

Chapter ATCP 70

FOOD PROCESSING PLANTS

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Note: Chapter Ag 40 as it existed on October 31, 1989, was repealed and a new chapter Ag 40 was created effective November 1, 1989; Chapter Ag 40 was renumbered ch.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 under s. ATCP 70.02 (17), regardless of whether the food processing plant is subject to licensing under s. 97.29, Stats., or this chapter.

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89.

ATCP 70.02 Definitions. As used in this chapter:

- (1) "Alcohol beverage" means an alcohol beverage as defined in s. 125.02 (1), Stats.
- (2) "Approved sanitizer" means a substance or compound approved by the department for the sanitizing of equipment or utensils under s. ATCP 70.11 (4).
- (3) "Bakery" means any place where bread, crackers, pasta, or pies, or any other food product for which flour or meal is the principal ingredient, are baked, cooked, or dried, or prepared or mixed for baking, cooking, or drying, for sale as food.
- (4) "Bottle" means the immediate package or container in which bottled drinking water, soda water beverage, or alcohol beverage is sold or distributed for consumption. "Bottle" includes a bottle cap or other seal for a bottle.
- (5) "Bottled drinking water" means all water packaged in bottles or similar containers and sold or distributed for drinking purposes. "Bottled drinking water" includes distilled water, artesian water, spring water, and mineral water, whether carbonated or uncarbonated.
- (6) "Bottling establishment" means any place where drinking water, soda water beverage, or alcohol beverage is manufactured or bottled for sale. "Bottling establishment" does not include a retail establishment engaged in the preparation and sale of beverages under a license issued under s. 125.26 or 125.51, Stats., or a restaurant permit or other permit issued under s. 97.605, Stats.
- (7) "C-I-P system" means equipment which is designed, constructed, and installed to be cleaned in place by the internal circulation of cleaning and sanitizing solutions onto product contact surfaces.
- (8) "Canning" means the preservation and packaging in hermetically sealed containers of low-acid or acidified foods.

(8m) "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.

(9) "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.

(9m) "Critical control point" means a point in food processing at which a failure to monitor a food safety variable such as pH, temperature, time, or water activity (a_w), or a failure to control any food safety variable within critical limits or according to specific criteria, may result in an unacceptable food safety risk having a potentially adverse impact on human health.

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

(11) "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.

(12) "Fish" means any kind of fresh or salt water fish, or seafood, without limitation.

(12m) "Fish processing plant" means a food processing plant which produces processed fish or fish products.

(13) "Food" means:

- (a) Articles used for food or drink by persons.
- (b) Chewing gum.
- (c) Articles used for components of matters specified in pars. (a) and (b).

(14) "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 food.

(15) "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.

(16) "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, con-

fectionary, or bottling establishment, and also includes the receipt and salvaging of distressed food for sale or use as food. "Food processing" does not include any of the following:

(a) Activities covered under a dairy plant license issued under s. 97.20, Stats.

(b) Activities covered under a meat or poultry establishment license issued under s. 97.42, Stats.

(c) The retail preparation and processing of meals for sale directly to consumers or through vending machines if the preparation and processing is covered under a restaurant permit or other permit 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.

(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.

(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.

(17) "Food processing plant" means any place where food processing is conducted. "Food processing plant" does not include any establishment subject to the requirements of s. 97.30, Stats., or any restaurant or other establishment holding a permit under s. 97.605, Stats., to the extent that the activities of that establishment are covered by s. 97.30, Stats., or the permit under s. 97.605, Stats.

(17g) "Hazard analysis and critical control point plan" or "HACCP plan" means a food processing plan under which a food processing plant operator effectively prevents, controls, or eliminates food safety hazards by monitoring food safety variables at critical control points, and by controlling those variables within critical limits.

(17n) "Hot-process smoked fish" or "hot-process smoke flavored fish" means fish that is all of the following:

(a) Fully cooked or heat treated, or sold or represented as being fully cooked or heat treated.

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

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

(18m) "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.

(19) "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 nonstriated part of such muscle, which part is known anatomically as the median superficial muscle.

(19m) "Major food allergen" means milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. "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).

(20) "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.

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

(21m) "Organoleptic quality" means quality as assessed by means of sight, smell, touch, or taste.

(22) "Potentially hazardous food" has the meaning given in ch. ATCP 75 Appendix (Wisconsin Food Code), section 1-201.10 (B)(66).

(22c) "Processed fish" means fish that is processed or preserved for human consumption by means of smoking, curing, salting, drying, marinating, pickling, fermenting, or related processes. "Processed fish" does not include fish processed in accordance with s. ATCP 70.13 or 70.14.

(22g) "Ready-to-eat food" has the meaning given in ch. ATCP 75 Appendix (Wisconsin Food Code), section 1-201.10(B)(71).

(22n) "Reduced oxygen packaging" has the meaning given in ch. ATCP 75 Appendix (Wisconsin Food Code), section 1-201.10 (B)(72).

(22p) "Roe" means fish eggs, including fish eggs that are still enclosed in the ovarian membrane.

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

(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 fish or fish products.

(d) Temperatures that maintain frozen food in a constantly frozen condition.

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

(25) "Sanitize" means to destroy pathogens and other microorganisms, to the maximum practicable extent, by the application of an approved sanitizer or sanitizing method to food contact surfaces of equipment, utensils, or food packages which are otherwise clean.

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

(27) "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.

(28) "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.

(29) "Utensil" means a hand-held or similarly portable container or device, such as a tong, 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.

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; cr. (8m), (9m), (17m), (17n), (22n), am. (12m), (16) (c), (20), r. and recr. (22), (23), Register, April, 1996, No. 484, eff. 5-1-96; CR 09-009: am. (6), (16) (d), (17), (20), renum. (17m) and (22m) to be (17g) and (22c) and am. (17g), cr. (18m), (19m), (21m), (22g), (22p), r. and recr. (22), (22n), (23) Register October 2009 No. 646, eff. 11-1-09; renumber of (21m) made under s. 13.92 (4) (b) 1., Stats., Register October 2009 No. 646; CR 14-037: cr. (16) (h), (i) Register April 2015 No. 712, eff. 5-1-15; correction in (6), (16) (c), (17) made under s. 13.92 (4) (b) 7., Stats., Register August 2016 No. 728.

Subchapter II — General Requirements

ATCP 70.03 Food processing plants; licensing; fees. (1) LICENSE REQUIRED. Except as provided under sub. (7), no person may operate a food processing plant without a valid license issued by the department for that food processing plant under s. 97.29, Stats. A food processing plant license expires on March 31 annually. A license is not transferable between persons or food processing plants.

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

(2m) ANNUAL LICENSE FEE. An applicant for a food processing plant license shall pay an annual license fee. Except as provided in sub. (2n), the fee amount is as follows:

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

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

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

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

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

(2n) CANNING OPERATIONS; LICENSE FEE SURCHARGE. If a food processing plant is engaged in canning operations and has an annual production of \$25,000 or more, the operator shall pay an annual license fee surcharge of \$320, which shall be added to the license fee under sub. (2m).

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

(2p) 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.

(2r) REINSPECTION FEE. (a) If the department reinspects a food processing plant because the department has found a violation of ch. 97, Stats., or this chapter on a regularly scheduled inspection, the department shall charge the food processing plant operator the reinspection fee specified under par. (b). A reinspection fee is payable when the reinspection is completed, and is due upon written demand from the department. The department may issue a demand for payment when it issues a license renewal application form to a food processing plant operator.

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

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

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

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

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

5. For a food processing plant that has an annual production of less than \$25,000 the reinspection fee is \$60.

(3) ACTION ON LICENSE APPLICATION. The department shall grant or deny a license application within 40 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. (5), the department may conditionally grant a license application by issuing a temporary license under sub. (4).

(4) 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 farm products from producers, except as specifically authorized by the department in writing. The department may not authorize a food processing plant operator to procure farm products from producers unless the food processing plant operator complies with subch. VI of ch. 126, Stats.

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

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

(6) 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.

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

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

1. The retail food establishment is licensed by the department under s. 97.30, Stats., or by an agent city, village, or county under ss. 97.30 and 97.41, Stats.

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

sales of dairy or meat products processed at the establishment shall be excluded from the calculation of food sales receipts under this subdivision.

3. The retail food establishment is not engaged in canning or production of processed fish.

(b) A restaurant holding a permit under s. 97.605, Stats., if any of the following applies:

1. The restaurant does not process food for wholesale distribution, and is not engaged in canning of food products or in the production of processed fish.

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

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

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

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

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

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

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

3. The meat establishment is not engaged in canning food other than meat or meat products, and is not engaged in production of processed fish.

(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 Safety
P.O. Box 8911
Madison, WI 53708

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

1. Repacking molluscan shellfish, provided that the licensed warehouse operator holds a licensee dealer certification as required under s. ATCP 70.21 (2), that annual inventory value of molluscan shellfish repacked at the licensed warehouse does not exceed 25% of the gross annual inventory value of the food ware-

house, and the licensed food warehouse meets all of the applicable requirements of s. ATCP 70.21.

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

3. Combining two or more food items that are already individually packaged and labeled for retail sale into a combination package for retail sale, if the label on each individual item inside the combination package remains visible or if the package of combined items is labeled for retail sale. All packaging and labels shall comply with s. ATCP 70.10.

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 70.07 (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.

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; am. (1) and (2), cr. (2m), (2n) and (2r), Register, January, 1998, No. 505, eff. 2-1-98; CR 05-044: am. (2), (2m), (2n), (2r), and (3) Register December 2005 No. 600, eff. 1-1-06; CR 06-028: am. (4) (b) Register November 2006 No. 611, eff. 12-1-06; CR 07-037: am. (2m) (a) to (e), (2n) and (2r) (b) 1. to 5. Register April 2008 No. 628, eff. 5-1-08; CR 08-075: am. (7) (d) 1. Register April 2009 No. 640, eff. 5-1-09; CR 09-009: cr. (2p), am. (7) (b) (intro.) Register October 2009 No. 646, eff. 11-1-09; CR 10-121, cr. (7) (e) Register October 2011 No. 670, eff. 11-1-11; CR 13-063: am. (7) (b) 1. Register April 2014 No. 700, eff. 5-1-14; CR 15-093: cr. (1) (f) Register August 2016 No. 728, eff. 9-1-16; correction in (1) (f) 1. to 4. made under s. 35.17, Stats., Register August 2016 No. 728; correction in (7) (b) (intro.) made under s. 13.92 (4) (b) 7., Stats., Register August 2016 No. 728.

ATCP 70.04 Construction and maintenance.

(1) CONSTRUCTION AND MAINTENANCE; GENERAL. Buildings, facilities, and equipment used in the operation of a food processing plant shall be of sound construction, and shall be capable of being maintained in a clean and sanitary condition. The interior and exterior portions of a food processing plant, and the premises on which the food processing plant is located, shall be kept free of unhealthful or unsanitary conditions, and shall be maintained in compliance with this chapter.

(2) FLOORS, WALLS, AND CEILINGS. Floors, walls, and ceilings in a food processing plant shall be kept clean and in good repair. 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. Walls and ceilings in processing areas shall be light colored. A food processing plant constructed or altered in a manner which changes the dimensions of a processing area after June 30, 1989, shall conform to the following requirements:

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

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

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

(3) PROCESSING AREA SEPARATED. 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.

(4) DOORS AND WINDOWS. Doors, windows, skylights, transoms, and other openings to the outside shall be tight-fitting, free of breaks, and effectively screened or protected against the entry of rodents, insects, birds, and other animals. External doors, other

than overhead doors in delivery areas, shall 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 from 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 or handled, 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. 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. Ventilation systems, if 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) A sufficient number of sanitary toilets to accommodate all employees, in accordance with applicable state and local regulations, shall be provided in convenient locations. Toilet rooms shall be completely enclosed, well-lighted, and equipped with tight-fitting, self-closing doors. Toilet rooms and fixtures shall be easily cleanable, and shall be kept clean and in good repair. Toilet rooms constructed, substantially reconstructed, or extensively altered after June 30, 1989:

1. Shall be separately vented to the outside;

2. Shall be equipped with an exhaust fan capable of creating a negative pressure within the toilet facility; and

3. Shall not open directly into a food processing area.

(b) 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 toilet rooms shall comply with all of the following requirements if they are installed 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. The facility shall be served by hot and cold running water provided through a mixing valve or combination faucet, or by potable tempered water.

2. Faucets shall be of a type which 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.

(c) An easily cleanable covered trash receptacle and an adequate supply of toilet tissue shall be available in every toilet room at all times.

(8) LOCKER AND LINEN FACILITIES. Lockers or comparable facilities shall be provided for clothing and similar personal items of employees. Personal clothing and other personal items of employees shall not be stored 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) Handwashing sinks with available hot and cold running water shall be provided 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 shall be provided for their disposal.

(b) A handwashing sink serving a food processing area shall comply with all of the following requirements if it is installed after 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 be of a type that is not hand operated. If a self-closing or metering faucet is used, that faucet shall provide a flow of water for at least 15 seconds without any need to reactivate the faucet.

(c) Handwashing sinks may not 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, shall have at least 3 compartments for washing, rinsing, and sanitizing equipment and utensils.

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

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

used in place of re-usable cloths if they are discarded after each use.

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

(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 trash, garbage, 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, backsiphonage, 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, leakproof, easily cleanable, and pest-resistant containers. Containers shall be kept covered with tight-fitting lids, and shall be cleaned when necessary to prevent insanitary conditions. Garbage and refuse shall not be burned on the premises, except in compliance with state and local laws. Garbage and refuse shall not be burned on the premises if burning may contaminate food.

(14) **CONTROL OF PESTS.** Effective measures shall be taken, 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 of the food processing plant shall notify the department in writing. Plans and specifications for the construction, conversion, 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) **VARIANCES.** The department may issue a written waiver granting a variance from a construction standard under this section if the department finds that the variance is reasonable and necessary under the circumstances, and that it will not compromise the purpose served by the construction standard. The administrator of the department's division of food safety may issue a waiver on behalf of the department. The department shall issue a waiver in writing, and shall keep a copy of the waiver on file for as long as the waiver remains in effect.

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

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

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; am. (6), (10) (d), cr. (16), Register, April, 1996, No. 484, eff. 5-1-96; CR 09-009: am. (7) (b) (intro.), r. and rec. (9) (b), cr. (9) (c) Register October 2009 No. 646, eff. 11-1-09; CR 14-037: cr. (17) Register April 2015 No. 712, eff. 5-1-15; correction in (17) made under s. 13.92 (4) (b) 7., Stats., Register April 2015 No. 712; **EmR 1704: emerg. cr. (18) eff. 3-7-17; CR 16-044: cr. (18) Register May 2017 No. 737, eff. 6-1-17.**

ATCP 70.05 Personnel standards. (1) GENERAL. (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 a maple sap concentration facility licensed as a food processing plant that is required to meet the provisions of s. ATCP 87.28.

(1m) **HAND CONTACT WITH FOOD.** (a) Except as provided in par. (b), 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.

(am) 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.

(b) 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.

(c) A food processing plant operator shall provide advance training under par. (b) 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. (b).

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.

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

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

(2) **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 and fingers before having any direct manual contact with food or food contact surfaces. Jewelry shall not be worn in a manner which creates a risk of food contamination. This subsection does not apply to plain band wedding rings.

(3) 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) A communicable disease.
- (b) Any symptom 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.

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

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; r. and recr. (3), Register, April, 1996, No. 484, eff. 5-1-96; CR 09-009: cr. (1m) Register October 2009 No. 646, eff. 11-1-09; CR 12-037: cr. (1m) Register May 2013 No. 689, eff. 6-1-13; **EmR 1704: emerg. renum. (1) to (1) (a), r. and recr. (1) (title), cr. (1) (b), eff. 3-7-17; CR 16-044: renum. (1) to (1) (a), r. and recr. (1) (title), cr. (1) (b) Register May 2017 No. 737, eff. 6-1-17.**

ATCP 70.06 Equipment and utensils. (1) CONSTRUCTION AND MAINTENANCE; GENERAL. (a) 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.

(b) Par. (a) 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 solu-

tions are circulated. Cleaning records shall be kept for at least 90 days after they are created.

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

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

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

(7) CLEANING AND SANITIZING EQUIPMENT AND UTENSILS; GENERAL. (a) Except as provided in pars. (b) to (d):

1. All food contact surfaces of equipment and utensils shall be cleaned and sanitized after each day's use, and prior to any change in use that may cross-contaminate food with major food allergens or other contaminants.

2. Sanitizers and methods used to sanitize equipment and utensils shall comply with s. ATCP 70.11.

(b) The department may approve alternative cleaning and sanitizing procedures under sub. (7m).

(c) Tanks used to store potentially hazardous food or potentially hazardous food ingredients shall be cleaned and sanitized whenever the food processing plant operator empties those tanks or more often if necessary.

(d) Paragraph (a) does not apply to the following equipment, provided that the food processing plant operator cleans and sanitizes the equipment according to manufacturer specifications:

1. Drying equipment.
2. Cloth-collector systems.
3. Dry product packaging equipment and storage containers.
4. Equipment used in brining, aging, curing, and dry product blending processes.

5. Food contact surfaces of equipment used solely to process foods or food ingredients with water activity not greater than 0.85, such as chocolate, fats and oils, liquid nutritive sweeteners, peanut butter or similar foods which are not potentially hazardous.

6. Equipment used solely for concentration of maple sap according to the provisions of s. ATCP 87.26.

(7m) ALTERNATIVE CLEANING AND SANITIZING PROCEDURES. (a) A food processing plant operator may ask the department to approve alternative cleaning and sanitizing procedures under par. (b). The operator shall submit the request in writing. The request shall include all of the following, and any other information required by the department:

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

2. The types of food produced with the affected equipment or utensils, the purposes for which the food will be used, and the tem-

peratures at which the food will be prepared, stored, and distributed.

3. 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.

4. A written statement, by the food processing plant operator, that the alternative cleaning and sanitizing procedure has been evaluated and determined to be effective in preventing food contamination and ensuring the microbiological safety of food. The written statement shall be based on a HACCP plan under subd. 5.

5. A HACCP plan, prepared by qualified personnel, to ensure that the alternative cleaning and sanitizing procedure will be effective in preventing food contamination and ensuring the microbiological safety of food. The HACCP plan 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.

(b) The department may approve alternative cleaning and sanitizing procedures that do not comply with sub. (7) (a) if the department believes that those procedures will be effective in preventing food contamination and ensuring the microbiological safety of food. The department shall give its approval in writing, based on a written request under par. (a).

(c) The department shall grant or deny a request under par. (a) 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.

(d) The department may qualify or limit its approval under par. (b), as it deems appropriate. The department may withdraw its approval for cause, including information that casts doubt on the efficacy or faithful implementation of the approved procedure.

(e) A food processing plant operator that implements an alternative cleaning and sanitizing procedure approved under par. (b) shall do all of the following:

1. Control and monitor to ensure that the procedure is faithfully implemented as approved, and is effective in preventing food contamination and ensuring the microbiological safety of food.

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

3. Collect and retain data and records to document, on a continuing basis, the faithful 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.

(8) 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 or sanitizing solution, and the length of time for which the C-I-P system was exposed to each cleaning and sanitizing solution. Records shall be signed or initialed by a responsible person at the food processing plant. Records shall be maintained on file at the food processing plant for at least 90 days, and shall be made available for inspection and copying by the department upon request.

(9) 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.

(10) 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 reused.

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

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; CR 09-009: am. (3), r. and recr. (7), cr. (7m) Register October 2009 No. 646, eff. 11-1-09; CR 14-037: cr. (11) Register April 2015 No. 712, eff. 5-1-15; **EmR 1704: emerg. renum. (1) to (1) (a), cr. (1) (b), am. (7) (d) 5., cr. (7) (d) 6., eff. 3-7-17; CR 16-044: renum. (1) to (1) (a), cr. (1) (b), am. (7) (d) 5., cr. (7) (d) 6. Register May 2017 No. 737, eff. 6-1-17.**

ATCP 70.07 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 or 812.

(b) Operations water shall be available in consistently adequate quantity, and shall comply with the health related drinking water standards in ch. NR 809.

(c) If a food processing plant operator obtains operations water from a privately owned water system, the operator shall sample that water at least once annually. The operator shall have each sample tested by a laboratory certified under ch. ATCP 77, for compliance with the microbiological standards under s. NR 809.30.

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

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

1. Washing subsequent deliveries of raw fruit or vegetables at the processing plant.

2. Flushing floors and gutters in the receiving area of the 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 or 812. Water reclaimed from food processing operations may not be used as an ingredient in bottled drinking water or in any soda water beverage.

(b) Ingredient water shall comply with the health related drinking water standards under ch. NR 809. If ingredient water for bottled drinking water or soda water beverages is obtained from a privately owned water supply, that water shall also comply with the health related enforcement standards under s. NR 140.10.

(c) If a food processing plant operator obtains ingredient water from a privately owned source, the operator shall sample that ingredient water at least once annually. The operator shall have each sample tested by a laboratory certified under ch. ATCP 77, for compliance with the microbiological standards under s. NR 809.30.

(d) If a food processing plant operator obtains ingredient water from a municipal source, the operator shall do all of the following:

1. Use current good manufacturing practices in handling that water, including safe and sanitary equipment, utensils, production controls, and process controls that conform to good public health practice.

2. Provide documentation to the department, at the department's request, that the water complies with the microbiological

standards under s. NR 809.30. Documentation may consist of information provided by the municipality.

(e) A food processing plant 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. The operator shall make the records available for inspection and copying by the department upon request.

(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 with department approval if all of the following apply:

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

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

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

4. The standard plate count of the reclaimed water does not exceed 500 per ml. of water and meets the bacteriological standards under s. NR 809.30.

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

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

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

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

8. 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.

9. The food processing plant operator tests the reclaimed water for bacteriological and organic content at least semi-annually. The operator shall test the reclaimed water for 14 working days after the department approves the reclamation system under subd. 2., and for at least 7 working days after any repairs or alterations to the system.

10. 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, or another method approved by the department.

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

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

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

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

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

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

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

8. The reclaimed water, if held for more than twenty-four (24) hours, is at all times held at a temperature of at least 145°F. (63°C.) or is chemically treated under subd. 5. to suppress bacterial propagation.

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

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

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

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

(4) WATER TREATMENT. (a) A food processing plant operator may not use any chemical to suppress bacterial growth in water, or to prevent off-tastes or odors in water, unless that chemical is approved for that purpose by the federal food and drug administration. Neither the chemical as applied, nor any compound produced by the chemical application, may contribute to the adulteration of food.

(b) A food processing plant operator shall apply chemicals under par. (a) according to label directions, using an automatic proportioning device. Treated water shall be held for the period of time specified on the chemical label before it is used as ingredient water or operations water. A food processing plant operator shall conduct a daily testing program for any chemical added to water, to ensure that the chemical concentration does not contribute to the adulteration of 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 ch. NR 811 or 812, as applicable.
2. Bacteriologically safe.
3. Protected from contamination.
4. Tested by the food processing plant operator at least semi-annually.

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

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

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

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

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

1. It shall be properly constructed and maintained to prevent contamination of the potable water or potable liquid. Food contact surfaces shall comply with s. ATCP 70.06 (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.

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; corrections made under s. 13.93 (2m) (b) 7., Stats., Register, April, 1993, No. 448; r. and recr. (1), (2), cr. (3), (4), Register, April, 1996, No. 484, eff. 5-1-96; corrections in (1) (c), (2) (c) and (3) (b) 5., made under s. 13.93 (2m) (b) 7., Stats., Register, February, 2001, No. 542; CR 09-009: r. and recr. (3), cr. (5) to (7) Register October 2009 No. 646, eff. 11-1-09; correction to numbering of (7) made under s. 13.92 (4) (b) 1., Stats., Register October 2009 No. 646; correction in (3) (b) 7. made under s. 13.92 (4) (b) 7., Stats., Register January 2012 No. 673; CR 12-037: cr. (8) Register May 2013 No. 689, eff.

6-1-13; EmR 1704: emerg. cr. (1) (f), eff. 3-7-17; CR 16-044: cr. (1) (f) Register May 2017 No. 737, eff. 6-1-17.

ATCP 70.08 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.

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; CR 09-009: am. (2) Register October 2009 No. 646, eff. 11-1-09.

ATCP 70.09 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 tend to 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. Under potable running water at a temperature of not more than 70°F (21°C). Water velocity shall be sufficient to agitate loose particles and drain or float them away from the food being thawed.
3. In a microwave oven if the food is fully cooked in the microwave oven, or if cooking is immediately completed in another cooking facility.
4. In any cooking facility, as part of the process by which the food is fully cooked.

(4) BULK FLOUR HANDLING SYSTEMS. (a) Food contact surfaces of bulk flour handling equipment shall comply with the provisions of s. ATCP 70.06 (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 is permitted to escape. Filters shall be readily removable for cleaning or replacement. Straight runs of pneumatic conveyors shall comply with the provisions of s. ATCP 70.06 (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. This subdivision does not include food or food packages damaged during normal conditions of food and food product handling, transit, or storage.

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

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

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

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

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

1. Reprocess for sale, as human food, any distressed food which is unwholesome or adulterated.

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

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

(f) A food processing plant operator shall keep, for at least one year, 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. If the distressed food is not sold directly at retail, the final disposition of the distressed food. The record of final disposition shall include the name and address of the person, such as the food wholesaler, food distributor, waste disposal firm or waste disposal site operator, to whom the food processing plant operator delivered the food.

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

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

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

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; am. (3) (c) 1., r. and recr. (6), Register, April, 1996, No. 484, eff. 5-1-96; CR 14-037: cr. (8) Register April 2015 No. 712, eff. 5-1-15.

ATCP 70.10 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 70.11. 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 adulterants, and any damage to product contact surfaces. Inspection shall be performed on surfaces lighted in compliance with s. ATCP 70.04 (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) Section 97.09, Stats., and federal regulations incorporated by reference in s. 97.09, Stats.

(c) Chapter ATCP 90.

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

(e) If the packaged food contains a major food allergen, the ingredient statement on the package shall disclose the common name of the major food allergen. The disclosure shall be equiva-

lent 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 species name such as bass, flounder, or cod. If the allergen originates from crustacean shellfish, the ingredient statement must disclose the common species name such as crab, lobster, or shrimp. If the allergen originates from tree nuts, the ingredient statement must disclose the common species 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) **MAPLE SYRUP LABELING.** Labeling of maple syrup shall also meet the requirements in s. ATCP 87.36.

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; CR 09-009: r. and recr. (title), cr. (5) Register October 2009 No. 646, eff. 11-1-09; CR 14-037: cr. (6) Register April 2015 No. 712, eff. 5-1-15; correction in (6) made under s. 13.92 (4) (b) 7., Stats., Register April 2015 No. 712; **EmR 1704: emerg. cr. (7), eff. 3-7-17; CR 16-044: cr. (7) Register May 2017 No. 737, eff. 6-1-17.**

ATCP 70.11 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 potentially hazardous foods, shall be sanitized prior to each use by one of the following sanitizing methods:

(a) Immersion for at least 30 seconds in clean water at a temperature of at least 170°F (77°C).

(b) Immersion for a period of at least 2 minutes in a sanitizing solution containing at least 100 ppm of available chlorine, and having a pH not higher than 8.3, at a temperature not less than 75°F (24°C) nor more than 110°F (44°C).

(c) Immersion for a period of at least one minute in a sanitizing solution containing at least 12.5 ppm of available iodine, and having an acid pH not higher than 5.0, at a temperature of not less than 75°F (24°C) nor more than 110°F (44°C).

(d) Immersion in a caustic sanitizing solution according to s. ATCP 70.24.

(e) Application, according to manufacturer's instructions, of a nontoxic chemical sanitizer or sanitizing method which has been demonstrated to be equally effective for sanitizing purposes as the methods described under pars. (a) through (d), and which has been approved by the department under sub. (4).

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

(3) **SANITIZERS; MAXIMUM CONCENTRATIONS.** Sanitizers and cleaning compounds used on food contact surfaces shall not be used in a way that leaves a toxic residue on the 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 at all times.

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

(4) **SANITIZERS; DEPARTMENT APPROVAL.** (a) Sanitizers approved under ch. ATCP 75 Appendix, *Wisconsin Food Code* section 4-501.114 are also approved by the department for purposes of sub. (1) (e). 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 approved under par. (a), regardless of whether that sanitizer or sanitizing method is approved by any

other state or federal agency, 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.

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; CR 09-009: r. and recr. (4) Register October 2009 No. 646, eff. 11-1-09.

ATCP 70.115 Ready-to-eat foods; reporting pathogens and toxins. (1) REQUIREMENT.

Except as provided under sub. (2), a food processing plant operator shall report to the department the results of any microbiological test or laboratory analysis which indicates that any ready-to-eat food produced by that operator contains pathogenic organisms or toxins. 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.

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

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

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

History: Cr. Register, April, 1996, No. 484, eff. 5-1-96.

ATCP 70.117 Recall plan. (1) PLAN REQUIRED.

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

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

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

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

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

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

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

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

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

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

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

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

History: CR 09-009: cr. Register October 2009 No. 646, eff. 11-1-09; renumber of (2) (i) made under s. 13.92 (4) (b) 1., Stats., Register October 2009 No. 646.

Subchapter III — Canning Operations; Supplementary Requirements

ATCP 70.12 General. Food processing plants engaged in canning operations shall comply with applicable provisions of subch. II. Food processing plants engaged in canning operations shall also comply with this subchapter.

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89.

ATCP 70.13 Low-acid foods packaged in hermetically sealed containers. Persons who process and package low-acid foods in hermetically sealed containers shall comply with applicable federal regulations under 21 CFR 113.

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

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; CR 09-009: am. Register October 2009 No. 646, eff. 11-1-09.

ATCP 70.14 Acidified foods. Persons who process acidified foods shall comply with applicable federal regulations under 21 CFR 114.

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

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89.

ATCP 70.15 Facilities and equipment; cleaning. Equipment used to handle raw agricultural commodities at a food processing plant shall be designed, constructed, and maintained so that the equipment is easily cleanable and accessible for cleaning. Equipment shall be kept clean. If necessary to prevent unsanitary conditions, both water and steam shall be used to clean machinery and equipment. Cleaning equipment, and an ample supply of water and steam shall be available for cleaning purposes. Cleaning equipment shall be adequate for cleaning purposes, and shall be kept in good repair.

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89.

ATCP 70.16 Food packages used in canning operations. Food packages used in canning operations, including metal cans and lids, shall be clean and sanitary. Food packages shall be stored in a manner which protects them from contamination, and shall be properly cleaned before being used. Effective mechanical washers shall be used to clean food packages prior to use. Washing machines shall be arranged so that waste water does not splash or drip onto cleaned or filled food packages.

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89.

ATCP 70.17 Handling raw agricultural commodities and by-products. (1) Raw agricultural commodities shall be washed, sorted, trimmed as necessary, and inspected before being canned. This does not require the washing of kraut.

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

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89.

Subchapter IV — Fish Processing Plants; Molluscan Shellfish Plants; Supplementary Requirements

ATCP 70.18 Fish processing. (1) Fish processing operations shall comply with subch. II and 21 CFR 123. Fish processing plant operators shall have 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) Raw or processed fish that is packaged in reduced-oxygen packaging, as defined in s. ATCP 70.02 (22n), shall immediately be refrigerated to a temperature of 38°F (3° C) or below, and shall be kept at or below that temperature until sold to consumers at retail, unless one of the following applies:

(a) The fish are salted fish and have a salt content of at least 20%.

(b) The fish are frozen immediately after processing, and kept frozen until sold to consumers at retail.

Note: Operators of smoked fish processing plants may wish to include, in their HACCP plans, relevant procedures and critical limits identified in Appendix A to this chapter, including critical limits related to smoking time and temperature, percent of water-phase salt in the finished product, and ppm of sodium nitrite in the product before smoking.

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; CR 09-009: r. and recr. Register October 2009 No. 646, eff. 11-1-09; CR 15-093: am. (2) Register August 2016 No. 728, eff. 9-1-16; correction in (2) made under s. 35.17, Stats., Register August 2016 No. 728.

ATCP 70.19 Labeling and sale of smoked fish.

(1) Every food 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 of the smoked fish processor or distributor.

(b) The name of the product, including the common species name of the fish from which the product is derived.

(c) The net weight of the package contents.

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

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

(f) The processing date of the smoked fish.

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

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

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

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

(b) The food is held at a temperature above 38° F. (3.4° C.) at any time prior to retail sale. This paragraph does not apply to a food which the department specifically exempts in writing because it is not a potentially hazardous food.

(5) 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.

(6) Smoked fish may not be sold or distributed in a frozen state unless the fish are frozen at the smoked fish processing plant and kept frozen until sold at retail. Frozen smoked fish may not be thawed for sale in an unfrozen state.

(7) Cold-process smoked fish may not be used as an ingredient in any other perishable, ready-to-eat food.

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; r. and recr. Register, April, 1996, No. 484, eff. 5-1-96; CR 09-009: r. and recr. Register October 2009 No. 646, eff. 11-1-09; CR 15-093: am. (1) (d) Register August 2016 No. 728, eff.

9-1-16; correction in (1) (d) made under s. 35.17, Stats., Register August 2016 No. 728.

ATCP 70.20 Fish roe. (1) REFRIGERATION. Roe and any attached entrails harvested from a fish shall at all times be refrigerated at a temperature of not more than 38° F. (3.4° C.), except that processing areas used to dry salted roe or salted roe product may be kept at a temperature of not more than 50° F. (10° C.).

(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 in 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 70.09 (1).

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

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

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

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

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

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

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

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

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

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

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; r. and recr. (1), (6), r. (7), Register, April, 1996, No. 484, eff. 5-1-96; CR 09-009: r. and recr. Register October 2009 No. 646, eff. 11-1-09.

ATCP 70.21 Molluscan shellfish processing. (1) DEFINITIONS. In this section:

(a) “Blower” means a device used for washing shucked shellfish which uses forced air as a means of agitation.

(b) “Broker” means any person who is not a dealer but who arranges the packaging, shipping, sale, or distribution of molluscan shellfish without taking ownership or physical custody of the shellfish.

(c) “Certification” or “certify” means the issuance of a numbered certificate to a licensee dealer for a particular activity or group of activities that indicates approval from the department to conduct the activity and compliance with this chapter.

(d) “Certification number” means the number that conforms to the United States food and drug administration generated-number in the ICSSL.

(e) “Commingle” means the act of combining different lots of food, including shellstock or shucked shellfish.

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

(g) “Cull” means to remove dead or unsafe shellstock from a lot of shellstock.

(h) “Dealer” means a licensee to whom certification is issued for the activities of shellstock shipper, shucker-packer, repacker, or reshipper.

(i) “Depuration processor” means a person who harvests or receives shellstock from growing areas designated in an approved or conditionally approved, restricted, or conditionally restricted classification by the governing authority and submits such shellstock to an approved depuration process.

(j) “Dry storage” means the storage of shellstock out of water.

(k) “Growing area” means any site which supports or could support the propagation of shellstock by natural or artificial means.

(L) “Harvest area” means a growing area from which commercial quantities of shellstock may be removed and may include aquaculture sites and facilities.

(m) “Harvester” means a person who takes shellstock by any means from a growing area.

(n) “Heat shock” means the process of subjecting shellstock to any form of heat treatment to facilitate shucking, including steam, hot water or dry heat, without substantially altering the physical or organoleptic characteristics of the shellfish.

(o) “ICSSL” means the Interstate Certified Shellfish Shippers List, United States food and drug administration publication of shellfish dealers, domestic and foreign, who have been certified by a state or foreign authority.

(p) “In-shell product” means non-living, processed shellfish with one or both shells present.

(q) “In-shell product packing” means the process of placing in-shell product into containers for introduction into commerce.

(r) “Label” means any written, printed, or graphic matter affixed to, or appearing upon, any package containing shellfish.

(s) “Licensee dealer” means a plant licensed in Wisconsin for the activities of shellstock shipper, shucker-packer, repacker, or reshipper.

(t) “Lot of in-shell product” means a single type of container of in-shell product from no more than one day’s harvest from a single defined growing area.

(u) “Lot of shellstock” means a single type of bulk shellstock or containers of shellstock from no more than one day’s harvest from a single defined growing area.

(v) “Lot of shucked shellfish” means a collection of containers of no more than one day’s shucked shellfish, produced under conditions as nearly uniform as possible and designated by a common container code or marking.

(w) "Molluscan shellfish" means any edible species, whether shucked or in one or 2 shells, of fresh or frozen oysters, clams, mussels, or edible portions of such species, or scallops except when the product consists entirely of the shucked adductor muscle.

(x) "NSSP" means the National Shellfish Sanitation Program.

(y) "Person" means any individual, receiver, trustee, guardian, fiduciary, or representative of any kind, and any partnership, association, corporation, or other entity. "Person" includes the federal government, the state, and any other public or private entity.

(z) "Potable water" means water obtained from a source that meets the requirements of ch. NR 809.

(za) "Raw shellfish" means shellfish that have not been thermally processed to an internal temperature of at least 145°F (62.8°C) for at least 15 seconds (or a temperature–time combination of equivalent lethality), or to an extent that the organoleptic characteristics of the shellfish are altered.

(zc) "Repacker" means any licensee dealer, other than the original certified shucker–packer, that repackages shucked shellfish into other containers.

(ze) "Repack shellstock" means the practice of removing shellstock from containers and placing it into other containers.

(zg) "Reshipper" means a licensee dealer that purchases shucked shellfish or shellstock from shellstock shippers, shucker–packers, and repackers and sells the product, without repacking or relabeling, to other dealers, wholesalers, or retailers.

(zi) "Restricted use shellstock" means shellstock that is harvested from growing areas classified by the governing authority as approved under conditions that do not allow the sale of shellstock for direct marketing for raw consumption and is identified with a tag indicating that the shellstock is intended for further processing prior to distribution retail or food service.

(zk) "Shellstock" means live molluscan shellfish in the shell.

(zm) "Shellstock packing" means the process of placing shellstock into containers for introduction into commerce.

(zp) "Shellstock shipper" means a licensee dealer that grows, harvests, buys, repacks, and sells shellstock, or transports shucked shellfish but may not shuck shellfish or repack shucked shellfish.

(zr) "Shucked shellfish" means molluscan shellfish that have one or both shells removed.

(zt) "Shucker–packer" means a licensee dealer that shucks and packs shellfish and may act as a shellstock shipper or reshipper or may repack shellfish originating from other certified dealers.

(zv) "Transaction record" means the form or forms, used to document each purchase or sale of shellfish at the wholesale level, and including shellfish harvest and sales records, ledgers, purchase records, invoices, and bills of lading.

(zx) "Wet storage" means the storage by a licensee dealer of shellstock from growing areas designated in the approved classification or in the open status of the conditionally approved classification by the governing authority, in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater at any permitted land–based activity or facility.

(2) PROHIBITED ACTS. (a) In order to ensure that molluscan shellfish in commerce in this state is not adulterated or misbranded as defined in ss. 97.02 and 97.03, Stats., it is unlawful to process, store, transport, handle, or sell molluscan shellfish or molluscan shellfish products unless the molluscan shellfish is received and tagged as coming from a certified dealer and thereafter protected from contamination and unclean, unhealthy, or insanitary conditions.

(b) No licensee may operate as a licensee dealer without providing the department with a business address at which inspections of facilities, activities, or equipment can be conducted, and obtaining certification from the department.

(c) Only a licensee dealer may handle, receive, store, sort, shuck, repack, or otherwise process molluscan shellfish for interstate commerce.

(d) No person may shuck shellfish for interstate commerce without being certified as a shucker–packer.

(e) No person may repack shucked shellfish for interstate commerce without being certified as a shucker–packer or repacker.

(f) No person may repack shellstock for interstate commerce without being certified as a shellstock shipper, shucker–packer, or repacker.

(g) No person may ship shellstock in interstate commerce without being certified as a shellstock shipper, shucker–packer, or repacker.

(h) No person may purchase shellstock or shucked shellfish from licensee or certified dealers and sell the product in interstate commerce, without repacking or relabeling, to other licensee or certified dealers, wholesalers, or retailers without being certified as a reshipper.

(i) No licensee dealer may commingle, sort, or repack shellstock or shucked shellfish in a way that loses the identity of the lot.

(j) No licensee dealer may handle, store, process, or ship shellstock or shucked shellfish unless it is accompanied by an existing tag or label, or a tag or label that accurately reproduces all information on the original tag or label that accompanied the lot or shipment.

(k) No licensee dealer certified as a reshipper may conduct wet storage activities.

(3) LICENSEE DEALER CERTIFICATION AND ENFORCEMENT. (a) A licensee dealer requesting certification shall be subject to a comprehensive, on–site inspection by a standardized department representative not more than 120 days before issuance or renewal of certification, and shall comply with par. (b) or (c). The department shall ensure that each certification meets all of the following:

1. Certification shall expire annually, with the expiration month set by the department.

2. Only one certification number shall be issued for each licensee dealer.

3. Each certification number shall be unique.

(b) Initial certification shall be given only to a licensee dealer once all of the following requirements have been met:

1. The department has approved any HACCP plans developed by the licensee dealer to meet the requirements of sub. (18).

2. The department has determined that the licensee dealer is in substantial compliance with subch. II and subs. (5) to (16) and (18).

3. The department has approved construction, operational, and remodeling plans, if appropriate, for wet storage operations.

(c) Renewal of certification shall be given only to a licensee dealer upon determination by the department that the licensee dealer is in substantial compliance with subch. II and subs. (5) to (16) and (18).

(d) No licensee dealer may operate as a licensee dealer with a revoked or suspended certification.

(e) Upon certification of a licensee dealer, the department shall notify the United States food and drug administration for the purpose of having the licensee dealer listed in the ICSSL.

(f) Upon suspension or revocation of a licensee dealer's certification, the department shall notify the United States food and drug administration for the purpose of having the licensee dealer removed from the ICSSL.

(g) The department shall inspect licensee dealers as required by one of the following:

1. Within 30 days of the licensee dealer beginning activities if the initial certification was based on a pre–operational inspection.

2. At least monthly for a licensee dealer certified as a depuration processor.

3. At least quarterly for a licensee dealer certified as a shucker-packer or repacker.

4. At least semiannually for a licensee dealer certified for other activities or operation of a wet storage operation.

5. At least annually for a licensee dealer who has demonstrated a history of satisfactory compliance for the past 3 years.

(h) The department shall provide the licensee dealer with a report describing the findings of each inspection, including a listing of deficiencies and corresponding citations of this chapter.

(i) When an inspection detects a deficiency that is critical for the protection of public health, the licensee dealer shall correct the deficiency during that inspection, or cease production affected by the deficiency, or the department shall begin the revocation or suspension of the licensee dealer's certificate.

(j) The department shall notify a licensee dealer, who is certified for wet storage, within 24 hours of any change in growing area classification or status affecting the operation of the wet storage facility.

(4) COMPLIANCE. A licensee dealer shall comply with subch. II and 21 CFR Part 123.

(5) TRUCKS ONLY LICENSEE. A licensee dealer, whose facilities consist of trucks only, shall have either a licensed facility for the storage of shellfish, or arrangements with an appropriately licensed facility for the storage of shellfish and a permanent business address at which records are maintained and inspections of those records can be performed.

(6) EQUIPMENT AND FACILITIES. (a) Before licensing, the department shall review all equipment for conformance with the Shellfish Industry Equipment Construction Guide, Section IV Chapter III .01, of the NSSP (2009). All equipment shall be constructed in a manner, and with materials, that can be cleaned and sanitized, maintained, or replaced in a way that prevents contamination of shellfish products.

Note: A copy of the Shellfish Industry Equipment Construction Guide is on file with the department and the legislative reference bureau. You may also obtain a copy from the following website: <http://www.fda.gov/food/guidanceregulation/federal-statefoodprograms/ucm2006754.htm>.

(b) A licensee dealer who is a certified shucker-packer shall provide shucking blocks which are solid, of one-piece construction, and easily removed from the shucking bench unless the block is an integral part of the bench. Shucking benches, contiguous walls, and stands or stalls and stools for shuckers shall be made of easily cleanable, corrosion-resistant impervious materials which are free from cracks. Shucking benches shall drain completely and rapidly away from any shellfish on the benches.

(c) When monitoring product temperatures, the licensee dealer shall use a temperature measuring device accurate to within 2°F (1°C).

(d) All equipment used in heat shock processing shall comply with the requirements of subch. II and this subchapter.

(e) All equipment used to handle ice shall be of sanitary design and construction, and kept clean and stored in a sanitary manner.

(f) Shellstock washing storage tanks and related plumbing shall be of sanitary design and construction, easily accessible for cleaning and inspection, self-draining, and cleaned and sanitized in the same manner as other food contact surfaces.

(g) Facilities for shucking and packing activities shall be separated by use of separate rooms, partitions, or sufficient spacing. Other food manufacturing activities which could result in the contamination of shellfish shall be separated by adequate barriers.

(h) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are prohibited.

(i) All door and window screens shall be not less than 15 mesh per inch.

(7) SANITATION. A licensee dealer shall comply with the sanitation requirements of subch. II and ensure that all of the following apply:

(a) Any operations water from a private source shall be sampled by a person recognized by the department and tested at a laboratory licensed by the department before use of the water supply, every 6 months while the water supply is in use, and after the water supply has been repaired and disinfected.

(b) Shellstock washing shall only be done using water from a potable water supply. If recirculated water is used to wash shellstock, the licensee dealer shall obtain approval for the construction or remodeling of the system and its operation from the department, treat the water so that it is potable and does not leave any unacceptable residues on the shellstock, and test the microbiological quality of the water daily.

(c) Employees working in both shucking and packing activities shall wash their hands before beginning shucking or packing. Employees shall comply with handwashing requirements of this chapter and after each handwashing shall sanitize their hands in a handwashing facility that meets all of the following requirements:

1. Supplies warm water at a temperature of at least 100°F (37.8°C), and shall be directly plumbed to an approved sewage disposal system.

2. Contains at least one handwashing sink available in a room used for shellfish packing.

3. Has a posted sign clearly visible to all employees at each handwashing sink that indicates handwashing is required. Each sign shall be translated in one or more languages understood by the employees using the sink.

(d) No clothing or personal belongings shall be stored in any area where shellfish are shucked or packed, and in any area which is used for the cleaning or storage of utensils used to shuck or pack shellfish.

(e) All employees shall immediately report to the licensee dealer any symptoms of disease transmissible through food. This reporting shall be in a manner that allows the licensee dealer to reduce the risk of shellfish-borne disease transmission, including providing information such as previous exposure to shellfish-borne disease, date of symptom onset, description of symptoms, and a diagnosis by a health practitioner. The licensee dealer shall notify the department within one working day when informed by an employee of hepatitis symptoms or diagnosis, and shall take immediate action to ensure that the employee is excluded from working in any capacity in which they may contact shellfish, contact food contact surfaces, or transmit the illness to other employees.

(f) The licensee dealer shall ensure that the only toxic substances present in the facility are those necessary for plant activities. Separate storage shall be provided for pesticides; detergents, sanitizers, and other related cleaning agents; and strong acids, bases, polishes, and other chemicals. No toxic substances shall be stored above shellfish or food contact surfaces.

(g) Chemicals, including those used for cleaning or sanitizing, and toxic substances shall be labeled and used in accordance with the manufacturer's label directions.

(h) Shell and other non-edible materials shall be promptly and effectively removed from the shucking bench or table.

(8) SUPERVISION AND TRAINING. (a) A licensee dealer shall designate an employee to supervise general plant management and activities.

(b) The supervisor shall be trained in proper food handling techniques and principles of food protection, and be knowledgeable of personal hygiene and sanitary practices.

(c) A licensee dealer shall ensure that the supervisor monitors sanitation and employee hygiene practices for compliance with the requirements of this chapter.

(d) A licensee dealer shall ensure that employees are trained in proper food handling, sanitation, and personal hygiene practices necessary for compliance with the requirements of this chapter.

(9) RECEIVING. (a) *Shipment acceptability.* Fresh molluscan shellfish shipments shall be considered acceptable when all of the following apply:

1. Each shipment is properly identified with tags and shipping documents.

2. All shellstock in the shipment is alive and cooled to an internal shellstock body temperature of 50°F (10°C) or less.

3. All shucked shellfish in the shipment is cooled to a temperature of 45°F (7.2°C) or less.

4. If the time-temperature indicating device shows that the ambient air temperature has exceeded 45°F (7.2°C) but the shellstock internal body temperature is 50°F (10°C) or less.

5. All other conditions of shipment in this chapter are met.

(b) *Shipment rejection.* The department shall notify the shipper, the licensee dealer, and the state where the shipment originated, of a shipment's rejection, when the department determines any of the following have occurred:

1. Any molluscan shellfish are not properly identified with tags or shipping documents.

2. Any internal shellstock body temperature exceeds 60°F (15.6°C).

3. Any shucked shellfish temperature exceeds 50°F (10°C).

4. Any shellfish purchased as frozen has thawed.

5. Any other reason that the product is adulterated or unsafe for human consumption.

(c) *Receiving molluscan shellfish.* The licensee dealer receiving molluscan shellfish shall do all of the following:

1. Reject or discard any molluscan shellfish shipments which do not originate from a licensed harvester or dealer listed in the ICSSL, are unwholesome or adulterated, inadequately protected, or whose source cannot be identified.

2. Place molluscan shellfish under temperature control within 2 hours after receipt from the harvester or when the shipper is also the harvester, when shellstock reaches the shipper's facility.

3. Ensure that once shellstock is placed in storage under temperature control and until sale to the processor or final consumer, it shall meet all of the following conditions:

a. The shellstock shall be iced or placed and stored in a storage area or conveyance with ambient air temperature maintained at 45°F (7.2°C) or colder.

b. The shellstock shall not be permitted to remain without ice, mechanical refrigeration, or other approved methods of refrigeration for more than 2 hours at points-of-transfer such as loading docks.

c. The shellstock shall not be permitted to be placed in wet storage.

4. Ensure that frozen shellfish remains frozen.

(10) SHELLSTOCK IDENTIFICATION. (a) The licensee dealer shall buy shellstock only from sources listed in the ICSSL.

(b) The licensee dealer shall keep the harvester's tag affixed to each container of shellstock until the container is either shipped, or emptied to wash, grade, or pack the shellstock.

(c) The identification tags of the licensee dealer shall be durable, waterproof, and approved by the department prior to use, at least 13.8 square inches in area, and contain all of the following indelible, legible information in the order specified below:

1. The licensee's name, address, and certification number as assigned by the department.

2. The original shellstock shipper's license or certification number. If the shellstock has been depurated, the original shellstock shipper's certification number is not required.

3. The date of harvest, or date of depuration processing, the original harvest date, and any harvest date from wet storage.

4. The wet storage or depuration cycle or lot number, if the shellstock has been wet stored or depurated. The wet storage lot number shall begin with the letter "w."

5. The most precise identification of the harvest location as is practicable including the capital initials of the state of harvest, and the designation of the growing area by indexing, administrative, or geographic designation.

6. When the shellstock has been transported across state lines and placed in wet storage in a licensee dealer's operation, the statement "This product is a product of (name of state) and was wet stored at (facility certification number) from (date) to (date)."

7. The type and quantity of shellstock.

8. In bold capitalized type on each tag, the statement "**THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR NINETY DAYS.**"

9. All shellstock intended for raw consumption shall include a consumer advisory with the statement "Retailers, inform your customers of the following: Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions" or an equivalent statement.

10. The statement "Keep Refrigerated" or an equivalent statement.

(d) When both the licensee dealer and harvester tags appear on the container, the licensee dealer's tag is not required to duplicate the information on the harvester's tag.

(e) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in par. (c). If the shellstock is received bearing a restricted use tag, all restricted use language shall be transferred to the new shipping tag.

(f) When shellstock intended for retail sale is packed in containers of not more than 5 pounds, and shipped in a master container which includes a tag in compliance with this chapter, the individual containers are not required to be tagged, but may be labeled in some other manner with indelible, legible information which is adequate for tracing the shellfish back to the lot of shellstock from which it originated.

(11) TAGGING OF SHELLSTOCK LOTS DURING INTERMEDIATE PROCESSING. (a) When the shellstock is removed from the original container, the licensee dealer shall do all of the following:

1. Keep the harvester tag for 90 days.

2. Keep a record of the growing area and date of harvest for shellstock.

3. Maintain the lot identity of all shellstock during any intermediate stage of processing.

(b) A licensee dealer receiving bulk tagged lots of shellstock shall have an intermediate processing plan approved by the department to ensure that each lot of shellstock is kept separate and identified in a way which prevents commingling or misidentification.

(c) In order for a licensee dealer to tag a lot container of shellstock, instead of meeting the requirement in sub. (10) (c), for a harvester or licensee tag on each individual container, the licensee dealer shall have an intermediate processing plan approved by the department which establishes the procedures the licensee dealer shall use to tag the lot during the washing, packing, or staging of molluscan shellfish.

(d) Unless the licensee dealer is included in a commingling plan approved by the department, the licensee dealer's intermediate processing plan for tagging a lot of shellstock during the intermediate stage of processing shall ensure that each lot of shellstock is separated and identified in a way which prevents commingling or misidentification. The identification shall be provided by a har-

vester's or licensee dealer's tag which meets the requirements of this chapter, or a tag for each lot of shellstock that contains all of the following:

1. The statement "All shellstock containers in this lot have the same harvest date and area."
2. The harvest date and growing area.
3. The original dealer certification number.
4. The number of individual containers in each lot of shellstock unit after washing, packing, or staging has been completed.

(e) When a licensee dealer has an intermediate processing plan approved by the department, the licensee dealer shall tag each lot of shellstock in accordance with the intermediate processing plan while the lot of shellstock is being processed in the licensee dealer's facility.

(f) All restricted use shellstock shall include a tag containing all information required in this chapter and specific language indicating the intended use of the shellstock.

(g) If shellstock is sold in bulk, the licensee dealer shall provide a transaction record prior to shipment. This transaction record shall contain the name of the consignee and all information specified in sub. (10) (c).

(12) BULK TAGGING SHELLSTOCK LOTS FOR SALES BETWEEN LICENSEE DEALERS. (a) When a single lot of shellstock is sold, multiple containers may be placed on a wrapped pallet, in a tote, in a net bailer, or another container, and the unit tagged with a single tag in accordance with sub. (10) (c).

(b) This bulk tagging provision shall not apply to sales to reshippers.

(c) The shipment shall be accompanied by a transaction record stating the name of the consignee who shall be a certified dealer.

(d) The unit tag shall include the statement "All shellstock containers in this lot have the same harvest date and area of harvest," the number of individual containers in the unit, and the requirements specified in sub. (10) (c).

(13) PROCESSING. (a) *Shellstock processing.* When processing shellstock, a licensee dealer shall do all of the following:

1. For shellstock refrigerated prior to shucking, chill the shucked meats to an internal temperature of 45°F (7.2°C) or less, within 4 hours of removal from refrigeration.

2. Ensure that shellstock for shucking is reasonably free of sediment and is not placed in containers with standing water for the purposes of washing shellstock or loosening sediment.

3. Cull to remove any dead or damaged shellstock.

4. Wash, blow, and rinse all shellfish meats in accordance with 21 CFR Part 161.130.

5. Thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after delivery to the packing room.

6. Not commingle shellstock lots during shucking unless all shellfish is from licensee dealers included in a commingling plan approved by the department.

7. Not allow the use of dip buckets for hand or knife rinsing, or sanitizing.

8. A licensee dealer that uses heat shock to prepare shellstock for shucking shall do all of the following:

a. Use only a scheduled heat shock process approved by the department. The scheduled process may be developed by the department or qualified persons with adequate facilities conducting the appropriate studies of critical factors including the type and size of shellfish, time and temperature of exposure, type of process, size of tank, tunnel, or retort, water-to-shellfish ratios in tanks, and temperature and pressure monitoring devices.

b. Post the schedule for the heat shock process in a conspicuous location.

c. Make sure all responsible persons are familiar with the requirements.

d. Cool all hot shellstock immediately after the heat shock process by either dipping in an ice bath or using flowing potable water.

e. If a heat shock water tank is used, and the water is maintained at or above a temperature of 140°F (60°C), completely drain and flush the tank at the end of each day's operation so that all mud and debris in the dip tank are removed. If the temperatures are maintained below 140°F (60°C), completely drain and flush the tank at not less than 3 hour intervals.

(b) *Shucked shellfish processing.* When processing shucked shellfish, a licensee dealer shall do all of the following:

1. If heat shock is used, once heat shocked shellstock is shucked, cool the shucked shellfish meats to 45°F (7.2°C) or less, within 2 hours after the heat shock process.

2. Wash, blow, and rinse all specified shucked shellfish meats in accordance with 21 CFR Part 161.130.

3. Thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after delivery to the packing room.

4. Completely empty shucking buckets at the packing room so no overage is returned to the shucker.

5. Store shucked and packed shellfish in covered containers in the storage area at an ambient air temperature of 45°F (7.2°C) or less.

6. Store packaged shellfish, if they are to be frozen, at an ambient air temperature of 0°F (-18°C) or less, so that they freeze solid within twelve hours following the start of freezing.

(c) *Repacking shucked shellfish.* When repacking shucked shellfish, a licensee dealer shall do all of the following:

1. Maintain repacked fresh or thawed shucked shellfish, including any portion of frozen shellfish for repacking at an internal temperature of 45°F (7.2°C) or less.

2. Store repacked, shucked shellfish in covered containers at an ambient air temperature of 45°F (7.2°C) or less.

(d) *Wet storage of shellstock.* A licensee dealer conducting wet storage of shellstock shall do all of the following:

1. Follow a plan approved by the department. The plan shall include procedures for ensuring water quality, washing and culling of shellstock before wet storage begins, and segregation of shellstock species and lots of shellstock.

2. Use only shellstock harvested from areas classified by the governing authority as approved or conditionally approved in the open status.

3. Comply with requirements in subs. (9) and (10).

4. Store depurated shellstock only within the facility in which the shellstock was depurated.

5. Store and handle shellstock before wet storage to protect against conditions which adversely affect shellstock survival.

6. Maintain shellstock in a sanitary condition.

7. Harvest, process, package, and label shellstock from wet storage in compliance with requirements of this chapter.

8. Keep complete and accurate records to enable a lot of shellstock to be traced back to the original harvest location and wet storage location, and include the dates the shellstock was held in wet storage. The records shall be maintained for at least one year.

9. Not commingle lots of shellstock unless in accordance with a commingling plan approved by the department. If 2 or more lots of shellstock are in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

(14) LABELING SHUCKED SHELLFISH. (a) The licensee dealer shall maintain lot integrity when shucked shellfish are stored using in-plant reusable containers.

(b) If the licensee dealer uses returnable containers to transport shucked shellfish to other licensee dealers in Wisconsin or certified dealers in other states for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in this subsection. When returnable containers are

used, the shipment shall be accompanied by a transaction record containing the original shucker-packer's name and license or certification number, the shucking date, and the quantity of shellfish per container, and the total number of containers.

(c) If the licensee dealer uses master shipping cartons, the master cartons are exempt from the labeling requirements in this subsection when the individual containers within the carton are properly labeled.

(d) The licensee dealer shall label each individual package containing fresh or frozen shucked shellfish meat in a legible and indelible form and in accordance with applicable requirements for declaration of quantity and drained weight specified in 21 CFR Parts 161.30 and 161.130.

(e) Each package containing less than 64 fluid ounces of fresh or frozen shellfish shall have the certification number on the label, and a "sell by date" which provides a reasonable subsequent shelf-life or the words "best if used by" followed by a date when the product would be expected to reach the end of its shelf-life. The date shall consist of the abbreviation for the month and number of the day of the month. For frozen shellfish, the year shall be added to the date.

(f) Each package containing more than 64 fluid ounces of fresh or frozen shellfish shall have the certification number on the label, and the "date shucked."

1. The date shucked for fresh shellfish shall consist of the number of the day of the year or the month and the number of the day of the month.

2. The date shucked for frozen shellfish shall include the number of the day of the year or the month and the number of the day of the month, and the year.

3. The date shucked shall appear on the lid and sidewall, or bottom of disposable containers.

(g) If the licensee dealer thaws and repacks frozen shellfish, the licensee dealer shall label the shellfish container as previously frozen.

(h) If the licensee dealer freezes fresh shucked shellfish, the licensee dealer shall label all frozen shellfish as frozen in type of equal prominence immediately adjacent to the type of shellfish and the year shall be included in the date on the label.

(i) The licensee dealer shall include on each package of fresh or frozen shucked shellfish a consumer advisory with the statement "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

(j) The licensee dealer shall provide all label information in a legible and indelible form and in accordance with applicable requirements for declaration of quantity and drained weight specified in 21 CFR Parts 161.30 and 161.130.

(k) If the licensee dealer elects to repack molluscan shellfish, the licensee dealer shall pack and label all shellfish in accordance with this subsection, except that the original date of shucking shall be used in establishing the sell by date.

(15) LABELING OF IN-SHELL PRODUCT. (a) Licensee dealers, packing any container holding in-shell product, shall label the container with tags that are legible and indelible and indicate all of the following:

1. The licensee dealer's name, address, and certification number assigned by the department.

2. The original shellstock shipper's certification number. If the shellfish has been deperated, the original shellstock shipper's certification number is not required.

3. The deperation cycle number or lot number, if the shellfish has been deperated.

4. The most precise identification of the harvest location as is practicable, including the capital initials of the state of harvest,

and that state authority's designation of the growing area by indexing, administrative, or geographic designation.

5. When in-shell product has been transported across state lines and placed in wet storage in a licensee dealer's operation, the statement "This product is a product of (name of state) and was wet stored at (facility certification number) from (date) to (date)."

6. A "sell by date" which provides a reasonable subsequent shelf-life or the words "best if used by" followed by a date when the product would be expected to reach the end of its shelf-life. The date shall consist of the abbreviation for the month and number of the day of the month. For frozen shellfish, the year shall be added to the date.

7. The type and quantity of in-shell product.

8. In bold capitalized type on each tag, the statement "**THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS.**"

9. The statement "Keep Refrigerated" or an equivalent statement.

(b) The container for all in-shell products intended for raw consumption shall bear a consumer advisory with the statement: "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

(c) If the in-shell product is removed from the original container, the tag on the new container shall meet the requirements of par. (a).

(d) When in-shell product intended for retail sale is packed in containers of 5 pounds or less, and shipped in a master container which includes a tag complying with par. (a), then labeling of the individual containers is not required to comply with par. (a), but may be labeled in some other manner with indelible, legible information which is adequate to trace the in-shell shellfish back to the lot [from] which it was derived. The consumer advisory required in part (b) shall be included on each individual retail package.

Note: The bracketed word was inadvertently omitted and will be inserted in future rulemaking.

(16) SHELLFISH STORAGE AND HANDLING. When storing and handling shellfish, the licensee dealer shall do all of the following:

(a) Assure that shellstock is reasonably free of sediment and culled.

(b) Assure that shucking buckets are completely empty at the packing room so that no overage is returned to the shucker.

(c) Inspect incoming shipments, and reject dead or inadequately protected shellstock.

(d) Assure that no usable containers or container covers bearing a certification number different from the one issued for those premises are present unless documentation exists to verify the legitimate source of the containers or container covers, and the containers contain shellfish from that source.

(e) Maintain shellfish received frozen in the frozen condition during storage.

(f) Assure that no shellstock is commingled during shucking unless all shellfish is from licensee dealers in Wisconsin or certified dealers outside Wisconsin included in a commingling plan approved by the department.

(17) TRANSPORTATION. (a) *Transportation of shellstock.* Trucks or other vehicles used to transport shellstock shall meet all of the following requirements:

1. All trucks used to transport shellstock shall be properly constructed, operated, and maintained by the harvester, or person who transports shellstock from the harvester to the original licensee dealer to prevent contamination, deterioration, and decomposition of shellstock.

2. Storage bins on trucks or other vehicles used in the transport of shellstock for direct marketing shall be kept clean with potable water; and provided with effective drainage.

3. Shellstock shall be transported in refrigerated trucks when the shellstock has been previously refrigerated or when ambient air temperature and time of travel are such that unacceptable bacterial growth or deterioration may occur.

4. A pre-chilling truck or other refrigerated vehicle is required when ambient air temperatures are such that unacceptable bacterial growth or deterioration may occur.

5. When any mechanical refrigeration unit is used, the unit shall be equipped with automatic controls, and capable of maintaining the ambient air temperature in the storage area at a temperature of 45°F (7.2°C) or less.

6. No animals shall be allowed in any part of any truck or other vehicle where shellstock is stored.

7. Transportation agents or common carriers used by a shipper are not required to be certified.

(b) *Transportation storage containers.* Transportation storage containers shall meet all of the following requirements:

1. Containers used to transport shellstock shall be clean, constructed of food-contact grade material, and free of any substance or organisms that may cause the shellstock to become adulterated.

2. Any container to be used more than one time to store and transport shellstock shall be constructed to allow easy cleaning, maintained to prevent product contamination, and cleaned with potable water and a detergent, other cleaning chemical, or sanitizer acceptable for food contact surfaces and used according to the manufacturer's specifications.

(c) *Shipment protection from cross contamination.* Molluscan shellfish shipments shall be protected from cross contamination and meet all of the following requirements:

1. Except for bulk shipments, when the entire shipment consists of molluscan shellfish products, shellstock shall be shipped on pallets. If the conveyance does not have a channeled floor, pallets shall be used for all shellfish.

2. When the conveyance has mixed shipments, the molluscan shellfish shall be shipped only when molluscan shellfish products are protected from contamination by the other cargo, all cargo is placed on pallets, and no other cargo is placed on or above the molluscan shellfish unless all cargo is packed in sealed, crush resistant, leak-proof, and waterproof containers.

(d) *Shipping times.* When shipping molluscan shellfish or shellstock, the shipper must ensure all of the following conditions are met:

1. When the expected shipping time for any molluscan shellfish or shellstock is 4 hours or less, the shipper shall use ice or mechanical refrigeration to maintain the required temperature of the molluscan shellfish or shellstock. Mechanical refrigeration units shall be equipped with automatic controls and capable of maintaining the ambient air in the storage area at temperatures of 45°F (7.2°C) or less. The shipper is not required to provide thermal recorders during shipment. Lack of ice or other acceptable types of refrigeration shall be considered an unsatisfactory shipping condition.

2. When the expected shipping time is greater than 4 hours, the shipper shall ship all shellfish in mechanically refrigerated conveyances which are equipped with automatic controls and capable of maintaining the ambient air in the storage area at a temperature of 45°F (7.2°C) or less, or in containers, the internal ambient air temperature of 45°F (7.2°C) or less.

a. Unless the shipper has a HACCP plan approved by the department with an alternate means of monitoring time-temperature, the shipper shall ensure that a suitable time-temperature recording device accompanies each shipment of shellfish.

b. The shipper shall note the date and time shown on the temperature-indicating device.

c. Each shipment receiver shall record the date and time shown on the temperature-indicating device when the shipment is received, and the doors of the conveyance or the containers are opened.

d. The final shipment receiver shall keep the time-temperature recording chart or other record of time-temperature in a file and shall make it available to the department upon request.

e. An inoperative temperature-indicating device shall be considered a failure to provide the required recording device.

(18) **HACCP PLAN.** (a) Prior to licensing and certification as a licensee dealer, each applicant shall develop any necessary HACCP plans to comply with subch. II and 21 CFR Part 123, addressing food safety hazards in its operations. HACCP plans shall be approved by the department as part of the license application process. The HACCP plan for shellfish processing shall include all of the following:

1. For a shellstock shipper, the critical control point of shellstock shipping.

2. For a shucker-packer, repacker, or reshipper, the critical control points of receiving, shellstock or in-shell product storage, processing, and shucked meat storage, and shipping, as appropriate.

3. A HACCP plan which includes the receiving critical control point shall include critical limits for the receiving critical control point that ensure all of the following:

a. Shellstock is obtained from a licensed harvester who has harvested the shellstock from an approved area or a conditionally approved area in the open status as indicated by the tag, and identified the shellstock with a tag on each container or transaction record on each bulk shipment.

b. Shellstock, if obtained from a dealer other than the original harvester, is shipped adequately iced, or in a conveyance at or below 45°F (7.2°C) ambient air temperature, or with an internal temperature of 50°F (10°C) or less, or in a conveyance capable of lowering the temperature of the shellstock and maintaining it at 50°F (10°C) or less, and is identified with a tag on each container or transaction record with each bulk shipment.

c. In-shell product is obtained from a dealer who has shipped the in-shell product adequately iced, or in a conveyance with an ambient air temperature at or below 45°F (7.2°C), or with an internal temperature of 45°F (7.2°C) or less, and the in-shell product is identified with a tag on each container.

4. A HACCP plan which includes the shellstock or in-shell product storage critical control point shall include critical limits for the shellstock or in-shell product storage critical control point that ensure any of the following:

a. Shellstock, once placed under temperature control and until sale to the processor or final consumer, shall be iced or placed and stored in a storage area or conveyance with ambient air temperature maintained at 45°F (7.2°C) or less, and not permitted to remain without ice, mechanical refrigeration, or other methods of refrigeration approved by the department for more than 2 hours at points-of-transfer such as loading docks.

b. In-shell products shall be iced or placed and stored in a storage area or conveyance with ambient air temperature maintained at 45°F (7.2°C) or less.

5. A HACCP plan which includes the processing critical control point shall include critical limits for the processing critical control point that ensure any of the following:

a. Shucked molluscan shellfish from shellstock that has not been refrigerated before shucking shall be chilled to an internal temperature of 45°F (7.2°C) or less, within 3 hours of shucking.

b. Shucked molluscan shellfish from shellstock that has been refrigerated before shucking shall be chilled to an internal temper-

ature of 45°F (7.2°C) or less, within 4 hours of removal from refrigeration.

c. Shucked molluscan shellfish from heat shocked shellstock shall be chilled to an internal temperature of 45°F (7.2°C) or less, within 2 hours after the heat shock process.

d. Heat shocked shellstock that are cooled and held under refrigeration for later shucking shall be chilled to an internal temperature of 45°F (7.2°C) or less, within 2 hours after the heat shock process.

e. In-shell product is processed such that the internal temperature of the shellfish meat shall not exceed 45°F (7.2°C) for more than 2 hours during processing.

f. Shucked shellfish that are received and repacked shall not exceed an internal temperature of 45°F (7.2°C) for more than 2 hours.

6. A HACCP plan which includes the shucked meat storage critical control point shall include critical limits for the shucked meat storage critical control point that ensure shucked and packed shellfish are stored in covered containers at an ambient air temperature of 45°F (7.2°C) or less, or covered with ice.

7. A HACCP plan which includes the shellstock shipping critical control point shall include critical limits for the shellstock shipping critical control point that ensure the shellstock containers are labeled and tagged in compliance with the requirements in sub. (10).

8. If a licensee dealer will be using heat shock, the licensee dealer shall include heat shock as a critical control point in the HACCP plan and ensure that heat shock does not change the physical and organoleptic properties of the species, kill the shellfish prior to shucking, or increase microbial deterioration of the shucked shellfish.

(19) SHIPPING DOCUMENTS AND TRANSACTION RECORDS. (a) *Shipping documents.* Each licensee dealer shall maintain shipping documents that meet the following requirements:

1. Each shellfish shipment shall be accompanied by a shipping document which contains the name, address, and certification number of the shipping licensee dealer, the name and address of the receiving facility, and the kind and quantity of the shellfish product.

3. The licensee dealer shall maintain in a file, a copy of the completed shipping document, and make the shipping document available to the department upon request.

4. If the shipment is subdivided to different facilities, each receiving facility shall maintain records sufficient to trace the portion received back to the original shipment.

5. Shellstock that is shipped bearing a restricted use tag shall only be shipped to a licensed shucker-packer and shall include specific language detailing the intended use of the shellstock.

(b) *Transaction records.* Each licensee dealer shall maintain transaction records that meet the following requirements:

1. Each licensee dealer shall have a business address at which transaction records are maintained.

2. Each licensee dealer shall maintain complete, accurate, and legible records of the required information.

3. Transaction records shall be sufficient to do all of the following:

a. Document that the shellfish are from an authorized source.

b. Permit a container of shucked shellfish to be traced back to the specific incoming lot of shucked shellfish or shellstock from which it was taken.

c. Permit a lot, or commingled lots, of shucked shellfish or a lot of shellstock to be traced back to the growing area, date of harvest, date and location of wet storage, if applicable, and if possible, the harvester or group of harvesters.

4. Purchases and sales shall be recorded in a permanently bound ledger book or using other recording methods acceptable to and approved by the department.

5. The transaction records shall be retained for at least one year in the case of fresh shellfish, and for at least 2 years or the shelf-life of frozen shellfish, whichever is longer.

6. If computer records are maintained, the records shall be made available for inspection by the department.

(20) 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 paralytic shellfish poisoning), the department shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing each consumer's food intake history and the shellfish handling practices of the consumer and retailer.

(b) When the department has determined an epidemiological association exists between an illness outbreak and shellfish consumption, the department shall conduct an investigation of the outbreak within 24 hours 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.

History: CR 12-037: cr. Register May 2013 No. 689, eff. 6-1-13; (1) (za) to (zx) renumbered from (1) (aa) to (kk) under s. 13.92 (4) (b) 1., Stats., Register May 2013 No. 689.

Subchapter V — Bottling Establishments; Supplementary Requirements

ATCP 70.23 Bottling establishments; general. Bottling establishments shall comply with subch. II and this subchapter. Bottling establishments producing bottled water shall comply with 21 CFR 129. Bottling establishments engaged in juice processing shall comply with 21 CFR 120.

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; CR 09-009: r. and recr. Register October 2009 No. 646, eff. 11-1-09; correction made under s. 13.92 (4) (b) 7., Stats., Register October 2009 No. 646.

ATCP 70.24 Automatic bottle washing. Bottles cleaned in an automatic bottle washer shall be sanitized while in the washer by a sanitizing method which complies with s. ATCP 70.11. If bottles are sanitized by being soaked in a caustic solution, the causticity of the sanitizing solution shall be monitored and maintained at an appropriate level in relation to solution temperature and soaking time. The following table shows minimum causticity levels required for sanitizing solutions (expressed in terms of percent concentration of sodium hydroxide, NaOH, in the sanitizing solution), based on applicable soaking times and temperatures:

Minimum Causticity Levels Required For Sanitizing Solutions (% Concentration of NaOH), Based on Soaking Time and Temperature

Time in Minutes	Temperature (Degrees)						
	F°170	160	150	140	130	120	110
	C 77	71	66	60	54	49	43
3	0.57	0.86	1.28	1.91	2.86	4.27	6.39
5	0.43	0.64	0.96	1.43	2.16	3.22	4.80
7	0.36	0.53	0.80	1.19	1.78	2.66	3.98

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89.

ATCP 70.25 Returnable and single-service bottles. Bottles shall comply with food package requirements under s.

ATCP 70.10 (1). Returnable bottles shall be cleaned, sanitized, and inspected in compliance with s. ATCP 70.10 (2) and (3). Single service bottles shall comply with s. ATCP 70.10 (4).

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89.

ATCP 70.26 Product sampling; recordkeeping; reports. (1) Operations water and ingredient water used in a bottling establishment shall comply with standards specified under s. ATCP 70.07.

(2) Bottled drinking water and soda water beverages shall comply with ch. NR 809 and the health related enforcement standards of s. NR 140.10.

(3) The operator of a bottling establishment shall collect and analyze representative samples of bottled product to provide reasonable assurance of compliance with sub. (2). For contaminant types identified in sub. (4), the operator shall collect and test samples at no less than the frequency required under sub. (4).

(4) The operator of a bottling establishment shall collect and analyze samples of bottled product for the following contaminants at the following minimum frequencies, and more frequently if necessary to provide reasonable assurance of compliance with sub. (2).

Contaminant	Test Frequency
Bacteria	Monthly, except that bottled water shall be tested weekly per 21 CFR 129.80(g)(1).
Nitrate	Quarterly
Volatile Organics Pesticides Inorganics	Every 3 years, except that the following tests shall be performed annually: <ul style="list-style-type: none"> • Tests on bottled water, per 21 CFR 129.80(g)(2). • Tests for any contaminant found in any sample in excess of the legal limit for that contaminant under s. ATCP 70.07 (2).
Radionuclides	Every 5 years, except that the following tests shall be performed annually: <ul style="list-style-type: none"> • Tests on bottled water, per 21 CFR 129.80(g)(2). • Tests for any contaminant found in any sample in excess of the legal limit for that contaminant under s. ATCP 70.07 (2).

(4m) Notwithstanding subs. (3) and (4), if the operator of a bottling establishment obtains ingredient water from a municipal source that complies with sub. (2), the operator is not required to test bottled product for any contaminant other than bacteria unless one of the following applies:

(a) The operator has reason to suspect that the contaminant may be present in that ingredient water or in the bottled product.

(b) Testing is required under 21 CFR 129.80(g) for bottled water.

(5) (a) Bottling establishment operators shall maintain records of all test results obtained from the analysis of operations water and ingredient water. Test results shall be made available for inspection and copying by the department upon request. Results of microbiological analyses shall be maintained for one year, chemical analyses for 6 years; and radiological analyses for 10 years.

(b) A processor of bottled water shall report the results of all required analyses under sub. (3) to the department. Results for each license year shall be reported to the department 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.

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89; r. and recr. (1), Register, April, 1996, No. 484, eff. 5-1-96; correction in (2) made under s. 13.93 (2m) (b) 7., Stats., Register, January, 1998, No. 505; CR 09-009: r. and recr. (3) and (4), cr. (4m) Register October 2009 No. 646, eff. 11-1-09; correction in (4m) (intro.) made under s. 13.92 (4) (b) 7., Stats., Register October 2009 No. 646.

ATCP 70.261 Water and potable liquids transported in bulk. (1) Water transported to a bottling establishment in a bulk tank or bulk container, for use as an ingredient or in other plant operations, shall comply with s. ATCP 70.07 (6) (a).

(2) The operator of the bottling establishment shall collect at least weekly, and analyze for coliform bacteria and heterotrophic plate count, representative samples of bulk ingredient water shipments received from each shipment source. If the operator receives bulk ingredient water shipments from any source less than weekly, the operator shall collect and analyze a representative sample from each shipment from that source.

(3) If potable water or another potable liquid is transported to or from a bottling establishment in a bulk tank or bulk container, all of the following apply:

(a) The potable water or potable liquid shall be loaded, transported, and unloaded in compliance with s. ATCP 70.07 (6) (b).

(b) The bulk tank or bulk container, and each of its equipment and fittings, shall comply with s. ATCP 70.07 (6) (c).

(4) An operator of a bottling establishment shall make a record of each bulk shipment under this section, and shall keep that record for at least 2 years. The record shall include all of the following:

(a) The name and address of the person sending, and the person receiving, the shipment contents.

(b) The name and address of the transport vehicle owner, and the name of the individual operator of the transport vehicle.

(c) The identification number of the transport vehicle, if an identification number is publicly displayed on that vehicle.

(d) The date on which the shipment was received at, or shipped from, the bottling establishment.

(e) All of the following information if the shipment originated from the bottling establishment:

1. The date on which the bulk tank or container was last cleaned and sanitized prior to the shipment.

2. The name and concentration of the sanitizer used to sanitize the bulk tank or container.

(f) Laboratory results under sub. (2), if any.

History: CR 09-009: cr. Register October 2009 No. 646, eff. 11-1-09.

ATCP 70.262 Labeling bottled products. (1) Bottled products shall be labeled according to s. ATCP 70.10 (5). Bottled water shall also be labeled according to 21 CFR 165.110.

(2) A juice label may not misrepresent that juice has been pasteurized. A juice label may not represent as "fresh" any juice that has been treated with ultra-violet light.

History: CR 09-009: cr. Register October 2009 No. 646, eff. 11-1-09.

Subchapter VI — Effect of Rules on Local Ordinances

ATCP 70.27 Effect of rules on local ordinances.

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

History: Cr. Register, October, 1989, No. 406, eff. 11-1-89.