

PROPOSED ORDER
OF THE WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION
ADOPTING RULES

The Wisconsin department of agriculture, trade and consumer protection hereby proposes the following rule *to repeal and recreate* ATCP 70 *relating to* food processing plants, and affecting small business.

**Analysis Prepared by the Department
of Agriculture, Trade and Consumer Protection**

This rule repeals and recreates ATCP 70, “Food Processing Plants.” This rule is necessary to update Wisconsin’s food processing standards and incorporate new federal requirements designed to improve the nation’s food safety system, to update and coordinate references to food processing in retail food establishments (as well as deal with products not currently being inspected in state and federal meat establishments), to address vending machine and micro-market commissaries, and to modernize and clarify Wisconsin’s standards for food processing.

Statutes Interpreted

Statutes Interpreted: ss. 97.20, Stats., “Dairy Plants;” 97.29, Stats., “Food processing plants;” 97.30, Stats., “Retail food establishments;” 97.34, Stats., “Bottled drinking water and soda water beverage; standards; sampling and analysis;” 97.42, Stats., “Compulsory Inspection of livestock or poultry, and meat or poultry products;” 97.605, “Lodging and vending licenses,” and 97.61, Stats., “Vending machine commissary outside the state.”

Statutory Authority

Statutory Authority: ss. 93.07 (1), 97.09 (4), 97.20 (4), 97.29 (5), Stats.

Explanation of Statutory Authority

The Wisconsin Department of Agriculture, Trade and Consumer Protection (“DATCP”) has broad general authority, under s. 93.07 (1), Stats., to adopt rules to implement programs under its jurisdiction. DATCP also has general authority under s. 97.09 (4), Stats., to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. DATCP has specific authority, under s. 97.29 (5) to adopt rules establishing fees, setting facility construction and maintenance standards, setting standards for the design, installation, maintenance, and cleaning of equipment and utensils, personnel sanitation, food handling and storage, sanitary production and processing of food, food sources, and labels.

Related Statutes and Rules

With DATCP’s Division of Food Safety merger with the Department of Health Services’ (DHS’) Food Safety and Recreational Licensing (“FSRL”) Section to form the new Division of Food and Recreational Safety (“DFRS”), DATCP’s authority, pursuant to ch. 97, Stats., currently includes responsibilities for the

related administrative rules covering all retail food establishments, including restaurants, dairy plants, warehouses, and meat and poultry processing.

Plain Language Analysis

DATCP has updated ATCP 70 with the incorporation by reference of provisions of Federal regulations that implement the requirements of the federal Food Safety Modernization Act (FSMA). This involves multiple subparts of the recently created 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, formerly 21 CFR 110, *Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding, Human Food*, pertaining to preventive food safety systems that have already been referenced in chs. ATCP 65 (Milk and Milk Products) and ATCP 71 (Food Warehouses and Milk Distributors). Since the majority of Wisconsin food facilities, already subject to this federal rule, are licensed as food processing plants, this proposed rule includes similar referencing for the sake of consistency. This revision also ensures that the requirements for Wisconsin-licensed food processing plants, not subject to the federal rule, are clearly articulated.

With DATCP's Division of Food Safety merger with DHS' FSRL to form the new Division of Food and Recreational Safety ("DFRS"), a merger of the two food safety regulatory systems became necessary. A major change involving food processing plants is the fact that restaurant operators were not allowed to wholesale food under DHS regulation, while retail food establishment operators, under DATCP's authority, could engage in a limited amount of wholesaling. At present, restaurant operators are now licensed as retail food establishments and therefore now enjoyed a limited ability to wholesale food. The new ATCP 70 clarifies both the exemption from the requirement to hold a food processing plant license as well as the requirements for food processing and subsequent wholesaling now allowed in licensed retail food establishments. The new ATCP 70 also incorporates, for the first time, specific definitions for wholesaling and retailing concomitantly being incorporated into ATCP 75 (Retail Food Establishments) and ATCP 55 (Meat and Meat Food Products). DATCP expects these updates to promote clarity, uniformity, and improved guidance to food businesses in Wisconsin.

In addition, the new ATCP 70 contains language designed to specifically clarify the responsibilities for operators of retail food establishments. Besides the afore-mentioned exemption from the requirement of holding a food processing plant license, operators will better understand their duty to follow the safety, processing, and labeling requirements in ATCP 70 for the production of food for wholesaling. These provisions not only level the playing field for industry, but, more importantly, also ensure that certain ATCP 70 requirements are in place to ensure food safety. Examples of such requirements include provisions for a written recall plan and a written food safety plan for facilities subject to FSMA rules. In revising this rule, DATCP sought to eliminate duplication, improve regulatory transparency, and, to the extent possible, ensure that food businesses are not required to hold multiple licenses, except when completely necessary. In doing so, DATCP never relinquishes its public health mission or compromises its directive to ensure that food is produced safely and pursuant to some responsible form of inspection. In some cases, such as meat establishments that produce some products under a state license or a federal grant of inspection and other products separate from that inspection, businesses will be allowed to obtain a retail food establishment license from the state or local agency with jurisdiction in that area, in addition to the state meat establishment license or federal grant of meat inspection. This ensures that those businesses will be allowed to sell product at retail that was not produced under either the federal or state meat inspection programs because those programs are not allowed to inspect and regulate retail operations.

Another substantive change is to end the licensing of food processing plants that are located in homes after the date this rule becomes effective. It should be noted that food processing plants currently located in residences will not be able to expand their facilities after the effective date of this rule. This rule also

requires that food processing plants that are currently located in residential or commercial buildings must have a door that opens to the outside or into a community space.

Further, the rule adopts the Model Ordinance for Molluscan Shellfish, now *Marine Shellfish*, which replaces all of s. ATCP 70.21, except the section on illnesses and outbreaks associated with shellfish. This modification will keep the state's regulations current with the national rules on shellfish processing and marketing.

Other clarifications, changes, and additions are as follow:

- This rule addresses requirements for vending machines, micro-markets, and the commissaries for both of these entities, as well as in the new ch. ATCP 75, and the Appendix to ATCP 75, *The Wisconsin Food Code*, to ensure consistency and clarity in requirements for both the food processing part of the operation and the retail food business.
- This rule clarifies extended runs and waivers allowing those runs, while clarifying and expanding the list of food processing activities during which daily cleaning and sanitizing are not required.
- This rule clarifies that filing and obtaining process-authority approval for processes used in the making of acidified or low acid canned foods is mandatory.
- This rule expands the ability of food processing plants to obtain waivers or variances from DATCP for non-standardized and innovative processing and procedural activities. Prior to this revision, these waivers and variances could only be obtained by food processing plants for structural and equipment issues.
- This rule updates and clarifies the language dealing with the standards and testing of operations water and ingredient water used in the various bottling and processing operations in Wisconsin, and finished product sampling and analysis for bottling establishments.
- This new rule also expands the scope of the bottling rules to cover more than just bottled water and soda to match the expansion of this rapidly changing and innovative segment of the bottling industry.
- This rule generally updates and clarifies definitions, licensing requirements and exemptions, as well as exempt wholesaling requirements and limitations, to keep pace with industry and regulatory needs.
- This rule removes the lower sales limit of \$25,000 on persons who must pay the canning surcharge to reflect the very real need for DATCP's staff to provide extensive information, consultation, and service to persons manufacturing canned foods.
- This rule will be consistent with the Retail Food Establishment and Meat and Meat Food Products rules to ensure consistency throughout food processing businesses of all types and a regulatory presence for all foods, regardless of where they are produced. This is in keeping with the scope of ch. 97, Stats., requiring the Department to regulate food safety wherever that food is produced, stored, or offered for sale.
- The proposed rule protects the consistent quality of the Wisconsin "brand" by removing many of the long-expired "Grandfather Clause" dates in the existing rule and replacing them with language about gaining compliance for structural standards in existing buildings and updating the expectations for structural standards in new plants. Most significantly, the proposed rule promotes consistent food safety by not allowing a food processing plant in a residence to be licensed after the effective date of this rule.

Federal and Surrounding State Programs

Federal Programs

A major objective was to include the updated language in 21 CFR 117 which replaced 21 CFR 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding for Human Food, and is the

cornerstone of the regulations implementing FSMA. ATCP 70.04 was specifically inserted to address this issue, and definitions for “facility” and “qualified facility” were also inserted to facilitate the department’s implementation of those federal requirements.

Current language on the molluscan shellfish program was deleted in order to adopt the Federal Model Ordinance, in order to provide that segment of the Wisconsin food industry regulatory consistency within interstate commerce.

Surrounding State Programs

Michigan, Iowa, Minnesota license and regulate food processing facilities within their borders as does Wisconsin. Illinois food processors are regulated only by the FDA. Wisconsin, Illinois, and Michigan also have state programs for the National Shellfish Sanitation Program which allows them to receive, process, and ship shellfish interstate.

Data and Analytical Methodologies

In order to identify potential changes to the rule, DATCP reviewed recent changes in FDA regulations and guidelines such as the rules implementing FSMA; Wisconsin statutes and rules for food processing plants, retail food establishments, meat establishments, and dairy plants; and current industrial practices.

Material Incorporated by Reference

21 CFR 117, Current Good Manufacturing Practice, Hazard Analysis and Risk based Preventive Controls for Human Food.

21 CFR 108, Emergency Permit Control (Canning Process Filing Requirements).

21 CFR 113, Thermally Processed Low-acid foods packaged in hermetically sealed containers (Canning).

21 CFR 114, Acidified Foods (Canning).

21 CFR 120, Hazard Analysis and Critical Control Point (HACCP) Systems (Juice HACCP).

21 CFR 123, Fish and Fishery Products (Seafood HACCP).

National Shellfish Sanitation Program – Guide for the Control of Molluscan Shellfish, Model Ordinance.

Effect on Small Business

The businesses affected by this rule run the gamut from very small to very large operations. The businesses range from one- and two-person popcorn wholesalers to multi-national corporations that are on the cutting edge of food science. The Department’s challenge is to write and then enforce applicable and consistent requirements that do not penalize either end of this range of business types.

If the proposed rule is adopted, some small food processing plants may incur immediate costs to meet the requirement to have a door that opens to the outside rather than to a residential vestibule. There is also a potential cost for a small number of businesses that have not upgraded their facilities since the “grandfather clauses” were put in place over thirty years ago. They will now need to upgrade warewashing and handwashing sinks or provide a non-residential restroom for the facility. Another cost that may be incurred

by a few very small businesses is the \$320 canning surcharge, which currently is not assessed for food processing plants manufacturing and selling less than \$25,000 of food per year. The Department's Manufactured Food Specialists spend a disproportionate amount of time working with very small canning businesses, and this surcharge recoups these costs. The service provided by the Department is comparable to that of consultants who are not economically available to operations in the <\$25,000/year category.

Much of the focus of the proposed rule revision is on clarification and the updating of existing regulations such as the various exemptions from a food processing plant license, and the clarification of the various record-keeping requirements.

A positive impact of this rule revision on all classes of business is the expanded ability of food processing plants to apply for processing or procedural waivers. This will potentially allow the use of new and innovative techniques and processes so long as the processor can demonstrate that food safety is not compromised.

No economic impact comments were received during the August 8 – September 7, 2017 comment period. However, meat establishments that produce some products under a state license or a federal grant of inspection, as well as other products separate from that inspection, may be required to hold a retail food establishment license from the state or local agency with jurisdiction in that area in addition to holding the state meat establishment license or federal grant of meat inspection. Allowing these meat establishments to also hold a retail food establishment license will make it possible for them to retail the unique meat and poultry products that the state is known for since those products will now be produced under inspection. This additional oversight more closely meets consumer expectations and provides a level playing field between these establishments and other, non-meat inspection establishments that produce the same types of meat and poultry products for sale at retail. These other non-meat inspection establishments have always been subject to licensing and regulation by the state or local food inspection system.

DATCP Contact

Questions and comments (including hearing comments) related to this rule may be directed to:

Peter Haase, Director
Bureau of Food and Recreational Businesses
Department of Agriculture, Trade and Consumer Protection
P.O. Box 8911
Madison, WI 53708-8911
Telephone: (608) 224-4711
E-Mail: Peter.Haase@Wisconsin.gov

Rule comments will be accepted up to two weeks after the last public hearing is held on this rule. Hearing dates will be scheduled after this rule is approved by the Board of Agriculture, Trade and Consumer Protection.

SECTION 1. ATCP 74 is repealed and recreated to read:

Chapter ATCP 70 FOOD PROCESSING PLANTS

Subchapter I. Scope and Definitions

ATCP 70.01	Scope.
ATCP 70.02	Definitions

ATCP 70.04 Federal Requirements.

Subchapter II. General Requirements

ATCP 70.06 Food processing plants; licensing; fees.

ATCP 70.08 Construction and maintenance.

ATCP 70.10 Personnel standards.

ATCP 70.12 Equipment and utensils.

ATCP 70.14 Cleaning and Sanitizing Equipment and Utensils: General

ATCP 70.16 Cleaning and Sanitizing Equipment: Exemptions

ATCP 70.18 Obtaining Approval of Alternative Cleaning and Sanitizing Frequency

ATCP 70.20 Water supply.

ATCP 70.22 Food ingredients.

ATCP 70.24 Food handling and storage.

ATCP 70.26 Food packaging and labeling.

ATCP 70.28 Sanitizers and sanitizing methods.

ATCP 70.30 Ready-to-eat foods; reporting pathogens and toxins.

ATCP 70.32 Recall plan.

Subchapter III. Canning Operations; Supplementary Requirements

ATCP 70.34 General.

ATCP 70.36 Low-acid foods packaged in hermetically sealed containers.

ATCP 70.38 Acidified foods.

ATCP 70.40 Facilities and equipment; cleaning.

ATCP 70.42 Handling raw agricultural commodities and by-products.

Subchapter IV. Fish Processing Plants; Marine Shellfish Plants; Supplementary Requirements.

ATCP 70.44 Fish processing.

ATCP 70.46 Labeling and sale of smoked fish.

ATCP 70.48 Fish roe.

ATCP 70.50 Marine molluscan shellfish processing.

Subchapter V. Bottling Establishments; Supplementary Requirements

ATCP 70.52 Bottling establishments; general.

ATCP 70.54 Returnable and single-service bottles.

ATCP 70.56 Bottled Water Product sampling; recordkeeping; reports.

ATCP 70.58 Labeling bottled products.

Subchapter VI. Juice and Juice HACCP

ATCP 70.60 Juice HACCP

Subchapter VII. Effect of Rules on Local Ordinances

ATCP 70.62 Effect of rules on local ordinances.

Subchapter VIII. Variances

ATCP 70.64 Variances

Note: Chapter Ag 40 as it existed on October 31, 1989, was repealed and a new chapter Ag 40 was created effective November 1, 1989; Chapter Ag 40 was renumbered ch. ATCP 70 under s. 13.93 (2m) (b) 1., Stats., Register, April, 1993, No. 448.

Subchapter I. Scope and Definitions

ATCP 70.01 Scope. This chapter applies to all food processing plants as defined in s. ATCP 70.02 (23), regardless of whether the food processing plant is subject to licensing under s. 97.29, Stats., or this chapter, and all retail food establishments, as defined in s. 97.30 (1) (c), Stats., performing food processing operations, as defined in ATCP 70.02 (22).

ATCP 70.02 Definitions. As used in this chapter:

- (1) "Alcohol beverage" means an alcohol beverage as defined in s. 125.02 (1), Stats.
- (2) "Approved sanitizer" means a substance or compound approved by the department for the sanitizing of equipment or utensils under s. ATCP 70.28 (4).
- (3) "Bakery" means any place where bread, cookies, crackers, pasta, or pies, or any other food product for which flour or ground meal is the principal ingredient, are baked, cooked, or dried, or prepared or mixed for baking, cooking, or drying, for sale as food.
- (4) "Bottle" means the immediate package or container in which bottled drinking water, soda water beverage, or alcohol beverage is sold or distributed for consumption. "Bottle" includes a bottle cap or other seal for a bottle.
- (5) "Bottled drinking water" means all water packaged in bottles or similar containers and sold or distributed for drinking purposes. "Bottled drinking water" includes distilled water, artesian water, spring water, and mineral water, whether carbonated or uncarbonated.
- (6) "Bottling establishment" means any place where drinking water, soda water beverage, or alcohol beverage is manufactured or bottled for sale. "Bottling establishment" does not include a retail establishment engaged in the preparation and sale of beverages under a license issued under s. 125.26 or 125.51, Stats., a retail food establishment under a license issued under s. 97.30, Stats., or other license issued under s. 97.605, Stats.
- (7) "C-I-P system" means equipment which is designed, constructed, and installed to be cleaned in place by the internal circulation of cleaning and sanitizing solutions onto product contact surfaces. "C-I-P System" includes separate equipment used to store or deliver cleaning and sanitizing solutions to the food contact surfaces.
- (8) "Canning" means the preservation and packaging in hermetically sealed containers of low-acid or acidified foods.
- (9) "Cold-process smoked fish" or "cold-process smoke flavored fish" means fish which is treated with smoke or smoke flavoring to give it a smoked flavor, but which is not fully cooked or heat treated to

coagulate protein in fish loin muscle. "Cold- process smoked fish" or "cold-process smoke flavored fish", and may not be heated above 90° F. during processing because the safety of the treatment is partially dependent on the survival of harmless microorganisms indigenous to the fish.

(10) "Confectionary" means any place where candy, fruit, nut meats, or any other food product is manufactured, coated, or filled with saccharine substances for sale as food.

(11) "Continuous operation" means operating without interruption beyond 24 hours, with no interruptions after 24 hours longer than a period approved by the department.

(12) "Critical control point" means a point in food processing at which a failure to monitor a food safety parameter such as pH, temperature, time, or water activity (a_w), or a failure to control any food safety parameter within critical limits or according to specific criteria, may result in the unacceptable risk of a potentially adverse impact on human health.

(13) "Department" means the state of Wisconsin department of agriculture, trade and consumer protection.

(14) "Equipment" means an implement, vessel, machine, or apparatus, other than a utensil, which has one or more food contact surfaces and is used in the handling or processing of food at a food processing plant. "Equipment" includes C-I-P systems.

(15) "Facility" as used in s. 70.04 of this rule has the meaning given in 21 CFR 117.3.

(16) "Fish" means fresh or saltwater finfish; crustaceans; forms of aquatic life other than birds or mammals including but not limited to, alligators, frogs, aquatic turtles, jellyfish, sea cucumber, and sea urchin, and their roe, and all mollusks, if intended for human consumption.

(17) "Fish processing plant" means a food processing plant which produces processed fish or fish products.

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

(19) "Food" means:

- (a) Articles ingested as food or drink by persons.
- (b) Chewing gum.
- (c) Components of articles specified in pars. (a) and (b).

(20) "Food contact surface" means any surface of equipment, utensils, or food packages with which food normally comes in direct contact, or from which materials may drain, drip, or otherwise be drawn into or onto food.

(21) "Food package" means the immediate container in which food is sold or shipped from a food processing plant. "Food package" includes a bulk container or shipping container which has one or more food contact surfaces.

(22) "Food processing" means the manufacture or preparation of food for sale through the process of canning, extracting, fermenting, distilling, pickling, freezing, baking, drying, smoking, grinding, cutting, mixing, coating, stuffing, packing, bottling or packaging, or through any other treatment or preservation process. 0163 "Food processing" includes the activities of a bakery, confectionary, vending machine commissary licensed under s. 97.605, Stats., or bottling establishment, and also includes the receipt and

salvaging of distressed food for sale or use as food. It also includes the packaging of seeds that have been harvested, and dried after the harvest for sale as food. These seeds include, but are not limited to unpopped popcorn whether shelled or on the cob, black beans, wild rice, sunflower seeds, pumpkin seeds, and soybeans. "Food processing" does not include any of the following:

- (a) Activities performed under a dairy plant license issued under s. 97.20, Stats.
- (b) Activities performed under a meat or poultry establishment license issued under s. 97.42, Stats.
- (c) The retail preparation and processing of meals for sale directly to consumers or through vending machines if the preparation and processing is covered under a restaurant permit or other license issued under s. 97.605, Stats.
- (d) Activities inspected by the United States department of agriculture under 21 USC 601 et seq. or 21 USC 451 et seq.
- (e) The extraction of honey from the comb, or the production and sale of raw honey or raw bee products by a beekeeper from their own apiaries.
- (f) The washing and packaging of fresh fruits and vegetables if the fruits and vegetables are not otherwise processed at the packaging establishment.
- (g) The receipt and salvaging of distressed food for sale or use as food if the food is received, salvaged, and used solely by a charitable organization, and if contributions to the charitable organization are deductible by corporations in computing net income under s. 71.26 (2) (a), Stats.
- (h) The collection, packing, and storage of eggs from a flock of not more than 150 laying birds by an egg producer who only sells the eggs directly to consumers at the premises where the eggs were laid, at a farmers' market, or on an egg-sales route as defined in s. ATCP 88.01.
- (i) The collection, packaging, and storage of nest-run eggs, as defined in s. ATCP 88.01, from a flock of laying birds by an egg producer who is registered with the department in accordance with s. ATCP 88.02 and who sells the nest-run eggs to an egg handler.
- (j) Seeds that have not been harvested until they have dried naturally in the field and are only handled by harvesting, storing, and packaging for sale as food.

(23) "Food processing plant" means any place where food processing is conducted. "Food processing plant" does not include any personal residence or building used as a personal domicile, mobile establishment, establishment subject to the requirements of s. 97.30, Stats., or any restaurant or other establishment holding a license under s. 97.605, Stats., to the extent that the activities of that establishment are covered by s. 97.30, Stats., or the license under s. 97.605, Stats.

(24) "Hazard analysis and critical control point plan" or "HACCP plan" means a food processing plan under which a food processing plant operator effectively identifies, and prevents, controls, or eliminates food safety hazards by monitoring food safety parameters at critical control points, and by controlling those parameters within critical limits.

(25) "Hot-process smoked fish" or "hot-process smoke flavored fish" means fish that is all of the following:

(a) Fully cooked or heat treated, or sold or represented as being fully cooked or heat treated, so that the internal temperature of the fish is maintained for at least 30 minutes at not less than 145° F (62.8° C.) or an equivalent process validated for lethality against pathogenic organisms.

(b) Treated with smoke or smoke flavoring to give it a smoked flavor.

(26) "Ingredient water" means water used by a food processing plant as an ingredient for food.

(27) "Juice" means aqueous liquids expressed or extracted from fruits or vegetables, purées of the edible portions of fruits or vegetables, or combinations or concentrates of those liquids or purées, which are used as whole beverages or beverage ingredients.

(28) "Loin muscle" means the longitudinal quarter of the great lateral muscle of a fish, freed from skin, scales, visible blood clots, bones, gills, and viscera, and from the non-striated part of such muscle, which part is known anatomically as the median superficial muscle.

(29) "Major food allergen" includes any food or food ingredient, other than highly refined oil or an ingredient derived from highly refined oil, which contains protein derived from milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, or soybeans. "Major food allergen" does not include a food that is exempted by the secretary of the United States department of health and human services pursuant to 21 USC 321(qq)(2).

(30) "Official Methods of Analysis" means the *Official Methods of AOAC International*, eighteenth edition revision 2 (2007).

Note: Those portions of the "Official Methods of Analysis" cited in this chapter are on file with the department and the legislative reference bureau. The Official Methods of Analysis of AOAC International may be obtained from the AOAC International, 2275 Research Blvd., Rockville, MD 20850.

(31) "Operations water" means water which is used by a food processing plant for cleaning equipment and utensils, handwashing, or other cleaning or sanitizing purposes.

(32) "Organoleptic quality" means quality as assessed by means of sight, smell, touch, or taste.

(33) "Potentially hazardous food" also means "TCS (time/temperature controlled for safety) Food", and has the meaning given in ch. ATCP 75 Appendix (Wisconsin Food Code), section 1-201.10 (B).

(34) "Processed fish" means fish that is preserved for human consumption by means of hot or cold smoking, curing, salting, drying, marinating, pickling, fermenting, or related processes. "Processed fish" does not include fish processed in accordance with s. ATCP 70.30 or 70.32.

(35) "Qualified facility" has the meaning given in 21 CFR 117.3.

(36) "Ready-to-eat food" has the meaning given in ch. ATCP 75 Appendix (Wisconsin Food Code), section 1-201.10(B).

(37) "Reduced oxygen packaging" has the meaning given in ch. ATCP 75 Appendix (Wisconsin Food Code), section 1-201.10 (B).

(38) "Retail" means the sale of food or food products to any consumer who will not re-sell it, but will consume it or provide it for consumption by his/her immediate family, or non-paying guests.

(39) "Roe" means fish eggs, including fish eggs that are still enclosed in the ovarian membrane.

(40) "Safe temperatures" for the holding or storage of potentially hazardous foods means one of the following as appropriate:

- (a) Temperatures at or above 135° F. (57° C.) for heated foods.
- (b) Temperatures at or below 41°F. (5°C.) for refrigerated foods, except as provided in par. (c).
- (c) Temperatures at or below 38°F. (3.4°C.) for refrigerated, raw fish, cold smoked fish, or raw fish products that are vacuum packed, and have only refrigeration as a critical control point.
- (d) Temperatures that maintain frozen food in a constantly frozen condition.

(41) "Salt content" or "salt in the water phase," means the percent salt (sodium chloride) as determined by the method described in sections 18.034 and 18.035 of the *Official Methods of Analysis*, multiplied by 100 and divided by the sum of the percent salt (sodium chloride) and the percent moisture in the finished product as determined by the method described in section 24.002 of the *Official Methods of Analysis*.

(42) "Sanitize" means the application of cumulative heat or chemicals that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction of representative disease-causing microorganisms of public health importance on a food contact surface that has been previously cleaned of all soil, residue, and visible contaminants.

(43) "Single service article" means any utensil or food package, or any part of a utensil or food package, which is designed to be used only once prior to disposal.

(44) "Smoked fish" means any food obtained by subjecting fresh fish, frozen fish, dried fish, or cured fish to the direct action of smoke or smoke flavor, whether by burning wood or a similar burning material, or by applying a smoke-flavored solution, for the primary purpose of imparting the flavor and color of smoke to fish. This includes both cold-process smoked and hot-process smoked fish, and is considered "fish processing".

(45) "Soda water beverage" means all beverages commonly known as soft drinks or soda water, whether carbonated, uncarbonated, sweetened, or flavored. "Soda water beverage" does not include alcohol beverages.

(46) "Utensil" means a hand-held or similarly portable container or device, such as a set of tongs, spatula, strainer, or scoop, which has one or more food contact surfaces and is used in the processing or handling of food at a food processing plant. "Utensil" does not include a food package.

(47) "Wholesale" means the sale of any food to a person or commercial entity who will either re-sell it or use it as an ingredient in a product that will be then offered for sale. "Wholesale" also means the transfer of food from the point of production to another location for sale during which control of the food is relinquished.

ATCP 70.04 Federal requirements. (1) QUALIFIED FACILITIES. A food processing plant which is also a qualified facility shall comply with the requirements of this chapter and applicable requirements of 21 CFR 117.

(2) FACILITIES. A food processing plant that is a facility, but is not a qualified facility, shall meet the requirements of this chapter and applicable requirements of 21 CFR 117.

Subchapter II. General Requirements

ATCP 70.06 Food processing plants; licensing; fees. (1) LICENSE REQUIRED. Except as provided under sub. (11), no person may operate a food processing plant without a valid license issued by the

department for that food processing plant under s. 97.29, Stats. A food processing plant license expires on March 31 annually. A license is not transferable between persons or food processing plants.

(2) LICENSE APPLICATION. Application for an annual food processing plant license shall be made on a form provided by the department. The application shall include applicable fees required under this section.

(3) ANNUAL LICENSE FEE. An applicant for a food processing plant license shall pay an annual license fee. Except as provided in sub. (4), the fee amount is as follows:

(a) For a food processing plant that has an annual production of at least \$25,000 but less than \$250,000, and is engaged in processing potentially hazardous food or in canning, an annual license fee of \$400.

(b) For a food processing plant that has an annual production of at least \$250,000, and is engaged in processing potentially hazardous food or in canning, an annual license fee of \$835.

(c) For a food processing plant that has an annual production of at least \$25,000 but less than \$250,000, and is not engaged in processing potentially hazardous food or in canning, an annual license fee of \$160.

(d) For a food processing plant that has an annual production of at least \$250,000, and is not engaged in processing potentially hazardous food or in canning, an annual license fee of \$520.

(e) For a food processing plant that has an annual production of less than \$25,000, an annual license fee of \$95.

(4) CANNING OPERATIONS; LICENSE FEE SURCHARGE. If a food processing plant is engaged in canning operations the operator shall pay an annual license fee surcharge of \$320, which shall be added to the license fee under sub. (3).

Note: The treatment of subs. (2m) and (2n) first applies to applications for new licenses that are filed on or after February 1, 1998 and to renewals of food processing plant licenses which expire on March 31, 1998.

(5) SURCHARGE FOR OPERATING WITHOUT A LICENSE. An applicant for a license under sub. (1) shall pay a license fee surcharge of \$100 if the department determines that, within one year prior to submitting the license application, the applicant operated the food processing plant without a license in violation of sub. (1). Payment of this license fee surcharge does not relieve the applicant of any other civil or criminal liability which results from the unlicensed operation of the food processing plant, but does not constitute evidence of a violation of any law.

(6) REINSPECTION FEE. (a) If the department reinspects a food processing plant because the department has found a violation of ch. 97, Stats., or this chapter, on a regularly scheduled inspection, the department shall charge the food processing plant operator the reinspection fee specified under par. (b). A reinspection fee is payable when the reinspection is completed, and is due upon written demand from the department. The department may issue a demand for payment when it issues a license renewal application form to a food processing plant operator.

(b) The reinspection fee required under par. (a) is as follows:

1. For a food processing plant that has an annual production of less than \$250,000, and is engaged in processing potentially hazardous food or in canning, the reinspection fee is \$255.

2. For a food processing plant that has an annual production of at least \$250,000, and is engaged in processing potentially hazardous food or in canning, the reinspection fee is \$525.
3. For a food processing plant that has an annual production of less than \$250,000, and is not engaged in processing potentially hazardous food or in canning, the reinspection fee is \$150.
4. For a food processing plant that has an annual production of \$250,000 or more, and is not engaged in processing potentially hazardous food or in canning, the reinspection fee is \$490.
5. For a food processing plant that has an annual production of less than \$25,000, the reinspection fee is \$60.

(7) ACTION ON LICENSE APPLICATION. The department shall grant or deny a license application within 30 business days after the department receives a complete application. If the department denies the license application, the department shall notify the applicant, in writing, of the reasons for the denial. Except as provided under sub. (9), the department may conditionally grant a license application by issuing a temporary license under sub. (8).

(8) TEMPORARY LICENSE. (a) The department may issue a temporary license, for a period not to exceed 30 business days, pending final action on an application for an annual food processing plant license. The department shall grant or deny the annual license application before the temporary license expires. If the department denies an annual license application before the applicant's temporary license expires, the temporary license is automatically terminated when the applicant receives written notice of the denial.

(b) The holder of a temporary license may not procure raw agricultural products as defined in s. 97.01 (14), Stats., from producers, except as specifically authorized by the department in writing. The department may not authorize a food processing plant operator to procure farm products from producers unless the food processing plant operator complies with subch. VI of ch. 126, Stats.

(c) The holder of a temporary license acquires no license rights beyond those conferred by the temporary license. A temporary license may not be issued in response to a renewal application by the holder of an existing license.

(9) PRE-LICENSE INSPECTION. The department may inspect a food processing plant, as the department deems necessary, before issuing a license for the food processing plant. The department may not issue a license or temporary license for a new food processing plant until the department inspects the new food processing plant for compliance with this chapter. A previously licensed food processing plant may not be considered a new food processing plant under this subsection solely because of a change of ownership.

(10) DENIAL, SUSPENSION, OR REVOCATION OF LICENSE; CONDITIONAL LICENSE. The department may deny, suspend, or revoke a license, or impose conditions on a license as provided under s. 93.06 (7) and (8), Stats. Except as otherwise provided by statute or rule, the suspension or revocation of a license shall comply with the prior notice requirements of s. 227.51, Stats.

(11) LICENSE EXEMPTIONS. A food processing plant license is not required under s. 97.29, Stats., or this section for:

(a) A retail food establishment which is engaged in food processing if all of the following apply:

1. The retail food establishment is licensed by the department under s. 97.30, Stats., or by an agent as defined in s. ATCP 74, under ss. 97.30 and 97.41, Stats.

2. Wholesale receipts from food processing operations at the retail food establishment comprise no more than 25% of gross annual food sales from the retail food establishment. If a licensed retail food establishment is also licensed as a dairy plant under s. 97.20, Stats., or as a meat establishment under s. 97.42, Stats., sales of dairy or meat products processed at the establishment shall be excluded from the calculation of food sales receipts under this subdivision.

3. The retail food establishment is not engaged in canning of food products, does not engage in juice processing subject to requirements of 21 CFR 120, does not engage in any fish or fishery products processing subject to requirements of 21 CFR 123, does not process smoked fish, and does not manufacture and bottle a beverage containing alcohol in excess of 2% if the product is liquid or 0.5% as an ingredient.

(b) A license holder under s. 97.605, Stats., operating a retail food establishment serving meals, if all of the following apply:

1. The retail food establishment does not process food for wholesale distribution in excess of 25% of total food sales, is not engaged in canning of food products, does not engage in juice processing subject to requirements of 21 CFR 120, does not engage in any fish or fishery products processing subject to requirements of 21 CFR 123, and does not manufacture or bottle beverages containing alcohol in excess of 2% if the product is liquid or 0.5% as an ingredient for sale to anyone other than the ultimate consumer, except for beer brewed and sold under the provisions in s. 125.295, Stats..

2. The retail food establishment is licensed and exempt from licensing as a food processing plant under par. (a).

(c) Food processing operations conducted at a dairy plant licensed under s. 97.20, Stats., if both of the following apply:

1. Receipts from non-dairy food processing operations at that location comprise no more than 25% of gross annual dairy and non-dairy food sales from that location.

2. The dairy plant is not engaged in canning foods other than dairy products, or the processing of fish.

(d) Food processing operations conducted at a meat establishment, by the operator of the meat establishment, if all of the following apply:

1. The meat establishment is licensed under s. 97.42, Stats., or inspected under 21 USC 601 et seq. or 21 USC 451 et seq.

2. The meat establishment is licensed as a retail food establishment under s. 97.30, Stats., and not engaged in the canning of food products other than meat or poultry products canned under s. 97.42, Stats., or the production of cold-smoked fish or fishery products.

(e) The processing of maple sap to produce maple syrup or concentrated maple sap if all of the following apply:

1. The processor sells the maple syrup or concentrated maple sap only to other processors for further processing.

2. The processor's combined gross receipts from all sales under subd. 1. during the license year total less than \$5,000.

3. The processor keeps a written record of every sale under subd. 1., retains that record for at least 2 years, and makes the record available for inspection and copying by the department upon request. The

record shall include the name and address of the purchasing processor, the date of sale, the amount of maple syrup or concentrated maple sap sold, and the sale price.

4. The processor registers with the department before engaging in any processing activities under this paragraph in any license year ending March 31. A registration expires at the end of the license year. A processor shall register in writing on a form provided by the department, or shall register online at <http://datcp.wi.gov>. The registration shall include information reasonably required by the department, including the registrant's name and address and information related to the nature, location, and scope of the registrant's processing activities and product sales. There is no fee to register, and the registrant is not required to hold a registration certificate from the department.

Note: A registration form under subd. 4. may be obtained by contacting the department at the following address:

Department of Agriculture, Trade and Consumer Protection
Division of Food and Recreational Safety
P.O. Box 8911
Madison, WI 53708

(f) A licensed food warehouse under s. 97.27, Stats., at which one or more of the following activities are the only food processing activities performed:

1. Reshipping marine molluscan shellfish, provided that the licensed warehouse operator holds a licensee dealer certification as required by FDA's *Guide for the Control of Molluscan Shellfish, The Model Ordinance*, that annual inventory value of molluscan shellfish repacked at the licensed warehouse does not exceed 25% of the gross annual inventory value of the food warehouse, and the licensed food warehouse meets all of the applicable requirements of s. ATCP 70.21.

2. Packing food items that are already packaged and labeled for retail sale into containers for further distribution.

3. Combining two or more food items that are already individually packaged and labeled for retail sale into a combination package for retail sale, if the label on each individual item inside the combination package remains visible or if the package of combined items is labeled for retail sale. All packaging and labels shall comply with s. ATCP 70.24.

4. Manufacturing ice for use in the shipment of foods, or to cool or keep foods cold while in transit or stored in the warehouse. Ice used for this purpose must meet the standards in s. ATCP 70.20 (8). Ice must be made on site in a commercial ice machine and may not be bagged, distributed or sold separately from food items that it is used to cool.

(g) Exemption from a food processing plant license under this section does not exempt retail food establishments, whether serving or not serving meals, but also performing activities normally licensed under this chapter, from the requirements of this chapter except for holding the license.

(12) RECORD REQUIREMENTS AND RETENTION. (a) If a food processing plant is deemed a facility, under 21 CFR 117, the operator shall create and retain all records to meet the requirements for records in 21 CFR 117.305, unless otherwise specified in this chapter or in 21 CFR 120 or 21 CFR 123.

(b) All records generated under par. (a) shall be retained and made available to the department, in accordance with the provisions set forth in 21 CFR 117.315, unless otherwise specified in this chapter or in 21 CFR 120 or 21 CFR 123.

(13) GENERAL REQUIREMENTS. (a) Every food processing plant shall be operated, equipped, and maintained with regard to public health and safety.

(b) The operator shall maintain on site at the food processing plant, and make available to the department or its agent when requested, all applicable approvals, variances, waivers, plans, and licenses pertaining to the operation and maintenance of the plant.

ATCP 70.08 Construction and maintenance. (1) CONSTRUCTION AND MAINTENANCE; GENERAL. The operator shall soundly construct and maintain in a clean and sanitary condition all buildings, facilities, and equipment used in food processing operations. The interior and exterior portions of a food processing plant, and the premises on which the food processing plant is located, shall be kept free of unhealthful or unsanitary conditions, and shall be maintained in compliance with this chapter.

(2) FLOORS, WALLS, AND CEILINGS. (a) Food processing plants shall be constructed and maintained in order to prevent adulteration as defined in s. 97.02, Stats.

(b) Walls and ceilings in processing areas shall be light colored.

(c) Floors, walls, and ceilings in processing areas, toilet rooms, and areas used for the cleaning or storage of equipment or utensils shall be constructed of smooth, impervious, and easily cleanable materials.

1. This does not prohibit the use of easily cleanable anti-slip floors.

2. Floors, walls, and ceilings in a food processing plant shall be kept clean and in good repair.

(3) A licensed food processing plant that is not a strictly seasonal business, e.g., an orchard or a maple sap processing facility, and that has ceased to operate continuously for more than 30 days at any time after the effective date of this rule, or has been structurally remodeled or altered in a manner which results in structural changes to a processing area, or a plant that has added product lines or processes after the effective date of this rule, shall be subject to current licensed plant requirements including, but not limited to:

(a) The junctions of walls and floors in processing areas shall be coved to facilitate cleaning.

(b) Floors that are water flushed for cleaning, or on which water or fluid wastes are discharged, shall have an adequate number of floor drains and be adequately sloped to ensure proper drainage to the floor drains.

(c) An adequate number of service sinks or curbed floor drains shall be provided for use in the cleaning of mops or wet floor cleaning tools, and for the disposal of mop water or similar liquids.

(4) PROCESSING AREA SEPARATED. (a) Within a food processing plant, food processing areas shall be separated by partition or be located at an adequate distance from other operations which may contaminate unpackaged food, so that contamination is effectively precluded. No processing may be conducted in a room used as living or sleeping quarters. If a food processing area shares one or more walls with adjacent living or sleeping quarters, processing operations shall be separated from the adjacent living or sleeping quarters by a tight-fitting, self-closing door.

(b) If a retail establishment serving meals also engages in food processing, under the exemption in 70.06 (11) (a) or (b), that processing shall only be done in specifically designated areas and not in areas accessible to the public such as the retail area of a grocery store or the dining room of a restaurant.

(5) DOORS AND WINDOWS. (a) Doors, windows, skylights, transoms, and other openings to the outside shall be tight-fitting, and effectively screened or protected against the entry of rodents, insects, birds, and other animals. External doors, other than overhead doors in delivery areas, shall open outward and shall be self-closing. External doors shall be kept closed when not in use.

(b) A food processing plant issued a license, after the date this rule is effective, is required to have a direct exterior entrance or a direct entrance from a common space or hallway if the food processing plant is located within a shared, non-residential building.

(c) After the effective date of this rule, no license shall be granted to a new food processing plant that consists of designated space in a building or in a garage attached to a building that is otherwise used as a residence.

(d) Food processing plants currently located in spaces existing in residential buildings or the attached garages of residential buildings may not be expanded or rebuilt following the effective date of this rule.

(6) LIGHTING. (a) Lighting in every area of a food processing plant, whether natural or artificial, shall be sufficient for the purpose for which the area is used. Artificial lights in processing areas shall be equipped with protective shields or shatter resistant bulbs.

(b) There shall be not less than 20 foot candles (215 lux) of illumination on all processing surfaces. On surfaces used to inspect washed returnable food packages prior to repackaging, there shall be not less than 100 foot candles (1075 lux) of illumination.

(c) Except as provided in par. (b), the interior of a food processing plant shall be illuminated to the following levels measured 3 feet above the floor:

1. Not less than 20 foot candles (215 lux) in processing areas, equipment and utensil cleaning areas, handwashing areas, and toilet areas.

2. Not less than 10 foot candles (108 lux) in food storage areas.

(7) VENTILATION. There shall be adequate ventilation in all areas where food is processed, handled, or stored; in all areas where equipment or utensils are cleaned or sanitized, and in all dressing rooms, locker rooms, toilet rooms, employee break rooms, and garbage or rubbish storage areas. Ventilation shall be adequate to remove excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes. Ventilation systems shall be positioned so that exhaust air is not vented onto exposed food, or onto clean food packages, equipment, or utensils. Intake fans shall be equipped with filters that are readily removable for cleaning and replacement. Intake filters shall be capable of removing at least 85% of particulate matter that is 5 microns or larger in size, or greater than 6 MERV (maximum efficiency reporting value) rating. Exhaust fans, intake fans, ventilation ducts, and filters shall be kept clean and in good repair, and shall be screened or louvered to prevent contamination of food by dust, dirt, insects, or other contaminants. Systems used to ventilate any area of a food processing plant where exposed potentially hazardous food is handled shall be capable of maintaining positive pressures in that area.

(8) TOILET FACILITIES. (a) The licensee shall provide sanitary toilets meeting applicable state and local regulations in sufficient number to accommodate employees. The toilets shall be located in toilet rooms meeting the requirements of this section, for any facility constructed or licensed after the effective date of this rule. Toilet rooms and fixtures shall be easily cleanable, and shall be kept clean and in good repair. Non-contiguous toilet facilities, serving facilities licensed prior to the effective date of this rule, shall be conveniently adjacent and accessible to the facility, and meet all applicable state and local regulations for unattached or portable toilet rooms.

(b) No toilet room shall open directly into a food processing area.

(c) Handwashing facilities shall be located in or adjacent to every toilet room. Handwashing facilities serving toilet rooms shall include hot and cold running water, soap in a soap dispenser, and a sanitary single-service means of drying the hands. A sign directing employees to wash their hands shall be prominently posted in every toilet room used by employees. Handwashing facilities serving a toilet room shall comply with all of the following requirements if they are installed after the effective date of this rule, or if they are located in a food processing plant that is initially licensed or licensed to a new operator after the effective date of this rule:

1. The facility shall be served by hot and cold running water provided through a mixing valve or combination faucet, or by potable tempered water.

2. Faucets shall be of a type that is not hand-operated. If a self-closing, slow-closing, or metering faucet is used, that faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

(d) The faucets of a handwashing sink in a licensed, non-seasonal food processing plant that has ceased to operate continuously for more than 30 days at any time after the effective date of this rule, or located on a sink in an area that has been structurally remodeled or altered in a manner which results in structural changes to a processing area, or located in a plant that adds more complex food processing after the effective date of this rule, shall be subject to current licensed plant requirements including, but not limited to, the requirements in pars. (c) 1. and 2, (e) and (f).

(e) An easily cleanable covered trash receptacle and an adequate supply of toilet tissue shall always be available in every toilet room when processing plant employees are present.

(f) If the toilets and toilet rooms do not conform to the standards in this paragraph, they shall be brought into compliance through a conditional license or other progressive enforcement method.

(9) LOCKER AND LINEN FACILITIES. The licensee shall provide lockers or comparable facilities for employees to store clothing and other personal items. The locker facility shall not be in food processing or food storage areas, or in areas where food, packages, equipment, or utensils are cleaned or stored. Protective clothing worn during processing shall be stored in an orderly and sanitary manner. Soiled linen and clothing shall be kept in non-absorbent containers or laundry bags until removed for laundering. Soiled linen and clothing shall be removed as often as necessary to prevent unsanitary conditions.

(10) HANDWASHING FACILITIES FOR PROCESSING AREAS. (a) The licensee shall provide handwashing sinks, with available hot and cold running water, for use by all persons working in food processing areas. The sinks shall be conveniently located for use, and shall be kept in a clean and sanitary condition. A

supply of soap or detergent, and sanitary single-service means for drying hands shall be kept available at the sink. If disposable towels are used, a clean, covered waste receptacle with other than hand operation for the lid shall be provided for their disposal.

(b) A handwashing sink serving a food processing area shall comply with all of the following requirements if it is installed after the effective date of this rule, or if it is located in a food processing plant that is initially licensed or licensed to a new operator after the effective date of this rule:

1. It shall be located in the processing area.
2. It shall be served by hot and cold running water provided under pressure, through a mixing valve or combination faucet, or by potable and tempered water.
3. It shall not be hand operated.

(c) A handwashing sink in a non-seasonal licensed food processing plant that has ceased to operate continuously for more than 30 days at any time after the effective date of this rule, or located in an area that has been structurally remodeled or altered in a manner which results in structural changes to a processing area, or located in a plant that adds more complex food processing after the effective date of this rule, shall comply with the requirements as referenced in sub. (b) 1-3.

(d) An automatic handwashing device may be substituted for a handwashing sink if the automatic handwashing device operates in a safe and effective manner.

(e) No handwashing sink may be used to clean, sanitize, or store equipment or utensils.

(11) CLEANING FACILITIES. (a) If equipment, utensils, or food packages are cleaned or sanitized manually, the food processing plant shall be equipped with washing, rinsing, and sanitizing warewashing sink compartments which are suitable for all manual cleaning and sanitizing operations. Sinks shall be conveniently located and adequate in number. Each sink shall be constructed of stainless steel or other approved materials.

(b) Each compartment in a manual warewashing sink shall be large enough to accommodate the immersion of the largest item to be washed, rinsed, and sanitized in the sink. Every sink compartment shall be served by hot and cold running water, and shall be cleaned prior to each use.

(c) Drain boards shall be provided in connection with every warewashing sink. Drain boards shall be large enough to accommodate soiled equipment and utensils prior to washing, and clean equipment and utensils after they are sanitized. Drain boards shall be located and constructed so that they do not interfere with washing and sanitizing operations. This paragraph does not prohibit the use of easily movable dish tables as drain boards if the dish tables comply with this paragraph.

(d) Brushes and cleaning tools shall be kept clean and in good repair. Wiping cloths used to clean equipment and utensils shall be cleaned and sanitized daily, and shall be stored in an approved sanitizing solution between uses. Sanitizing solutions for wiping cloths shall be changed at least daily. Wiping cloths used to clean food contact surfaces of equipment and utensils shall not be used for any other purpose. Single service disposable towels may be used in place of re-usable cloths if they are discarded after each use.

(e) If a mechanical system is used to clean or sanitize equipment, utensils, or food containers, the mechanical system shall be designed, installed, and maintained so that it is fully effective for the purpose used.

(12) EXTERIOR PREMISES. The premises surrounding a food processing plant shall be well drained and shall be kept in a clean and orderly condition. The premises shall be kept free of accumulations of garbage and refuse, potential vermin harborages, and other potential health nuisances. Driveways and parking lots shall be surfaced or maintained to minimize airborne dust and dirt.

(13) PLUMBING SYSTEM AND SEWAGE DISPOSAL. Sewage and waste materials from a food processing plant shall be removed in a sanitary manner, in compliance with applicable state and local regulations. All plumbing, plumbing fixtures, and equipment shall be designed, installed, and maintained to prevent backflow, back siphonage, and cross-connections.

Note: Plumbing and plumbing fixtures are subject to the requirements of chs. SPS 381 to 387, enforced by the department of safety and professional services.

(14) GARBAGE AND REFUSE DISPOSAL. Garbage and refuse shall not be allowed to accumulate in or around a food processing plant. Garbage and refuse shall be removed as often as necessary to maintain the premises in a clean and sanitary condition. Garbage storage areas shall be constructed and maintained so that they do not attract or harbor insects, rodents, or other animals. Garbage and refuse shall be held in durable, leakproof, easily cleanable, and pest-resistant containers. Containers shall be kept covered with tight-fitting lids, and shall be cleaned when necessary to prevent insanitary conditions. Garbage and refuse shall not be burned on the premises, except in compliance with state and local laws. Garbage and refuse shall not be burned on the premises if burning may contaminate food.

(15) CONTROL OF PESTS. The licensee shall take effective measures, as necessary, to control insects, rodents, and other pests in a food processing plant. Pesticides and other hazardous substances shall not be stored or used in a manner which may contaminate food, or which may constitute a hazard to employees or the public. Pesticides shall not be stored, handled, or used in a manner inconsistent with label directions, or in a negligent manner.

Note: Pesticide storage and use must comply with ss. 94.67 to 94.71, Stats., and ch. ATCP 29. Pesticides must be registered for use by the U.S. environmental protection agency or by the department.

(16) CONSTRUCTION; PLAN REVIEW. Before a food processing plant is constructed, substantially reconstructed, or extensively altered, the new operator or licensee shall notify the department in writing. Plans and specifications for the construction, reconstruction, or alteration may be submitted to the department for review before the work is begun. Plans and specifications shall be available for review by the department upon request.

(17) EGG HANDLING FACILITIES. Egg handling facilities shall meet the requirements in ss. ATCP 88.06 and 88.08.

ATCP 70.10 Personnel standards. (1) CLEANLINESS. Persons engaged in food processing shall maintain a high degree of personal cleanliness, and shall observe good hygienic practices during all

working periods. Persons engaged in food processing shall wash their hands before beginning work and upon returning to work after using toilet facilities, eating, smoking, or engaging in other activities which may contaminate the hands. Persons engaged in food processing shall keep their fingernails clean and neatly trimmed, and shall not wear fingernail polish unless they wear sanitary gloves at all times when handling food.

(2) HAND CONTACT WITH FOOD. (a) Except as provided in par. (d), individuals engaged in food processing or handling may not contact ready-to-eat food with their bare hands but shall use suitable food handling aids such as deli-tissue, spatulas, tongs, single-use gloves, or dispensing equipment to avoid bare-hand contact.

(b) If used, finger cots or gloves shall be:

1. Made of impermeable materials, except where the use of such material is inappropriate or incompatible with the work being done.
2. Sanitized at least twice daily or more often if necessary.
3. Properly stored until used.
4. Maintained in a clean, intact, and sanitary condition prior to use.

(c) Hands shall be washed prior to putting on gloves, and upon changing gloves if the person wearing the gloves will be performing a different function or if the gloves are being replaced because hands have become soiled or contaminated due to failure of glove integrity.

(d) Individuals may contact ready-to-eat food with their bare hands if that contact is reasonably necessary, and does not contaminate food. The individuals shall be trained in, and shall follow, written policies and procedures to ensure safe use of bare hands. The policies and procedures shall identify all of the following:

1. The individuals or positions authorized to contact ready-to-eat food with bare hands.
2. The specific tasks for which bare-hand contact is authorized.
3. The types of ready-to-eat food that may be contacted with bare hands.
4. The procedures that authorized individuals are required to follow in order to prevent food contamination from bare-hand contact.

(e) A food processing plant operator shall provide prior training on procedures and policies that cover parts (a) through (d) of this subsection to all individuals who may contact ready-to-eat food with their bare hands. The operator shall have a written training plan that identifies all of the following:

1. The individuals or positions responsible for implementing the training, maintaining training records, and ensuring compliance with training requirements.
2. The content of the training, including the written procedures required under par. (d).
3. The form of initial training, and the form and frequency of follow-up training if any.
4. Monitoring and control procedures to ensure that individuals are trained before they contact ready-to-eat food with bare hands.
5. Procedures to evaluate training effectiveness.

(f) The operator of a food processing plant shall review the training program under par. (e) at least annually.

(g) A food processing plant operator shall maintain records to document the operator's compliance with this subsection. Records shall be retained for at least one year after they are made, and shall be available to the department for inspection and copying upon request.

(3) CLOTHING AND JEWELRY. Persons in food processing areas or handling unpackaged food shall wear clean, washable outer garments and effective hair restraints, including effective hair restraints for beards longer than $\frac{1}{2}$ inch. Hair restraints may include hair nets, caps, and snoods, but do not include hairsprays, visors, or headbands. Persons working in food processing areas or handling unpackaged food shall remove all jewelry from their hands, fingers, and arms before having any direct manual contact with food or food contact surfaces. Jewelry shall not be worn in any part of the body in a manner which creates a risk of food contamination. This subsection does not apply to plain band wedding rings.

(4) EMPLOYEE HEALTH. No person who, by medical examination or supervisory observation, has or is reasonably suspected of having any of the following conditions may work in a food processing plant in any capacity that may result in the contamination of food, or in the contamination of equipment or utensils used to process or handle food:

(a) One or more reportable symptoms of communicable disease as defined in ch. ATCP 75 Appendix, 2-201.11 (A).

(b) One or more symptoms of an acute gastrointestinal illness.

(c) A discharging or open wound, sore, or lesion on the hands, arms, or other exposed portions of the body.

(5) FOOD CONTAMINATION. No person who has received a reportable diagnosis of communicable disease, as defined in ch. ATCP 75 Appendix, *The Wisconsin Food Code*, 2-201.11 (A) (2), may work in a food processing plant in any capacity that may contaminate food products.

(6) CONSUMPTION OF FOOD, BEVERAGES, AND TOBACCO. No person may consume food, beverages, or tobacco in any food processing area, or in any area where food processing equipment or utensils are cleaned or stored. Employees may not consume food, beverages, or tobacco except in designated areas which are separated from food processing areas. This subsection does not prohibit a sanitary water fountain in a processing area, nor does it prohibit on-line quality control sampling in accordance with written quality control procedures written and followed by the food processing plant operator.

ATCP 70.12 Equipment and utensils. (1) CONSTRUCTION AND MAINTENANCE; GENERAL. Equipment and utensils shall be of sanitary design and construction. Equipment and utensils shall be readily accessible for cleaning and inspection and shall be constructed so that they can be easily cleaned. Equipment and utensils shall be kept clean and in good repair.

(2) FOOD CONTACT SURFACES. Food contact surfaces of equipment and utensils shall be constructed of stainless steel or other materials which are smooth, impervious, nontoxic, noncorrosive, 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, other than food contact surfaces of approved

C-I-P systems, shall be readily accessible for manual cleaning. Joints and fittings shall be of sanitary design and construction.

Note: Hard maple or other material which is non-absorbent may be used for cutting blocks, boards, and bakers' tables. Sanitary wooden paddles in good condition may be used in confectionaries.

(3) C-I-P SYSTEMS. C-I-P systems shall be of sanitary design and construction, and shall be installed and maintained for sanitary operation. A C-I-P system shall be installed and maintained so that cleaning and sanitizing solutions can be circulated throughout all interior product contact surfaces of the system. C-I-P systems shall be equipped with adequate inspection ports or other access points. C-I-P systems shall be self-draining, or shall be capable of being easily and completely drained. A temperature recording device, which accurately records the return temperatures of cleaning and sanitizing solutions, shall be installed in all circuits through which cleaning and sanitizing solutions are circulated. Cleaning records shall be kept for at least 90 days after they are created.

(4) LOCATION AND INSTALLATION OF EQUIPMENT. Equipment which cannot be easily moved shall be installed in a manner which prevents liquid or debris from accumulating under or around the equipment. Equipment shall be installed so that there is adequate clearance on all sides for cleaning and maintenance. This does not apply to that portion of a tank or container which is designed and installed to protrude into or through the wall or ceiling of a food processing plant. Air intake vents for food or ingredient storage containers shall be located in processing areas or shall be properly filtered.

(5) MEASURING DEVICES AND CONTROLS. Every freezer and cold storage compartment used to store or hold potentially hazardous food shall be equipped with a thermometer or other device which accurately indicates the temperature in the compartment. Instruments and controls used for measuring, regulating, and recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate, and shall be adequate for their intended use.

(6) LUBRICATION. Equipment shall be designed and constructed so that gear and bearing lubricants do not come in contact with food or food contact surfaces. Only food grade lubricants may be used in equipment if incidental food contact may occur.

ATCP 70.14 Cleaning and Sanitizing Equipment and Utensils. (1) GENERAL. Except as provided in s. ATCP 70.16, the food processing plant operator shall do all of the following.

(a) Comply with provisions in s. ATCP 70.28 for sanitizers and methods used to sanitize equipment and utensils.

(b) Except as provided in par. (c), (d) and (e), clean and sanitize all food contact surfaces of equipment and utensils after each day's use, and before any change in use that may cross-contaminate food with major food allergens or other contaminants.

(c) Clean and sanitize tanks, used to store potentially hazardous food or potentially hazardous food ingredients, at least once after the food processing plant operator empties those tanks.

(d) Clean and sanitize all food contact surfaces of equipment used for the distillation of alcohol products, such as distilled spirits, after each distillation batch.

(e) Request alternative cleaning and sanitizing procedures for department approval, under ss. ATCP 70.16 and 70.18, as provided in those sections.

(2) **CLEANING AND SANITIZING C-I-P SYSTEMS.** C-I-P systems shall be cleaned and sanitized in compliance with manufacturer specifications. Cleaning and sanitizing records shall be maintained for all C-I-P systems. The records shall identify every C-I-P system which has been cleaned or sanitized, the date and time when each C-I-P system was cleaned and sanitized, the temperature of the cleaning and sanitizing solutions, and the length of time for which the C-I-P system was exposed to each cleaning and sanitizing solution. Records shall be signed or initialed by a responsible person at the food processing plant. Records shall be maintained on file at the food processing plant for at least 90 days, and shall be made available for inspection and copying by the department upon request.

(3) **CLEANING COMPOUNDS, DETERGENTS, AND SANITIZERS: STORAGE AND LABELING.** Cleaning compounds, detergents, and sanitizers used in a food processing plant shall be clearly labeled. When they are not being used, they shall be stored in designated areas and in an appropriate manner so that they do not contaminate food products, ingredients, equipment, or utensils.

(4) **STORAGE OF CLEAN EQUIPMENT AND UTENSILS.** Equipment and utensils, unless stored in an approved sanitizing solution, shall be stored so as to drain dry. Equipment and utensils shall be protected from contamination prior to use.

(5) **SINGLE-SERVICE ARTICLES.** Single-service articles shall be stored in the original containers in which they were received, or in other closed containers which will protect them from contamination prior to use. Single-service articles shall not be re-used.

(6) **EQUIPMENT AND UTENSILS IN EGG HANDLING FACILITIES.** Equipment for candling, grading, and weighing eggs shall meet the requirements of s. ATCP 88.12 (5).

ATCP 70.16 Cleaning and Sanitizing Equipment and Utensils; Exemptions. (1) **APPROVAL REQUIRED FOR AN ALTERNATIVE CLEANING AND SANITIZING FREQUENCY.** Except as provided in s. ATCP 74.16 (2), if a food processing plant operator seeks to clean and sanitize equipment and utensils at a frequency other than that required in s. ATCP 70.14 (1) because the equipment and utensils are used with food products, processes, or conditions reducing the risk of foodborne illness, the food processing plant operator shall submit an alternate cleaning and sanitizing procedure in compliance with s. ATCP 70.18 to the department for written approval.

(a) Factors reducing the risk of foodborne illness may include competitive microorganisms, intended use or targeted consumer demographic, inhibitory compounds, temperatures, and any other factors that reduce the risk of pathogenic organism growth or toxin formation.

(b) Upon review, the department will issue a letter of approval applicable for not more than five years that is to be maintained on file at the food processing facility.

(c) If changes are planned for the product or any process that affects the food safety validation factors of that product, the operator shall inform the department in writing prior to making those changes.

(2) **NO APPROVAL REQUIRED FOR AN ALTERNATIVE CLEANING AND SANITIZING FREQUENCY.** A food processing plant operator is not required to obtain written department approval for use of an alternative equipment and utensil cleaning and sanitizing frequency for the following equipment and processes,

provided that the food processing plant operator cleans and sanitizes the equipment according to manufacturer specifications or according to a validated cleaning process filed with the department:

- (a) Drying equipment.
- (b) Cloth-collector systems.
- (c) Dry product packaging equipment and storage containers.
- (d) Equipment used in brining, aging, curing, and dry product blending processes.
- (e) Food contact surfaces of equipment used solely to process foods or food ingredients with low water activity (≤ 0.85), or foods which are considered non-PHF/non-TCS foods based on Table A or Table B in Section 2 of ATCP 75 Appendix, (Time/Temperature Control for Safety Food), such as chocolate, fats and oils, liquid nutritive sweeteners, peanut butter, or similar foods.
- (f) Ice makers maintained in a cold/frozen state. A food processing plant operator shall clean and sanitize the ice maker in accordance with ice maker manufacturer instructions for cleaning, or shall clean and sanitize using a validated cleaning process.
- (g). Food contact surfaces of equipment used for brewing or fermentation of alcoholic beverages, such as brewing of beer or wine fermentation. A food processing plant operator shall clean and sanitize equipment used following each brewing or fermentation batch.
- (h) Surfaces of aseptic processing equipment that contact food after the food has been sterilized, as long as system sterility is maintained. If system sterility is lost, a food processing plant operator shall clean, sanitize and re-sterilize equipment.
- (i) Equipment used for food fermentations, such as the manufacture of sauerkraut or cucumber pickles; development of one or more pure bacterial cultures, and development of starter cultures. A food processing plant operator shall clean and sanitize all equipment following each fermentation batch.
- (j) Equipment used for processing of products with a natural pH ≤ 4.0 . A food processing plant operator shall clean and sanitize all equipment at the end of a continuous operation, not to exceed 30 days (720 hours).
- (k) Equipment used for maple syrup processing. A food processing plant operator shall clean and sanitize all equipment at the end of a continuous operation, not to exceed 40 days (960 hours).
- (m) Equipment used for bottled water processing. A food processing plant operator shall clean and sanitize all equipment at the end of a continuous operation, not to exceed 30 days (720 hours).

ATCP 70.18 Obtaining approval of alternative cleaning and sanitizing frequency. (1)

SUBMISSION OF REQUEST FOR APPROVAL OF ALTERNATIVE CLEANING AND SANITIZING FREQUENCY. A food processing plant operator may submit a written request for the department to approve alternative cleaning and sanitizing procedures. The request shall include all of the following, and any other information required by the department:

- (a) A clear and complete description of the affected food processing equipment and utensils, including any continuously-operated equipment. The description shall identify sanitary design features that are relevant to the proposed cleaning and sanitizing procedures.

(b) The types of food produced with the affected equipment or utensils, the purposes for which the food will be used, and the temperatures at which the food will be prepared, stored, and distributed.

(c) A clear and complete description of the alternative cleaning and sanitizing procedure, including cleaning and sanitizing equipment, frequency, methods, materials, and relevant process parameters such as time and temperature. The description shall include a flow diagram of the cleaning and sanitizing procedure.

(d) A written statement, by the food processing plant operator, that the alternative cleaning and sanitizing procedure has been determined by competent authority (e.g., a process authority, or is validated by a published or unpublished, peer-reviewed article, challenge studies, or regulatory standards) and determined to be effective in preventing food contamination and ensuring the microbiological safety of food. The written statement shall be based on the structure of a written plan under subd. 5.

(e) A written plan used to ensure that the alternative cleaning and sanitizing procedure will be effective in preventing food contamination and ensuring the microbiological safety of food shall identify and assess foreseeable hazards, identify critical control points, identify critical safety parameters and limits, and identify monitoring procedures and controls to ensure that the procedure is effective and appropriately implemented.

(f) The department may approve a proposal for an alternative cleaning and sanitizing procedure that does not comply with sub. (a), if the department believes that the procedure will be effective in preventing food contamination and ensuring the microbiological safety of food. The department shall give its approval in writing.

(2) DEPARTMENT DECISION ON REQUEST FOR APPROVAL OF ALTERNATIVE CLEANING AND SANITIZING FREQUENCY. The department shall grant or deny a request under sub (1) within 60 days after it receives a complete request, except that the department may give written notice extending the action deadline for reasons stated in the notice.

(3) QUALIFICATIONS, LIMITS, AND WITHDRAWAL OF DEPARTMENT APPROVAL. The department may qualify or limit its approval under sub. (2), as deemed appropriate. The department may withdraw its approval for cause, including obtaining information that casts doubt on the efficacy or consistent implementation of the approved procedure or when changes are made that could affect the validity of the procedures or process.

(4) EXPIRATION OF DEPARTMENT APPROVAL OF ALTERNATIVE CLEANING AND SANITIZING FREQUENCY. All approvals granted under this section shall expire in five years from the date of issuance.

(5) OPERATION OF AN ALTERNATIVE CLEANING AND SANITIZING FREQUENCY. A food processing plant operator that implements an alternative cleaning and sanitizing procedure approved under sub. (2) shall do all of the following:

(a) Control and monitor to ensure that the procedure is strictly implemented as approved, and is effective in preventing food contamination and ensuring the microbiological safety of food.

(b) Promptly notify the department of any material deviation from the approved procedure, and any information that casts doubt on the efficacy of the procedure.

(c) Collect and retain data and records to document, on a continuing basis, the implementation and efficacy of the approved procedure. The operator shall retain the data and records for at least 90 days, and shall make them available upon request for inspection and copying by the department.

ATCP 70.20 Water supply. (1) OPERATIONS WATER. (a) Operations water, other than water reclaimed according to sub. (3), shall be obtained from a source that complies with ch. NR 811, for municipal water systems, or NR 812, for private or non-community water systems.

(b) Operations water shall be available in consistently adequate quantity, and shall not exceed the maximum contaminant levels set forth in the drinking water standards in ch. NR 809.07.

(c) Operations water sourced from either municipal, private, or non-community water systems shall comply with the microbiological standards under NR 809.30. Operations water from a privately owned water system shall be sampled by the food processing plant operator not less than once every twelve months and be tested at a laboratory, certified to perform the appropriate tests, under ch. ATCP 77

(d) A food processing plant operator shall keep on file, for at least one year, the results of all microbiological and other tests conducted on operations water sampled at the food processing plant.

(e) Operations water used to wash field soil from raw fruits or vegetables may be reused for the following purposes if it is first filtered to remove soil and other particulate matter:

1. Washing subsequent deliveries of raw fruit or vegetables at the processing plant if the fruit or vegetable will undergo canning.
2. Flushing floors and gutters in the receiving areas for raw fruit or vegetables in the processing plant.

(2) INGREDIENT WATER. (a) Ingredient water, other than water reclaimed according to sub. (3), shall be obtained from a source that complies with ch. NR 811, for municipal water systems, or NR 812 for private or non-community water systems. Water reclaimed from food processing operations may not be used as an ingredient in bottled drinking water or in any beverage where water is a characterizing ingredient.

(b) Ingredient water obtained from either municipal, private, or non-community water systems shall not exceed the maximum contaminant levels set forth in the drinking water standards in ch. NR 809.07, the microbiological standards under s. NR 809.30, and the health-related enforcement standards under s. NR 140.10. At the department's request, a food processing plant operator shall provide documentation to the department that the water complies with the microbiological standards of NR 809.30. Documentation may consist of results from tests performed at a laboratory certified under s. ATCP 77 for the entity providing the water.

(c) If ingredient water is obtained from a privately owned water system, it shall be sampled by the operator not less than once every twelve months, and be tested at a laboratory, certified to perform the appropriate tests, under ch. ATCP 77.

(d) A food processing plant operator shall keep on file, for at least five years, the results of all microbiological and other tests conducted on ingredient water sampled at the food processing plant

(3) RECLAIMED WATER. (a) Water reclaimed from a heat exchanger process, from a compressor cooling unit, from the condensation of food products, or from other food processing plant systems or processes, may be used as ingredient water if all of the following apply:

1. The water is reclaimed by means of evaporation, reverse osmosis, ultra-filtration, a heat exchanger, or another method approved by the department.

2. The reclaimed water has less than 1 coliform bacterium per 100 ml. of water.

3. The standard plate count of the reclaimed water does not exceed 500 per ml. of water and complies with the bacteriological standards of s. NR 809.30.

4. The water, if reclaimed from the condensation of food products, has a standard turbidity of less than 5 units or organic content of less than 12 mg. per liter, as measured by the chemical oxygen demand or permanganate-consumed test specified in *Standard Methods for the Examination of Water and Waste Water*, twenty-first edition (2005), published by the American Public Health Association, the American Water Works Association and the Water Environment Federation. The food processing plant operator shall use an automatic fail-safe monitoring device to identify, and automatically divert to a waste water system, any reclaimed water that fails to comply with this subdivision.

Note: Copies of the *Standard Methods for the Examination of Water and Waste Water*, twenty-first edition (2005), published by the American Public Health Association (APHA), the American Water Works Association and the Water Environment Federation, are on file with the department and the legislative reference bureau. Copies may be obtained by contacting the "APHA Bookstore" at www.apha.org/publications/bookstore/.

5. The reclaimed water is of satisfactory organoleptic quality and has no off-odors, off-flavors, or slime formations. The food processing plant operator shall sample and organoleptically test reclaimed water at weekly intervals.

6. Chemical treatment of the reclaimed water, if any, complies with sub. (4).

7. The reclaimed water is stored in a properly constructed tank. The tank shall be constructed of a material that will not contaminate the water and can be easily cleaned.

8. The food processing plant operator tests the reclaimed water for compliance with subd. 1-4 above at least once during any 6 month interval. The operator shall test the reclaimed water daily for 14 working days after the department approves the reclamation system under subd. 1., and for at least 7 working days after any repairs or alterations to the system.

9. There are no cross-connections between reclaimed water lines and any public or private water system.

(b) Water reclaimed from a heat exchanger process, from a compressor cooling unit, from the condensation of food products, or from other food processing plant systems or processes may be used as operations water with department approval if the water complies with par. (a) or if all of the following apply:

1. The water is reclaimed by means of evaporation, reverse osmosis, ultra-filtration, a heat exchanger, or another method approved by the department.

2. The department pre-inspects the reclamation system, and reviews any proposed chemical treatment of the reclaimed water.

3. The water, if reclaimed from the condensation of food products, has a standard turbidity of less than 5 units, an electrical conductivity maintained in correlation with organic content of less than 12 mg. per liter, or an organic content of less than 12 mg. per liter, as measured by the chemical oxygen demand or permanganate-consumed test as specified in *Standard Methods for the Examination of Water and Waste Water*, twenty-first edition (2005), published by the American Public Health Association, the American Water Works Association and the Water Environment Federation. The food processing plant operator shall use an automatic fail-safe monitoring device to identify, and automatically divert to a waste water system, any reclaimed water that fails to comply with this subdivision.

Note: Copies of the *Standard Methods for the Examination of Water and Waste Water*, twenty-first edition (2005), published by the American Public Health Association (APHA), the American Water Works Association and the Water Environment Federation, are on file with the department and the legislative reference bureau. Copies may be obtained by contacting the "APHA Bookstore" at www.apha.org/publications/bookstore/.

4. The reclaimed water is of satisfactory organoleptic quality and has no off-odors, off-flavors, or slime formations. The food processing plant operator shall sample and organoleptically test reclaimed water at weekly intervals.

5. Chemical treatment of the reclaimed water, if any, complies with sub. (4).

6. The reclaimed water is stored in a properly constructed tank. The tank shall be constructed of a material that will not contaminate the water and can be easily cleaned.

7. There are no cross-connections between reclaimed water lines and any public or private water system, except for lines with backflow preventers that meet the requirements of chs. SPS 382 and 384.

8. The reclaimed water, if held for more than twenty-four (24) hours, is at all times held at a temperature of at least 145°F. (63° C.) or is chemically treated under subd. 4 to suppress bacterial growth.

9. Distribution lines and hose stations used to distribute the reclaimed water are clearly identified as "limited-use reclaimed water."

10. The food processing plant operator posts clear instructions for the use of the reclaimed water. The operator shall post the instructions so that they will be seen and understood by persons using the reclaimed water. The instructions shall disclose the limited purposes for which the reclaimed water may be used.

11. Water lines distributing the reclaimed water are not permanently connected to food product vessels. If a water line is temporarily connected to a food product vessel, there shall be an atmospheric break and automatic controls to prevent the reclaimed water from contacting food products.

(c) Water reclaimed from food processing operations may be used for cleaning or other purposes but may not be used for any purpose involving contact with food or food contact surfaces except as provided in par. (a) or (b).

(4) WATER TREATMENT. (a) A food processing plant operator may not use any chemical to suppress bacterial growth in water, or to prevent off-tastes or odors in water, unless that chemical is approved for that purpose by the federal Environmental Protection Agency (EPA). Neither the chemical as applied, nor any

compound produced by the chemical application, may adulterate food in the food processing plant in which it was used.

(b) A food processing plant operator shall apply chemicals, under par. (a), according to label directions using an automatic proportioning device. Treated water shall be held for the period of time specified on the chemical label before it is used as ingredient water or operations water. A food processing plant operator shall conduct a daily testing program for any chemical added to water, to ensure that the chemical concentration does not adulterate food.

(c) Monitoring records of chemicals used and times for the holding of treated water prior to use, as well as any tests performed under this subsection, shall meet the standards set forth in 21 CFR 117.305, and maintained and made available according to 21 CFR 117.315.

(5) RE-CIRCULATED WATER SYSTEMS. (a) If re-circulated water used in a cooler or heat exchanger may come in contact with any food product or food contact surface, the re-circulated water shall be all of the following:

1. Obtained from a source that complies with ch. NR 811 or 812, as applicable.
2. Bacteriologically safe.
3. Protected from contamination.
4. Tested by the food processing plant operator for compliance with subd. 2 above at 6 month intervals.

(b) If a re-circulating water system, under par. (a), becomes contaminated, that system may not be used until it is properly treated and analytical results indicate that the contamination has been eliminated.

(c) Freezing point depressants used in re-circulating water systems under par. (a) shall be nontoxic.

(6) WATER AND POTABLE LIQUIDS TRANSPORTED IN BULK. (a) Water transported to a food processing plant in a bulk tanker or bulk container, for use as an ingredient or in other plant operations, shall be potable and shall be obtained from a source that complies with ch. NR 811 or 812.

(b) Whenever potable water or another potable liquid is transported to or from a food processing plant in a bulk tanker or bulk container, it shall be loaded, transported, and unloaded in a sanitary manner that prevents contamination. The bulk tanker or bulk container shall be thoroughly cleaned and sanitized before being filled. Suitable pumps, hoses, and fittings shall be used to transfer potable water and potable liquids to and from bulk tankers and bulk containers shall be cleaned and sanitized prior to use.

(c) Whenever potable water or another potable liquid is transported to or from a food processing plant in a bulk tanker or bulk container, the bulk tanker or bulk container and each of its fittings and equipment shall meet all of the following requirements:

1. It shall be properly constructed and maintained to prevent contamination of the potable water or potable liquid. Food contact surfaces shall comply with s. ATCP 70.12 (2).
2. It shall be cleaned, sanitized, and inspected on a routine basis.
3. It may not be used to transport materials that may contaminate potable water or potable liquid that is subsequently transported in the bulk tanker or bulk container.
4. It shall be effectively sealed to protect the potable water or potable liquid from contamination during transit.

Note: Effective sealing systems include manhole cover gaskets and seals.

5. It shall be properly stored and serviced to prevent contamination. When not in use, pumps, hoses, and fittings shall be properly maintained, capped, stored, and protected from contamination.

(7) CULINARY STEAM. Water used to produce culinary steam shall be potable. Water reclaimed from food processing operations may not be used to produce culinary steam unless it complies with sub. (3) (a) or (b). In boilers used to produce culinary steam, boiler water additives shall comply with 21 CFR 173.310.

(8) ICE. Ice used to cool or maintain the temperature of foods shall be made from potable water. Ice used to cool or maintain the temperature of ready-to-eat foods shall not have been previously used for any other purpose. Ice shall be received, handled, and stored in a manner to prevent contamination or adulteration. Any ice which is not made on site shall be inspected upon receipt, and rejected if it is delivered in a way that has not adequately protected the ice from contamination.

ATCP 70.22 Food ingredients. (1) GENERAL. Food ingredients shall be safe, wholesome, and unadulterated, and shall comply with applicable standards of identity under s. 97.09, Stats. Raw agricultural commodities and other food ingredients shall be segregated and examined as necessary to determine whether they are clean and fit for processing. Processed foods and dairy products which are used as food ingredients shall be obtained from sources which comply with applicable licensing and inspection requirements.

(2) EGGS AND EGG PRODUCTS. Only clean whole eggs, pasteurized eggs in liquid, frozen or dry form, or pasteurized egg products may be used in food processing. Eggs and egg products may be pasteurized during processing. Clean whole eggs shall be equivalent to USDA Grade B or better with shells intact.

ATCP 70.24 Food handling and storage. (1) GENERAL. Food shall be protected from contamination and decomposition while being processed, handled, conveyed, or held at a food processing plant. Food shall be processed and held in a manner which keeps the food in a safe, wholesome, and unadulterated condition. Potentially hazardous foods shall be processed and held at temperatures, or in a manner, which minimizes the potential for growth of undesirable microorganisms.

(2) FOOD STORAGE. Food storage areas shall be maintained in a clean, sanitary, and orderly condition, free from conditions which may result in the adulteration of food. Potentially hazardous foods shall be stored at safe temperatures. Storage areas shall be constructed and maintained so that waste water and other waste liquids do not drain into, or accumulate in, any storage area. Food shall not be stored in a manner which may attract or harbor pests.

(3) FOOD PROCESSING. (a) Food processing shall be conducted under appropriate conditions and controls to minimize the potential for growth of undesirable microorganisms, or the contamination of food.

Note: One way to comply with this requirement is to follow a HACCP plan which monitors and controls food safety variables at critical control points in the manufacturing process. Monitoring and controlling food safety variables such as time, temperature, humidity, water activity (a_w), pH, pressure, and flow rate at critical control points can ensure that mechanical breakdowns, time delays, temperature fluctuations, and other conditions do not contribute to the decomposition or contamination of food.

(b) If potentially hazardous food is heated, refrigerated, or frozen in the course of processing, the internal temperature of the food shall be accurately monitored, as necessary, to ensure that safe temperatures are promptly attained and maintained.

(c) Any testing and monitoring done to minimize the potential for growth of undesirable microorganisms, or the contamination of food during processing and storage as required in paragraph (3) of this section shall be recorded, the records shall be maintained on site for one year, and shall be made available to the department or its agents on request for copying or photographing.

(d) Potentially hazardous frozen foods, if thawed for processing, shall be thawed by one of the following methods:

1. By placing the frozen food in a refrigerated space at a temperature of not more than 41°F. (5°C.).
2. Placing under potable running water, at a temperature of not more than 70°F. (21°C.), for no more time than is needed to thaw the food. Water velocity shall be sufficient to agitate loose particles and drain or float them away from the food being thawed.
3. In a microwave oven if the food is fully cooked in the microwave oven, or if cooking is immediately completed in another cooking facility.
4. In any cooking facility, as part of the process by which the food is fully cooked.

(4) BULK FLOUR HANDLING SYSTEMS. (a) Food contact surfaces of bulk flour handling equipment shall comply with the provisions of s. ATCP 70.12 (2). Pneumatic systems using storage bins constructed of semi-permeable cloth material are exempt from the requirement that surfaces be smooth and nonabsorbent, provided the surfaces can be effectively cleaned. Attachment mechanisms for holding inspection port covers, access doors, delivery pipe caps, or other removable accessories shall have no loose parts. Delivery pipe caps shall be kept in place, and secured against removal, except when a bulk flour handling system is in use. Outside installations shall be watertight or suitably covered to prevent entry of water and foreign material.

(b) Intake air used in pneumatic flour handling systems shall be filtered to exclude particles of 50 microns or larger. Air discharged from the system shall be filtered so that no visible dust escapes. Filters shall be readily removable for cleaning or replacement. Straight runs of pneumatic conveyors shall comply with the provisions of s. ATCP 70.12 (1), except that piping which is self-purging is exempt from accessibility requirements.

(5) RAW INGREDIENTS AND FINISHED PRODUCTS; SEPARATE HANDLING. Effective measures shall be taken to prevent cross contamination between raw ingredients and finished food products. Raw ingredients shall not be handled simultaneously with finished products in any part of a food processing plant if either the raw materials or the finished products are uncovered or unprotected, and if the handling may result in contamination.

(6) SALVAGING DISTRESSED FOOD. (a) In this subsection:

1. "Distressed food" means processed food exposed to a fire, flood, transportation accident, refrigeration breakdown, or other unusual condition which may affect its safety or suitability as human food. "Distressed food" does not include food or food packages damaged during normal conditions of food and food product handling, transit, or storage.

2. "Reconditioned food" means packaged distressed food which is distributed or offered for sale as human food after its package is repaired or relabeled without being opened.

3. "Reprocessed food" means distressed food that is subsequently processed in accordance with the requirements under this chapter and distributed or offered for sale as human food.

(b) A food processing plant operator shall notify the department within 3 days after the operator takes possession of any distressed food, or within 3 days after food in the operator's custody becomes distressed food. The operator shall notify the department before the operator reprocesses or reconditions the distressed food.

(c) A food processing plant operator shall identify distressed food as such, and shall separate it from other food. No operator may store distressed food in a processing area, or under conditions which may lead to the contamination of other food, equipment, utensils, or packaging materials.

(d) No food processing plant operator may do either of the following:

1. Reprocess for sale, as human food, any distressed food which is unwholesome or adulterated.
2. Offer for sale, sell, or distribute food in packages that are damaged to such an extent that the food may have been exposed or subjected to possible contamination, including packages with bulging ends, ruptures, hairline fractures, breakage along critical seams, or openings which may have exposed food to contamination.

(e) No food processing plant operator may sell or distribute reprocessed or reconditioned food at wholesale unless the operator gives the purchaser or recipient written notice that the food is reprocessed or reconditioned. The notice shall also include the name and address of the person who reprocessed or reconditioned the distressed food. The notice may be included on an invoice, bill of lading, or other documentation of the sale or distribution of the food.

(f) A food processing plant operator shall keep, for the period of time set forth in 21 CFR 117.315, all of the following records related to distressed food handled by that operator:

1. A description of the distressed food, including the type of food, the package or container style, and the amount of the food.
2. The source of the distressed food, or the conditions which caused it to become distressed food.
3. The date on which the operator received the distressed food.
4. The nature of any reprocessing or reconditioning which the operator performed on the distressed food.
5. The final disposition of the distressed food if the distressed food was not sold directly at retail. That record shall include the name and address of the person, such as the food wholesaler, food distributor, waste disposal firm or waste disposal site operator, to whom the food processing plant operator delivered the food.

(7) FOOD IRRADIATION. Irradiation in the production, processing and handling of food shall comply with applicable federal regulations under 21 CFR 179.

Note: Copies of 21 CFR 179 are on file with the department and the legislative reference bureau.

(8) EGG CLEANING AND STORAGE. Cleaning and storage of eggs shall be done in compliance with the requirements of s. ATCP 88.20.

ATCP 70.26 Food packaging and labeling. (1) GENERAL. Food packages shall be of sanitary design and construction, so as to protect food contents from reasonably foreseeable risks of contamination. Food packages shall be clean, sanitary, and free of any extraneous or deleterious substance. Food shall not be sold or distributed in packages which are damaged to the extent that food contents may be adulterated as a result of the damage. A sealed food package is damaged within the meaning of this subsection if the package or seal is broken or bulged.

(2) CLEANING AND SANITIZING RETURNABLE FOOD PACKAGES. Returnable or multi-use food packages, including returnable bottles, shall be effectively cleaned and sanitized before being reused. Cleaning and sanitizing processes shall remove all extraneous matter and potential adulterants from a food package before the food package is reused. Sanitizing methods shall comply with s. ATCP 70.28. No food package may be reused unless it is specifically designed and constructed for that purpose.

(3) INSPECTION OF RETURNABLE FOOD PACKAGES. Returnable or multi-use packages, after being cleaned and sanitized, shall be inspected before being reused. Inspection shall be adequate to detect extraneous material and visible adulterants, and any damage to product contact surfaces. Inspection shall be performed on surfaces lighted in compliance with s. ATCP 70.08 (6) (b).

(4) SINGLE-SERVICE FOOD PACKAGES. Single-service food packages, including bottle caps and other single-service articles used to package food, shall be made from clean, sanitary materials. Single-service food packages shall be clean and sanitary at the time of use. Single service food packages shall be protected from contamination prior to use, and shall be handled in a sanitary manner. Single-service food packages, including single-service bottles and bottle caps, shall not be re-used.

(5) FOOD PACKAGE LABELING. Packaged food shall be packaged and labeled according to all of the following, as applicable:

(a) 21 CFR 101.

(b) Section 97.09, Stats., and federal regulations incorporated by reference in s. 97.09, Stats.

(c) Chapter ATCP 90.

(d) Chapter ATCP 75 Appendix, *Wisconsin Food Code* section 3-201.11(C).

(e) If the packaged food contains a major food allergen, the ingredient statement on the package shall disclose the common name of the major food allergen. The disclosure shall be equivalent in size and prominence to the rest of the ingredient statement. If an allergen originates from fish, crustacean shellfish, or tree nuts, the disclosure shall include the common name of the source species.

Note: For example, if a food product includes an allergen that originates from fish, the ingredient statement must disclose the common name such as bass, flounder, or cod. If the allergen originates from crustacean shellfish, the ingredient statement must disclose the common name such as crab, lobster, or shrimp. If the allergen originates from tree nuts, the ingredient statement must disclose the common name such as almond, pecan, walnut, or coconut.

(6) EGG PACKAGING AND LABELING. The packaging and labeling of eggs shall be done in compliance with the requirements of ss. ATCP 88.32, 88.34, and 88.38.

ATCP 70.28 Sanitizers and sanitizing methods. (1) SANITIZING METHODS. All returnable or multi-use food packages, and all food contact surfaces of equipment and utensils used to handle foods, shall be effectively sanitized prior to each use.

(1m) The food processing plant operator shall use only chemical sanitizers that comply with 21 CFR 178.1010, are registered with the U.S. environmental protection agency, are applied according to manufacturer's instructions, labeled for use in food processing plants on food contact surfaces and, when used appropriately, do not leave residue on the food contact surface.

(2) BAKING AND COOKING CONTAINERS; EXEMPTION. Subsection (1) does not apply to baking and cooking containers if heating time and temperature combinations meet industry standards and are adequate to destroy pathogenic microorganisms, provided that the containers are cleaned, stored, and used in a manner which prevents contamination of food.

(3) SANITIZERS; MAXIMUM CONCENTRATIONS. The food processing plant operator shall use sanitizers and cleaning compounds so no toxic residue is left on any food contact surface. Sanitizing solutions shall not exceed the maximum concentrations established by the food and drug administration, United States department of health and human services, under 21 CFR 178.1010. A test kit or other device that measures the concentration of sanitizing solutions in parts per million shall be used as necessary to ensure compliance with this subsection.

Note: Copies of 21 CFR 178.1010 are on file with the department and the legislative reference bureau.

(4) SANITIZERS; DEPARTMENT APPROVAL. (a) Sanitizers approved by the EPA and labeled for use on food contact surfaces are also accepted by the department for use according to their labels. The department may approve other sanitizers and sanitizing methods that it finds to be safe and effective for the purpose used.

(b) The department may deny or withdraw approval of any sanitizer or sanitizing method if the department determines that the sanitizer or sanitizing method is not safe or effective for the purpose or under the conditions used, or that it adversely affects the sanitary characteristics of equipment, utensils or food packages.

ATCP 70.30 Ready-to-eat foods; reporting pathogens and toxins. (1) REQUIREMENT. Except as provided under sub. (2), a food processing plant operator shall report to the department the results of any microbiological test or laboratory analysis which indicates that any ready-to-eat food produced by that operator contains pathogenic organisms, toxins resulting from the growth of pathogenic organisms, or any other adulterant capable of causing disease or injury if ingested. The operator shall report to the department within 24 hours after the operator obtains the test results. The operator may report orally, electronically, or in writing.

Note: The Department's emergency phone number is (608) 224-4714. The general number is (608) 224-4700, and the FAX number is (608) 224-4710.

(2) EXEMPTION. A food processing plant operator is not required to report test results under sub. (1) if all of the following apply:

(a) The ready-to eat-food is identified by a product code or production lot number.

(b) The food processing plant operator has not yet sold or distributed any of the ready-to-eat food represented by the product code or production lot number under par. (a), but retains direct control over all of that ready-to-eat food.

ATCP 70.32 Recall plan. (1) PLAN REQUIRED. A food processing plant operator shall have a written plan for identifying and recalling food produced at that plant, should a food recall become necessary. The operator shall update the plan as necessary, and shall make it available to the department for inspection and copying upon request.

(2) PLAN CONTENTS. A plan, under sub. (1), shall do all of the following:

(a) Identify key individuals or positions that are responsible for planning, approving, and implementing recalls on behalf of the food processing plant operator.

(b) Identify key individuals or entities to be contacted or consulted in connection with a recall.

(c) Include procedures for the routine identification, dating, and tracking of food production lots, so that affected lots can be identified and distinguished from unaffected lots in the event of a recall.

(d) Include procedures to enable routine identification, dating, and tracking of food shipments from the food processing plant. Tracking shall identify shipment recipients and contents, cross-referenced to production lots, so that recipients of affected lots can be contacted in the event of a recall.

(e) Include procedures for determining the nature and scope of a recall, including affected food production lots, shipments, and shipment recipients.

(f) Include procedures for identifying and communicating with affected persons, including suppliers, food shipment recipients, down-line buyers, consumers, government agencies, and others.

(g) Identify potential target audiences for recall information, including consumers, distributors, and government agencies.

(h) Identify potential methods for communicating with target audiences under par. (g).

(i) Identify key information, including the identity of the affected food, the reason for the recall, and suggested actions to be taken by affected persons, which may need to be communicated in the event of a recall.

(3) DEVIATIONS FROM PLAN. Actual recall procedures may deviate from the recall plan under sub. (1), as circumstances warrant.

Subchapter III. Canning Operations; Supplementary Requirements

ATCP 70.34 General. (1) APPLICABLE REQUIREMENTS. Food processing plants engaged in canning operations shall comply with applicable provisions of subch. II. Food processing plants engaged in canning operations shall also comply with this subchapter and shall file processes, as required, with the FDA according to the provisions in 21 CFR 108.

(2) RESTRICTIONS ON SALE, DISTRIBUTION, AND DONATION OF HOME-CANNED FOODS. Home-canned low-acid or acidified foods may not be donated to charitable organizations, food banks, food pantries, or other non-profit organizations that will distribute or sell the home-canned foods. The individual canning processor may not sell the home-canned foods at a food bank or food pantry, or on behalf of a charitable or non-profit organization, unless exempted by statute or rule.

ATCP 70.36 Low-acid foods packaged in hermetically sealed containers. The operator of a food processing plant that processes and packages low-acid foods in hermetically sealed containers shall comply with applicable federal regulations under 21 CFR 108.35 (c) and 21 CFR 113.

Note: Section ATCP 70.13 applies to all low-acid foods processed and packaged in hermetically sealed containers, including thermally processed and aseptically processed low-acid foods.

ATCP 70.38 Acidified foods. Persons who process acidified foods shall comply with applicable federal regulations under 21 CFR 108.25 (c) and 21 CFR 114.

Note: Copies of 21 CFR 114 are on file with the department and the legislative reference bureau.

ATCP 70.40 Facilities and equipment; cleaning. (1) EQUIPMENT DESIGN, CONSTRUCTION, AND ACCESSIBILITY. The operator, of a food processing plant facility handling raw agricultural commodities to prepare the commodities for canning, shall use product-handling equipment that is kept clean and in good repair and is designed and constructed in a way that allows easy accessibility for maintenance and cleaning.

(2) EQUIPMENT, WATER, AND SUPPLIES USED FOR CLEANING. The food processing plant operator of a canning facility shall use cleaning equipment that is adequate and in good repair, and shall provide ample supplies of water and steam or other approved cleaning and sanitizing materials for cleaning purposes at the facility.

(3) CLEANING REQUIREMENTS FOR EQUIPMENT USED TO PROCESS FOOD BEFORE THERMAL PROCESSING. The food processing plant operator at a canning facility shall clean equipment used to process food before thermal processing, in accordance with a written plan kept at the canning facility and made available to the department for review upon request. The written plan shall include:

(a) A clear and complete description of the affected food processing equipment and utensils, including any continuously-operated equipment. The description shall identify sanitary design features that are relevant to the proposed cleaning and sanitizing procedures.

(b) The types of food produced with the affected equipment or utensils, the purposes for which the food will be used, and the thermal processing conditions to which the food will be subjected.

(c) A clear and complete description of the alternative procedures used to clean and, if appropriate, sanitize the equipment, including equipment used to administer the cleaning and sanitizing treatments, frequency, methods, materials, and relevant process parameters such as time and temperature. The description shall include a flow diagram of the cleaning and sanitizing procedure.

(d) A written statement, by the food processing plant operator, that the alternative cleaning and sanitizing procedure has been determined by competent authority (e.g., a process authority, or is validated by a published or unpublished, peer-reviewed article, challenge studies, or regulatory standards) and determined to be effective in preventing finished food product contamination and ensuring the microbiological safety of food.

(e) Identification of foreseeable hazards, critical control points, critical safety parameters and limits, and monitoring procedures and controls to ensure that the procedure is effective and appropriately implemented.

ATCP 70.42 Handling raw agricultural commodities and by-products. (1) PRE-CANNING OPERATIONS. Raw agricultural commodities shall be washed, sorted, trimmed as necessary, and inspected before being canned. This requirement does not apply to the washing of cabbage being prepared to make sauerkraut.

(2) WASTE HANDLING. Waste and by-products from canning operations shall be stored and handled in a sanitary manner.

Subchapter IV. Fish Processing Plants; Marine Shellfish Plants; Supplementary Requirements

ATCP 70.44 Fish processing. (1) APPLICABLE REGULATIONS. Fish processing operations shall comply with subch. II and 21 CFR 123. Fish processing plant operators shall have and operate in accordance with HACCP plans that comply with 21 CFR 123 and address food safety hazards that may occur in fish processing. If a fish processing plant produces smoked fish products or smoke-flavored fish products, the HACCP plan for that fish processing plant shall address potential botulism risks as provided in 21 CFR 123 part B.

(2) RESTRICTION ON USE OF COLD-PROCESS SMOKED FISH. Cold-process smoked fish may not be used as an ingredient in any other ready-to-eat, potentially hazardous food.

ATCP 70.46 Labeling and sale of smoked fish. (1) MANDATORY LABEL INFORMATION. Every package containing smoked fish shall be clearly and conspicuously labeled, on the principal display panel of that package, with all of the following information:

(a) The name and address, including the zip code, of the smoked fish processor or distributor.

(b) The name of the product, including the common name of the fish from which the product is derived as found in Table 3-2 of the Fourth Edition of Fish and Fishery Products Hazards and Controls Guidance.

(c) The net weight of the package contents.

(d) If cold-smoked fish is contained in reduced-oxygen packaging as defined in s. ATCP 70.02 (22n) and sold or distributed in an unfrozen state, the words "PERISHABLE – KEEP REFRIGERATED AT OR BELOW 38° F" in conspicuous letters at least the size of those used in the food name.

(e) If smoked fish contained in the package are sold or distributed in a frozen state, the words "PERISHABLE — KEEP FROZEN PRIOR TO USE" in conspicuous letters at least the size of those used in the food name.

(f) The processing date of the smoked fish.

(2) PROHIBITION AGAINST COMMINGLING. Smoked fish processed on different dates may not be commingled in the same container, either at the processing plant or while the fish are being stored, distributed, or offered for sale at wholesale or retail.

(3) MISREPRESENTATION OF PROCESSING DATE PROHIBITED. No person may misrepresent a smoked fish processing date, or sell or distribute smoked fish labeled with any processing date other than the original processing date stated by the processor.

(4) REMOVAL OF MISLABELED OR MISHANDLED SMOKED FISH. Food consisting of or containing smoked fish shall be immediately removed from sale, and shall be destroyed or treated to render it unattractive and unfit for human consumption, if any of the following occurs:

(a) The food package is not labeled with a processing date.

(b) The vacuum-packaged, cold-smoked fish is held, other than for brief periods during distribution, at a temperature above 38° F. (3.4° C.) prior to retail sale. This paragraph does not apply to a food which the department specifically exempts in writing because it is not a potentially hazardous food.

(5) APPLICABILITY OF SMOKED FISH REGULATIONS IN WISCONSIN. No smoked fish may be sold, distributed, or offered or exposed for sale in this state unless the smoked fish have been processed, labeled, and handled in compliance with this subchapter. This subsection applies to every person engaged in the sale or distribution of smoked fish in this state, regardless of whether the person processes smoked fish in this state.

ATCP 70.48 Fish roe. (1) REFRIGERATION. Roe and any attached entrails harvested from a fish shall be refrigerated at a temperature of not more than 38° F. (3.4° C.). Processing of dry salted roe or salted roe product shall be accomplished under 21 CFR 123.

(2) HARVESTING AND HANDLING. Roe and attached entrails, if any, shall be harvested, stored, and transported for processing in covered food grade containers. Each container shall be conspicuously labeled to indicate when each of the following operations was performed, if that operation has been performed:

(a) The roe and attached entrails, if any, were harvested from the fish.

(b) The roe sacks were separated from attached entrails, if any. Roe sacks shall be separated from attached entrails within 48 hours after the roe sacks and entrails are harvested from the fish.

(c) The roe was separated from the roe sacks. Roe shall be separated from roe sacks within 72 hours after the roe sacks are harvested from the fish, unless the roe is processed and packed in roe sacks. Roe processed and packed without being separated from roe sacks shall be processed and packed within 72 hours after the roe sacks are harvested from the fish.

(3) RECEIPT FOR PROCESSING. A fish processing plant operator may not accept for processing any roe that has been held, transported, or processed in violation of sub. (1) or (2).

(4) PROCESSING STANDARDS. (a) Roe shall be held and processed according to s. ATCP 70.24 (1).

(b) Processed roe shall contain a minimum of 2.5% salt by weight, as determined by quantitative analysis for total salt content.

(c) No fish processing plant personnel may have direct hand contact with finished, ready-to-eat roe.

(5) PRODUCT REPRESENTATION. (a) No roe product may be labeled or represented as "caviar" unless one of the following applies:

1. The product consists only of the eggs of sturgeon prepared by a salting and separation process traditionally associated with the term "caviar."

2. The product consists of roe prepared by a salting and separation process traditionally associated with the term "caviar," and the name of the fish species is clearly disclosed with the term "caviar" whenever that term is used.

Note: For example, a caviar-type product made from whitefish eggs, using the traditional caviar process, may not be labeled as "caviar" unless it is labeled as "whitefish caviar." All packaged food product labels, including "caviar" labels, must also include a statement of ingredients listed by their common or usual names in descending order of prominence (see ATCP 70.10).

(b) No person may misrepresent the identity or value of any roe product by adding a color additive to the roe product. This paragraph does not prohibit the use of color additives in roe products if all of the following apply:

1. The color additive is approved by the United States food and drug administration.

2. The product includes a conspicuous label disclosure, such as "artificially colored" or "color added," which clearly indicates that the product includes a color additive. The disclosure shall appear on the product label directly below the product name in type at least one-third the size of the type used in the product name.

3. The color additive is included in the ingredient statement on the product label.

ATCP 70.50 Marine molluscan shellfish processing. (1) APPLICABLE FEDERAL REGULATIONS. Shellfish processing and shipping operations shall comply with subch. II of this rule, FDA's *Guide for the Control of Molluscan Shellfish, The Model Ordinance*, and applicable sections of 21 CFR 123. Shellfish processing plant operators shall have HACCP plans that comply with 21 CFR 123 and address food safety hazards that may occur in shellfish processing. If a shellfish processing plant produces smoked shellfish products or smoke-flavored shellfish products, the HACCP plan for that fish processing plant shall address potential botulism risks as provided in 21 CFR 123 part B.

(2) ILLNESS OUTBREAKS ASSOCIATED WITH SHELLFISH. (a) At any time shellfish are potentially implicated in an illness outbreak involving at least 2 (two) persons not from the same household (or at least one person in the case of paralytic shellfish poisoning), the department shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing each consumer's food intake history and the shellfish handling practices of the consumer and retailer.

(b) When the department has determined an epidemiological association exists between an illness outbreak and shellfish consumption, the department shall conduct an investigation of the outbreak to determine whether the illness is related to the shellfish growing area or to post-harvest contamination or mishandling.

(c) Upon completion of the investigation, the department shall notify receiving states and the United States food and drug administration of the findings, and take appropriate steps in cooperation with the licensee dealer to recall the affected product and, if necessary, inform consumers about the outbreak and associated product.

(3) DOCUMENTS ASSOCIATED WITH SHELLFISH PROCESSING. Any documents generated by the facility in the course of its operation shall be available to the department within 24 hours of request by the department or its agent..

Subchapter V. Bottling Establishments; Supplementary Requirements

ATCP 70.52 Bottling establishments; general. Bottling establishments shall comply with subch. II and this subchapter. Bottling establishments producing bottled water shall comply with 21 CFR 129.

ATCP 70.54 Returnable and single-service bottles. Bottles shall comply with food package requirements under s. ATCP 70.26 (1). Returnable bottles shall be cleaned, sanitized, and inspected in compliance with s. ATCP 70.26 (2) and (3). Single service bottles shall comply with s. ATCP 70.26 (4).

ATCP 70.56 Bottled water product sampling; record keeping; reports.

(1) SAMPLING AND ANALYSIS. The operator of a bottled water plant shall collect and analyze samples of bottled product for the following contaminants at the following minimum frequency, and more frequently if necessary, to provide reasonable assurance of compliance with this subsection.

(a) A weekly total coliform analysis. Pursuant to 21 CFR 129.80 (g) (1), a positive total coliform analysis requires follow-up testing for *E. coli* and, pursuant to 21 CFR 165.110 (b) (2) (B), if *E. coli* is present the bottled water will be deemed adulterated.

(b) An annual physical analysis pursuant to 21 CFR 165.110 (b) (3) for turbidity, color and odor analysis.

(c) An annual chemical analysis pursuant to 21 CFR 165.110 (b) (4).

(d) An annual radiological analysis pursuant to 21 CFR 165.110 (b) (5).

(2) REPORTING OF ANALYTICAL RESULTS. A processor of bottled water shall report the results of all required analyses, under sub. (1), to the department, for each license year upon request. If the result of any individual analysis exceeds the established enforcement standard, the bottled water processor shall submit a copy of that analytical report to the department within 7 days of the completion of the analysis.

ATCP 70.58 Labeling bottled products. (1) Bottled products shall be labeled according to s. ATCP 70.26 (5). Bottled water shall also be labeled according to 21 CFR 165.110. Juice shall be labeled according to 21 CFR 120, and any applicable state regulations found in this chapter.

Subchapter VI. Juice and Juice HACCP

ATCP 70.60 Juice and Juice HACCP. (1) APPLICABLE REGULATIONS. Food processing plants producing and packaging or bottling juice shall comply with subch. II and this subchapter. Food processing plants engaged in juice processing and packaging or bottling shall comply with 21 CFR 120.

(2) LABELING REQUIREMENTS. A juice label may not misrepresent that juice has been pasteurized or has undergone a process equivalent to pasteurization. A juice label may not represent as "fresh" any juice that has been treated with ultra-violet light.

Subchapter VII. Effect of Rules on Local Ordinances

ATCP 70.62 Effect of rules on local ordinances. (1) NON-CONFLICTING LOCAL ORDINANCES PERMITTED. This chapter does not prohibit or nullify any local government ordinance with which it is not in direct conflict as provided in sub. (2).

(2) PRE-EMPTION OF CONFLICTING LOCAL ORDINANCES. If this chapter conflicts directly with any local government ordinance, so that it is impossible to comply with one except by violating the other, this chapter controls.

(3) DUTY TO COMPLY. Compliance with local government ordinances does not relieve any person from the duty of complying with this chapter.

Subchapter VIII. Variances

ATCP 70.64 Variances. (1) ISSUANCE. The department may issue a written waiver granting a variance from a construction, equipment, or processing standard under this section if the department finds that the variance is reasonable and necessary under the circumstances, and that it will not compromise the purpose served by the construction, equipment, or processing and recreational standard. The administrator of the department's division of food and recreational safety may issue a waiver on behalf of the department. The department shall keep a copy of the waiver on file for as long as the waiver remains in effect.

(2) SUBMISSION OF REQUEST FOR A VARIANCE. A variance request shall be submitted to the department through the sanitarian assigned by the department to inspect the food processing plant, and shall include all validation documents as well as a HACCP Plan or FSMA preventive controls as applicable if it is for a waiver of accepted processing protocols.

(3) DURATION AND EXPIRATION. All waivers granted under this section shall expire in five years from the date of issuance or when changes are made that could have an effect on the validity of the procedures or process.

SECTION 2. EFFECTIVE DATE: This rule shall take effect on the first day of the month following publication in the Wisconsin administrative register, as provided under s. 227.22 (2) (intro).