



State of Wisconsin  
Governor Tony Evers

**Department of Agriculture, Trade and Consumer Protection**  
Bradley M. Pfaff, Secretary

**DATE:** September 6, 2019

**TO:** Board of Agriculture, Trade and Consumer Protection

**FROM:** Brad Pfaff, Secretary *Brad Pfaff*  
Steve Ingham, Division of Food and Recreational Safety Administrator *Steve Ingham*

**SUBJECT:** ATCP 70, Wholesale Food Manufacturing

**PRESENTED BY:** Steve Ingham

**REQUESTED ACTION:**

At the September 19, 2019, Board meeting, the Department will request approval of a germane modification to ch. ATCP 70 (Wholesale Food Manufacturing).

**SUMMARY:**

A final draft of this rule was approved by the Board at its November 2018 meeting. After approval by the Governor and transmittal to the Legislature, the rule was referred for review to the Senate Committee on Public Benefits, Licensing and State-Federal Relations ("the committee").

At its May 29, 2019, Executive Session meeting, the committee asked the Department to consider modifications to the rule. Further, the committee indicated that if the Department did not provide written acceptance of its request, the committee would formally object to the rule. On May 30, 2019, the Department indicated its intent to consider modifying the rule.

Of concern to the committee were provisions in the proposed rule to: 1) end "grandfather" exemptions related to several food processing plant facility requirements, 2) charge a surcharge to the license fee for all sizes of food processing plants that can produce foods (instead of only those with annual production of \$25,000 or more), and 3) mandate automatic expiration of waivers granted to food processing plants from construction, maintenance, equipment, utensil, process, or procedure requirements. The committee also requested that the Department conduct a revised economic impact analysis.

The final rule presented to the Board has addressed each of the committee's concerns, often by reverting to language that is in the current version of ch. ATCP 70. The grandfather exemption related to wall-floor junctions in food processing areas, slope and drainage of floors exposed to large volumes of liquids, and facilities for disposal of mop water or similar liquids has been retained with the same effective date as in the current ch. ATCP 70—June 30, 1989. Consistent with the statutory prohibition on license transfer, under the revised rule this grandfather exemption will be lost when a new license-holder assumes operation of the food processing plant after June 30, 1989. The revised rule also retains the existing grandfather exemption related to

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toilet rooms. The grandfather exemption will not apply to toilet rooms constructed, substantially reconstructed, or extensively altered after the effective date in the current rule—June 30, 1989. The exemption also will not apply to toilet rooms located in a food processing plant that is initially licensed or licensed to a new operator after the effective date. The Department has modified a proposed requirement that all toilet rooms be contiguous to the food processing plant so that the requirement is only applicable for toilet rooms installed after the effective date of the revised rule or any time thereafter when a food processing plant is initially licensed or licensed to a new operator. Existing non-contiguous toilet rooms will be compliant provided they comply with applicable state and local requirements. The Department also chose to modify a grandfather exemption for handwashing sinks in toilet rooms and processing areas so that the exemption is lost if the handwashing facilities are substantially reconstructed or extensively altered after the grandfather exemption date currently in ch. ATCP 70—November 1, 2009. Finally, the Department chose to retain a grandfather exemption from the requirement for manual warewashing sinks to have at least three compartments, although the Department modified the exemption such that it would be lost if a previously exempted food processing plant was licensed to a new operator after June 30, 1989.

Although not an issue noted by the committee, the Department clarified a requirement for food processing plant external doors to open outward. The rule now indicates that this requirement applies to exit doors only. This requirement is consistent with the building code, although in certain situations it may be waived if a suitable variance is requested.

The Department retained language in the current ch. ATCP 70 indicating that the canning surcharge will only be applied to food processing plants engaged in canning with annual production of \$25,000 or more. Originally, the Department proposed to apply the surcharge to all canning businesses due to the increase complexity of inspections necessary at these establishments. In consideration of the economic impact on very small businesses, the Department agreed with the committee to retain the original sales-volume floor.

An important feature of the proposed rule is that it allows the Department to grant waivers for variances from a broader range of requirements than in the current ch. ATCP 70: construction, equipment, utensils, processes, and procedures vs. only construction. Originally the Department proposed an automatic expiration after five years of such waivers, along with waivers for alternative cleaning and sanitizing schedules. In consideration of the committee's concerns about inconsistency for businesses resulting from a hard-stop expiration date, the Department revised the rule to indicate that waivers related to construction and maintenance would not expire as long as no changes in construction or maintenance had jeopardized the clean and sanitary condition of the facility or would result in food adulteration. For the other types of waivers and the approval of alternative cleaning and sanitizing schedules, the Department is proposing that expiration is not automatic provided the food processing plant operator requests a reissuance at least 180 days before the expiration date. The waiver / approval will remain in place until the Department completes its review and makes a decision. The Department will approve renewal as long as the requested variance continues to allow safe and sanitary operation of the food processing plant.

In addition, wording and organizational changes have been made in several sections, notably those related to record keeping and facility requirements, to improve readability.

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

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

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

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

***Statutes Interpreted***

Statutes Interpreted:

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

***Statutory Authority***

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

### ***Explanation of Statutory Authority***

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

### ***Related Statutes and Rules***

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

### ***Plain Language Analysis***

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

The transfer of the Department of Health Services’ (DHS) Food Safety and Recreational Licensing program to DATCP’s Division of Food Safety necessitated the merger of two food safety regulatory systems. One regulatory issue was particularly in need of resolution: Restaurant operators were not allowed to wholesale food under the DHS regulation, while retail food establishment operators under DATCP’s authority could engage in a limited amount of wholesaling without holding a food processing plant license. By statute, restaurants are now licensed as retail food establishments and therefore also enjoy the same limited ability to wholesale food. In the current rule-making process, DATCP initially proposed to retain certain existing limits and requirements from its prior rule concerning food processing activities for wholesale

conducted by a retail food establishment. The Board of Agriculture, Trade and Consumer Protection (“Board”) approved a draft rule reflecting this approach at its January 2018 meeting. This final draft also for the first time included definitions of “wholesale” and “retail”. However, after the Board meeting, it became apparent that industry participants felt that less restrictive limits and definitions would still adequately protect public health.

As a result of this feedback, DATCP formed a work group comprised of industry personnel and local health department agent program representatives. The group was tasked with further revision of the rule. During deliberations, the work group concluded that the safety of many wholesale food processing activities, when performed by retail food establishments, could be ensured by compliance with Wis. Admin. Code ch. ATCP 75 and the appendix thereto, *Wisconsin Food Code*. Thus, compliance with the additional requirements in Wis. Admin. Code ch. ATCP 70 was unnecessary. The work group recognized that additional training would be needed for local health department agent personnel, as well as DATCP sanitarians, who were assigned to retail food establishments performing these wholesale food processing activities. DATCP, as part of its ongoing mission to thoroughly train food safety personnel at the state and local level, is committed to providing both the necessary initial training and ongoing technical support.

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

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

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

between residential and processing activities or access for DATCP inspections. Accordingly, the proposed revision was deleted.

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

This revised rule also:

- Updates the definition of “food processing” to include the activities of a vending machine commissary.
- Updates the definition of “food processing plant” to conform to the statutory definition.
- Clarifies the definition of extended runs, i.e., continuous processing not interrupted by daily cleaning and sanitizing, and the scope of waivers allowing those runs, while clarifying and expanding the list of food processing activities during which daily cleaning and sanitizing are not required. The duration and review of such waivers are also defined.
- Updates certain outdated restrictions on hot-smoked, vacuum-packed fish. Previous requirements were unique to Wisconsin whereas the updates mirror requirements in other states and are based on current FDA guidance.
- Mandates filing and obtaining process-authority approval for processes used in the preparation of canned acidified or low acid foods.
- Enables food processing plants to obtain waivers from DATCP for variances to allow non-standardized and innovative equipment, utensil, processes and procedures. Prior to this revision, waivers and variances could only be obtained by food processing plants for structural and equipment issues. Waivers related to facility construction do not have an expiration date while waivers related to equipment, utensils, processes, procedures, and alternative cleaning and sanitizing frequencies are for a period of five years, but do not expire until the department takes action on a request for reissuance as long as the license holder makes a timely application for reissuance.
- Updates and clarifies language pertaining to the standards for, and testing of, operations water and ingredient water used in the various bottling and processing operations in Wisconsin, as well as finished product sampling and analysis for bottling establishments.

- Expands the scope of bottling rules to encompass more than bottled water and soda, thereby keeping pace with this rapidly changing and innovative segment of the bottling industry.
- Maintains the regulatory floor of \$25,000 in sales for food processing plants that are required to pay the canning license fee surcharge.
- Clearly specifies requirements exempted by so-called “grandfather clauses,” that apply to a continuing license-holder who does not increase processing area dimensions (floor-wall junctions, floor drainage, and service sink or curbed drain); install, substantially reconstruct, or extensively alter toilet facilities (separately vented to the outside, equipped with an exhaust fan capable of creating a negative pressure, and do not open directly into a food processing area); install, substantially reconstruct, or extensively alter hand-washing facilities for toilet rooms (tempered or hot-cold mixed water, non-hand operated faucets) or for food processing areas (not located in the food processing area, tempered or hot-cold mixed water, non-hand operated faucets); or install a warewashing sink (3 compartments).
- Requires license holders that install toilet rooms after the effective date of the rule and food processing plants that are initially licensed or licensed to a new operator after the effective date of the rule to have toilet rooms contiguous with the food processing plant.

### *Federal and Surrounding State Programs*

#### **Federal Programs**

The major federal regulations implementing FSMA and applicable to food processing plants are found in 21 CFR 117. Other federal regulations apply to canned low acid (21 CFR 113) and acidified (21 CFR 114) foods, seafood processing (21 CFR 123) and juice processing (21 CFR 120). Current language on the molluscan shellfish program was deleted in order to adopt the Federal Model Ordinance, applicable to marine shellfish shipped for wholesale, in order to provide that segment of the Wisconsin food industry with regulatory consistency within interstate commerce.

#### **Surrounding State Programs**

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

### *Data and Analytical Methodologies*

In order to identify potential changes to the rule, DATCP reviewed recent changes in FDA regulations such as those implementing FSMA, FDA guidance on the applicability of Hazard

Analysis and Critical Control Point (“HACCP”) requirements for juice and seafood processors; Wisconsin statutes and rules for food processing plants, retail food establishments, meat establishments, and dairy plants; and current industrial practices. Upon learning of industry concerns about proposed licensing and regulatory requirements for retail food establishments conducting food processing for wholesale activities, DATCP delayed further consideration of the rule and convened a collaborative work group comprised of industry and local health department agent personnel to review and revise the requirements. The work group’s conclusions are reflected in the present revised rule.

### *Effect on Small Business*

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

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

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

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

The rule requires handwashing sinks in toilet rooms or food processing areas to meet modern requirements for mixing of hot and cold water and hands-free operation in newly licensed facilities or in facilities operated by a license-holder continuing since on or before November 1, 2009 in which the handwashing sinks are substantially reconstructed or extensively altered. The requirement is already in place for new license-holders or installations of handwashing sinks in already-licensed food processing plants. DATCP estimates that not more than 40 businesses would face the costs of new sink installation. DATCP estimates that costs for these businesses would not exceed \$1,000 apiece. The total cost estimate includes \$40,000 for handwash sink upgrades.

Survey response data support this estimate as approximately 70% of respondents indicated that "none" or "slight" costs would be imposed. Comments indicated a high level of existing compliance with this requirement. Cost estimates listed in the comments ranged from a few hundred dollars to less than \$10,000 per business. Some commenters who provided relatively higher cost estimates were apparently unaware that less-expensive "wrist paddle" or "foot pedal" operation would meet the requirement and described the costs and challenges of installing and using electronic-sensor operated faucets.

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

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

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

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

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

***DATCP Contact***

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

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| 22 | ATCP 70.30   | Ready-to-eat foods; reporting pathogens and toxins.        |
| 23 | ATCP 70.32   | Recall plan.   |
| 24 | <b>Subchapter III. Canning Operations; Supplementary Requirements</b>                |  |
| 25 | ATCP 70.34   | General.   |
| 26 | ATCP 70.36   | Low-acid foods packaged in hermetically sealed containers. |
| 27 | ATCP 70.38   | Acidified foods.   |
| 28 | ATCP 70.40   | Facilities and equipment; cleaning.                        |
| 29 | ATCP 70.42   | Handling raw agricultural commodities and by-products.     |
| 30 | <b>Subchapter IV. Fish Processing Plants; Marine Shellfish Plants; Supplementary</b> |  |
| 31 | <b>Requirements</b>  |  |
| 32 | ATCP 70.44   | Fish processing.   |
| 33 | ATCP 70.46   | Labeling and sale of smoked fish.                          |
| 34 | ATCP 70.48   | Fish roe.  |
| 35 | ATCP 70.50   | Marine molluscan shellfish processing.                     |
| 36 | <b>Subchapter V. Bottling Establishments; Supplementary Requirements</b>             |  |
| 37 | ATCP 70.52   | Bottling establishments; general.                          |
| 38 | ATCP 70.54   | Returnable and single-service bottles.                     |
| 39 | ATCP 70.56   | Bottled water product sampling; record keeping; reports.   |
| 40 | ATCP 70.58   | Labeling bottled products.                                 |
| 41 | <b>Subchapter VI. Juice and Juice HACCP</b>  |  |
| 42 | ATCP 70.60   | Juice and Juice HACCP.                                     |



67       **(6)** “Bottling establishment” means any place where drinking water, soda water beverage, or  
68 alcohol beverage is manufactured or bottled for sale. “Bottling establishment” does not include a  
69 retail establishment either engaged in the preparation and sale of beverages, under a license issued  
70 under s. 125.26 or 125.51, Stats., or licensed under s. 97.30 or s. 97.605, Stats.

71       **(7)** “C-I-P system” means equipment which is designed, constructed, and installed to be  
72 cleaned in place by the internal circulation of cleaning and sanitizing solutions onto product  
73 contact surfaces. “C-I-P System” includes separate equipment used to store or deliver cleaning and  
74 sanitizing solutions to the food contact surfaces.

75       **(8)** “Canning” means the preservation and packaging in hermetically sealed containers of low-  
76 acid or acidified foods.

77       **(9)** “Cold-process smoked fish” or “cold-process smoke flavored fish” means fish which is  
78 treated with smoke or smoke flavoring to give it a smoked flavor, but which is not fully cooked or  
79 heat treated to coagulate protein in fish loin muscle. “Cold-process smoked fish” or “cold-process  
80 smoke flavored fish” may not be heated above 90° F. during processing because the safety of the  
81 treatment is partially dependent on the survival of harmless microorganisms indigenous to the fish.

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

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

86       **(12)** “Critical control point” means a step in food processing at which a failure to monitor a  
87 food safety parameter such as pH, temperature, time, or water activity ( $a_w$ ), or a failure to control

88 any food safety parameter within critical limits or according to specific criteria, may result in the  
89 unacceptable risk of a potentially adverse impact on human health.

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

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

95 (15) "Facility" as used in s. ATCP 70.04 has the meaning given in 21 CFR 117.3.

96 (16) "Fish" means fresh or saltwater finfish; crustaceans; forms of aquatic life other than  
97 birds or mammals including alligators, frogs, aquatic turtles, jellyfish, sea cucumber, sea urchin,  
98 and their roe; and all mollusks, if intended for human consumption.

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

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

103 (19) "Food" means:

104 (a) Articles ingested as food or drink by persons.

105 (b) Chewing gum.

106 (c) Components of articles specified in pars. (a) and (b).

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

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

113       (22) "Food processing" means the manufacture or preparation of food for sale through the  
114 process of canning, extracting, fermenting, distilling, pickling, freezing, baking, drying, smoking,  
115 grinding, cutting, mixing, coating, stuffing, packing, bottling or packaging, or through any other  
116 treatment or preservation process. "Food processing" includes the activities of a bakery,  
117 confectionary, vending machine commissary licensed under s. 97.605, Stats., or bottling  
118 establishment, and also includes the receipt and salvaging of distressed food for sale or use as  
119 food. It also includes the packaging of seeds that have been harvested, and dried after the harvest  
120 for sale as food. These seeds include unpopped popcorn whether shelled or on the cob, black  
121 beans, wild rice, sunflower seeds, pumpkin seeds, and soybeans. "Food processing" does not  
122 include any of the following:

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

124       (b) Activities performed under a meat establishment license issued under s. 97.42, Stats.

125       (c) The retail preparation and processing of meals for sale directly to consumers or through  
126 vending machines if the preparation and processing is covered under a retail food establishment  
127 license issued under s. 97.30, Stats., or other license issued under s. 97.605, Stats.

128       (d) Activities inspected by the United States department of agriculture under 21 USC 601 et  
129 seq. or 21 USC 451 et seq.

130       (e) The extraction of honey from the comb, or the production and sale of raw honey or raw bee  
131 products by a beekeeper from their own apiaries.

132 (f) The washing and packaging of fresh fruits and vegetables if the fruits and vegetables are  
133 not otherwise processed at the packaging establishment.

134 (g) The receipt and salvaging of distressed food for sale or use as food if the food is received,  
135 salvaged, and used solely by a charitable organization, and if contributions to the charitable  
136 organization are deductible by corporations in computing net income under s. 71.26 (2) (a), Stats.

137 (h) The collection, packing, and storage of eggs from a flock of not more than 150 laying birds  
138 by an egg producer who only sells the eggs directly to consumers at the premises where the eggs  
139 were laid, at a farmers' market, or on an egg-sales route as defined in s. ATCP 88.01.

140 (i) The collection, packaging, and storage of nest-run eggs, as defined in s. ATCP 88.01, from  
141 a flock of laying birds by an egg producer who is registered with the department in accordance  
142 with s. ATCP 88.02 and who sells the nest-run eggs to an egg handler.

143 (j) Seeds that have not been harvested until they have dried naturally in the field and are only  
144 handled by harvesting, storing, and packaging for sale as food.

145 **(23)** "Food processing plant" means any place used primarily for food processing, where the  
146 processed food is not intended to be sold or distributed directly to a consumer. "Food processing  
147 plant" does not include any mobile establishment, retail food establishment subject to the  
148 requirements of s. 97.30, Stats., or any restaurant or other establishment holding a license under s.  
149 97.605, Stats., to the extent that the activities of that establishment are covered by s. 97.30, Stats.,  
150 or the license under s. 97.605, Stats.

151 **(24)** "Hazard analysis and critical control point plan" or "HACCP plan" means a food  
152 processing plan under which a food processing plant operator effectively identifies, and prevents,

153 controls, or eliminates food safety hazards by monitoring food safety parameters at critical control  
154 points, and by controlling those parameters within critical limits.

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

157 (a) Fully cooked or heat treated, or sold or represented as being fully cooked or heat treated, so  
158 that the internal temperature of the fish has been maintained for at least 30 minutes at not less than  
159 145° F (62.8° C) or an equivalent process validated for lethality against pathogenic organisms.

160 (b) Fully cooked or heated in accordance with par. (a) and treated with smoke or smoke  
161 flavoring to give it a smoked flavor.

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

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

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

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

174       **(30)** “Official Methods of Analysis” means the *Official Methods of AOAC International*,  
175 eighteenth edition revision 2 (2007).

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

179  
180       **(31)** “Operations water” means water used by a food processing plant for cleaning equipment  
181 and utensils, transporting food, handwashing, or other cleaning or sanitizing purposes.

182       **(32)** “Organoleptic quality” means quality as assessed by means of sight, smell, touch, or  
183 taste.

184       **(33)** “Potentially hazardous food” also means “TCS (time/temperature controlled for safety)  
185 Food”, and has the meaning given in ch. ATCP 75 Appendix (Wisconsin Food Code), part  
186 1201.10 (B).

187       **(34)** “Processed fish” means fish that is preserved for human consumption by means of hot or  
188 cold smoking, curing, salting, drying, marinating, pickling, fermenting, or related processes.  
189 “Processed fish” does not include fish processed in accordance with ss. ATCP 70.36 or 70.38.

190       **(35)** “Qualified facility” as used in s. ATCP 70.04 has the meaning given in 21 CFR 117.3.

191       **(36)** “Ready-to-eat food” has the meaning given in ch. ATCP 75 Appendix (Wisconsin Food  
192 Code), part 1-201.10 (B).

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

195       **(38)** “Retail” means selling food or food products directly to any consumer only for  
196 consumption by the consumer or the consumer’s immediate family or non-paying guests.

197       **(39)** "Roe" as used in s. ATCP 70.48 means fish eggs, including fish eggs that are still  
198 enclosed in the ovarian membrane.

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

201       (a) Temperatures at or above 135° F (57° C.) for heated foods.

202       (b) Temperatures at or below 41° F (5° C) for refrigerated foods, except as provided in par. (c).

203       (c) Temperatures at or below 38° F (3.4° C) for refrigerated, raw fish, cold smoked fish, or raw  
204 fish products that are vacuum packed, and have only refrigeration as a critical control point.

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

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

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

215       **(43)** "Single-service" means any utensil, container, or package, or any part of a utensil,  
216 container, or package, which is designed to be used only once.

217       **(44)** "Smoked fish" means any food obtained by subjecting fresh fish, frozen fish, dried fish,  
218 or cured fish to the direct action of smoke or smoke flavor, whether by burning wood or a similar

219 burning material, or by applying a smoke-flavored solution, for the primary purpose of imparting  
220 the flavor and color of smoke to fish. This includes both cold-process smoked and hot-process  
221 smoked fish, and is considered “fish processing”.

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

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

229 (47) “Wholesale” means the sale of any food to a person or commercial entity who will either  
230 re-sell it, distribute it for re-sale, or use it as an ingredient in a product that will be then offered for  
231 sale. Wholesale includes those activities in which the processor relinquishes control of the food.  
232 Wholesale does not include the movement of food between two food processing plants or retail  
233 food establishments licensed to the same licensee, except for the movement of dairy products as  
234 specified in s. ATCP 65.04.

## 235 SUBCHAPTER II

### 236 GENERAL REQUIREMENTS

237 **ATCP 70.04 Federal and record keeping requirements. (1) FACILITIES AND QUALIFIED**  
238 **FACILITIES.** A food processing plant that is also a facility or a qualified facility shall comply with  
239 the requirements of this chapter and applicable requirements of 21 CFR 117.

240       **(2) RECORD REQUIREMENTS AND RETENTION.** (a) The operator of a food processing plant that  
241 is a facility shall create all records to meet the requirements for records in 21 CFR 117.305, unless  
242 otherwise specified in this chapter or in 21 CFR 120 or 21 CFR 123.

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

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

249       **ATCP 70.06 Food processing plants; licensing; fees. (1) LICENSE REQUIRED.** Except as  
250 provided under sub. (11), no person may operate a food processing plant without a valid license  
251 issued by the department for that food processing plant under s. 97.29, Stats. A food processing  
252 plant license expires on March 31 annually. A license is not transferable between persons or food  
253 processing plants.

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

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

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

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

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

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

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

273 **(4) CANNING OPERATIONS; LICENSE FEE SURCHARGE.** If an operator of a food processing plant  
274 is engaged in canning operations and has annual food sales of more than \$25,000, the operator  
275 shall pay an annual license fee surcharge of \$320, which shall be added to the license fee under  
276 sub. (3).

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

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

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

290       1. For a license holder of a food processing plant that has an annual production of less than  
291 \$250,000, and the license holder is engaged in processing potentially hazardous food or in  
292 canning, the reinspection fee is \$255.

293       2. For a license holder of a food processing plant that has an annual production of at least  
294 \$250,000, and the license holder is engaged in processing potentially hazardous food or in  
295 canning, the reinspection fee is \$525.

296       3. For a license holder of a food processing plant that has an annual production of less than  
297 \$250,000, and the license holder is not engaged in processing potentially hazardous food or in  
298 canning, the reinspection fee is \$150.

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

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

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

309       **(8) TEMPORARY LICENSE.** (a) The department may issue a temporary license, for a period not  
310 to exceed 40 business days, pending final action on an application for an annual food processing  
311 plant license. The department shall grant or deny the annual license application before the  
312 temporary license expires. If the department denies an annual license application before the  
313 applicant's temporary license expires, the temporary license is automatically terminated when the  
314 applicant receives written notice of the denial.

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

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

322       **(9) PRE-LICENSE INSPECTION.** The department may inspect a food processing plant, as the  
323 department deems necessary, before issuing a license to operate the food processing plant. The  
324 department may not issue a license or temporary license to operate a new food processing plant  
325 until the department inspects the new food processing plant for compliance with this chapter. A

326 previously licensed food processing plant may not be considered a new food processing plant  
327 under this subsection solely because of a change of ownership.

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

332 **(11) LICENSE EXEMPTIONS.** A license to operate a food processing plant is not required under s.  
333 97.29, Stats., or this section for:

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

336 1. The operator is licensed by the department under s. 97.30, Stats., or by an agent as defined  
337 in ch. ATPCP 74, under ss. 97.30 and 97.41, Stats.

338 2. Wholesale receipts from food processing operations at the retail food establishment  
339 comprise no more than 25% of gross annual food sales from the retail food establishment. If the  
340 operator of a licensed retail food establishment is also licensed to operate a dairy plant under s.  
341 97.20, Stats., or to operate a meat establishment under s. 97.42, Stats., sales of dairy or meat and  
342 poultry products processed at the establishment shall be excluded from the calculation of food  
343 sales receipts under this subdivision.

344 3. The operator is not engaged in canning of food products at the retail food establishment.

345 4. The operator may move food between retail food establishments licensed to the same  
346 operator.

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

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

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

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

356 1. Receipts from non-dairy food processing operations at that location comprise no more than  
357 25% of gross annual dairy and non-dairy food sales from that location.

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

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

362 1. The operator of the meat establishment is licensed under s. 97.42, Stats., or inspected under  
363 21 USC 601 et seq. or 21 USC 451 et seq.

364 2. The operator is also licensed at the meat establishment to operate a retail food  
365 establishment under s. 97.30, Stats., and not engaged in the canning of food products other than  
366 meat or poultry products canned under s. 97.42, Stats., or the production of cold-smoked fish or  
367 fishery products.

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

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

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

374 3. The processor keeps a written record of every sale under subd. 1., retains that record for at  
375 least 2 years, and makes the record available for inspection and copying by the department upon  
376 request. The record shall include the name and address of the purchasing processor, the date of  
377 sale, the amount of maple syrup or concentrated maple sap sold, and the sale price.

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

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

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

392

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

395 1. Reshipping marine molluscan shellfish, provided that the licensed warehouse operator  
396 holds a licensee dealer certification as required by the U.S. food and drug administration's *Guide*  
397 *for the Control of Marine Shellfish, The Model Ordinance*, that annual inventory value of  
398 molluscan shellfish reshipped at the licensed warehouse does not exceed 25% of the gross annual  
399 inventory value of the food warehouse, and the licensed food warehouse meets all of the applicable  
400 requirements of subch. IV of ch. ATCP 70.

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

403 3. Combining 2 or more food items that are already individually packaged and labeled for  
404 retail sale into a combination package for retail sale, if the label on each individual item inside the  
405 combination package remains visible or if the package of combined items is labeled for retail sale.  
406 All packaging and labels shall comply with s. ATCP 70.26.

407 4. Manufacturing ice for use in the shipment of foods, or to cool or keep foods cold while in  
408 transit or stored in the warehouse. Ice used for this purpose must meet the standards in s. ATCP  
409 70.20 (8). Ice must be made on site in a commercial ice machine and may not be bagged,  
410 distributed or sold separately from food items that it is used to cool.

411 **ATCP 70.08 Construction and maintenance. (1) CONSTRUCTION AND MAINTENANCE;**  
412 GENERAL. Food processing plants shall be soundly constructed and maintained in order to prevent  
413 adulteration as defined in s. 97.02, Stats. The license holder shall maintain in a clean and sanitary  
414 condition all buildings, facilities, and equipment used in food processing operations. The interior

415 and exterior portions of a food processing plant, and the premises on which the food processing  
416 plant is located, shall be maintained in a sanitary condition in compliance with this chapter.

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

419 (b) Floors, walls, and ceilings in processing areas, toilet rooms, and areas used for the cleaning  
420 or storage of equipment or utensils shall be constructed of smooth, impervious, and easily  
421 cleanable materials. This does not prohibit the use of easily cleanable anti-slip floors.

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

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

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

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

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

433 **(3) PROCESSING AREA SEPARATED.** (a) Within a food processing plant, food processing areas  
434 shall be separated by partition or be located at an adequate distance from other operations which  
435 may contaminate unpackaged food, so that contamination is effectively precluded. No processing  
436 may be conducted in a room used as living or sleeping quarters. If a food processing area shares

437 one or more walls with adjacent living or sleeping quarters, processing operations shall be  
438 separated from the adjacent living or sleeping quarters by a tight-fitting, self-closing door.

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

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

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

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

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

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

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

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

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

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

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

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

483 (e) Toilet rooms serving a food processing plant shall be contiguous to the food processing  
484 plant if they are installed after the effective date of this paragraph ... [LRB inserts date], or if the  
485 food processing plant is initially licensed or is licensed to a new operator after the effective date of  
486 this paragraph ... [LRB inserts date].

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

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

493 (f) Handwashing facilities shall be located in or adjacent to every toilet room. Handwashing  
494 facilities serving toilet rooms shall include hot and cold running water, soap in a soap dispenser,  
495 and a sanitary single-service means of drying the hands. A sign directing employees to wash their  
496 hands shall be prominently posted in every toilet room used by employees. Handwashing facilities  
497 serving a toilet room shall comply with all of the following requirements if they are installed,  
498 substantially reconstructed, or extensively altered after November 1, 2009, or if they are located in  
499 a food processing plant that is initially licensed or licensed to a new operator after November 1,  
500 2009:

501 1. Handwashing facilities shall be served by hot and cold running water provided through a  
502 mixing valve or combination faucet, or by potable tempered water.

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

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

513 **(9) HANDWASHING FACILITIES FOR PROCESSING AREAS.** (a) The operator shall provide  
514 handwashing sinks, with available hot and cold running water, for use by all persons working in  
515 food processing areas. The sinks shall be conveniently located for use, and shall be kept in a clean  
516 and sanitary condition. A supply of soap or detergent, and sanitary single-service means for  
517 drying hands shall be kept available at the sink. If disposable towels are used, a clean, covered  
518 waste receptacle with other than hand operation for the lid shall be provided for their disposal.

519 (b) A handwashing sink serving a food processing area shall comply with all of the following  
520 requirements if it is installed, substantially reconstructed, or extensively altered after November 1,  
521 2009, or if it is located in a food processing plant that is initially licensed or licensed to a new  
522 operator after November 1, 2009:

523 1. It shall be located in the processing area.

524 2. It shall be served by hot and cold running water provided under pressure, through a mixing  
525 valve or combination faucet, or by potable and tempered water.

526 3. It shall not be hand operated.

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

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

530 **(10) CLEANING FACILITIES.** (a) If equipment, utensils, or food packages are cleaned or  
531 sanitized manually, the food processing plant shall be equipped with wash and rinse sinks which  
532 are suitable for all manual cleaning and sanitizing operations. Sinks shall be conveniently located  
533 and adequate in number. Each sink shall be constructed of stainless steel or other approved  
534 materials. Each sink shall have at least 2 compartments. A sink installed after June 30, 1989, or a  
535 sink in a food processing plant that is initially licensed or is licensed to a new operator after June  
536 30, 1989, shall have at least 3 compartments for washing, rinsing, and sanitizing equipment and  
537 utensils.

538 (b) Each compartment in a manual warewashing sink shall be large enough to accommodate  
539 the immersion of at least 50% of the largest item to be cleaned or sanitized in the sink. Every sink  
540 compartment shall be served by hot and cold running water, and shall be cleaned prior to each use.

541 (c) Drain boards shall be provided in connection with every warewashing sink. Drain boards  
542 shall be large enough to accommodate soiled equipment and utensils prior to washing, and clean  
543 equipment and utensils after they are sanitized. Drain boards shall be located and constructed so

544 they do not interfere with washing and sanitizing operations. This paragraph does not prohibit the  
545 use of easily movable dish tables as drain boards if the dish tables comply with this paragraph.

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

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

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

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

563 **Note:** Plumbing and plumbing fixtures are subject to the requirements of chs. SPS 381 to 387, enforced  
564 by the department of safety and professional services.  
565

566 (13) GARBAGE AND REFUSE DISPOSAL. Garbage and refuse shall not be allowed to accumulate  
567 in or around a food processing plant. Garbage and refuse shall be removed as often as necessary to

568 maintain the premises in a clean and sanitary condition. Garbage storage areas shall be constructed  
569 and maintained so that they do not attract or harbor insects, rodents, or other animals. Garbage and  
570 refuse shall be held in durable, leak-proof, easily cleanable, and pest-resistant containers.  
571 Containers shall be kept covered with tight-fitting lids, and shall be cleaned when necessary to  
572 prevent insanitary conditions. Garbage and refuse shall not be burned on the premises, except in  
573 compliance with state and local laws. Garbage and refuse shall not be burned on the premises if  
574 burning may contaminate food.

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

580       **Note:** Pesticide storage and use must comply with ss. 94.67 to 94.71, Stats., and ch. ATCP 29.  
581 Pesticides must be registered for use by the U.S. environmental protection agency or by the department.  
582

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

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

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

592 **ATCP 70.10 Personnel standards. (1) CLEANLINESS.** (a) Persons engaged in food processing  
593 shall maintain a high degree of personal cleanliness, and shall observe good hygienic practices  
594 during all working periods. Persons engaged in food processing shall wash their hands before  
595 beginning work and upon returning to work after using toilet facilities, eating, smoking, or  
596 engaging in other activities which may contaminate the hands. Persons engaged in food  
597 processing shall keep their fingernails clean and neatly trimmed, and shall not wear fingernail  
598 polish unless they wear sanitary gloves at all times when handling food.

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

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

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

606 1. Made of impermeable materials, except where the use of such material is inappropriate or  
607 incompatible with the work being done.

608 2. Sanitized at least twice daily or more often if necessary.

609 3. Properly stored until used.

610 4. Maintained in a clean, intact, and sanitary condition prior to use.

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

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

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

623 (e) The operator shall provide prior training on procedures and policies that cover pars. (a) to  
624 (d) to all individuals who may contact ready-to-eat food with their bare hands. The operator shall  
625 have a written training plan that identifies all of the following:

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

633 (f) The operator shall review the training program under par. (e) at least annually.

634 (g) The operator shall maintain records to document compliance with this subsection. Records  
635 shall be retained for at least one year after they are made, and shall be available to the department  
636 for inspection and copying upon request.

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

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

649 (a) One or more reportable symptoms of communicable disease as defined in ch. ATCP  
650 75 Appendix, 2-201.11 (A).

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

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

654 (5) FOOD CONTAMINATION. No person who has received a reportable diagnosis of  
655 communicable disease, as defined in ch. ATCP 75 Appendix, part 2–201.11 (A) (2), may work in  
656 a food processing plant in any capacity that may contaminate food products.

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

663 **ATCP 70.12 Equipment and utensils. (1) CONSTRUCTION AND MAINTENANCE; GENERAL.**

664 Equipment and utensils shall be of sanitary design and construction. Equipment and utensils shall  
665 be readily accessible for cleaning and inspection and shall be constructed so that they can be easily  
666 cleaned. Equipment and utensils shall be kept clean and in good repair. This subsection does not  
667 apply to a maple sap concentration facility licensed as a food processing plant that is required to  
668 meet the provisions of s. ATCP 87.26.

669 (2) FOOD CONTACT SURFACES. Food contact surfaces of equipment and utensils shall be  
670 constructed of stainless steel or other materials which are smooth, impervious, nontoxic,  
671 noncorrosive, nonabsorbent, and durable under normal use conditions. Food contact surfaces shall  
672 be easily cleanable, and shall be free of breaks, open seams, cracks, or similar defects. Food  
673 contact surfaces shall not impart any odor, color, taste, or adulterating substance to food. Food  
674 contact surfaces, other than food contact surfaces of approved C-I-P systems, shall be readily  
675 accessible for manual cleaning. Joints and fittings shall be of sanitary design and construction.

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

678  
679 **(3) C-I-P SYSTEMS.** C-I-P systems shall be of sanitary design and construction, and shall be  
680 installed and maintained for sanitary operation. A C-I-P system shall be installed and maintained  
681 so that cleaning and sanitizing solutions can be circulated throughout all interior product contact  
682 surfaces of the system. C-I-P systems shall be equipped with adequate inspection ports or other  
683 access points. C-I-P systems shall be self-draining, or shall be capable of being easily and  
684 completely drained. A temperature recording device, which accurately records the return  
685 temperatures of cleaning and sanitizing solutions, shall be installed in all circuits through which  
686 cleaning and sanitizing solutions are circulated. Cleaning records shall be kept for at least 90 days  
687 after they are created.

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

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

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

703       **ATCP 70.14 Cleaning and sanitizing equipment and utensils. (1) GENERAL.** Except as  
704 provided in ss. ATCP 70.16 and 70.40, the operator shall do all of the following:

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

707       (b) Except as provided in par. (c), (d) and (e), clean all food contact surfaces of equipment and  
708 utensils after each day's use, and before any change in use that may cross-contaminate food with  
709 major food allergens or other contaminants. If wet cleaning occurs, surfaces must also be sanitized.

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

712       (d) Clean and sanitize all food contact surfaces of equipment used for the distillation of alcohol  
713 products, such as distilled spirits, after each distillation batch. This paragraph does not apply to  
714 equipment used to distill smoke for the manufacture of liquid smoke products.

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

717       **(2) CLEANING AND SANITIZING C-I-P SYSTEMS.** C-I-P systems shall be cleaned and sanitized in  
718 compliance with manufacturer specifications. Cleaning and sanitizing records shall be maintained  
719 for all C-I-P systems. The records shall identify every C-I-P system which has been cleaned or  
720 sanitized, the date and time when each C-I-P system was cleaned and sanitized, the temperature of  
721 the cleaning and sanitizing solutions, and the length of time for which the C-I-P system was

722 exposed to each cleaning and sanitizing solution. Records shall be signed or initialed by a  
723 responsible person, maintained on file for at least 90 days, and made available for inspection and  
724 copying by the department upon request.

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

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

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

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

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

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

741 APPROVAL REQUIRED FOR AN ALTERNATIVE CLEANING AND SANITIZING FREQUENCY. Except as  
742 provided in sub. (2) or s. ATCP 70.40, if an operator seeks to clean and sanitize equipment and  
743 utensils at a frequency other than that required in s. ATCP 70.14 (1), because the equipment

744 and utensils are used with food products, processes, or conditions reducing the risk of  
745 foodborne illness or presence of major food allergens, then the operator shall submit to the  
746 department, for written approval, an alternate cleaning and sanitizing procedure that includes a  
747 monitoring and recording requirement in compliance with s. ATCP 70.18.

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

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

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

758 **(2) NO APPROVAL REQUIRED FOR AN ALTERNATIVE CLEANING AND SANITIZING FREQUENCY.** An  
759 operator is not required to obtain written department approval for use of an alternative equipment  
760 and utensil cleaning and sanitizing frequency for the following equipment, provided that the  
761 operator cleans and sanitizes the equipment according to manufacturer specifications or according  
762 to a validated cleaning process filed with the department:

763 (a) Drying equipment.

764 (b) Cloth-collector systems.

765 (c) Dry product packaging equipment and storage containers.

- 766 (d) Equipment used in brining, aging, curing, and dry product blending processes.
- 767 (e) Food contact surfaces of equipment used solely to process foods or food ingredients with  
768 low water activity ( $\leq 0.85$ ), or foods which are considered non-Potentially Hazardous Food (non-  
769 PHF/non-TCS) foods based on (2) (b) Table A or Table B for Potentially Hazardous Food  
770 (time/temperature control for safety food) in par. 1-201.10 (B) of ch. ATCP 75 Appendix, such as  
771 chocolate, fats and oils, liquid nutritive sweeteners, peanut butter, or similar foods.
- 772 (f) Ice makers maintained in a cold/frozen state.
- 773 (g) Food contact surfaces of equipment used for brewing or fermentation of alcohol-containing  
774 beverages, such as beer brewing or wine fermentation, so long as the operator cleans and sanitizes  
775 equipment used following each brewing or fermentation batch.
- 776 (h) Surfaces of aseptic processing equipment that contact food after the food has been  
777 sterilized, as long as system sterility is maintained. If system sterility is lost, an operator shall  
778 clean, sanitize and re-sterilize equipment.
- 779 (i) Equipment used for food fermentations such as the manufacture of sauerkraut or cucumber  
780 pickles, development of one or more pure bacterial cultures, or development of starter cultures, so  
781 long as the operator cleans and sanitizes all equipment following each fermentation batch.
- 782 (j) Equipment used for processing of products with a natural pH  $\leq 4.0$ , so long as the operator  
783 cleans and sanitizes all equipment at the end of a continuous operation, not to exceed 30 days (720  
784 hours).
- 785 (k) Equipment used for maple syrup processing, so long as the operator cleans and sanitizes all  
786 equipment at the end of a continuous operation, not to exceed 40 days (960 hours).

787 (L) Equipment used for bottled water processing, so long as the operator cleans and sanitizes  
788 all equipment at the end of a continuous operation, not to exceed 30 days (720 hours).

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

790 SUBMISSION OF REQUEST FOR APPROVAL OF ALTERNATIVE CLEANING AND SANITIZING FREQUENCY.

791 An operator may submit a written request for the department to approve alternative cleaning and  
792 sanitizing procedures. The request shall include all of the following, and any other information  
793 required by the department:

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

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

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

804 (d) A written statement, by the operator, that the alternative cleaning and sanitizing procedure  
805 has been determined by competent authority, such as evaluated by a process authority or validated  
806 by a published or unpublished peer-reviewed article, challenge studies, or regulatory standards, to  
807 be effective in preventing food contamination and ensuring the microbiological safety of food.

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

813 (f) The department may approve a proposal for an alternative cleaning and sanitizing  
814 procedure that does not comply with par. (a) if the operator can show that the procedure will be  
815 effective in preventing food contamination and ensuring the safety of food. The department shall  
816 give its approval in writing.

817 **(2) DEPARTMENT DECISION ON REQUEST FOR APPROVAL OF ALTERNATIVE CLEANING AND**  
818 **SANITIZING FREQUENCY.** The department shall grant or deny a request under sub. (1) and (4)  
819 within 60 days after it receives a complete request, except that the department may give written  
820 notice extending the action deadline for reasons stated in the notice.

821 **(3) QUALIFICATIONS, LIMITS, AND WITHDRAWAL OF DEPARTMENT APPROVAL.** The  
822 department may qualify or limit its approval under sub. (2), as it deems appropriate. The  
823 department may withdraw its approval for cause, including obtaining information that casts  
824 doubt on the efficacy or consistent implementation of the approved procedure or observing  
825 changes in operations that could affect the validity of the procedures or process.

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

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

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

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

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

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

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

849 (c) Collect and retain data and records to document, on a continuing basis, the implementation  
850 and efficacy of the approved procedure. The operator shall retain the data and records for at least

851 90 days, and shall make them available upon request for inspection and copying by the department.

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

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

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

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

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

865 1. Washing subsequent deliveries of raw fruit or vegetables at the food processing plant if the  
866 fruit or vegetable will undergo canning.

867 2. Flushing floors and gutters in the receiving areas for raw fruit or vegetables in the food  
868 processing plant.

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

872 **(2) INGREDIENT WATER.** (a) Ingredient water, other than water reclaimed according to sub.

873 (3), shall be obtained from a source that complies with ch. NR 811, for municipal water systems,  
874 or ch. NR 812 for private or non-community water systems. Water reclaimed from food  
875 processing operations may not be used as an ingredient in bottled drinking water or in any  
876 beverage where water is a characterizing ingredient.

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

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

887 (d) An operator shall keep on file, for at least 5 years, the results of all microbiological and  
888 other tests conducted on ingredient water sampled at the food processing plant.

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

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

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

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

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

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

910  
911 5. The reclaimed water is of satisfactory organoleptic quality and has no off-odors, off-  
912 flavors, or slime. The operator shall sample and organoleptically test reclaimed water at weekly  
913 intervals.

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

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

917 8. The operator tests the reclaimed water for compliance with subs. 1. to 4. at least once  
918 during any 6 month interval. The operator shall test the reclaimed water daily for 14 working days

919 after the department approves the reclamation system under subd. 1., and for at least 7 working  
920 days after any repairs or alterations to the system.

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

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

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

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

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

943

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

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

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

950 6. There are no cross-connections between reclaimed water lines and any public or private  
951 water system, except for lines with backflow preventers that meet the requirements of chs. SPS  
952 382 and 384.

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

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

957 9. The operator posts clear instructions for the use of the reclaimed water. The operator shall  
958 post the instructions so that they will be seen and understood by persons using the reclaimed water.  
959 The instructions shall disclose the limited purposes for which the reclaimed water may be used.

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

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

967 **(4) WATER TREATMENT.** (a) An operator may not use any chemical to suppress bacterial  
968 growth in water, or to prevent off-tastes or odors in water, unless that chemical is approved for that  
969 purpose by the U.S. environmental protection agency. Neither the chemical as applied, nor any  
970 compound produced by the chemical application, may adulterate food in the food processing plant  
971 in which it was used.

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

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

- 980 1. Obtained from a source that complies with chs. NR 811 or 812, as applicable.
- 981 2. Bacteriologically safe.
- 982 3. Protected from contamination.
- 983 4. Tested by the operator for compliance with subd. 2. at 6 month intervals.

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

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

989 **(6) WATER AND POTABLE LIQUIDS TRANSPORTED IN BULK.** (a) Water transported to a food  
990 processing plant in a bulk tanker or bulk container, for use as an ingredient or in other plant  
991 operations, shall be potable and shall be obtained from a source that complies with chs. NR 811 or  
992 812.

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

999 (c) Whenever potable water or another potable liquid is transported to or from a food  
1000 processing plant in a bulk tanker or bulk container, the bulk tanker or bulk container and each of  
1001 its fittings and equipment shall meet all of the following requirements:

1002 1. It shall be properly constructed and maintained to prevent contamination of the potable  
1003 water or potable liquid. Water contact surfaces shall comply with s. ATCP 70.12 (2).

1004 2. It shall be cleaned, sanitized, and inspected on a routine basis.

1005 3. It may not be used to transport materials that may contaminate potable water or potable  
1006 liquid that is subsequently transported in the bulk tanker or bulk container.

1007 4. It shall be effectively sealed to protect the potable water or potable liquid from  
1008 contamination during transit.

1009 **Note:** Effective sealing systems include manhole cover gaskets and seals.

1010 5. It shall be properly stored and serviced to prevent contamination. When not in use, pumps,  
1011 hoses, and fittings shall be properly maintained, capped, stored, and protected from contamination.

1012 **(7) CULINARY STEAM.** Water used to produce culinary steam shall be potable. Water  
1013 reclaimed from food processing operations may not be used to produce culinary steam unless it  
1014 complies with sub. (3) (a) or (b). In boilers used to produce culinary steam, boiler water additives  
1015 shall comply with 21 CFR 173.310.

1016 **(8) ICE.** Ice used to cool or maintain the temperature of foods shall be made from potable  
1017 water. Ice used to cool or maintain the temperature of ready-to-eat foods shall not have been  
1018 previously used for any other purpose. Ice shall be received, handled, and stored in a manner to  
1019 prevent contamination or adulteration. Any ice which is not made on site shall be inspected upon  
1020 receipt, and rejected if it is delivered in a way that has not adequately protected the ice from  
1021 contamination.

1022 **ATCP 70.22 Food ingredients. (1) GENERAL.** Food ingredients shall be safe, wholesome,  
1023 and unadulterated, and shall comply with applicable standards of identity under s. 97.09, Stats.  
1024 Raw agricultural commodities and other food ingredients shall be segregated and examined as  
1025 necessary to determine whether they are clean and fit for processing. Processed foods and dairy

1026 products which are used as food ingredients shall be obtained from sources which comply with  
1027 applicable licensing and inspection requirements.

1028       **(2) EGGS AND EGG PRODUCTS.** Only clean whole eggs, pasteurized eggs in liquid, frozen or dry  
1029 form, or pasteurized egg products may be used in food processing. Eggs and egg products may be  
1030 pasteurized during processing. Clean whole eggs shall be equivalent to USDA Grade B or better  
1031 with shells intact.

1032       **ATCP 70.24 Food handling and storage. (1) GENERAL.** Food shall be protected from  
1033 contamination and decomposition while being processed, handled, conveyed, or held at a food  
1034 processing plant. Food shall be processed and held in a manner which keeps the food in a safe,  
1035 wholesome, and unadulterated condition. Potentially hazardous foods shall be processed and held  
1036 at temperatures, or in a manner, which minimizes the potential for growth of undesirable  
1037 microorganisms.

1038       **(2) FOOD STORAGE.** Food storage areas shall be maintained in a clean, sanitary, and orderly  
1039 condition, free from conditions which may result in the adulteration of food. Potentially hazardous  
1040 foods shall be stored at safe temperatures. Storage areas shall be constructed and maintained so  
1041 that waste water and other waste liquids do not drain into, or accumulate in, any storage area.  
1042 Food shall not be stored in a manner which may attract or harbor pests.

1043       **(3) FOOD PROCESSING. (a)** Food processing shall be conducted under appropriate conditions  
1044 and controls to minimize the potential for growth of undesirable microorganisms, or the  
1045 contamination of food.

1046       **Note:** One way to comply with this requirement is to follow a HACCP plan which monitors and  
1047 controls food safety variables at critical control points in the manufacturing process. Monitoring and  
1048 controlling food safety variables such as time, temperature, humidity, water activity ( $a_w$ ), pH, pressure, and

1049 flow rate at critical control points can ensure that mechanical breakdowns, time delays, temperature  
1050 fluctuations, and other conditions do not contribute to the decomposition or contamination of food.

1051

1052 (b) If potentially hazardous food is heated, refrigerated, or frozen in the course of processing,  
1053 the internal temperature of the food shall be accurately monitored, as necessary, to ensure that safe  
1054 temperatures are promptly attained and maintained.

1055 (c) Potentially hazardous frozen foods, if thawed for processing, shall be thawed by one of  
1056 the following methods:

1057 1. By placing the frozen food in a refrigerated space at a temperature of not more than 41° F  
1058 (5° C).

1059 2. Placing the frozen food under potable running water, at a temperature of not more than 70°  
1060 F (21° C), for no more time than is needed to thaw the food. Water velocity shall be sufficient to  
1061 agitate loose particles and drain or float them away from the food being thawed.

1062 3. By microwave heating, if the food is fully cooked in the microwave oven, or if cooking is  
1063 immediately completed in another cooking facility.

1064 4. In any cooking facility, as part of the process by which the food is fully cooked.

1065 **(4) BULK FLOUR HANDLING SYSTEMS.** (a) Food contact surfaces of bulk flour handling  
1066 equipment shall comply with the provisions of s. ATCP 70.12 (2). Pneumatic systems using  
1067 storage bins constructed of semi-permeable cloth material are exempt from the requirement that  
1068 surfaces be smooth and nonabsorbent, provided the surfaces can be effectively cleaned.  
1069 Attachment mechanisms for holding inspection port covers, access doors, delivery pipe caps, or  
1070 other removable accessories shall have no loose parts. Delivery pipe caps shall be kept in place,  
1071 and secured against removal, except when a bulk flour handling system is in use. Outside  
1072 installations shall be watertight or suitably covered to prevent entry of water and foreign material.

1073 (b) Intake air used in pneumatic flour handling systems shall be filtered to exclude particles of  
1074 50 microns or larger. Air discharged from the system shall be filtered so that no visible dust  
1075 escapes. Filters shall be readily removable for cleaning or replacement. Straight runs of  
1076 pneumatic conveyors shall comply with the provisions of s. ATCP 70.12 (1), except that piping  
1077 which is self-purging is exempt from accessibility requirements.

1078 (5) RAW INGREDIENTS AND FINISHED PRODUCTS; SEPARATE HANDLING. Effective measures  
1079 shall be taken to prevent cross contamination between raw ingredients and finished food products.  
1080 Raw ingredients shall not be handled simultaneously with finished products in any part of a food  
1081 processing plant if either the raw materials or the finished products are uncovered or unprotected,  
1082 and if the handling may result in contamination.

1083 (6) SALVAGING DISTRESSED FOOD. (a) In this subsection:

1084 1. "Distressed food" means processed food exposed to a fire, flood, transportation accident,  
1085 refrigeration breakdown, or other unusual condition which may affect its safety or suitability as  
1086 human food. "Distressed food" does not include food or food packages damaged during normal  
1087 conditions of food and food product handling, transit, or storage.

1088 2. "Reconditioned food" means packaged distressed food distributed or offered for sale as  
1089 human food after its package is repaired or relabeled without being opened.

1090 3. "Reprocessed food" means distressed food subsequently processed in accordance with the  
1091 requirements under this chapter and distributed or offered for sale as human food.

1092 (b) An operator shall notify the department within 3 days after the operator takes possession of  
1093 any distressed food, or within 3 days after food in the operator's custody becomes distressed food.

1094 The operator shall notify the department before the operator reprocesses or reconditions the  
1095 distressed food.

1096 (c) An operator shall identify distressed food as such, and shall separate it from other food.

1097 No operator may store distressed food in a processing area, or under conditions which may lead to  
1098 the contamination of other food, equipment, utensils, or packaging materials.

1099 (d) No operator may do either of the following:

1100 1. Reprocess for sale, as human food, any distressed food which is unwholesome or  
1101 adulterated.

1102 2. Offer for sale, sell, or distribute food in packages that are damaged to such an extent that  
1103 the food may have been exposed or subjected to possible contamination, including packages with  
1104 bulging ends, ruptures, hairline fractures, breakage along critical seams, or openings which may  
1105 have exposed food to contamination.

1106 (e) No operator may sell or distribute reprocessed or reconditioned food at wholesale unless  
1107 the operator gives the purchaser or recipient written notice that the food is reprocessed or  
1108 reconditioned. The notice shall also include the name and address of the person who reprocessed  
1109 or reconditioned the distressed food. The notice may be included on an invoice, bill of lading, or  
1110 other documentation of the sale or distribution of the food.

1111 (f) An operator shall keep, for the period of time set forth in 21 CFR 117.315, all of the  
1112 following records related to distressed food handled by that operator:

1113 1. A description of the distressed food, including the type of food, the package or container  
1114 style, and the amount of the food.

1115 2. The source of the distressed food, or the conditions which caused it to become distressed  
1116 food.

1117 3. The date on which the operator received the distressed food.

1118 4. The nature of any reprocessing or reconditioning which the operator performed on the  
1119 distressed food.

1120 5. The final disposition of the distressed food if the distressed food was not sold directly at  
1121 retail. That record shall include the name and address of the person, such as the food wholesaler,  
1122 food distributor, waste disposal firm or waste disposal site operator, to whom the food processing  
1123 plant operator delivered the food.

1124 (7) FOOD IRRADIATION. Irradiation in the production, processing, and handling of food shall  
1125 comply with applicable federal regulations under 21 CFR 179.

1126 (8) EGG CLEANING AND STORAGE. Cleaning and storage of eggs shall be done in compliance  
1127 with the requirements of s. ATCP 88.20.

1128 **ATCP 70.26 Food packaging and labeling. (1) GENERAL.** Food packages shall be of  
1129 sanitary design and construction, so as to protect food contents from reasonably foreseeable risks  
1130 of contamination. Food packages shall be clean, sanitary, and free of any extraneous or deleterious  
1131 substance. Food shall not be sold or distributed in packages which are damaged to the extent that  
1132 food contents may be adulterated as a result of the damage. A sealed food package is damaged  
1133 within the meaning of this subsection if the package or seal is broken or bulged.

1134 (2) CLEANING AND SANITIZING RETURNABLE FOOD PACKAGES. Returnable or multi-use food  
1135 packages, including returnable bottles, shall be effectively cleaned and sanitized before being  
1136 reused. Cleaning and sanitizing processes shall remove all extraneous matter and potential

1137 adulterants from a food package before the food package is reused. Sanitizing methods shall  
1138 comply with s. ATCP 70.28. No food package may be reused unless it is specifically designed and  
1139 constructed for that purpose.

1140 **(3) INSPECTION OF RETURNABLE FOOD PACKAGES.** Returnable or multi-use packages, after  
1141 being cleaned and sanitized, shall be inspected before being reused. Inspection shall be adequate  
1142 to detect extraneous material and visible adulterants, and any damage to product contact surfaces.  
1143 Inspection shall be performed on surfaces lighted in compliance with s. ATCP 70.08 (5) (b).

1144 **(4) SINGLE-SERVICE FOOD PACKAGES.** Single-service food packages, including bottle caps and  
1145 other single-service articles used to package food, shall be made from clean, sanitary materials.  
1146 Single-service food packages shall be clean and sanitary at the time of use. Single-service food  
1147 packages shall be protected from contamination prior to use, and shall be handled in a sanitary  
1148 manner. Single-service food packages, including single-service bottles and bottle caps, shall not  
1149 be re-used.

1150 **(5) FOOD PACKAGE LABELING.** Packaged food shall be packaged and labeled according to all  
1151 of the following, as applicable:

1152 (a) 21 CFR 101.

1153 (b) S. 97.09, Stats., and federal regulations incorporated by reference in s. 97.09, Stats.

1154 (c) Ch. ATCP 90.

1155 (d) Ch. ATCP 75 Appendix, part 3-201.11(C).

1156 (e) If the packaged food contains a major food allergen, the ingredient statement on the  
1157 package shall disclose the common name of the major food allergen. The disclosure shall be  
1158 equivalent in size and prominence to the rest of the ingredient statement. If an allergen originates

1159 from fish, crustacean shellfish, or tree nuts, the disclosure shall include the common name of the  
1160 source species.

1161 **Note:** For example, if a food product includes an allergen that originates from fish, the ingredient  
1162 statement must disclose the common name such as bass, flounder, or cod. If the allergen originates from  
1163 crustacean shellfish, the ingredient statement must disclose the common name such as crab, lobster, or  
1164 shrimp. If the allergen originates from tree nuts, the ingredient statement must disclose the common name  
1165 such as almond, pecan, walnut, or coconut.

1166  
1167 **(6) EGG PACKAGING AND LABELING.** The packaging and labeling of eggs shall be done in  
1168 compliance with the requirements of ss. ATCP 88.32, 88.34, and 88.38.

1169 **(7) ALCOHOL RESTRICTIONS AND LABELING.** If a product contains more than 1.0% but less  
1170 than 7.0% alcohol it is regulated by the labeling provisions of this subsection and the alcohol  
1171 would be declared as an ingredient in normal descending order of predominance. If the alcohol is  
1172 part of other ingredients such as a flavoring, and it is less than 0.5% of the finished product by  
1173 volume, then it is considered an incidental ingredient.

1174 **ATCP 70.28 Sanitizers and sanitizing methods. (1) SANITIZING METHODS.** All returnable or  
1175 multi-use food packages, and all food contact surfaces of equipment and utensils used to handle  
1176 foods, shall be effectively sanitized prior to each use.

1177 **(2) CHEMICAL SANITIZERS; REQUIREMENTS.** The operator shall use only chemical sanitizers that  
1178 are specified as acceptable for use in 21 CFR 178.1010, are registered with the U.S. environmental  
1179 protection agency, are applied according to manufacturer's instructions, labeled for use in food  
1180 processing plants on food contact surfaces, and do not leave an unacceptable residue on the food  
1181 contact surface when used appropriately.

1182 **(3) BAKING AND COOKING CONTAINERS; EXEMPTION.** Sub. (1) does not apply to baking and  
1183 cooking containers if heating time and temperature combinations meet industry standards and are

1184 adequate to destroy pathogenic microorganisms, provided that the containers are cleaned, stored,  
1185 and used in a manner which prevents contamination of food.

1186 (4) SANITIZERS; MAXIMUM CONCENTRATIONS. The operator shall use sanitizers and cleaning  
1187 compounds so no toxic or otherwise unacceptable residue is left on any food contact surface.

1188 Sanitizing solutions shall not exceed the maximum concentrations established by the food and drug  
1189 administration, United States department of health and human services, under 21 CFR 178.1010.

1190 A test kit or other device that measures the concentration of sanitizing solutions in parts per million  
1191 shall be used as necessary to ensure compliance with this subsection.

1192 (5) SANITIZERS; DEPARTMENT APPROVAL. (a) Sanitizers approved by the U.S. environmental  
1193 protection agency and labeled for use on food contact surfaces are also accepted by the department  
1194 for use according to their labels. The department may approve other sanitizers and sanitizing  
1195 methods that it finds to be safe and effective for the purpose used.

1196 (b) The department may deny or withdraw approval of any sanitizer or sanitizing method if the  
1197 department determines that the sanitizer or sanitizing method is not safe or effective for the  
1198 purpose or under the conditions used, or that it adversely affects the sanitary characteristics of  
1199 equipment, utensils, or food packages.

1200 **ATCP 70.30 Ready-to-eat foods; reporting pathogens and toxins. (1) REQUIREMENT.**

1201 Except as provided under sub. (2), an operator shall report to the department the results of any  
1202 microbiological test or laboratory analysis which indicates that any ready-to-eat food produced by  
1203 that operator contains pathogenic organisms, toxins resulting from the growth of pathogenic  
1204 organisms, or any other adulterant capable of causing disease or injury if ingested. The operator

1205 shall report to the department within 24 hours after the operator obtains the test results. The  
1206 operator may report orally, electronically, or in writing.

1207 **Note:** The State of Wisconsin's Emergency Management phone number is (800) 943-0003. The general  
1208 number of the Division of Food and Recreational Safety is (608) 224-4700, and its FAX number is (608) 224-  
1209 4710.

1210  
1211 **(2) EXEMPTION.** An operator is not required to report test results under sub. (1) if all of the  
1212 following apply:

1213 (a) The ready-to eat-food is identified by a product code or production lot number.

1214 (b) The operator has not yet sold or distributed any of the ready-to-eat food represented by the  
1215 product code or production lot number under par. (a), but retains direct control over all of that  
1216 ready-to-eat food.

1217 **ATCP 70.32 Recall plan. (1) PLAN REQUIRED.** An operator shall have a written plan for  
1218 identifying and recalling food produced at that plant, should a food recall become necessary. The  
1219 operator shall update the plan as necessary, and shall make it available to the department for  
1220 inspection and copying upon request.

1221 **(2) PLAN CONTENTS.** A plan, under sub. (1), shall do all of the following:

1222 (a) Identify key individuals or positions that are responsible for planning, approving, and  
1223 implementing recalls on behalf of the operator.

1224 (b) Identify key individuals or entities to be contacted or consulted in connection with a recall.

1225 (c) Include procedures for the routine identification, dating, and tracking of food production  
1226 lots, so that affected lots can be identified and distinguished from unaffected lots in the event of a  
1227 recall.

1228 (d) Include procedures to enable routine identification, dating, and tracking of food shipments  
1229 from the food processing plant. Tracking shall identify shipment recipients and contents, cross-  
1230 referenced to production lots, so that recipients of affected lots may be contacted in the event of a  
1231 recall.

1232 (e) Include procedures for determining the nature and scope of a recall, including affected food  
1233 production lots, shipments, and shipment recipients.

1234 (f) Include procedures for identifying and communicating with affected persons, including  
1235 suppliers, food shipment recipients, down-line buyers, consumers, government agencies, and  
1236 others.

1237 (g) Identify potential target audiences for recall information, including consumers, distributors,  
1238 and government agencies.

1239 (h) Identify potential methods for communicating with target audiences under par. (g).

1240 (i) Identify key information, including the identity of the affected food, the reason for the  
1241 recall, and suggested actions to be taken by affected persons, which may need to be communicated  
1242 in the event of a recall.

1243 **(3) DEVIATIONS FROM PLAN.** Actual recall procedures may deviate from the recall plan under  
1244 sub. (1), as circumstances warrant.

### 1245 SUBCHAPTER III

#### 1246 CANNING OPERATIONS; SUPPLEMENTARY REQUIREMENTS

1247 **ATCP 70.34 General. (1) APPLICABLE REQUIREMENTS.** Operators engaged in canning  
1248 operations shall comply with applicable provisions of subch. II. Operators engaged in canning

1249 operations shall also comply with this subchapter and shall file processes, as required, with the  
1250 U.S. food and drug administration according to the provisions in 21 CFR 108.

1251 **(2) RESTRICTIONS ON SALE, DISTRIBUTION, AND DONATION OF HOME-CANNED FOODS.** Home-  
1252 canned low-acid or acidified foods may not be donated to charitable organizations, food banks,  
1253 food pantries, or other non-profit organizations that will distribute or sell the home-canned foods.  
1254 The individual canning processor may not sell the home-canned foods at a food bank or food  
1255 pantry, or on behalf of a charitable or non-profit organization, unless exempted by statute or rule.

1256 **ATCP 70.36 Low-acid foods packaged in hermetically sealed containers.** The operator of  
1257 a food processing plant that processes and packages low-acid foods in hermetically sealed  
1258 containers shall comply with applicable federal regulations under 21 CFR 108.35 (c) and 21 CFR  
1259 113.

1260 **Note:** Section ATCP 70.36 applies to all low-acid foods processed and packaged in hermetically sealed  
1261 containers, including thermally processed and aseptically processed low-acid foods.

1262 **ATCP 70.38 Acidified foods.** Persons who process acidified foods shall comply with  
1263 applicable federal regulations under 21 CFR 108.25 (c) and 21 CFR 114.

1264 **ATCP 70.40 Facilities and equipment; cleaning. (1) EQUIPMENT DESIGN, CONSTRUCTION,**  
1265 **AND ACCESSIBILITY.** The operator of a food processing plant facility handling raw agricultural  
1266 commodities to prepare the commodities for canning, shall use product-handling equipment that is  
1267 kept clean and in good repair and is designed and constructed in a way that allows easy  
1268 accessibility for maintenance and cleaning.

1269 **(2) EQUIPMENT, WATER, AND SUPPLIES USED FOR CLEANING.** The operator of a food processing  
1270 plant conducting canning operations shall use cleaning equipment that is adequate and in good

1271 repair, and shall provide ample supplies of water and steam or other approved cleaning and  
1272 sanitizing materials for cleaning purposes at the facility.

1273 **(3) CLEANING REQUIREMENTS FOR EQUIPMENT USED TO PROCESS FOOD BEFORE THERMAL**  
1274 **PROCESSING.** The operator at a canning facility shall clean equipment used to process food before  
1275 thermal processing, in accordance with a written plan kept at the canning facility and made  
1276 available to the department for review upon request. The written plan shall include:

1277 (a) A clear and complete description of the affected food processing equipment and utensils,  
1278 including any continuously-operated equipment. The description shall identify sanitary design  
1279 features that are relevant to the proposed cleaning and, if deemed appropriate, sanitizing  
1280 procedures.

1281 (b) The types of food produced with the affected equipment or utensils, the purposes for which  
1282 the food will be used, and the thermal processing conditions to which the food will be subjected.

1283 (c) A clear and complete description of the alternative procedures used to clean and, if deemed  
1284 appropriate, sanitize the equipment, including equipment used to conduct these procedures,  
1285 frequency, methods, materials, and relevant process parameters such as time and temperature. The  
1286 description shall include a flow diagram of the alternative procedures.

1287 (d) A written statement, by the operator, that the alternative cleaning and sanitizing procedures  
1288 have been determined by competent authority, such as a process authority or validated by a  
1289 published or unpublished, peer-reviewed article, challenge studies, or regulatory standards, to be  
1290 effective in preventing finished food product contamination and ensuring the microbiological  
1291 safety of food.

1292 (e) Identification of foreseeable hazards, critical control points, critical safety parameters and  
1293 limits, and monitoring procedures and controls to ensure that the procedure is effective and  
1294 appropriately implemented.

1295 **ATCP 70.42 Handling raw agricultural commodities and by-products. (1) PRE-**  
1296 **CANNING OPERATIONS.** Raw agricultural commodities shall be washed, sorted, trimmed as  
1297 necessary, and inspected before being canned. This requirement does not apply to the washing of  
1298 cabbage being prepared to make sauerkraut.

1299 **(2) WASTE HANDLING.** Waste and by-products from canning operations shall be stored and  
1300 handled in a sanitary manner.

#### 1301 SUBCHAPTER IV

#### 1302 FISH PROCESSING PLANTS; MARINE SHELLFISH PLANTS; SUPPLEMENTARY 1303 REQUIREMENTS

1304 **ATCP 70.44 Fish processing. (1) APPLICABLE REGULATIONS.** A fish processing plant  
1305 operator shall comply with subch. II and 21 CFR 123. The operator shall have and operate in  
1306 accordance with HACCP plans that comply with 21 CFR 123 and address food safety hazards that  
1307 may occur in fish processing. If a fish processing plant produces smoked fish products or smoke-  
1308 flavored fish products, the HACCP plan for that fish processing plant shall address potential  
1309 botulism risks as provided in 21 CFR 123 part B.

1310 **(2) RESTRICTION ON USE OF COLD-PROCESS SMOKED FISH.** Cold-process smoked fish may  
1311 not be used as an ingredient in any other ready-to-eat, potentially hazardous food.

1312       **ATCP 70.46 Labeling and sale of smoked fish. (1) MANDATORY LABEL INFORMATION.** Every  
1313 package containing smoked fish shall be clearly and conspicuously labeled, on the principal  
1314 display panel of that package, with all of the following information:

1315           (a) The name and address, including the zip code, of the smoked fish processor or  
1316 distributor.

1317           (b) The name of the product, including the common name of the fish from which the product  
1318 is derived as found in Table 3-2 of the Fourth Edition of *Fish and Fishery Products Hazards and*  
1319 *Controls Guidance*.

1320       **Note:** A copy of the current edition of the *Fish and Fishery Products Hazards and Controls Guidance*,  
1321 may be obtained from the University of Florida Bookstore by calling (800) 226-1764, or it may be  
1322 downloaded from the U.S. food and drug administration website:  
1323 <http://www.fda.gov/Food/GuidanceRegulation/Guidance DocumentsRegulatoryInformation/default.htm/>  
1324

1325           (c) The net weight of the package contents.

1326           (d) If cold-smoked fish is contained in reduced-oxygen packaging and sold or distributed in  
1327 an unfrozen state, the words “PERISHABLE – KEEP REFRIGERATED AT OR BELOW 38°  
1328 F” in conspicuous letters at least the size of those used in the food name.

1329           (e) If smoked fish contained in the package are sold or distributed in a frozen state, the words  
1330 “PERISHABLE — KEEP FROZEN PRIOR TO USE” in conspicuous letters at least the size of  
1331 those used in the food name.

1332           (f) The processing date or processing date code of the smoked fish.

1333       **(2) PROHIBITION AGAINST COMMINGLING.** Smoked fish processed on different dates or codes  
1334 may not be commingled in the same container, either at the processing plant or while the fish are  
1335 being stored, distributed, or offered for sale at wholesale or retail.

1336           **(3) MISREPRESENTATION OF PROCESSING DATE OR PROCESSING DATE CODE PROHIBITED.** No  
1337 person may misrepresent a smoked fish processing date or processing date code, or sell or  
1338 distribute smoked fish labeled with any processing date or processing date code other than the  
1339 original date or code affixed by the processor.

1340           **(4) REMOVAL OF MISLABELED OR MISHANDLED SMOKED FISH.** Food consisting of or containing  
1341 smoked fish shall be immediately removed from sale, and shall be destroyed or treated to render it  
1342 unattractive and unfit for human consumption, if any of the following occurs:

1343           (a) The food package is not labeled with a processing date or processing date code.

1344           (b) Vacuum-packaged, cold-smoked fish is held, other than for brief periods during  
1345 distribution, at a temperature above 38° F (3.4° C) prior to retail sale. This paragraph does not  
1346 apply to a food which the department specifically exempts in writing because it is not subject to  
1347 spoilage and does not support pathogen growth.

1348           **(5) APPLICABILITY OF SMOKED FISH REGULATIONS IN WISCONSIN.** No smoked fish may be sold,  
1349 distributed, or offered or exposed for sale in this state unless the smoked fish have been processed,  
1350 labeled, and handled in compliance with this subchapter. This subsection applies to every person  
1351 engaged in the sale or distribution of smoked fish in this state, regardless of whether the person  
1352 processes smoked fish in this state.

1353           **ATCP 70.48 Fish roe. (1) REFRIGERATION.** Roe and any attached entrails harvested from a  
1354 fish shall be refrigerated at a temperature of not more than 38° F (3.4° C). Processing of dry salted  
1355 roe or salted roe product shall be done in accordance with 21 CFR 123.

1356           **(2) HARVESTING AND HANDLING.** Roe and attached entrails, if any, shall be harvested, stored,  
1357 and transported for processing in covered food grade containers. Each container shall be

1358 conspicuously labeled to indicate when each of the following operations was performed, if that  
1359 operation has been performed:

1360 (a) The roe and attached entrails, if any, were harvested from the fish.

1361 (b) The roe sacks were separated from attached entrails, if any. Roe sacks shall be separated  
1362 from attached entrails within 48 hours after the roe sacks and entrails are harvested from the fish.

1363 (c) The roe was separated from the roe sacks. Roe shall be separated from roe sacks within 72  
1364 hours after the roe sacks are harvested from the fish, unless the roe is processed and packed in roe  
1365 sacks. Roe processed and packed without being separated from roe sacks shall be processed and  
1366 packed within 72 hours after the roe sacks are harvested from the fish.

1367 **(3) RECEIPT FOR PROCESSING.** A fish processing plant operator may not accept for processing  
1368 any roe that has been held, transported, or processed in violation of sub. (1) or (2).

1369 **(4) PROCESSING STANDARDS.** (a) Roe shall be held and processed according to s. ATCP 70.24  
1370 (1).

1371 (b) Processed roe shall contain a minimum of 2.5% salt by weight, as determined by  
1372 quantitative analysis for total salt content.

1373 (c) No fish processing plant personnel may have direct hand contact with finished, ready-to-eat  
1374 roe.

1375 **(5) PRODUCT REPRESENTATION.** (a) No roe product may be labeled or represented as "caviar"  
1376 unless one of the following applies:

1377 1. The product consists only of the eggs of sturgeon prepared by a salting and separation  
1378 process traditionally associated with the term "caviar."

1379 2. The product consists of roe prepared by a salting and separation process traditionally  
1380 associated with the term "caviar," and the name of the fish species is clearly disclosed with the  
1381 term "caviar" whenever that term is used.

1382 **Note:** For example, a caviar-type product made from whitefish eggs, using the traditional caviar  
1383 process, may not be labeled as "caviar" unless it is labeled as "whitefish caviar." All packaged food product  
1384 labels, including "caviar" labels, must also include a statement of ingredients listed by their common or  
1385 usual names in descending order of prominence (see s. ATCP 70.26).

1386 (b) No person may misrepresent the identity or value of any roe product by adding a color  
1387 additive to the roe product. This paragraph does not prohibit the use of color additives in roe  
1388 products if all of the following apply:

1390 1. The color additive is approved by the United States food and drug administration.

1391 2. The product includes a conspicuous label disclosure, such as "artificially colored" or "color  
1392 added," which clearly indicates that the product includes a color additive. The disclosure shall  
1393 appear on the product label directly below the product name in type at least one-third the size of  
1394 the type used in the product name.

1395 3. The color additive is included in the ingredient statement on the product label.

1396 **ATCP 70.50 Marine molluscan shellfish processing. (1) APPLICABLE FEDERAL**  
1397 **REGULATIONS.** Shellfish processing and shipping operations shall comply with subch. II, the U.S.  
1398 food and drug administration's *Guide for the Control of Marine Shellfish, The Model Ordinance,*  
1399 and applicable sections of 21 CFR 123. Shellfish processing plant operators shall have HACCP  
1400 plans that comply with 21 CFR 123 and address food safety hazards that may occur in shellfish  
1401 processing. If a shellfish processing plant produces smoked shellfish products or smoke-flavored  
1402 shellfish products, the HACCP plan for that fish processing plant shall address potential botulism  
1403 risks as provided in 21 CFR 123 part B.



1426       **ATCP 70.54 Returnable and single-service bottles.** Bottles shall comply with food package  
1427 requirements under s. ATCP 70.26 (1). Returnable bottles shall be cleaned, sanitized, and  
1428 inspected in compliance with ss. ATCP 70.26 (2) and (3). Single service bottles shall comply with  
1429 s. ATCP 70.26 (4).

1430       **ATCP 70.56 Bottled water product sampling; record keeping; reports.**

1431       **(1) SAMPLING AND ANALYSIS.** The operator of a bottled water plant shall collect and analyze  
1432 samples of bottled product for the following contaminants at the following minimum frequency,  
1433 and more frequently if necessary, to provide reasonable assurance of compliance with this  
1434 subsection:

1435       (a) A weekly total coliform analysis. Pursuant to 21 CFR 129.80 (g) (1), a positive total  
1436 coliform analysis requires follow-up testing for *E. coli* and, pursuant to 21 CFR 165.110 (b) (2)

1437 (B), if *E. coli* is present the bottled water will be deemed adulterated.

1438       (b) An annual physical analysis pursuant to 21 CFR 165.110 (b) (3) for turbidity, color, and  
1439 odor analysis.

1440       (c) An annual chemical analysis pursuant to 21 CFR 165.110 (b) (4).

1441       (d) An annual radiological analysis pursuant to 21 CFR 165.110 (b) (5).

1442       **(2) REPORTING OF ANALYTICAL RESULTS.** A processor of bottled water shall report the results  
1443 of all required analyses, under sub. (1), to the department, for each license year upon request. If  
1444 the result of any individual analysis exceeds the established enforcement standard, the bottled  
1445 water processor shall submit a copy of that analytical report to the department within 7 days of the  
1446 completion of the analysis.

1447       **ATCP 70.58 Labeling bottled products.** Bottled products shall be labeled according to

1448 s. ATCP 70.26 (5). Bottled water shall also be labeled according to 21 CFR 165.110. Juice shall  
1449 be labeled according to 21 CFR 120, and any applicable regulations found in this chapter.

1450 SUBCHAPTER VI

1451 JUICE AND JUICE HACCP

1452 **ATCP 70.60 Juice and Juice HACCP. (1) APPLICABLE REGULATIONS.** Food processing  
1453 plants producing and packaging or bottling juice shall comply with subch. II and this subchapter.  
1454 Food processing plants engaged in juice processing and packaging or bottling shall comply with 21  
1455 CFR 120.

1456 **(2) LABELING REQUIREMENTS.** A juice label may not misrepresent that juice has been  
1457 pasteurized or has undergone a process equivalent to pasteurization. A juice label may not  
1458 represent as "fresh" any juice that has been treated with ultra-violet light.

1459 SUBCHAPTER VII

1460 EFFECT OF RULES ON LOCAL ORDINANCES

1461 **ATCP 70.62 Effect of rules on local ordinances. (1) NON-CONFLICTING LOCAL**  
1462 **ORDINANCES PERMITTED.** This chapter does not prohibit or nullify any local government ordinance  
1463 with which it is not in direct conflict as provided in sub. (2).

1464 **(2) PRE-EMPTION OF CONFLICTING LOCAL ORDINANCES.** If this chapter conflicts directly with  
1465 any local government ordinance, so that it is impossible to comply with one except by violating the  
1466 other, this chapter controls.

1467 **(3) DUTY TO COMPLY.** Compliance with local government ordinances does not relieve any  
1468 person from the duty of complying with this chapter.

1469

1470 SUBCHAPTER VIII

1471 VARIANCES

1472 **ATCP 70.64 Variances. (1) ISSUANCE.** The department may issue a written waiver granting  
1473 a variance from a construction, equipment, utensils, processing or procedure standard under this  
1474 chapter if the department finds that the variance is reasonable and necessary under the  
1475 circumstances, and that it will not compromise the purpose served by the construction, equipment,  
1476 or processing standards. The administrator of the department's division of food and recreational  
1477 safety may issue a waiver on behalf of the department. The department shall keep a copy of the  
1478 waiver on file for as long as the waiver remains in effect.

1479 **(2) SUBMISSION OF REQUEST FOR A VARIANCE.** A variance request shall be submitted to the  
1480 department through the sanitarian assigned by the department to inspect the food processing plant,  
1481 and shall include all validation documents as well as a HACCP plan required under 21 CFR, parts  
1482 120 or 123, if applicable; or food safety preventive controls plan as required under 21 CFR 117,  
1483 Subpart C, if it is for a waiver of accepted processing protocols.

1484 **(3) DEPARTMENT DECISION ON REQUEST FOR A VARIANCE.** The department shall grant or deny a  
1485 request under sub. (2) and (4) within 60 days after it receives a complete request, except that the  
1486 department may give written notice extending the action deadline for reasons stated in the notice.

1487 **(4) DURATION, EXPIRATION, AND REISSUANCE.** (a) Waivers to construction and maintenance  
1488 standards under s. ATCP 70.08 shall remain in effect as long as no material changes to  
1489 construction or maintenance of the food processing plant result in failure to meet the standard in  
1490 sub. ATCP 70.08 (1). All waivers to standards under ss. ATCP 70.10 to 70.32 granted under this  
1491 section shall expire five years from the date of issuance.

1492 (b) A license holder who wishes to continue a variance to standards under ss. ATCP 70.10 to  
1493 70.32 after the expiration of the waiver shall file a request with the department for reissuance of  
1494 the waiver at least 180 days prior to its expiration, unless permission for a later date has been  
1495 granted by the department.

1496 (c) When a license holder has made timely and sufficient application for the reissuance of a  
1497 waiver or a new variance request with reference to any activity of a continuing nature, the existing  
1498 waiver does not expire until the application has been finally acted upon by the department, and, if  
1499 the application is denied or the terms of the new request are limited, until the last day for seeking  
1500 review of the agency decision or a later date fixed by order of the reviewing court.

1501 (d) A waiver shall be reissued by the department if the equipment, utensils, processes, or  
1502 procedures described in it continue to meet the criteria in sub. (1) or if the food processing plant  
1503 operator updates the original variance request to ensure compliance with the criteria in sub. (1).

1504 **SECTION 2. EFFECTIVE DATE.** This rule shall take effect on the first day of the month  
1505 following publication in the Wisconsin Administrative Register, as provided under s. 227.22 (2)  
1506 (intro.), Stats.

Dated this \_\_\_\_\_ day of \_\_\_\_\_, 2019.

STATE OF WISCONSIN  
DEPARTMENT OF AGRICULTURE, TRADE  
AND CONSUMER PROTECTION

By \_\_\_\_\_  
Bradley M. Pfaff, Department Secretary

## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

|   |  |
|---|--|
| <b>1. Type of Estimate and Analysis</b><br><input type="checkbox"/> Original <input checked="" type="checkbox"/> Updated <input type="checkbox"/> Corrected   | <b>2. Date</b><br>9-5-2019                           |
| <b>3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)</b><br>ATCP 70, Wholesale Food Manufacturing, Clearinghouse Number 17-073  |  |
| <b>4. Subject</b><br>Food Processing Plants, and relating to small business   |  |
| <b>5. Fund Sources Affected</b><br><input type="checkbox"/> GPR <input type="checkbox"/> FED <input type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S  | <b>6. Chapter 20, Stats. Appropriations Affected</b> |
| <b>7. Fiscal Effect of Implementing the Rule</b><br><input checked="" type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs<br><input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input checked="" type="checkbox"/> Could Absorb Within Agency's Budget  |  |
| <b>8. The Rule Will Impact the Following (Check All That Apply)</b><br><input type="checkbox"/> State's Economy <input checked="" type="checkbox"/> Specific Businesses/Sectors<br><input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers<br><input checked="" type="checkbox"/> Small Businesses (if checked, complete Attachment A)  |  |
| <b>9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).</b><br>\$656,000  |  |
| <b>10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?</b><br><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No   |  |
| <b>11. Policy Problem Addressed by the Rule</b><br>Updating to: 1) reconcile previously different (DATCP vs. DHS) rules on wholesale food processing activities that may be conducted by retail food establishments, 2) revise definitions of wholesale and retail processing to be consistent with industry practices and federal policies, 3) remain consistent with federal regulations applicable to food processing plants and thereby enable DATCP to conduct contract inspections for the FDA under state authority, 4) provide additional flexibility to wholesale food manufacturers seeking variances from requirements related to equipment, utensils, processes, and procedures; 5) expand the range of food processing activities for which daily cleaning and sanitizing of equipment is not required, 6) clarify the duration and review of waivers granted by the department for variances from construction, equipment, utensil, process and procedure requirements, 7) clarify the duration and review for department approval of alternative cleaning and sanitizing schedules, 8) adopt the federal model ordinance as required for Wisconsin to continue participating in the national shellfish sanitation program, 9) clarify requirements for use of reclaimed water in food processing plants, and 10) continue providing appropriate flexibility in certain construction standards. |  |
| <b>12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.</b><br>Supervisors of DATCP staff who inspect all of licensed food processing plants were surveyed to provide an estimate of the number of license-holders that would be affected by new requirements. DATCP staff knowledgeable in facility construction costs were queried about likely costs of new facility requirements. These staff, in turn, consulted commercial equipment and construction personnel to obtain or verify cost estimates. Finally, all licensed food processing plants were contacted by either e-mail (1,378 businesses) or mail (531 businesses) and asked for their assessment of costs they would have to bear due to new requirements. Over 200 responses (greater than 11%) were received.  |  |
| <b>13. Identify the Local Governmental Units that Participated in the Development of this EIA.</b><br>None. The rule does not affect Local Governmental Units.  |  |
| <b>14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be</b>   |  |

## ADMINISTRATIVE RULES

### Fiscal Estimate & Economic Impact Analysis

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Incurred)

The estimated economic impact listed in item 9 is \$656,000 across 1900 businesses. Costs have been attributed to possible one-time upgrades in handwashing sinks, toilet rooms, and exit doors that some firms may have to make. The rule requires handwashing sinks in toilet rooms or food processing areas to meet modern requirements for mixing of hot and cold water and hands-free operation in newly licensed facilities or in facilities operated by a license-holder continuing since on or before November 1, 2009 in which the handwashing sinks are substantially reconstructed or extensively altered. The requirement is already in place for new license-holders or installations of handwashing sinks in already-licensed food processing plants. DATCP estimates that not more than 40 businesses would face the costs of new sink installation. DATCP estimates that costs for these businesses would not exceed \$1,000 apiece. The figure in item 9 includes \$40,000 for handwash sink upgrades. Survey response data supports this estimate as approximately 70% of respondents indicated that "none" or "slight" costs would be imposed. Comments indicated a high level of existing compliance with this requirement. Cost estimates listed in the comments ranged from a few hundred dollars to less than \$10,000 per business. Some commenters who provided relatively higher cost estimates were apparently unaware that less-expensive "wrist paddle" or "foot pedal" operation would meet the requirement and described the costs and challenges of installing and using electronic-sensor operated faucets.

The rule requires newly installed toilet rooms to be contiguous to the food processing area. This requirement applies if either the toilet room was constructed after the date of this rule or in food processing plants newly opened or operated by a new license-holder after the date of this rule. Pre-existing non-contiguous toilet rooms in a food processing plant operated by the same license-holder since on or before the date of this rule would be allowed, provided applicable state and local regulations were met. DATCP estimates that, based on history, not more than 40 businesses choose to install a toilet room in a given year. Costs of construction could vary widely depending on the situation, but a worst-case estimate of \$10,400 per business was used in arriving at the figure of \$416,000 included in the item 9 total. Survey responses corroborate DATCP's estimate as more than 80% of respondents indicated none or slight costs for compliance. Most of the written comments indicated that firms were in compliance, either with contiguous toilet rooms or non-contiguous toilet rooms that complied with state and local requirements.

The rule contains a provision that food processing plant exit doors open outwards, consistent with long-standing building code requirements. More than 70% of survey respondents indicated none or slight costs of compliance. Most written comments described compliant exit doors or doors that likely would be approved following the Department's variance process. The costs of door replacements described by a small number of commenters were less than \$10,000. DATCP estimates that not more than 40 businesses would face costs of \$5,000 or less; a figure of \$200,000 is included in the item 9 total.

The rule continues to allow firms operated without changes in processing area dimensions by the same license-holder since on or before June 30, 1989, to be exempt from requirements for coving of floor-wall junctions, floor slope and drains, and provision of service sinks or curbed floor drains for disposal of mop water and similar wastes. Since 1989, these requirements have been enforced on all new license holders pursuant to state statute requiring licenses to be non-transferable. The rule clarifies this interrelationship of statute and administrative rule and thus no "new" costs are added to industry or included in the total amount shown for item 9. The Department has added flexibility to the previous requirement for coving to reduce costs that would be faced by "grandfathered" businesses that choose to alter their processing area dimensions or by new license-holders operating in a previously grandfathered facility.

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#### 15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

Under the rule, Wisconsin food processing plants will be able to use current industry best practices without running afoul of out-of-date regulatory requirements. DATCP will be able to continue to conduct paid contract inspections for the FDA under state authority, thereby increasing consistency in inspection reports received from DATCP staff and avoiding the costs of credentialing DATCP staff to conduct FDA inspections under federal authority. Multi-state firms will be

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## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

able to operate under Wisconsin rules that are consistent with other state and federal rules. All sizes of food processing plants will be able to apply for variances from a wider range of requirements, thereby having greater opportunities for innovation. Clear limits to the range and amount of wholesale food processing activities done by retail food establishments will be in place, eliminating a possible source of confusion.

The alternative to promulgating this rule, maintaining the current rule, could stifle industry innovation and hinder consistent DATCP conduct of state and FDA-contract inspections.

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### 16. Long Range Implications of Implementing the Rule

Implementation of the rule will ensure that Wisconsin's wholesale food manufacturers can continue to produce and sell products in fair competition with businesses across the country.

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### 17. Compare With Approaches Being Used by Federal Government

The rule, via reference citation, is consistent with federal requirements implemented under the Food Safety Modernization Act (21 CFR Part 117), federal rules for Hazard Analysis Critical Control Point (HACCP) food safety systems for juice and seafood processors (21 CFR Parts 120 and 123), federal canning rules (21 CFR Parts 108, 113, and 114) and the federal model ordinance for harvesting, shucking, packing, shipping and re-packing of marine shellfish.

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### 18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Michigan, Iowa, and Minnesota license and regulate food processing facilities within their borders in a manner similar to Wisconsin. Each of these states is an active participant, as is Wisconsin, in the FDA Manufactured Foods Regulatory Program Standards program which requires a state to have a regulatory foundation equivalent to the FDA's. Illinois food processing plants are not licensed at the state level. Illinois and Michigan have state programs in the national shellfish sanitation program which allows permitted businesses in these states to receive, process, and ship shellfish wholesale across state borders.

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|  |   |
|--|---|
| <h3>19. Contact Name</h3> <p>Steve Ingham, Administrator, Division of Food and Recreational Safety</p> | <h3>20. Contact Phone Number</h3> <p>608-224-4701</p> |
|--|---|

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This document can be made available in alternate formats to individuals with disabilities upon request.

## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

### ATTACHMENT A

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1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

Only a very small proportion of food processing plants will face the costs associated with facility updates described in the preceding summary. The Department wasn't able to clearly identify survey responses were from small businesses because small businesses, as defined for the purposes of this analysis, could hold any of the size-defined categories for a food processing plant license (the largest category has annual sales of \$250,000 or more). Thus, no differentiation by size was done in the department's economic analysis. The Department believes that the majority of businesses identified by staff as facing new facility-related costs are relatively small in size. The vast majority of businesses achieving compliance by virtue of various grandfather clauses are also toward the smaller side of the size spectrum.

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2. Summary of the data sources used to measure the Rule's impact on Small Businesses

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

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3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
- Less Stringent Schedules or Deadlines for Compliance or Reporting
- Consolidation or Simplification of Reporting Requirements
- Establishment of performance standards in lieu of Design or Operational Standards
- Exemption of Small Businesses from some or all requirements
- Other, describe:

DATCP continued to not charge a canning surcharge on the license of food processing plants with annual food sales of less than \$25,000. Many grandfather exemptions were retained in consideration of small businesses operated continuously by the same license-holder.

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4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

The broader range of requirements from which a variance may be requested will likely prove to be useful to small business operators seeking less expensive ways to meet the public health objective that a rule requirement is intended to meet. The costs facility upgrades necessitated by the loss of a grandfather exemption may be mitigated if the license-holder requests a variance from a facility requirement, provided the variance meets the public health intent of the requirement.

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5. Describe the Rule's Enforcement Provisions

DATCP uses a "progressive compliance" approach in which the least stringent step to encourage compliance is the first step taken. Typical compliance steps include increased inspection frequencies or conditions on the license-holder's license related to specific food safety activities the plant operator must take. Quite often these activities are simply industry best practices.

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6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes     No
-