Hazard Analysis Critical Control Point] apply to the production of all Class 3 meat products.

(3) Licensed food processing plants shall make and retain records related to meat from an animal processed by the facility for human consumption, which shall be retained pursuant to Sec. 3.10 [Recordkeeping]. The record shall include the following:

(a) The date and time the animal was harvested;

(b) The date and time the animal was processed;

(c) The type and amount of meat processed, the disposition of that meat, and any lot number or other identifier created for that meat;

(d) The Harvester Certificate of Guarantee; and

(e) Any other information required by the _____ [tribal licensing authority].

(4) All establishments which produce class 2 and 3 meat products shall create a written recall plan to protect the public from products that may cause health problems or possible death. Written recall plans must include the following:

(a) Identification of recall personnel, with their roles and responsibilities specified.

(b) Detailed specification of the procedures that will take place.

(c) Evaluation of the health hazards as identified in the establishment's HACCP plans.

(d) Scope of the recall (dependent on the type of product and risks involved).

(e) Depth of the recall (dependent on the degree of hazard, extent of distribution and the amount of product distributed).

(f) Recall communication plan, including notification of retail and other establishments distributing the product.

(g) Public notification.

(h) Effectiveness checks to ensure that retail and other establishments took the appropriate action.

(i) Returned product control and disposition.

(j) Recall simulations conducted periodically by the establishment.

Chapter 6 – Fish

6.01 Receipt and Processing of Freshly Harvested Fish

(1) Each lot of raw, unfrozen fish received by a food processing plant, and prior to beginning any processing, shall be inspected prior to being received by the food processing plant to ensure that the product is fresh and wholesome, and arrives consistent with one or more of the following:

(a) Accompanied by transportation records that show that the product was held at or below an ambient or internal temperature of 38°F or below throughout transit; or

(b) Completely surrounded by ice at the time of delivery; or

(c) Delivered under a sufficient quantity of chemical cooling media that remain frozen, have kept the product at an internal temperature of 38°F or below throughout transit, and the internal temperature of the product at the time of delivery is 38°F or below; or

(d) Delivered refrigerated with a transit time of 4 hours or less, verified by transportation records, and the internal temperature of the product at the time of delivery is 38°F or less.

(2) Only fish accompanied by proof of legal harvest shall be received by a food processing plant. For Class 1 fish products, produced outside of a fish processing plant, the processor shall receive proof of legal harvest. These records shall be maintained by the processor consistent with the schedules set forth in Sec. 3.10 [Recordkeeping].

(3) All fish sold to anyone, donated to a tribal government program or school, or transferred to a food processing plant shall be accompanied by a Harvester Certificate of Guarantee documenting the waterbody of harvest. Fish harvested from waterbodies with mercury do not eat consumption guidance published by the Great Lakes Indian Fish and Wildlife Commission for pregnant women, women of childbearing age and children under 15 years of age, for that species of fish, may not be sold, donated or received by a food processing plant.

6.02 Fish Processing

Appropriate quality controls must be employed to ensure that fish products sold or donated pursuant to this Title are suitable for human consumption and that fish packaging materials are suitable and safe.

(1) Raw fish and eggs (roe), after being removed from the sac (skein), must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying fish products must be safe and of adequate sanitary quality.

(2) Fish products must be held in clean and sanitized containers designed and constructed so as to protect against contamination.

(3) Preventative measures must be employed to reduce pathogenic bacteria growth and toxin formation, including the following, as applicable:

(a) Storing the product in contact with ice or refrigerated at or below 38°F;

(b) While processing fish and fish products, controlling the amount of time that the product is exposed to temperatures that would permit pathogenic bacteria growth or toxin formation; and

(c) Rapid cooling of the product (including after cooking).

(4) When ice is used in contact with fish, it must be made from water that is safe and of adequate sanitary quality in accordance with 21 C.F.R. § 117.37(a), and must be used only if it has been manufactured in accordance with current sanitation practice as outlined in this Title.

(5) Frozen fish must be kept frozen. If thawing is required prior to its use, it must be done in a manner that prevents the fish from becoming adulterated. Frozen fish packaged in reduced oxygen packaging must be labeled in accordance with Sec. 3.02(2)(b)(v).

6.03 Smoked Fish Products

(1) Any product that will be preserved by salting or drying should be eviscerated prior to processing. Evisceration of fish is the careful and complete removal of all internal organs in the body cavity without puncturing or cutting them, including the gonads.

(2) Critical limits for smoked fish products.

(a) For fish smoked via hot smoking, the internal temperature of the product must be maintained at or above 145°F (throughout entire product) for at least 30 minutes.

(b) Refrigerated smoked fish products offered for sale or donation pursuant to this Title shall have not less than 3.5% water phase salt (wps) for vacuum packaged smoked fish with an approved tribal variance, or 3% water phase salt (wps) packaged with an air permeable membrane, or equivalent packaging.

(c) For smoked fish sausage, commercial pre-mixed seasonings may be used so long as the final product contains a minimum of 100 ppm nitrite. When nitrite is used, it must be included in the ingredient list, along with its function consistent with Sec. 3.02(2)(b)(ii)(III).

(3) Brining loads shall be restricted to a single species and portions of approximately the same size, with brine treated or replaced regularly to minimize harmful microbial contamination.

(4) Finished refrigerated smoked fish products shall be stored at or below 38° F and labeled with handling instructions pursuant to Sec. 3.02(2)(b)(v).

6.04 Fish Egg Products

(1) Fish egg (roe) products shall be processed to limit the growth and formation of toxins controlled by adding sufficient salt to produce a ratio of 1 pound of salt to 33 pounds of roe (skeins removed). The salt must be carefully mixed in with the eggs to ensure that the water phase salt level is uniform throughout the product and media. Canning salt should be used as it is free from anti-caking chemicals which can cause unpleasant flavors.

(2) Strict refrigeration control (maintaining the product at or below 38°F) should be maintained during storage and distribution.

(3) Finished products shall be labeled with handling instructions pursuant to Sec. 3.02(2)(b)(v).

6.05 Class 1 Fish Products

(1) Class 1 fish products are limited to fresh fish filets that have not been frozen.

(2) A valid fresh fish vendor license issued by the _____ [Tribe] is required to produce Class 1 fish products outside of a tribally-licensed food processing plant. Fresh fish vendor licenses shall be issued upon the submission of complete applications and satisfactory inspections, if inspection is required. Fresh fish vendor licenses may be revoked or suspended for non-compliance with the standards set forth within the applicable portions of this Title. The _____ [tribal licensing authority] may refuse to issue a fresh fish vendor license to an individual with ownership or management interest in an operation which has been subject to any serious, or ongoing or unresolved violations. An application for a fish vendor permit must be submitted to the _____ [tribal licensing authority] annually, for each physical location used to process fish as a Class 1 food, containing the following information:

- (a) The name of the food producer and mailing address;
- (b) Physical address of the facility or residence used to process the fish;
- (c) A statement agreeing to comply with the requirements and standards set forth in this Chapter, including any required inspections required by the _____ [tribal licensing authority]; and
- (e) Payment of required fees.

(3) Inspections

(a) An annual inspection is required for all facilities used to process and package fresh fish.

(b) The _____ [tribal licensing authority] may inspect facilities licensed to process and package fresh fish upon a reasonable belief that the operation is in violation of the requirements contained in this chapter or in response to a public health emergency (e.g. such as a foodborne illness outbreak associated with the consumption of foods produced by the operation).

(c) Inspections may include a walk-through of the premises used for the cleaning and sanitizing of surfaces, tools and equipment, for processing and packaging fresh fish and storage areas, and an inspection of documents. Additionally, during the inspection, the vendor must demonstrate an understanding of the applicable food safety standards contained within this chapter, and the capacity to comply.

6.06 Class 2 and 3 Fish Products

(1) Class 2 fish products are limited to fresh fish filets and frozen vacuum sealed fish filets.

(2) Class 3 fish products are limited to fresh fish filets, frozen vacuum sealed fish filets, smoked fish and refrigerated or frozen fish egg (roe) products.

(3) Class 2 and class 3 fish products may only be produced within facilities licensed under Sec.

3.07 [Food Processing Plants].

Chapter 7 – Produce

7.01 General Provisions

(1) All personnel engaged in activities that involve the handling of produce sold or donated pursuant to this Title shall:

(a) Wear clean and washable outer clothing, including footwear, and shall wash and rinse their hands sufficiently during the operations to prevent contamination of the harvested foods consistent with Sec. 3.04 [Personnel].

(b) Have access to toilet facilities, which may include transportation to an off-site location for toileting, and an area designated for taking breaks, eating and smoking;

(c) Have received training on, and follow, procedures on proper hand-washing techniques, hygienic practices and how to identify and reduce food safety risks related to their assigned duties consistent with Sec. 3.04 [Personnel].

(d) Be excluded from those activities if the person has an illness or disease that is communicable through the food which will be sold or donated, for the duration of the illness consistent with Sec. 3.04 [Personnel].

(e) Have access to clean, potable drinking water served in a sanitary manner.

7.02 Produce Harvesting

(1) Equipment and tools used for produce harvesting shall be designed and constructed to work effectively and be adequately cleaned consistent with Sec. 3.06 [Equipment and Utensils]. Additionally, any equipment, vehicles and conveyances (e.g. bins, coolers, etc.) used to transport produce shall be adequately cleaned before their use and must be adequate for their use.

(2) Produce that appear to be contaminated by animal excreta or other dangerous or filthy substance may not be sold or donated pursuant to this Title.

(a) Produce matter harvested from the exposed parts of upland plant or fungi species located on land which was flooded during the plant or fungus' current growing cycle shall be deemed contaminated for the purpose of this subsection.

(b) Dropped produce, except for roots (e.g. wild onions) and crops that grow on the ground (e.g. morel mushrooms), shall be considered contaminated for the purpose of this subsection.

(c) Any contaminated produce which was inadvertently harvested shall be kept separate from any food intended for sale or donation. Contaminated plant or fungi matter may be respectfully disposed of, or maintained within physically separate containers clearly marked as "NOT FOR SALE OR DONATION."

7.03 Procedures for Class 2 and 3 Covered Produce Sales

(1) The following only applies to Harvesters of Class 2 and Class 3 covered produce with covered produce sales exceeding \$25,000 annually for the past 3 years (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment, and are not exempted as a qualified small or very small business.

(2) A valid non-exempt produce harvester license issued by the _____ [Tribe] is required for the production and sale of treaty-harvested covered produce by individuals and entities covered in subsection (1), above. Non-exempt produce harvester licenses shall be issued upon the submission of complete applications and satisfactory inspection. Non-exempt produce harvester licenses may be revoked or suspended for non-compliance with the standards set forth within this Chapter. The _____ [tribal licensing authority] may refuse to issue a non-exempt produce harvester license to an individual with ownership or management interest in an operation which has been subject to any serious, or ongoing or unresolved violations of this Chapter. An application for a Non-exempt produce harvester license must be submitted to the _____ [tribal

licensing authority] annually, for each physical location used to package covered produce, containing the following information:

(f) The name of the food producer and mailing address;

(g) Physical address of the facility or residence used to package the covered produce;

(h) The type of foods which will be packaged at the facility or residence;

(i) A statement agreeing to comply with the requirements and standards set forth in this Chapter, including any required inspections required by the _____ [tribal licensing authority]; and

(j) Payment of required fees.

(3) Worker Health, Hygiene and Training.

(a) At least one supervising harvester shall have completed food safety training at least equivalent to the standardized curriculum recognized by the FDA for produce safety.

(b) All personnel shall be trained as appropriate to their duties, upon hiring, and periodically thereafter, at least once per year. Personnel training must be supervised by a qualified person and conducted in a manner that is easily understood by the person being trained. In addition to general food handling training topics required by Sec. 3.04 [Personnel], personnel training shall include: (1) recognizing covered produce that should not be harvested due to contamination; (2) inspecting harvest containers, tools and equipment to ensure they are clean and operating appropriately; and (3) correcting food safety problems as they arise, or reporting them to a supervisor.

(c) Personnel engaged in harvesting and handling covered produce shall:

(i) Maintain adequate personal cleanliness to protect against the contamination of covered produce and food contact surfaces;

(ii) Avoid contact with animals;

(iii) Wash hands frequently and adequately, and prior to starting work and after engaging in any activity which may lead to the contamination of their hands;

(iv) Remove or cover any hand jewelry that cannot be adequately cleaned and sanitized; and

(v) Refraining from eating, chewing gum or tobacco, or smoking.

(d) Harvesters shall take measures to protect contamination of covered produce and food contact surfaces from microorganisms of public health significance by:

(i) requiring personnel to report symptoms of illness, or other indicia of illness, which is consistent with infectious disease;

(ii) requiring personnel to report injuries that result in bleeding or open wounds; and

(iii) excluding personnel from food handling activities, or taking other precautions (e.g. requiring a worker with an open wound on their hand to bandage the wound and wear a glove).

(e) Records on personnel training, including persons trained, topics covered, and the date of training sessions, shall be maintained consistent with subsection (6), below.

(4) Preventing the Contamination of Covered Produce by Animals.

(a) The harvester, or designee, shall survey the area to be harvested at least one week in advance of any plant harvesting, documenting any evidence of animal presence (e.g. signs of grazing or significant amounts of excreta) through a visual depiction of the area that is reasonably proportionally accurate (i.e. a map) or a narrative description of the area that effectively describes the layout of the area to be harvested and any notable findings.

(b) Immediately before harvesting covered produce, the harvester or designee shall again survey the area where covered produce will be harvested, physically roping off areas where animal excreta are observed, using flagging material, rope and removable stakes or other similar materials. No covered produce shall be harvested from within the roped-off areas. The materials used to physically separate these areas shall be removed at the end of each harvesting day.

(c) To the extent possible, domesticated animals, including pets, shall be excluded from harvest zones when harvesting activities are taking place. In the event that presence of a domesticated animal is observed within the area to where covered produce will be harvested, the specific areas where domesticated animal presence is observed shall be segregated in the manner described in 7.02(3)(b) and harvest shall not occur within these areas.

(5) Tool and Equipment Maintenance.

(a) All food contact surfaces of equipment and tools used during harvesting, packing and holding covered produce shall be inspected, maintained and cleaned, and when necessary, sanitized, as frequently as necessary to prevent the contamination of covered produce.

(b) All non-food contact surfaces of equipment and tools used for harvesting, packing and holding covered produce shall be maintained and cleaned as frequently as necessary to prevent the contamination of covered produce.

(c) Equipment such as forklifts, utility vehicles and trucks, if used in covered produce operations, shall be used in a manner that minimizes the potential for contamination of covered produce and food contact surfaces with known or reasonably foreseeable hazards.

(6) Post-Harvest Handling and Sanitation.

(a) Covered Produce Packing Areas. The standards articulated in Sec. 3.11 [Food Processing Plants] are not required for facilities dedicated solely for the harvesting, packing and holding of covered produce. Instead, the following standards apply.

(i) Any buildings used for cleaning, packing and storing of covered produce shall be suitable in size, construction and design to reduce the potential for contamination of the covered produce and food contact surfaces due to foreseeable hazards such as: waste water, drip, condensate and other sources of filth or contamination.

(ii) Physical barriers, such as fencing, walls and screens, shall be employed as necessary to exclude wild and domestic animals, and pests (e.g. mice, rats, flies, etc.), and their waste, from entering the buildings.

(iii) Any toilet facilities shall be designed, located and maintained to prevent the contamination of covered produce and shall include hand-washing service.

(iv) The building shall be supplied with an appropriate mechanism or service to convey, store and dispose of trash, litter and waste, in order to minimize the potential to harbor and attract pests and to protect against the contamination of covered produce, food contact surfaces and related items.

(v) If plumbing is employed, it shall operate to perform to the following specifications:

(i) Distribute in sufficient quantity, and under sufficient pressure, potable water for the use in covered activities, and for the toileting and handwashing facilities as applicable;

(ii) Proper conveyance of sewage and liquid disposable waste to the sewage or septic system or other adequate means of controlling and disposing of liquid waste;

(iii) Avoid being a source of contamination of covered produce, food contact surfaces and critical areas; and

(iv) Not allow backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for covered produce activities, maintaining sanitary operations or handwashing.

(b) Water Used for Post-Harvest Activities. Only water with no detectable generic *E. coli* per 100 mL sample may be used for the following post-harvest activities:

(i) Direct contact with covered produce before or after harvest;

(ii) Direct contact with food contact surfaces;

(iii) To make ice; and

(iv) For handwashing during and after harvest activities.

If untreated groundwater is used, a sample of that water shall be tested for generic *E. coli* at least 4 times during the growing season. If water from a public water supply is used, the food producer must retain a copy of the water supply certificate of compliance, documenting that the water meets or exceeds the requirement of the Safe Water Drinking Act, or that it is free of detectable generic *E. coli* in 100 mL of water. Water used must be managed as necessary to maintain its safety to prevent the build-up of organic materials, improper temperature or pH level or other hazardous condition.

(7) Documentation and Records.

(a) The harvester or designee shall document the actions taken in accordance with Sec. 7.01 [General Provisions], Sec. 7.03 (2) to (5) and Sec. 3.05 [Food Transportation and Storage] for each week of covered produce harvesting conducted, assigning that week of harvested food with a unique lot number. All records related to a specific harvest shall bear that same lot number. These written records shall be maintained by the harvester for 2 years after the sale of the covered produce.

(b) The harvester or designee shall also maintain records documenting personnel training, utensil and equipment maintenance, cleaning and sanitizing schedules and performance and the maintenance of a hygienic operation. These records shall be updated frequently and maintained for 2 years from the time of their creation.

(c) The maintenance of records on computers or electronic databases is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(d) All records required by this part and all plans and procedures required by this part shall be available for official review and copying by the _____ (tribal licensing authority) at reasonable times.

7.04 Packaging Produce

(1) Produce, if packaged in a raw and unpreserved state, shall be contained within clean packaging materials that discourage the growth of pathogenic bacteria or fungi. Except for mushrooms, produce is exempt from labeling requirements of Sec. 3.02.

(2) Fresh mushrooms shall be packaged in clean packaging materials, labeled according to Sec. 3.02(2) [Debwewin; Truth in Labeling; mushrooms]. If fresh mushrooms are enclosed within packaging materials, aerobic packaging (i.e. oxygen permeable materials) shall be used to discourage decomposition.

Chapter 8 Low-Risk Foods

8.01 General Provisions

(1) This chapter applies to the production of low-risk foods. Low-risk foods are foods that carry a lower risk of food-borne pathogens and can be safely produced outside of tribally-licensed food processing plants. A non-exclusive list of low-risk foods includes: manoomin (wild rice) and manoomin flours, low-acid fruit preserves, low-acid pickled produce, dried teas or dried tea blends, dried fruit (excepting melons), candy, syrups and sugar made from tree sap.

(2) A valid low-risk food vendor license issued by the _____ [Tribe] is required for the production of low-risk foods produced outside of a tribally-licensed food processing plant, except that Class 1 manoomin and Class 1 syrup and sugar may be processed without a low-risk food vendor license. Low-risk food vendor licenses shall be issued upon the submission of complete applications and satisfactory inspection. Low-risk food vendor licenses may be revoked or suspended for non-compliance with the standards set forth within this Chapter. The _____ [tribal licensing authority] may refuse to issue a low-risk food vendor license to an individual with ownership or management interest in an operation which has been subject to any serious, or ongoing or unresolved violations of any applicable portions of this Title. An application for a low-risk food vendor permit must be submitted to the _____ [tribal licensing authority] annually, for each physical location used to produce a low-risk food, containing the following information:

- (a) The name of the food producer and mailing address;
- (b) Physical address of the facility or residence used to process the low-risk foods;
- (c) The type of food(s) which will be produced at the facility or residence;
- (d) A statement agreeing to comply with the applicable requirements and standards set forth in this Title, including any required inspections required by the _____ [tribal licensing authority]; and

(e) Payment of required fees.

(2) Inspections

(a) An annual inspection is required for all facilities used by all licensed low-risk food vendors to prepare and package low-risk foods.

(b) The _____ [tribal regulatory agency] may inspect facilities licensed to produce a low-risk food upon a reasonable belief that the operation is in violation of the requirements contained in this chapter or in response to a public health emergency (e.g. a foodborne illness outbreak associated with the consumption of foods produced by the operation).

(c) Inspections may include a walk-through of the premises used for the cleaning and sanitizing of surfaces, tools and equipment, for preparation and packaging of low-risk foods and any storage areas, and the review of applicable records. Additionally, during the inspection, the vendor must demonstrate an understanding of the applicable food safety standards contained within this chapter, and the capacity to comply.

(3) The following provisions apply to the preparation and packaging of low-risk foods outside of a tribally-licensed food processing plant.

(a) Low-risk foods shall be prepared consistent with traditionally safe methods.

(b) Produce shall be washed, sorted and trimmed as necessary, and inspected before being canned. Waste and by-products shall be stored and handled in a sanitary manner.

(c) If the food is prepared using water, it must be potable water that meets applicable drinking water standards. Potable water must be used to clean surfaces and equipment that will come into contact with the food.

(d) Individuals engaged in the preparing and packaging of low-risk foods shall wear clean and cleanable clothing, wash their hands sufficiently during the operations and not be infected with a reportable communicable illness, experiencing any symptom of acute gastrointestinal illness or have a discharging open wound, sore or lesion on the hand, arm, or other exposed portion of the body. While engaged in the production of low-risk foods, no person may consume food, use tobacco recreationally or drink beverages in any area used for food processing, except in designated areas which are separated from the processing areas. This subsection does not prohibit a sanitary drinking water fountain in a processing, storage or packaging area, or the drinking of water through a straw in an otherwise closed container.

(e) The tools and equipment used to measure the sugar content of syrup and the pH of low-acid fruit preserves and low-acid pickled vegetables shall be maintained in good repair and calibrated prior to each use.

(f) The premises, tools and equipment used for preparing and packaging low-risk foods shall be kept clean and sanitary, to the degree necessary to remain consistent with traditionally safe methods. While preparing and packaging foods intended for sale, pets and other domestic animals shall be excluded from the workspace, and no other domestic activities (e.g. family meal preparation, dishwashing, clothes washing, etc.) shall be conducted.

(g) The materials used to package low-risk foods shall be kept clean and dry prior to their use, and be clean, single-use containers or containers which were cleaned and sterilized prior to their use.

(h) Lead or lead-alloy shall not be used in the construction or repair of food-contact surfaces, including taps and sap-collection devices.

(i) Food contact surfaces of equipment and utensils shall be constructed of stainless steel or of one or more other food-grade materials which are smooth, impervious, nontoxic, non-corrodible, nonabsorbent and durable under normal use conditions. Food contact surfaces shall be easily cleanable, and shall be free of breaks, open seams, cracks or similar defects. Food contact surfaces shall not impart any odor, color, taste or adulterating substance to food. Food contact surfaces shall be readily accessible for manual cleaning.

(4) Low-risk vendors who earn less than \$50,000 annually in gross annual sales from low-risk foods during the annual licensing period, and are producing low-risk foods outside of a food processing plant are exempt from the provisions of Chapters 3 and 4 for the preparation, packaging and sale of low-risk foods, except that Sec. 3.01 [Zhawenindiwig; Respect for Traditional Foods and Consumers], Sec. 3.02 [Debwewin; Truth in Labeling], Sec. 3.03 [Food Additives], Sec. 3.05 [Food Transportation and Storage], and Sec. 3.06 [Equipment and Utensils] shall apply, and the retention schedule for low-risk foods in Sec. 3.10 [Recordkeeping] shall apply. Sales of manoomin and syrup and sugar derived from tree sap shall not be included in the calculation of gross annual sales from low-risk foods. The \$50,000 limit shall be adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

(5) Except for sales of manoomin, syrup and sugar, all low-risk foods produced outside of a food processing plant must be sold directly to consumers.

8.02 Syrup and Sugar Derived from Tree Sap

(1) Sap that is intended for processing as a low-risk food shall remain covered prior to processing, with care taken to avoid spoilage.

(2) Any filtering and defoaming agents used in the processing of syrup and sugar shall be nontoxic and food grade.

(3) All food contact surfaces used in the condensing of sap into syrup for shall be cleaned and sanitized prior to the addition of unfinished sap and after each batch, not to exceed 40 days of

continuous operation without any interruption exceeding 30 minutes, or more frequently to avoid the adulteration of products. A variance for the use of food contact surfaces for the processing of tree sap that are not stainless steel or comprised of food grade materials should be available as long the materials in contact with the sap, sugar or syrup are nontoxic (i.e. lead or lead-alloy soldering shall not be used).

(4) Syrup and sugar may be sold as Class 2 and Class 3 food as long as the final boiling and packaging of the product occurs in a licensed food processing plant or within premises that are exempt from registering as a food facility pursuant to 21 CFR 1.225. Syrup and sugar sold or donated as Class 1 foods are exempt from this provision.

(5) The sugar content of each batch of finished syrup shall be measured using a refractometer calibrated at 68°F, and to which any applicable temperature correction has been made, or by any other method that gives equivalent results. A record of this measurement shall be created and maintained pursuant to Sec. 3.10 [Recordkeeping].

8.03 Manoomin

(1) Manoomin which is sold pursuant to this Title shall be processed in manner that is consistent with the cultural traditions specific to the _____ [Tribe], and may include the use of machines for parching, threshing and separating hulls from the finished product. A variance for the use of food contact surfaces for the processing of manoomin that are not stainless steel or comprised of food grade materials should be available as long the materials in contact with the manoomin are nontoxic (i.e. lead or lead-alloy soldering shall not be used).

(2) Prior to packaging manoomin harvested for donation or sale pursuant to this Title, the manoomin shall be examined to ensure that it does not contain any fragments of hard, inedible material (e.g. pebbles, mud, metal shavings) exceeding 7 mm in length, with reasonable efforts made to remove all inedible materials.

8.02 Low-acid Fruit Preserves and Low-acid Pickled Vegetables

The pH of each batch of finished low-acid fruit preserves and low-acid pickled vegetables shall be measured using a pH meter, or by any other method that gives equivalent results. A record of this measurement shall be created and maintained pursuant to Sec. 3.10 [Recordkeeping]. When not in use, the probe of the pH meter should be stored in a buffer solution to prolong its use.