

**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 Wis. Admin Code ch. ATCP 70 (Food Processing Plants.) The rule is necessary to update and clarify Wisconsin's food processing plant standards, and to incorporate new federal requirements designed to improve the nation's food safety system.

Statutes Interpreted

Statutes Interpreted:

- Wis. Stat. § 97.29, "Food processing plants."
- Wis. Stat. § 97.30, "Retail food establishments."
- Wis. Stat. § 97.34, "Bottled drinking water and soda water beverage; standards; sampling and analysis."
- Wis. Stat. § 97.42, "Compulsory inspection of livestock or poultry, and meat or poultry products."
- Wis. Stat. § 97.605, "Lodging and vending licenses."
- Wis. Stat. § 97.61, "Vending machine commissary outside the state."

Statutory Authority

Statutory Authority: Wis. Stat. §§ 93.07 (1), 97.09 (4), and 97.29 (5).

Explanation of Statutory Authority

The Wisconsin Department of Agriculture, Trade and Consumer Protection ("DATCP") has broad general authority, under Wis. Stat. § 93.07 (1), to adopt rules to implement programs under its jurisdiction. DATCP also has general authority under Wis. Stat. § 97.09 (4) to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. DATCP has specific authority, under Wis. Stat. § 97.29 (5), to adopt rules establishing fees; setting facility construction and maintenance standards; and setting rules for the design, installation, maintenance, and cleaning of equipment and

utensils; personnel sanitation; food handling and storage; sanitary production and food processing; and food sources and food labeling.

Related Statutes and Rules

21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, is a critical foundation for the current rule. Related Wisconsin administrative rules include those pertaining to retail food establishments (Wis. Admin. Code ch. ATCP 75 and the Appendix to that rule); dairy plants (Wis. Admin. Code ch. ATCP 65), food warehouses (Wis. Admin. Code ch. ATCP 71), and meat and poultry establishments (Wis. Admin. Code ch. ATCP 55).

Plain Language Analysis

The proposed rule updates Wis. Admin. Code ch. ATCP 70 by adopting certain federal regulations that implement the requirements of the federal Food Safety Modernization Act (“FSMA”) for facilities subject to the new requirements. Specifically, the revised rule incorporates multiple subparts of 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, which has superseded 21 CFR 110, *Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food*. The subparts of 21 CFR 117 pertain to preventive food safety systems, and have already been referenced in Wis. Admin. Code chs. ATCP 65 (Milk and Milk Products) and ATCP 71 (Food Warehouses and Milk Distributors). Since the majority of Wisconsin federally-registered food facilities subject to 21 CFR 117 are licensed as food processing plants, this rule features similar referencing to inform affected businesses. This revision also ensures that the requirements for Wisconsin-licensed food processing plants that are not subject to the federal rule, are clearly articulated.

The transfer of the Department of Health Services’ (DHS) Food Safety and Recreational Licensing program to DATCP’s Division of Food Safety necessitated the merger of two food safety regulatory systems. One regulatory issue was particularly in need of resolution: Restaurant operators were not allowed to wholesale food under the DHS regulation, while retail food establishment operators under DATCP’s authority could engage in a limited amount of wholesaling without holding a food processing plant license. By statute, restaurants are now licensed as retail food establishments and therefore also enjoy the same limited ability to wholesale food. In the current rule-making process, DATCP initially proposed to retain certain existing limits and requirements from its prior rule concerning food processing activities for wholesale conducted by a retail food establishment. The Board of Agriculture, Trade and Consumer Protection (“Board”) approved a draft rule reflecting this approach at its January 2018 meeting. This final draft also for the first time included definitions of “wholesale” and “retail”. However, after the Board meeting, it became apparent that industry participants felt that less restrictive limits and definitions would still adequately protect public health.

As a result of this feedback, DATCP formed a work group comprised of industry personnel and local health department agent program representatives. The group was tasked with further revision of the rule. During deliberations, the work group concluded that the safety of many wholesale food processing activities, when performed by retail food establishments, could be ensured by compliance with Wis. Admin. Code ch. ATCP 75 and the appendix thereto, *Wisconsin Food Code*. Thus, compliance with the additional requirements in Wis. Admin. Code ch. ATCP 70 was unnecessary. The work group recognized that additional training would be needed for local health department agent personnel, as well as DATCP

sanitarians, who were assigned to retail food establishments performing these wholesale food processing activities. DATCP, as part of its ongoing mission to thoroughly train food safety personnel at the state and local level, is committed to providing both the necessary initial training and ongoing technical support.

The work group's efforts culminated in a newly revised final draft of Wis. Admin. Code ch. ATCP 70 that redefined "wholesale" and "retail", clarified the exemption for retail food establishments from the requirement to hold a food processing plant license when conducting limited (not more than 25% of gross annual food sales) wholesale food processing activities, and redrew the boundaries for permitted types of wholesale food processing activities. Perhaps the most salient change was that a transfer of food between two food processing plants or retail food establishments is not regarded as wholesaling, as long as the two businesses involved are operated by the same licensed entity, and the firm transferring the food does not relinquish control of the food. This change reflects current guidance from the United States Food and Drug Administration ("FDA") and the United States Department of Agriculture, Food Safety and Inspection Service.

The revised definitions of "wholesale" and "retail" reflect industry practice and the current interpretation of these terms in the marketplace, as well as FDA's recent guidance and its sanction of industry practice. The revised definitions also appear in the pending revision to Wis. Admin. Code ch. ATCP 75 (Retail Food Establishments). While the revised rule continues to prohibit retail food establishments from processing canned low-acid or acidified foods for wholesale without holding a food processing plant license and complying with Wis. Admin. Code ch. ATCP 70 requirements, DATCP expects the other updates to clarify and facilitate enhanced business opportunities for retail food establishments in Wisconsin.

Another theme of early discussions of the proposed rule revision was the question of whether additional regulations were necessary to ensure sanitary conditions in food processing plants sharing a building with a residence. The initial draft of the revised rule forbade the licensing of any new or remodeled food processing plant in this situation. However, the working group agreed there was no need for an outright ban or other additional regulation to ensure adequate separation between residential and processing activities or access for DATCP inspections. Accordingly, the proposed revision was deleted.

In addition to resolving these complex issues, the revised rule makes several other changes. The rule adopts the Model Ordinance for molluscan shellfish, now *marine shellfish*, with the Ordinance replacing all of Wis. Admin. Code s. ATCP 70.21 except for the existing subsection addressing illnesses and outbreaks associated with shellfish. This modification will keep Wisconsin's regulations current with national standards for shellfish processing and marketing.

This revised rule also:

- Updates the definition of "food processing" to include the activities of a vending machine commissary.
- Updates the definition of "food processing plant" to conform to the statutory definition.
- Clarifies the definition of extended runs, i.e., continuous processing not interrupted by daily cleaning and sanitizing, and the scope of waivers allowing those runs, while clarifying and expanding the list of food processing activities during which daily cleaning and sanitizing are not required. The duration and review of such waivers are also defined.

- Updates certain outdated restrictions on hot-smoked, vacuum-packed fish. Previous requirements were unique to Wisconsin whereas the updates mirror requirements in other states and are based on current FDA guidance.

- Mandates filing and obtaining process-authority approval for processes used in the preparation of canned acidified or low acid foods.

- Enables food processing plants to obtain waivers from DATCP for variances to allow non-standardized and innovative equipment, utensil, processes and procedures. Prior to this revision, waivers and variances could only be obtained by food processing plants for structural and equipment issues. Waivers related to facility construction do not have an expiration date while waivers related to equipment, utensils, processes, procedures, and alternative cleaning and sanitizing frequencies are for a period of five years, but do not expire until the department takes action on a request for reissuance as long as the license holder makes a timely application for reissuance.

- Updates and clarifies language pertaining to the standards for, and testing of, operations water and ingredient water used in the various bottling and processing operations in Wisconsin, as well as finished product sampling and analysis for bottling establishments.

- Expands the scope of bottling rules to encompass more than bottled water and soda, thereby keeping pace with this rapidly changing and innovative segment of the bottling industry.

- Maintains the regulatory floor of \$25,000 in sales for food processing plants that are required to pay the canning license fee surcharge.

- Clearly specifies requirements exempted by so-called “grandfather clauses,” that apply to a continuing license-holder who does not increase processing area dimensions (floor-wall junctions, floor drainage, and service sink or curbed drain); install, substantially reconstruct, or extensively alter toilet facilities (separately vented to the outside, equipped with an exhaust fan capable of creating a negative pressure, and do not open directly into a food processing area); install, substantially reconstruct, or extensively alter hand-washing facilities for toilet rooms (tempered or hot-cold mixed water, non-hand operated faucets) or for food processing areas (not located in the food processing area, tempered or hot-cold mixed water, non-hand operated faucets); or install a warewashing sink (3 compartments).

- Requires license holders that install toilet rooms after the effective date of the rule and food processing plants that are initially licensed or licensed to a new operator after the effective date of the rule to have toilet rooms contiguous with the food processing plant.

Federal and Surrounding State Programs

Federal Programs

The major federal regulations implementing FSMA and applicable to food processing plants are found in 21 CFR 117. Other federal regulations apply to canned low acid (21 CFR 113) and acidified (21 CFR 114) foods, seafood processing (21 CFR 123) and juice processing (21 CFR 120). Current language on the molluscan shellfish program was deleted in order to adopt the Federal Model Ordinance, applicable to

marine shellfish shipped for wholesale, in order to provide that segment of the Wisconsin food industry with regulatory consistency within interstate commerce.

Surrounding State Programs

Michigan, Iowa, and Minnesota license and regulate food processing facilities within their borders as Wisconsin does. 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 such as those implementing FSMA, FDA guidance on the applicability of Hazard Analysis and Critical Control Point (“HACCP”) requirements for juice and seafood processors; Wisconsin statutes and rules for food processing plants, retail food establishments, meat establishments, and dairy plants; and current industrial practices. Upon learning of industry concerns about proposed licensing and regulatory requirements for retail food establishments conducting food processing for wholesale activities, DATCP delayed further consideration of the rule and convened a collaborative work group comprised of industry and local health department agent personnel to review and revise the requirements. The work group’s conclusions are reflected in the present revised rule.

Effect on Small Business

A positive impact of this rule revision on all classes of business is the expanded ability of food processing plants to apply for waivers from requirements related to equipment, utensils, processes or procedures. This change may allow the use of new and innovative techniques and processes so long as the processor can demonstrate that food safety is not compromised. In addition, the costs of facility upgrades necessitated by the loss of a grandfather exemption (see following paragraphs) may be mitigated if the license-holder requests a variance from a facility requirement, provided the variance meets the public health intent of the requirement.

No economic impact comments were received during the August 8, 2017-September 7, 2017 comment period.

Supervisors of DATCP staff who inspect all of licensed food processing plants were surveyed to provide an estimate of the number of license-holders that would be affected by new requirements. DATCP staff knowledgeable in facility construction costs were queried about likely costs of new facility requirements. These staff, in turn, consulted commercial equipment and construction personnel to obtain or verify cost estimates. Finally, an informal economic impact comment period was held between August 20 and September 3, 2019. All licensed food processing plants were contacted by either e-mail (1,378 businesses) or mail (531 businesses) and asked for their assessment of costs they would have to bear due to new requirements. Over 200 responses (greater than 11%) were received.

The estimated economic impact is \$656,000 across 1900 businesses. Costs have been attributed to possible one-time upgrades in handwashing sinks, toilet rooms, and exit doors that some firms may have to make.

The rule requires handwashing sinks in toilet rooms or food processing areas to meet modern requirements for mixing of hot and cold water and hands-free operation in newly licensed facilities or in facilities operated by a license-holder continuing since on or before November 1, 2009 in which the handwashing sinks are substantially reconstructed or extensively altered. The requirement is already in place for new license-holders or installations of handwashing sinks in already-licensed food processing plants. DATCP estimates that not more than 40 businesses would face the costs of new sink installation. DATCP estimates that costs for these businesses would not exceed \$1,000 apiece. The total cost estimate includes \$40,000 for handwash sink upgrades. Survey response data support this estimate as approximately 70% of respondents indicated that "none" or "slight" costs would be imposed. Comments indicated a high level of existing compliance with this requirement. Cost estimates listed in the comments ranged from a few hundred dollars to less than \$10,000 per business. Some commenters who provided relatively higher cost estimates were apparently unaware that less-expensive "wrist paddle" or "foot pedal" operation would meet the requirement and described the costs and challenges of installing and using electronic-sensor operated faucets.

The rule requires newly installed toilet rooms to be contiguous to the food processing area. This requirement applies if either the toilet room was constructed after the date of this rule or in food processing plants newly opened or operated by a new license-holder after the date of this rule. Pre-existing non-contiguous toilet rooms in a food processing plant operated by the same license-holder since on or before the date of this rule would be allowed, provided applicable state and local regulations were met. DATCP estimates that, based on history, not more than 40 businesses choose to install a toilet room in a given year. Costs of construction could vary widely depending on the situation, but a worst-case estimate of \$10,400 per business was used in arriving at the figure of \$416,000 included in the total estimated economic impact. Survey responses corroborate DATCP's estimate as more than 80% of respondents indicated none or slight costs for compliance. Most of the written comments indicated that firms were in compliance, either with contiguous toilet rooms or non-contiguous toilet rooms that complied with state and local requirements.

The rule contains a provision that food processing plant exit doors open outwards, consistent with long-standing building code requirements. More than 70% of survey respondents indicated none or slight costs of compliance. Most written comments described compliant exit doors or doors that likely would be approved following the Department's variance process. The costs of door replacements described by a small number of commenters were less than \$10,000. DATCP estimates that not more than 40 businesses would face costs of \$5,000 or less; a figure of \$200,000 is included in the total estimated economic impact.

The rule continues to allow firms operated without changes in processing area dimensions by the same license-holder since on or before June 30, 1989, to be exempt from requirements for coving of floor-wall junctions, floor slope and drains, and provision of service sinks or curbed floor drains for disposal of mop water and similar wastes. Since 1989, these requirements have been enforced on all new license holders pursuant to state statute requiring licenses to be non-transferable. The rule clarifies this interrelationship of statute and administrative rule and thus no "new" costs are added to industry or included in the total estimated economic impact. The Department has added flexibility to the previous requirement for coving to reduce costs that would be faced by "grandfathered" businesses that choose to alter their processing area dimensions or by new license-holders operating in a previously grandfathered facility.

Aside from the above facility-related issues, much of the focus of the proposed rule revision is on the clarification and updating of existing regulations, such as the various exemptions from a food processing plant license and the clarification of various record-keeping requirements. These changes are not anticipated to have a significant financial or other impact.

The rule and revised economic impact analysis were posted for comment September 5-19, 2019.

DATCP Contact

Questions and comments related to this rule may be directed to:

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[SEE PDF FOR PROPER FORMATTING OF RULE]

SECTION 1. ATCP 70 is repealed and recreated to read:

Chapter ATCP 70

WHOLESALE FOOD MANUFACTURING

SUBCHAPTER I

SCOPE AND DEFINITIONS

ATCP 70.01 Scope.

ATCP 70.02 Definitions.

Subchapter II. General Requirements

ATCP 70.04 Federal and record keeping 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.
ATCP 70.16	Cleaning and sanitizing equipment and utensils; 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; record keeping; reports.
- ATCP 70.58 Labeling bottled products.

Subchapter VI. Juice and Juice HACCP

- ATCP 70.60 Juice and 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).

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 sanitizing solution" means a substance or compound approved by the department for the sanitizing of equipment or utensils under s. ATCP 70.28 (5).
- (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 either engaged in the preparation and sale of beverages, under a license issued under s. 125.26 or 125.51, Stats., or licensed under s. 97.30 or 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" 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 step 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. ATCP 70.04 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 alligators, frogs, aquatic turtles, jellyfish, sea cucumber, 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 fishery 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. "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 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 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 retail food establishment license issued under s. 97.30, Stats., 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 used primarily for food processing, where the processed food is not intended to be sold or distributed directly to a consumer. "Food processing plant" does not include any mobile establishment, retail food 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 either 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 has been 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) Fully cooked or heated in accordance with par. (a) and 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 used by a food processing plant for cleaning equipment and utensils, transporting food, 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), part 1201.10 (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 ss. ATCP 70.36 or 70.38.

(35) "Qualified facility" as used in s. ATCP 70.04 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), part 1-201.10 (B).

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

(38) "Retail" means selling food or food products directly to any consumer only for consumption by the consumer or the consumer's immediate family or non-paying guests.

(39) "Roe" as used in s. ATCP 70.48 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" 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" means any utensil, container, or package, or any part of a utensil, container, or package, which is designed to be used only once.

(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, distribute it for re-sale, or use it as an ingredient in a product that will be then offered for sale. Wholesale includes those activities in which the processor relinquishes control of the food. Wholesale does not include the movement of food between two food processing plants or retail food establishments licensed to the same licensee, except for the movement of dairy products as specified in s. ATCP 65.04.

SUBCHAPTER II

GENERAL REQUIREMENTS

ATCP 70.04 Federal and record keeping requirements. (1) FACILITIES AND QUALIFIED FACILITIES.

A food processing plant that is also a facility or a qualified facility shall comply with the requirements of this chapter and applicable requirements of 21 CFR 117.

(2) RECORD REQUIREMENTS AND RETENTION. (a) The operator of a food processing plant that is a facility shall create 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.

(c) The license holder 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 70.06 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 license to operate a food processing plant 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 license to operate a food processing plant shall pay an annual license fee. Except as provided in sub. (4), the fee amount is as follows:

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

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

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

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

(e) For operating 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 an operator of a food processing plant is engaged in canning operations and has annual food sales of more than \$25,000, the operator shall pay an annual license fee surcharge of \$320, which shall be added to the license fee under sub. (3).

(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 regular inspection, the department

shall charge the licensee 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 licensee.

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

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

2. For a license holder of a food processing plant that has an annual production of at least \$250,000, and the license holder is engaged in processing potentially hazardous food or in canning, the reinspection fee is \$525.

3. For a license holder of a food processing plant that has an annual production of less than \$250,000, and the license holder is not engaged in processing potentially hazardous food or in canning, the reinspection fee is \$150.

4. For a license holder of a food processing plant that has an annual production of \$250,000 or more, and the license holder is not engaged in processing potentially hazardous food or in canning, the reinspection fee is \$490.

5. For a license of 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 40 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 an operator to procure farm products from producers unless the 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 to operate the food processing plant. The department may not issue a license or temporary license to operate 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 license to operate a food processing plant is not required under s. 97.29, Stats., or this section for:

(a) An operator of a retail food establishment engaged in food processing if all of the following apply:

1. The operator is licensed by the department under s. 97.30, Stats., or by an agent as defined in ch. 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 the operator of a licensed retail food establishment is also licensed to operate a dairy plant under s. 97.20, Stats., or to operate a meat establishment under s. 97.42, Stats., sales of dairy or meat and poultry products processed at the establishment shall be excluded from the calculation of food sales receipts under this subdivision.
3. The operator is not engaged in canning of food products at the retail food establishment.
4. The operator may move food between retail food establishments licensed to the same operator.

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

1. The operator does not process food for wholesale distribution in excess of 25% of total food sales and is not engaged in canning of food products. The operator may brew beer at the retail food establishment serving meals under the provisions in s. 125.295, Stats.

2. The operator of 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 operator of 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 operator of 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 operator is also licensed at the meat establishment to operate 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) The operator of 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 the U.S. food and drug administration's *Guide for the Control of Marine Shellfish, The Model Ordinance*, that annual inventory value of molluscan shellfish reshipped 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 subch. IV of ch. ATCP 70.

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

3. Combining 2 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 70.26.

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.

ATCP 70.08 Construction and maintenance. (1) CONSTRUCTION AND MAINTENANCE; GENERAL. Food processing plants shall be soundly constructed and maintained in order to prevent adulteration as defined in s. 97.02, Stats. The license holder shall 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 maintained in a sanitary condition in compliance with this chapter.

(2) FLOORS, WALLS, CEILINGS, AND SERVICE SINKS. (a) Walls and ceilings in processing areas shall be light colored.

(b) 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. This does not prohibit the use of easily cleanable anti-slip floors.

(c) All floors, walls, and ceilings shall be kept clean and in good repair.

(d) A food processing plant constructed or altered in a manner that changes the dimensions of a processing area after June 30, 1989, or a food processing plant that is initially licensed or is licensed to a new operator after June 30, 1989, shall conform to the following requirements:

1. The junctions of walls and floors in processing areas shall be coved, or otherwise constructed so that each junction does not form a right angle, to facilitate cleaning.

2. 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.

3. 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.

(3) 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 an operator of a retail establishment serving meals also engages in food processing, under the exemption in s. ATCP 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.

(4) DOORS AND WINDOWS. 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. Exit 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.

(5) 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.

(6) 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.

(7) TOILET FACILITIES. (a) The operator shall provide sanitary toilets in sufficient number to accommodate employees, in accordance with applicable state and local regulations.

(b) The sanitary toilets shall be in toilet rooms that are completely enclosed, well-lighted, and equipped with tightfitting self-closing doors. Toilet rooms constructed, substantially reconstructed, or extensively altered after June 30, 1989, or if they are located in a food processing plant that is initially licensed or licensed to a new operator after June 30, 1989, shall be separately vented to the outside, equipped with an exhaust fan capable of creating a negative pressure within the toilet room, and may not open directly into a food processing area.

(c) The sanitary toilets, toilet rooms, and fixtures shall be easily cleanable, and shall be kept clean and in good repair.

(d) When a toilet room is available for use by employees, it shall be equipped with an easily cleanable covered trash receptacle and an adequate supply of toilet tissue.

(e) Toilet rooms serving a food processing plant shall be contiguous to the food processing plant if they are installed after the effective date of this paragraph ... [LRB inserts date], or if the food processing plant

is initially licensed or is licensed to a new operator after the effective date of this paragraph ... [LRB inserts date].

1. Toilet rooms serving a food processing plant may be noncontiguous to the food processing plant if they were installed before the effective date of this subdivision ... [LRB inserts date] and if the food processing plant is initially licensed or is licensed to a new operator before the effective date of this subdivision ... [LRB inserts date].

2. Noncontiguous toilet rooms shall be conveniently adjacent and accessible to the food processing plant, and meet all applicable state and local regulations.

(f) 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, substantially reconstructed, or extensively altered after November 1, 2009, or if they are located in a food processing plant that is initially licensed or licensed to a new operator after November 1, 2009:

1. Handwashing facilities 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.

(8) LOCKER AND LINEN FACILITIES. The operator 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.

(9) HANDWASHING FACILITIES FOR PROCESSING AREAS. (a) The operator 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, substantially reconstructed, or extensively altered after November 1, 2009, or if it is located in a food processing plant that is initially licensed or licensed to a new operator after November 1, 2009:

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

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

(10) CLEANING FACILITIES. (a) If equipment, utensils, or food packages are cleaned or sanitized manually, the food processing plant shall be equipped with wash and rinse sinks 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. Each sink shall have at least 2

compartments. A sink installed after June 30, 1989, or a sink in a food processing plant that is initially licensed or is licensed to a new operator after June 30, 1989, shall have at least 3 compartments for washing, rinsing, and sanitizing equipment and utensils.

(b) Each compartment in a manual warewashing sink shall be large enough to accommodate the immersion of at least 50% of the largest item to be cleaned or 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 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 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.

(11) 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, and other potential health nuisances. Driveways and parking lots shall be surfaced or maintained to minimize airborne dust and dirt.

(12) 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.

(13) 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, leak-proof, 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.

(14) CONTROL OF PESTS. The operator 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.

(15) CONSTRUCTION; PLAN REVIEW. Before a food processing plant is constructed, substantially reconstructed, or extensively altered, the operator 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.

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

(17) MAPLE SAP CONCENTRATION FACILITIES. A facility licensed as a food processing plant and used solely for the concentration of maple sap, shall meet the requirements of s. ATCP 87.14.

ATCP 70.10 Personnel standards. (1) CLEANLINESS. (a) 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.

(b) Par. (a) does not apply to an operator of a maple sap concentration facility licensed to operate a food processing plant that is required to meet the provisions of s. ATCP 87.28.

(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) The operator shall provide prior training on procedures and policies that cover pars. (a) to (d) 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 shall review the training program under par. (e) at least annually.

(g) The operator shall maintain records to document 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, part 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 quality control procedures written and followed by the license holder.

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. This subsection does not apply to a maple sap concentration facility licensed as a food processing plant that is required to meet the provisions of s. ATCP 87.26.

(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 that cannot be easily moved shall be installed in a manner preventing liquid or debris from accumulating under or around the equipment. Equipment shall be installed so there is adequate clearance on all sides for cleaning and maintenance. This does not apply to that portion of a tank or container 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 accurately indicating 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 adequate for their intended use.

(6) LUBRICATION. Equipment shall be designed and constructed so 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 ss. ATCP 70.16 and 70.40, the 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 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. If wet cleaning occurs, surfaces must also be sanitized.

(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. This paragraph does not apply to equipment used to distill smoke for the manufacture of liquid smoke products.

(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, maintained on file for at least 90 days, and 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 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).

(7) EQUIPMENT AND UTENSILS IN MAPLE SAP CONCENTRATION FACILITIES. The equipment and utensils in a facility used solely for the concentration of maple sap shall conform to the applicable regulations in s. ATCP 87.26.

ATCP 70.16 Cleaning and sanitizing equipment and utensils; exemptions. (1)

APPROVAL REQUIRED FOR AN ALTERNATIVE CLEANING AND SANITIZING FREQUENCY.

Except as provided in sub. (2) or s. ATCP 70.40, if an 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 or presence of major food allergens, then the operator shall submit to the department, for written approval, an alternate cleaning and sanitizing procedure that includes a monitoring and recording requirement in compliance with s. ATCP 70.18.

(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) After review by the department, the proposed process may be denied and the department shall issue a letter of denial. If the alternate cleaning and sanitizing procedure is approved, the department shall issue a letter of approval, applicable for not more than 5 years, which shall be maintained on file at the food processing plant.

(c) If a change is planned for the product or any process that affects the critical factors ensuring the safety of that product, the operator shall inform the department in writing prior to making a change.

(2) NO APPROVAL REQUIRED FOR AN ALTERNATIVE CLEANING AND SANITIZING FREQUENCY. An 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, provided that the 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-Potentially Hazardous Food (non-PHF/non-TCS) foods based on (2) (b) Table A or Table B for Potentially Hazardous Food (time/temperature control for safety food) in par. 1-201.10 (B) of ch. ATPC 75 Appendix, such as chocolate, fats and oils, liquid nutritive sweeteners, peanut butter, or similar foods.

(f) Ice makers maintained in a cold/frozen state.

(g) Food contact surfaces of equipment used for brewing or fermentation of alcohol-containing beverages, such as beer brewing or wine fermentation, so long as the operator cleans and sanitizes 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, an 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, or development of starter cultures, so long as the operator cleans and sanitizes all equipment following each fermentation batch.

(j) Equipment used for processing of products with a natural $\text{pH} \leq 4.0$, so long as the operator cleans and sanitizes all equipment at the end of a continuous operation, not to exceed 30 days (720 hours).

(k) Equipment used for maple syrup processing, so long as the operator cleans and sanitizes all equipment at the end of a continuous operation, not to exceed 40 days (960 hours).

(L) Equipment used for bottled water processing, so long as the operator cleans and sanitizes 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. An 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 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 operator, that the alternative cleaning and sanitizing procedure has been determined by competent authority, such as evaluated by a process authority or validated by a published or unpublished peer-reviewed article, challenge studies, or regulatory standards, to be effective in preventing food contamination and ensuring the microbiological safety of food.

(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 par. (a) if the operator can show that the procedure will be effective in preventing food contamination and ensuring the 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) and (4) 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 it deems 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 observing changes in operations that could affect the validity of the procedures or process.

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

(b) A license holder who wishes to continue to use an alternative cleaning and sanitizing frequency after the expiration of the approval shall file a request with the department for reissuance of the approval at least 180 days prior to its expiration, unless permission for a later date has been granted by the department.

(c) When a license holder has made timely and sufficient application for the reissuance of an approval of alternative cleaning and sanitizing frequency, or for the approval of a new request with reference to any activity of a continuing nature, the existing approval does not expire until the application has been finally acted upon by the department, or, if the application is denied or the terms of the new request are limited, until the last day for seeking review of the agency decision or a later date fixed by order of the reviewing court.

(d) Approval shall be reissued by the department if the proposal continues to meet the criteria in sub. (1) or if the food processing plant operator updates the original proposal to ensure compliance with the criteria in sub. (1).

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

(a) Control and monitor the procedure to ensure that it 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 ch. 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 s. NR 809.07.

(c) Operations water sourced from either municipal, private, or non-community water systems shall comply with the microbiological standards under s. NR 809.30. Operations water from a privately owned water system shall be sampled by the operator not less than once every 12 months and be tested at a laboratory, certified to perform the appropriate tests, under ch. ATCP 77.

(d) An 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 food 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 food processing plant.

(f) This subsection does not apply to food processing plants processing liquid maple products, as defined in s. ATCP 87.11 (7), or maple sap water, as defined in s. ATCP 87.11 (9), that are required to meet the provisions of s. ATCP 87.24.

(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 ch. 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 s. NR 809.07, the microbiological standards in s. NR 809.30, and the health-related enforcement standards in s. NR 140.10.

At the department's request, an operator shall provide documentation to the department that the water complies with the microbiological standards of s. NR 809.30.

Documentation may consist of results from tests performed at a laboratory certified under ch.

ATCP 77 for the entity providing the water.

(c) If ingredient water is obtained from a privately owned water system, the operator shall sample the water at least once every 12 months, and have the sample tested at a laboratory, certified to perform the appropriate tests, under ch. ATCP 77.

(d) An operator shall keep on file, for at least 5 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 Wastewater*, twenty-first edition (2005), published by the American Public Health Association, the American Water Works Association, and the Water Environment Federation. The 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 Wastewater*, 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. The 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 operator tests the reclaimed water for compliance with subds. 1. to 4. 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 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*

Wastewater, twenty-first edition (2005), published by the American

Public Health Association, the American Water Works Association, and the Water Environment Federation.

The 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 Wastewater*, 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/.

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

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

5. 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.

6. 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.

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

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

9. The 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.

10. 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) An 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 U.S. environmental protection agency. 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) An 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. An operator shall conduct a daily testing program for any chemical added to water, to ensure that the chemical concentration does not adulterate food.

(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 chs. NR 811 or 812, as applicable.
2. Bacteriologically safe.

3. Protected from contamination.

4. Tested by the operator for compliance with subd. 2. 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 chs. 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. Water 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) 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 the frozen food 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. By microwave heating, 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 distributed or offered for sale as human food after its package is repaired or relabeled without being opened.

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

(b) An 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) An 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 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 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) An 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.

(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 (5) (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) S. 97.09, Stats., and federal regulations incorporated by reference in s. 97.09, Stats.

(c) Ch. ATCP 90.

(d) Ch. ATCP 75 Appendix, part 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.

(7) ALCOHOL RESTRICTIONS AND LABELING. If a product contains more than 1.0% but less than 7.0% alcohol it is regulated by the labeling provisions of this subsection and the alcohol would be declared as an ingredient in normal descending order of predominance. If the alcohol is part of other ingredients such as a flavoring, and it is less than 0.5% of the finished product by volume, then it is considered an incidental ingredient.

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.

(2) CHEMICAL SANITIZERS; REQUIREMENTS. The operator shall use only chemical sanitizers that are specified as acceptable for use in 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 do not leave an unacceptable residue on the food contact surface when used appropriately.

(3) BAKING AND COOKING CONTAINERS; EXEMPTION. Sub. (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.

(4) SANITIZERS; MAXIMUM CONCENTRATIONS. The operator shall use sanitizers and cleaning compounds so no toxic or otherwise unacceptable 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.

(5) SANITIZERS; DEPARTMENT APPROVAL. (a) Sanitizers approved by the U.S. environmental protection agency 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), an 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 State of Wisconsin's Emergency Management phone number is (800) 943-0003. The general number of the Division of Food and Recreational Safety is (608) 224-4700, and its FAX number is (608) 224-4710.

(2) EXEMPTION. An 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 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. An 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 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 may 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. Operators engaged in canning operations shall comply with applicable provisions of subch. II. Operators engaged in canning operations shall also comply with this subchapter and shall file processes, as required, with the U.S. food and drug administration 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 70.36 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.

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 operator of a food processing plant conducting canning operations 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 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, if deemed appropriate, 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 deemed appropriate, sanitize the equipment, including equipment used to conduct these procedures, frequency, methods, materials, and relevant process parameters such as time and temperature. The description shall include a flow diagram of the alternative procedures.

(d) A written statement, by the operator, that the alternative cleaning and sanitizing procedures have been determined by competent authority, such as a process authority or validated by a published or unpublished, peer-reviewed article, challenge studies, or regulatory standards, 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. A fish processing plant operator shall comply with subch. II and 21 CFR 123. The operator 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*.

Note: A copy of the current edition of the *Fish and Fishery Products Hazards and Controls Guidance*, may be obtained from the University of Florida Bookstore by calling (800) 226-1764, or it may be downloaded from the U.S. food and drug administration website:
[http://www.fda.gov/Food/GuidanceRegulation/Guidance DocumentsRegulatoryInformation/default.htm/](http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm/)

(c) The net weight of the package contents.

(d) If cold-smoked fish is contained in reduced-oxygen packaging 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 or processing date code of the smoked fish.

(2) PROHIBITION AGAINST COMMINGLING. Smoked fish processed on different dates or codes 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 OR PROCESSING DATE CODE PROHIBITED. No person may misrepresent a smoked fish processing date or processing date code, or sell or distribute smoked fish labeled with any processing date or processing date code other than the original date or code affixed 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 or processing date code.

(b) 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 subject to spoilage and does not support pathogen growth.

(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 done in accordance with 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 s. ATCP 70.26).

(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, the U.S. food and drug administration's *Guide for the Control of Marine 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 persons not from the same household, or at least one person in the case of shellfish toxicity poisoning associated with marine biotoxins, 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 ss. 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. 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 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, utensils, processing or procedure standard under this chapter 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 standards. 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 required under 21 CFR, parts 120 or 123, if applicable; or food safety preventive controls plan as required under 21 CFR 117, Subpart C, if it is for a waiver of accepted processing protocols.

(3) DEPARTMENT DECISION ON REQUEST FOR A VARIANCE. The department shall grant or deny a request under sub. (2) and (4) 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.

(4) DURATION, EXPIRATION, AND REISSUANCE. (a) Waivers to construction and maintenance standards under s. ATCP 70.08 shall remain in effect as long as no material changes to construction or maintenance of the food processing plant result in failure to meet the standard in sub. ATCP 70.08 (1). All waivers to standards under ss. ATCP 70.10 to 70.32 granted under this section shall expire five years from the date of issuance.

(b) A license holder who wishes to continue a variance to standards under ss. ATCP 70.10 to 70.32 after the expiration of the waiver shall file a request with the department for reissuance of the waiver at least 180 days prior to its expiration, unless permission for a later date has been granted by the department.

(c) When a license holder has made timely and sufficient application for the reissuance of a waiver or a new variance request with reference to any activity of a continuing nature, the existing waiver does not expire until the application has been finally acted upon by the department, and, if the application is denied or the terms of the new request are limited, until the last day for seeking review of the agency decision or a later date fixed by order of the reviewing court.

(d) A waiver shall be reissued by the department if the equipment, utensils, processes, or procedures described in it continue to meet the criteria in sub. (1) or if the food processing plant operator updates the original variance request to ensure compliance with the criteria in sub. (1).

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.), Stats.

Dated this _____ day of _____, 2019.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE, TRADE
AND CONSUMER PROTECTION

By _____
Randy J. Romanski, Interim Secretary