

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

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

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

This rule repeals and recreates Wis. Admin Code ch. ATCP 70 (Food Processing Plants.) The rule is necessary to update Wisconsin's food processing plant standards, to incorporate new federal requirements designed to improve the nation's food safety system, and to clarify requirements for two specific types of food processing plants, vending machines, and micro-market commissaries.

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 substrate of the current rule. Related Wisconsin administrative rules include rules 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”). Specifically, the revised rule incorporates multiple subparts of the recently issued 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, that has superseded 21 CFR 110, *Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food*. These federal regulations pertain to preventive food safety systems that 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 are already subject to this federal rule and licensed as food processing plants, this rule features similar referencing for the sake of consistency. This revision also ensures that the requirements for Wisconsin-licensed food processing plants, which are not subject to the federal rule, are clearly articulated.

The transfer of DHS’ FSRL to DATCP’s Division of Food Safety necessitated the merger of two food safety regulatory systems. One regulatory paradox 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 philosophy 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 opted to form a work group comprised of industry personnel and local health department agent program representatives. They were tasked with further revision of the rule. During deliberations, the work group concluded that the safety of many food processing activities for wholesale, 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, recourse to the requirements 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 food processing activities for wholesale. 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 this newly revised final draft of Wis. Admin. Code ch. ATCP 70 that redefines "wholesale" and "retail", clarifies 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) food processing activities for wholesale, and redraws the boundaries delimiting the permissible types of food processing activities for wholesale. Perhaps the most salient change to the regulatory territory is that a transfer of food between two food processing plants or retail food establishments will not be regarded as wholesaling, as long as the two businesses involved are operated by the same licensed entity, and the firm transferring the food does not relinquish control of the food. This change reflects current guidance by 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 praxis. The revised definitions also appear in the pending revision to Wis. Admin. Code ch. ATCP 75 (Retail Food Establishments). 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 these updates to promote clarity and uniformity and to 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 context. However, feedback from the working group militated against the 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 threading a path through these complex issues, the revised rule propounds 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 addressed to 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 plant” to conform to the statutory definition.
- Addresses requirements for vending machine commissaries, including those that support micro markets, just as the revised Wis. Admin. Code ch. ATCP 75 and the Appendix thereto (*Wisconsin Food Code*) specify requirements for vending machines and micro markets. These revisions incorporate recently enacted statutory language and ensure consistency and clarity in requirements for both the food processing plant portion of these operations and the retail food establishment business.
- Clarifies the definition of extended runs 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.
- Updates certain outdated restrictions on hot-smoked, vacuum-packed fish. The archaic rules were unique to Wisconsin whereas the updates mirror requirements in other states and are based on current, science-based FDA guidance.
- Mandates filing and obtaining process-authority approval for processes used in the preparation of acidified or low acid canned foods.
- Enables food processing plants to obtain waivers or variances from DATCP for non-standardized and innovative processing and procedural activities. Prior to this revision, waivers and variances could only be obtained by food processing plants for structural and equipment issues.

- 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 the expansion of this rapidly changing and innovative segment of the bottling industry.
- Removes the regulatory floor of \$25,000 in sales for food processing plants that are required to pay the canning license fee surcharge, in order to reflect the considerable time that has proved to be necessary for DATCP staff to provide information, consultation, and service to persons manufacturing small amounts of canned foods.
- Protects the consistent quality of the Wisconsin “brand” by eliminating many long-expired “grandfather clause” dates in the existing rule and replacing them with language relating to achieving compliance with structural standards in existing buildings.

Federal and Surrounding State Programs

Federal Programs

21 CFR 117 is the cornerstone of the regulations implementing FSMA. The FDA has published a Food Code designed to serve as a model for states. Current language on the molluscan shellfish program was deleted in order to adopt the Federal Model Ordinance, in order to provide that segment of the Wisconsin food industry with regulatory consistency within interstate commerce.

Surrounding State Programs

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

Data and Analytical Methodologies

In order to identify potential changes to the rule, DATCP reviewed recent changes in FDA regulations 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 approved requirements in the present revised rule.

Effect on Small Business

If the revised rule is adopted, some small food processing plants may incur immediate costs to meet requirements that will be in effect after the elimination of various “grandfather clauses” dating from over thirty years ago. For example, small plants may now need to upgrade warewashing and handwashing sinks. Another cost that may be incurred by a few very small businesses is the \$320 canning surcharge, which currently is not assessed for food processing plants manufacturing and selling less than \$25,000 of food per year. DATCP’s Manufactured Food Specialists spend a considerable amount of time working with very small canning businesses, and this surcharge recoups a portion of these costs. The service provided by DATCP is comparable to that provided by consultants, but at a significantly lower cost for operations in the sub-\$25,000/year category.

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. Many of these changes are not anticipated to have a financial or other impact.

A positive impact of this rule revision on all classes of business is the expanded ability of food processing plants to apply for processing or procedural waivers. This 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.

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

DATCP Contact

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

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

45 **Subchapter VII. Effect of Rules on Local Ordinances**

46 ATCP 70.62 Effect of rules on local ordinances.

47 **Subchapter VIII. Variances**

48 ATCP 70.64 Variances.

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

52 **Subchapter I. Scope and Definitions**

53 **ATCP 70.01 Scope.** This chapter applies to all food processing plants, as defined in s.
54 ATCP 70.02 (23), regardless of whether the food processing plant is subject to licensing under s.
55 97.29 (2), Stats., or this chapter.

56 **ATCP 70.02 Definitions.** As used in this chapter:

57 (1) "Alcohol beverage" means an alcohol beverage as defined in s. 125.02 (1), Stats.

58 (2) "Approved sanitizing solution" means a substance or compound approved by the
59 department for the sanitizing of equipment or utensils under s. ATCP 70.28 (4).

60 (3) "Bakery" means any place where bread, cookies, crackers, pasta, or pies, or any other food
61 product for which flour or ground meal is the principal ingredient, are baked, cooked, or dried, or
62 prepared or mixed for baking, cooking, or drying, for sale as food.

63 (4) "Bottle" means the immediate package or container in which bottled drinking water, soda
64 water beverage, or alcohol beverage is sold or distributed for consumption. "Bottle" includes a
65 bottle cap or other seal for a bottle.

66 (5) "Bottled drinking water" means all water packaged in bottles or similar containers and sold
67 or distributed for drinking purposes. "Bottled drinking water" includes distilled water, artesian
68 water, spring water, and mineral water, whether carbonated or uncarbonated.

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

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

77 (8) "Canning" means the preservation and packaging in hermetically sealed containers of low-
78 acid or acidified foods.

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

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

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

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

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

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

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

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

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

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

105 (19) "Food" means:

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

107 (b) Chewing gum.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

151 97.605, Stats., to the extent that the activities of that establishment are covered by s. 97.30, Stats.,
152 or the license under s. 97.605, Stats.

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

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

159 (a) Fully cooked or heat treated, or sold or represented as being fully cooked or heat treated, so
160 that the internal temperature of the fish has been maintained for at least 30 minutes at not less than
161 145° F (62.8° C.) or an equivalent process validated for lethality against pathogenic organisms.

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

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

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

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

171 (29) "Major food allergen" includes any food or food ingredient, other than highly refined oil
172 or an ingredient derived from highly refined oil, which contains protein derived from milk, eggs,

173 fish, crustacean shellfish, tree nuts, wheat, peanuts, or soybeans. "Major food allergen" does not
174 include a food that is exempted by the secretary of the United States department of health and
175 human services pursuant to 21 USC 321(qq)(2).

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

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

181
182 (31) "Operations water" means water used by a food processing plant for cleaning equipment
183 and utensils, transporting food, handwashing, or other cleaning or sanitizing purposes.

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

186 (33) "Potentially hazardous food" also means "TCS (time/temperature controlled for safety)
187 Food", and has the meaning given in ch. ATCP 75 Appendix (Wisconsin Food Code), part
188 1201.10 (B).

189 (34) "Processed fish" means fish that is preserved for human consumption by means of hot or
190 cold smoking, curing, salting, drying, marinating, pickling, fermenting, or related processes.
191 "Processed fish" does not include fish processed in accordance with s. ATCP 70.36 or 70.38.

192 (35) "Qualified facility" as used in s. ATCP 70.04 has the meaning given in 21 CFR 117.3.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

238 **ATCP 70.04 Federal requirements.** A food processing plant that is also a facility or a qualified
239 facility shall comply with the requirements of this chapter and applicable requirements of 21 CFR
240 117.

241 **Subchapter II. General Requirements**

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

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

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

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

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

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

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

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

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

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

275 **(6) REINSPECTION FEE.** (a) If the department reinspects a food processing plant because the
276 department has found a violation of ch. 97, Stats., or this chapter, on a regular inspection, the
277 department shall charge the licensee the reinspection fee specified under par. (b). A reinspection
278 fee is payable when the reinspection is completed, and is due upon written demand from the

279 department. The department may issue a demand for payment when it issues a license renewal
280 application form to a licensee.

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

282 1. For a license holder of a food processing plant that has an annual production of less than
283 \$250,000, and the license holder is engaged in processing potentially hazardous food or in
284 canning, the reinspection fee is \$255.

285 2. For a license holder of a food processing plant that has an annual production of at least
286 \$250,000, and the license holder is engaged in processing potentially hazardous food or in
287 canning, the reinspection fee is \$525.

288 3. For a license holder of a food processing plant that has an annual production of less than
289 \$250,000, and the license holder is not engaged in processing potentially hazardous food or in
290 canning, the reinspection fee is \$150.

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

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

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

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

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

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

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

320 **(10) DENIAL, SUSPENSION, OR REVOCATION OF LICENSE; CONDITIONAL LICENSE.** The
321 department may deny, suspend, or revoke a license, or impose conditions on a license as provided

322 under s. 93.06 (7) and (8), Stats. Except as otherwise provided by statute or rule, the suspension or
323 revocation of a license shall comply with the prior notice requirements of s. 227.51, Stats.

324 (11) LICENSE EXEMPTIONS. A license to operate a food processing plant is not required under s.
325 97.29, Stats., or this section for:

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

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

330 2. Wholesale receipts from food processing operations at the retail food establishment
331 comprise no more than 25% of gross annual food sales from the retail food establishment. If the
332 operator of a licensed retail food establishment is also licensed to operate a dairy plant under s.
333 97.20, Stats., or to operate a meat establishment under s. 97.42, Stats., sales of dairy or meat and
334 poultry products processed at the establishment shall be excluded from the calculation of food
335 sales receipts under this subdivision.

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

338 4. The operator may move food between retail food establishments licensed to the
339 same operator.

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

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

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

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

349 1. Receipts from non-dairy food processing operations at that location comprise no more than
350 25% of gross annual dairy and non-dairy food sales from that location.

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

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

355 1. The operator of the meat establishment is licensed under s. 97.42, Stats., or inspected under
356 21 USC 601 et seq. or 21 USC 451 et seq.

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

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

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

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

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

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

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

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

385
386 (f) The operator of a licensed food warehouse under s. 97.27, Stats., at which one or more of
387 the following activities are the only food processing activities performed:

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

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

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

400 4. Manufacturing ice for use in the shipment of foods, or to cool or keep foods cold while in
401 transit or stored in the warehouse. Ice used for this purpose must meet the standards in s. ATCP
402 70.20 (8). Ice must be made on site in a commercial ice machine and may not be bagged,
403 distributed or sold separately from food items that it is used to cool.

404 **(12) RECORD REQUIREMENTS AND RETENTION.** (a) If a food processing plant is deemed a
405 facility, under 21 CFR 117, the operator shall create all records to meet the requirements for
406 records in 21 CFR 117.305, unless otherwise specified in this chapter or in 21 CFR 120 or 21 CFR
407 123.

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

411 **(13) GENERAL REQUIREMENTS.** (a) Every food processing plant shall be operated, equipped,
412 and maintained to protect public health and safety.

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

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

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

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

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

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

428 2. All floors, walls, and ceilings shall be kept clean and in good repair.

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

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

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

435 (3) APPLICABILITY OF REQUIREMENTS. A license holder shall be subject to food processing
436 plant requirements in this section if the plant ceases to operate continuously for more than 30 days
437 at any time after the effective date of this section ... [LRB inserts date], has been structurally
438 remodeled or altered in a manner which results in structural changes to a processing area, or has
439 added product lines or processes after the effective date of this section ... [LRB inserts date]. This
440 section does not apply to a food processing plant that closes because of seasonal natural food
441 production cycles of the food processed by that plant, such as an orchard or a maple sap processing
442 facility.

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

449 (b) If an operator of a retail establishment serving meals also engages in food processing, under
450 the exemption in s. ATCP 70.06 (11) (a) or (b), that processing shall only be done in specifically

451 designated areas and not in areas accessible to the public such as the retail area of a grocery store
452 or the dining room of a restaurant.

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

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

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

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

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

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

468 (7) VENTILATION. There shall be adequate ventilation in all areas where food is processed,
469 handled, or stored; in all areas where equipment or utensils are cleaned or sanitized, and in all
470 dressing rooms, locker rooms, toilet rooms, employee break rooms, and garbage or rubbish storage
471 areas. Ventilation shall be adequate to remove excessive heat, steam, condensation, vapors,
472 obnoxious odors, smoke, and fumes. Ventilation systems shall be positioned so that exhaust air is

473 not vented onto exposed food, or onto clean food packages, equipment, or utensils. Intake fans
474 shall be equipped with filters that are readily removable for cleaning and replacement. Intake
475 filters shall be capable of removing at least 85% of particulate matter that is 5 microns or larger in
476 size, or greater than 6 MERV (maximum efficiency reporting value) rating. Exhaust fans, intake
477 fans, ventilation ducts, and filters shall be kept clean and in good repair, and shall be screened or
478 louvered to prevent contamination of food by dust, dirt, insects, or other contaminants. Systems
479 used to ventilate any area of a food processing plant where exposed potentially hazardous food is
480 handled shall be capable of maintaining positive pressures in that area.

481 **(8) TOILET FACILITIES.** (a) The operator shall provide sanitary toilets meeting applicable state
482 and local regulations in sufficient number to accommodate employees. The toilets shall be located
483 in toilet rooms meeting the requirements of this section, for any food processing plant constructed
484 or first licensed after the effective date of this section ... [LRB inserts date]. Toilet rooms and
485 fixtures shall be easily cleanable, and shall be kept clean and in good repair. Non-contiguous toilet
486 facilities, serving food processing plants licensed prior to the effective date of this section ... [LRB
487 inserts date], shall be conveniently adjacent and accessible to the facility, and meet all applicable
488 state and local regulations for unattached or portable toilet rooms.

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

490 (c) Handwashing facilities shall be located in or adjacent to every toilet room. Handwashing
491 facilities serving toilet rooms shall include hot and cold running water, soap in a soap dispenser,
492 and a sanitary single-service means of drying the hands. A sign directing employees to wash
493 their hands shall be prominently posted in every toilet room used by employees. Handwashing
494 facilities serving a toilet room shall comply with all of the following requirements if they are

495 installed after the effective date of this section ... [LRB inserts date], or if they are located in a
496 food processing plant that is initially licensed or licensed to a new operator after the effective
497 date of this section ... [LRB inserts date]:

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

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

503 (d) The faucets of a handwashing sink in a licensed, non-seasonal food processing plant that
504 has ceased to operate continuously for more than 30 days at any time after the effective date of this
505 section ... [LRB inserts date], or located on a sink in an area that has been structurally remodeled
506 or altered in a manner which results in structural changes to a processing area, or located in a food
507 processing plant where an operator adds more complex food processing after the effective date of
508 this section ... [LRB inserts date], shall be subject to licensed plant requirements including the
509 requirements in pars. (c) 1. and 2, (e) and (f).

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

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

515 (9) LOCKER AND LINEN FACILITIES. The operator shall provide lockers or comparable facilities
516 for employees to store clothing and other personal items. The locker facility shall not be in food

517 processing or food storage areas, or in areas where food, packages, equipment, or utensils are
518 cleaned or stored. Protective clothing worn during processing shall be stored in an orderly and
519 sanitary manner. Soiled linen and clothing shall be kept in non-absorbent containers or laundry
520 bags until removed for laundering. Soiled linen and clothing shall be removed as often as
521 necessary to prevent unsanitary conditions.

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

528 (b) A handwashing sink serving a food processing area shall comply with all of the following
529 requirements if it is installed after the effective date of this section ... [LRB inserts date], or if it is
530 located in a food processing plant that is initially licensed or licensed to a new operator after the
531 effective date of this section ... [LRB inserts date]:

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

536 (c) A handwashing sink in a licensed, non-seasonal food processing plant that has ceased to
537 operate continuously for more than 30 days at any time after the effective date of this section ...
538 [LRB inserts date], or located in an area that has been structurally remodeled or altered in a

539 manner which results in structural changes to a processing area, or located in a plant that adds
540 more complex food processing after the effective date of this section ... [LRB inserts date], shall
541 comply with the requirements as referenced in par. (b) 1.-3.

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

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

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

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

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

558 (d) Brushes and cleaning tools shall be kept clean and in good repair. Wiping cloths used to
559 clean equipment and utensils shall be cleaned and sanitized daily and stored in an approved
560 sanitizing solution between uses. Sanitizing solutions for wiping cloths shall be changed at least

561 daily. Wiping cloths used to clean food contact surfaces of equipment and utensils shall not be
562 used for any other purpose. Single service disposable towels may be used in place of re-usable
563 cloths if they are discarded after each use.

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

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

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

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

578
579 (14) GARBAGE AND REFUSE DISPOSAL. Garbage and refuse shall not be allowed to accumulate
580 in or around a food processing plant. Garbage and refuse shall be removed as often as necessary to
581 maintain the premises in a clean and sanitary condition. Garbage storage areas shall be
582 constructed and maintained so that they do not attract or harbor insects, rodents, or other animals.
583 Garbage and refuse shall be held in durable, leak-proof, easily cleanable, and pest-resistant
584 containers. Containers shall be kept covered with tight-fitting lids, and shall be cleaned when

585 necessary to prevent insanitary conditions. Garbage and refuse shall not be burned on the
586 premises, except in compliance with state and local laws. Garbage and refuse shall not be burned
587 on the premises if burning may contaminate food.

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

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

595
596 (16) CONSTRUCTION; PLAN REVIEW. Before a food processing plant is constructed,
597 substantially reconstructed, or extensively altered, the operator shall notify the department in
598 writing. Plans and specifications for the construction, reconstruction, or alteration may be
599 submitted to the department for review before the work is begun. Plans and specifications shall be
600 available for review by the department upon request.

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

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

605 **ATCP 70.10 Personnel standards. (1) CLEANLINESS.** (a) Persons engaged in food processing
606 shall maintain a high degree of personal cleanliness, and shall observe good hygienic practices
607 during all working periods. Persons engaged in food processing shall wash their hands before

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

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

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

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

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

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

622 3. Properly stored until used.

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

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

627 (d) Individuals may contact ready-to-eat food with their bare hands if that contact is reasonably
628 necessary, and does not contaminate food. The individuals shall be trained in, and shall follow,

629 written policies and procedures to ensure safe use of bare hands. The policies and procedures shall
630 identify all of the following:

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

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

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

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

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

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

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

662 (a) One or more reportable symptoms of communicable disease as defined in ch. ATCP
663 75 Appendix, 2–201.11 (A).

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

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

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

670 **(6) CONSUMPTION OF FOOD, BEVERAGES, AND TOBACCO.** No person may consume food,
671 beverages, or tobacco in any food processing area, or in any area where food processing equipment

672 or utensils are cleaned or stored. Employees may not consume food, beverages, or tobacco except
673 in designated areas which are separated from food processing areas. This subsection does not
674 prohibit a sanitary water fountain in a processing area, nor does it prohibit on-line quality control
675 sampling in accordance with quality control procedures written and followed by the license holder.

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

677 Equipment and utensils shall be of sanitary design and construction. Equipment and utensils shall
678 be readily accessible for cleaning and inspection and shall be constructed so that they can be easily
679 cleaned. Equipment and utensils shall be kept clean and in good repair.

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

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

689 **(3) C-I-P SYSTEMS.** C-I-P systems shall be of sanitary design and construction, and shall be
690 installed and maintained for sanitary operation. A C-I-P system shall be installed and maintained
691 so that cleaning and sanitizing solutions can be circulated throughout all interior product contact
692 surfaces of the system. C-I-P systems shall be equipped with adequate inspection ports or other
693 access points. C-I-P systems shall be self-draining, or shall be capable of being easily and
694 completely drained. A temperature recording device, which accurately records the return
695

696 temperatures of cleaning and sanitizing solutions, shall be installed in all circuits through which
697 cleaning and sanitizing solutions are circulated. Cleaning records shall be kept for at least 90 days
698 after they are created.

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

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

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

714 **ATCP 70.14 Cleaning and Sanitizing Equipment and Utensils. (1) GENERAL.** Except as
715 provided in ss. ATCP 70.16 and 70.40, the operator shall do all of the following.

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

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

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

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

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

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

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

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

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

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

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

751 **ATCP 70.16 Cleaning and Sanitizing Equipment and Utensils: Exemptions. (1)**

752 APPROVAL REQUIRED FOR AN ALTERNATIVE CLEANING AND SANITIZING FREQUENCY. Except as
753 provided in sub. (2) or s. ATCP 70.40, if an operator seeks to clean and sanitize equipment and
754 utensils at a frequency other than that required in s. ATCP 70.14 (1), because the equipment and
755 utensils are used with food products, processes, or conditions reducing the risk of foodborne
756 illness or presence of major food allergens, then the operator shall submit to the department, for
757 written approval, an alternate cleaning and sanitizing procedure that includes a monitoring and
758 recording requirement in compliance with s. ATCP 70.18.

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

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

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

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

774 (a) Drying equipment.

775 (b) Cloth-collector systems.

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

777 (d) Equipment used in brining, aging, curing, and dry product blending processes.

778 (e) Food contact surfaces of equipment used solely to process foods or food ingredients with
779 low water activity (≤ 0.85), or foods which are considered non-Potentially Hazardous Food
780 (nonPHF/non-TCS) foods based on (2) (b) Table A or Table B for Potentially Hazardous Food
781 (time/temperature control for safety food) in par. 1-201.10 (B) of ch. ATCP 75 Appendix, such as
782 chocolate, fats and oils, liquid nutritive sweeteners, peanut butter, or similar foods.

783 (f) Ice makers maintained in a cold/frozen state, so long as the operator cleans and sanitizes
784 the ice maker in accordance with ice maker manufacturer instructions for cleaning, or shall clean
785 and sanitize using a validated cleaning process.

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

789 (h) Surfaces of aseptic processing equipment that contact food after the food has been
790 sterilized, as long as system sterility is maintained. If system sterility is lost, an operator shall
791 clean, sanitize and re-sterilize equipment.

792 (i) Equipment used for food fermentations such as the manufacture of sauerkraut or cucumber
793 pickles, development of one or more pure bacterial cultures, or development of starter cultures, so
794 long as the operator cleans and sanitizes all equipment following each fermentation batch.

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

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

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

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

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

804 An operator may submit a written request for the department to approve alternative cleaning and

805 sanitizing procedures. The request shall include all of the following, and any other information
806 required by the department:

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

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

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

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

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

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

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

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

839 (4) EXPIRATION OF DEPARTMENT APPROVAL OF ALTERNATIVE CLEANING AND SANITIZING
840 FREQUENCY. All approvals granted under this section shall expire 5 years from the date of
841 issuance.

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

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

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

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

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

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

- 891 2. The reclaimed water has less than 1 coliform bacterium per 100 ml. of water.
- 892 3. The standard plate count of the reclaimed water does not exceed 500 per ml. of water and
893 complies with the bacteriological standards of s. NR 809.30.
- 894 4. The water, if reclaimed from the condensation of food products, has a standard turbidity of
895 less than 5 units or organic content of less than 12 mg. per liter, as measured by the chemical
896 oxygen demand or permanganate-consumed test specified in *Standard Methods for the*
897 *Examination of Water and Waste Water*, twenty-first edition (2005), published by the American
898 Public Health Association, the American Water Works Association and the Water Environment
899 Federation. The operator shall use an automatic fail-safe monitoring device to identify, and
900 automatically divert to a waste water system, any reclaimed water that fails to comply with this
901 subdivision.

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

- 907
- 908 5. The reclaimed water is of satisfactory organoleptic quality and has no off-odors, off-
909 flavors, or slime. The operator shall sample and organoleptically test reclaimed water at weekly
910 intervals.
- 911 6. Chemical treatment of the reclaimed water, if any, complies with sub. (4).
- 912 7. The reclaimed water is stored in a properly constructed tank. The tank shall be constructed
913 of a material that will not contaminate the water and can be easily cleaned.
- 914 8. The operator tests the reclaimed water for compliance with subds. 1. to 4. at least once
915 during any 6 month interval. The operator shall test the reclaimed water daily for 14 working days

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

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

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

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

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

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

937 **Note:** Copies of the *Standard Methods for the Examination of Water and Waste Water*, twenty-first
938 edition (2005), published by the American Public Health Association (APHA), the American Water Works

939 Association and the Water Environment Federation, are on file with the department and the legislative
940 reference bureau. Copies may be obtained by contacting the "APHA Bookstore" at
941 www.apha.org/publications/bookstore/.

942
943 4. The reclaimed water is of satisfactory organoleptic quality and has no off-odors, off-
944 flavors, or slime. The operator shall sample and organoleptically test reclaimed water at weekly
945 intervals.

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

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

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

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

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

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

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

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

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

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

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

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

- 982 1. Obtained from a source that complies with chs. NR 811 or 812, as applicable.
- 983 2. Bacteriologically safe.
- 984 3. Protected from contamination.

985 4. Tested by the operator for compliance with subd. 2. at 6 month intervals.

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

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

991 **(6) WATER AND POTABLE LIQUIDS TRANSPORTED IN BULK.** (a) Water transported to a food
992 processing plant in a bulk tanker or bulk container, for use as an ingredient or in other plant
993 operations, shall be potable and shall be obtained from a source that complies with chs. NR 811 or
994 812.

995 (b) Whenever potable water or another potable liquid is transported to or from a food
996 processing plant in a bulk tanker or bulk container, it shall be loaded, transported, and unloaded in
997 a sanitary manner that prevents contamination. The bulk tanker or bulk container shall be
998 thoroughly cleaned and sanitized before being filled. Suitable pumps, hoses, and fittings shall be
999 used to transfer potable water and potable liquids to and from bulk tankers, and bulk containers
1000 shall be cleaned and sanitized prior to use.

1001 (c) Whenever potable water or another potable liquid is transported to or from a food
1002 processing plant in a bulk tanker or bulk container, the bulk tanker or bulk container and each of
1003 its fittings and equipment shall meet all of the following requirements:

1004 1. It shall be properly constructed and maintained to prevent contamination of the potable
1005 water or potable liquid. Water contact surfaces shall comply with s. ATCP 70.12 (2).

1006 2. It shall be cleaned, sanitized, and inspected on a routine basis.

1007 3. It may not be used to transport materials that may contaminate potable water or potable
1008 liquid that is subsequently transported in the bulk tanker or bulk container.

1009 4. It shall be effectively sealed to protect the potable water or potable liquid from
1010 contamination during transit.

1011 **Note:** Effective sealing systems include manhole cover gaskets and seals.

1012 5. It shall be properly stored and serviced to prevent contamination. When not in use, pumps,
1013 hoses, and fittings shall be properly maintained, capped, stored, and protected from contamination.

1014 (7) CULINARY STEAM. Water used to produce culinary steam shall be potable. Water
1015 reclaimed from food processing operations may not be used to produce culinary steam unless it
1016 complies with sub. (3) (a) or (b). In boilers used to produce culinary steam, boiler water additives
1017 shall comply with 21 CFR 173.310.

1018 (8) ICE. Ice used to cool or maintain the temperature of foods shall be made from potable
1019 water. Ice used to cool or maintain the temperature of ready-to-eat foods shall not have been
1020 previously used for any other purpose. Ice shall be received, handled, and stored in a manner to
1021 prevent contamination or adulteration. Any ice which is not made on site shall be inspected upon
1022 receipt, and rejected if it is delivered in a way that has not adequately protected the ice from
1023 contamination.

1024 **ATCP 70.22 Food ingredients.** (1) GENERAL. Food ingredients shall be safe, wholesome,
1025 and unadulterated, and shall comply with applicable standards of identity under s. 97.09, Stats.
1026 Raw agricultural commodities and other food ingredients shall be segregated and examined as
1027 necessary to determine whether they are clean and fit for processing. Processed foods and dairy

1028 products which are used as food ingredients shall be obtained from sources which comply with
1029 applicable licensing and inspection requirements.

1030 (2) EGGS AND EGG PRODUCTS. Only clean whole eggs, pasteurized eggs in liquid, frozen or dry
1031 form, or pasteurized egg products may be used in food processing. Eggs and egg products may be
1032 pasteurized during processing. Clean whole eggs shall be equivalent to USDA Grade B or better
1033 with shells intact.

1034 **ATCP 70.24 Food handling and storage. (1) GENERAL.** Food shall be protected from
1035 contamination and decomposition while being processed, handled, conveyed, or held at a food
1036 processing plant. Food shall be processed and held in a manner which keeps the food in a safe,
1037 wholesome, and unadulterated condition. Potentially hazardous foods shall be processed and held
1038 at temperatures, or in a manner, which minimizes the potential for growth of undesirable
1039 microorganisms.

1040 (2) FOOD STORAGE. Food storage areas shall be maintained in a clean, sanitary, and orderly
1041 condition, free from conditions which may result in the adulteration of food. Potentially
1042 hazardous foods shall be stored at safe temperatures. Storage areas shall be constructed and
1043 maintained so that waste water and other waste liquids do not drain into, or accumulate in, any
1044 storage area.

1045 Food shall not be stored in a manner which may attract or harbor pests.

1046 (3) FOOD PROCESSING. (a) Food processing shall be conducted under appropriate conditions
1047 and controls to minimize the potential for growth of undesirable microorganisms, or the
1048 contamination of food.

1049 **Note:** One way to comply with this requirement is to follow a HACCP plan which monitors and
1050 controls food safety variables at critical control points in the manufacturing process. Monitoring and

1051 controlling food safety variables such as time, temperature, humidity, water activity (a_w), pH, pressure, and
1052 flow rate at critical control points can ensure that mechanical breakdowns, time delays, temperature
1053 fluctuations, and other conditions do not contribute to the decomposition or contamination of food.

1054
1055 (b) If potentially hazardous food is heated, refrigerated, or frozen in the course of processing,
1056 the internal temperature of the food shall be accurately monitored, as necessary, to ensure that safe
1057 temperatures are promptly attained and maintained.

1058 (c) Any testing and monitoring done to minimize the potential for growth of undesirable
1059 microorganisms or the contamination of food during processing and storage as required in this
1060 section shall be recorded, the records shall be maintained on site for one year, and shall be made
1061 available to the department or its agents on request for copying or photographing.

1062 (d) Potentially hazardous frozen foods, if thawed for processing, shall be thawed by one of the
1063 following methods:

1064 1. By placing the frozen food in a refrigerated space at a temperature of not more than 41°F.
1065 (5°C.).

1066 2. Placing the frozen food under potable running water, at a temperature of not more than
1067 70°F. (21°C.), for no more time than is needed to thaw the food. Water velocity shall be sufficient
1068 to agitate loose particles and drain or float them away from the food being thawed.

1069 3. By microwave heating, if the food is fully cooked in the microwave oven, or if cooking is
1070 immediately completed in another cooking facility.

1071 4. In any cooking facility, as part of the process by which the food is fully cooked.

1072 **(4) BULK FLOUR HANDLING SYSTEMS.** (a) Food contact surfaces of bulk flour handling
1073 equipment shall comply with the provisions of s. ATCP 70.12 (2). Pneumatic systems using
1074 storage bins constructed of semi-permeable cloth material are exempt from the requirement that

1075 surfaces be smooth and nonabsorbent, provided the surfaces can be effectively cleaned.
1076 Attachment mechanisms for holding inspection port covers, access doors, delivery pipe caps, or
1077 other removable accessories shall have no loose parts. Delivery pipe caps shall be kept in place,
1078 and secured against removal, except when a bulk flour handling system is in use. Outside
1079 installations shall be watertight or suitably covered to prevent entry of water and foreign material.

1080 (b) Intake air used in pneumatic flour handling systems shall be filtered to exclude particles of
1081 50 microns or larger. Air discharged from the system shall be filtered so that no visible dust
1082 escapes. Filters shall be readily removable for cleaning or replacement. Straight runs of
1083 pneumatic conveyors shall comply with the provisions of s. ATCP 70.12 (1), except that piping
1084 which is self-purging is exempt from accessibility requirements.

1085 (5) RAW INGREDIENTS AND FINISHED PRODUCTS; SEPARATE HANDLING. Effective measures
1086 shall be taken to prevent cross contamination between raw ingredients and finished food products.
1087 Raw ingredients shall not be handled simultaneously with finished products in any part of a food
1088 processing plant if either the raw materials or the finished products are uncovered or unprotected,
1089 and if the handling may result in contamination.

1090 (6) SALVAGING DISTRESSED FOOD. (a) In this subsection:

1091
1092 1. "Distressed food" means processed food exposed to a fire, flood, transportation accident,
1093 refrigeration breakdown, or other unusual condition which may affect its safety or suitability as
1094 human food. "Distressed food" does not include food or food packages damaged during normal
1095 conditions of food and food product handling, transit, or storage.

1096 2. "Reconditioned food" means packaged distressed food distributed or offered for sale as
1097 human food after its package is repaired or relabeled without being opened.

1098 3. "Reprocessed food" means distressed food subsequently processed in accordance with the
1099 requirements under this chapter and distributed or offered for sale as human food.

1100 (b) An operator shall notify the department within 3 days after the operator takes possession of
1101 any distressed food, or within 3 days after food in the operator's custody becomes distressed food.
1102 The operator shall notify the department before the operator reprocesses or reconditions the
1103 distressed food.

1104 (c) An operator shall identify distressed food as such, and shall separate it from other food.
1105 No operator may store distressed food in a processing area, or under conditions which may lead to
1106 the contamination of other food, equipment, utensils, or packaging materials.

1107 (d) No operator may do either of the following:

1108 1. Reprocess for sale, as human food, any distressed food which is unwholesome or
1109 adulterated.

1110 2. Offer for sale, sell, or distribute food in packages that are damaged to such an extent that
1111 the food may have been exposed or subjected to possible contamination, including packages with
1112 bulging ends, ruptures, hairline fractures, breakage along critical seams, or openings which may
1113 have exposed food to contamination.

1114 (e) No operator may sell or distribute reprocessed or reconditioned food at wholesale unless
1115 the operator gives the purchaser or recipient written notice that the food is reprocessed or
1116 reconditioned. The notice shall also include the name and address of the person who reprocessed
1117 or reconditioned the distressed food. The notice may be included on an invoice, bill of lading, or
1118 other documentation of the sale or distribution of the food.

1119 (f) An operator shall keep, for the period of time set forth in 21 CFR 117.315, all of the
1120 following records related to distressed food handled by that operator:

1121 1. A description of the distressed food, including the type of food, the package or container
1122 style, and the amount of the food.

1123 2. The source of the distressed food, or the conditions which caused it to become distressed
1124 food.

1125 3. The date on which the operator received the distressed food.

1126 4. The nature of any reprocessing or reconditioning which the operator performed on the
1127 distressed food.

1128 5. The final disposition of the distressed food if the distressed food was not sold directly at
1129 retail. That record shall include the name and address of the person, such as the food wholesaler,
1130 food distributor, waste disposal firm or waste disposal site operator, to whom the food processing
1131 plant operator delivered the food.

1132 (7) FOOD IRRADIATION. Irradiation in the production, processing, and handling of food shall
1133 comply with applicable federal regulations under 21 CFR 179.

1134 (8) EGG CLEANING AND STORAGE. Cleaning and storage of eggs shall be done in compliance
1135 with the requirements of s. ATCP 88.20.

1136 **ATCP 70.26 Food packaging and labeling. (1) GENERAL.** Food packages shall be of
1137 sanitary design and construction, so as to protect food contents from reasonably foreseeable risks
1138 of contamination. Food packages shall be clean, sanitary, and free of any extraneous or deleterious
1139 substance. Food shall not be sold or distributed in packages which are damaged to the extent that

1140 food contents may be adulterated as a result of the damage. A sealed food package is damaged
1141 within the meaning of this subsection if the package or seal is broken or bulged.

1142 (2) CLEANING AND SANITIZING RETURNABLE FOOD PACKAGES. Returnable or multi-use food
1143 packages, including returnable bottles, shall be effectively cleaned and sanitized before being
1144 reused. Cleaning and sanitizing processes shall remove all extraneous matter and potential
1145 adulterants from a food package before the food package is reused. Sanitizing methods shall
1146 comply with s. ATCP 70.28. No food package may be reused unless it is specifically designed and
1147 constructed for that purpose.

1148 (3) INSPECTION OF RETURNABLE FOOD PACKAGES. Returnable or multi-use packages, after
1149 being cleaned and sanitized, shall be inspected before being reused. Inspection shall be adequate
1150 to detect extraneous material and visible adulterants, and any damage to product contact surfaces.
1151 Inspection shall be performed on surfaces lighted in compliance with s. ATCP 70.08 (6) (b).

1152 (4) SINGLE-SERVICE FOOD PACKAGES. Single-service food packages, including bottle caps and
1153 other single-service articles used to package food, shall be made from clean, sanitary materials.
1154 Single-service food packages shall be clean and sanitary at the time of use. Single service food
1155 packages shall be protected from contamination prior to use, and shall be handled in a sanitary
1156 manner. Single-service food packages, including single-service bottles and bottle caps, shall not
1157 be re-used.

1158 (5) FOOD PACKAGE LABELING. Packaged food shall be packaged and labeled according to all
1159 of the following, as applicable:

1160 (a) 21 CFR 101.

1161 (b) S. 97.09, Stats., and federal regulations incorporated by reference in s. 97.09, Stats.

1162 (c) Ch. ATCP 90.

1163 (d) Ch. ATCP 75 Appendix, part 3-201.11(C).

1164 (e) If the packaged food contains a major food allergen, the ingredient statement on the
1165 package shall disclose the common name of the major food allergen. The disclosure shall be
1166 equivalent in size and prominence to the rest of the ingredient statement. If an allergen originates
1167 from fish, crustacean shellfish, or tree nuts, the disclosure shall include the common name of the
1168 source species.

1169 **Note:** For example, if a food product includes an allergen that originates from fish, the ingredient
1170 statement must disclose the common name such as bass, flounder, or cod. If the allergen originates from
1171 crustacean shellfish, the ingredient statement must disclose the common name such as crab, lobster, or
1172 shrimp. If the allergen originates from tree nuts, the ingredient statement must disclose the common name
1173 such as almond, pecan, walnut, or coconut.

1174
1175 (6) EGG PACKAGING AND LABELING. The packaging and labeling of eggs shall be done in
1176 compliance with the requirements of ss. ATCP 88.32, 88.34, and 88.38.

1177 (7) ALCOHOL RESTRICTIONS AND LABELING. If a product contains more than 1.0 % but less
1178 than 7.0 % alcohol it is regulated by the labeling provisions of this subsection and the alcohol
1179 would be declared as an ingredient in normal descending order of predominance.

1180 (a) Ice cream containing more than 2.0% alcohol is not regulated by this chapter.

1181 (b) If the alcohol is part of other ingredients such as a flavoring, and it is less than 0.5% of the
1182 finished product by volume, then it is considered an incidental ingredient.

1183 **ATCP 70.28 Sanitizers and sanitizing methods. (1) SANITIZING METHODS.** All returnable or
1184 multi-use food packages, and all food contact surfaces of equipment and utensils used to handle
1185 foods, shall be effectively sanitized prior to each use.

1186 **(1m) CHEMICAL SANITIZERS; REQUIREMENTS.** The operator shall use only chemical sanitizers
1187 that comply with 21 CFR 178.1010, are registered with the U.S. environmental protection agency,
1188 are applied according to manufacturer's instructions, labeled for use in food processing plants on
1189 food contact surfaces, and, do not leave an unacceptable residue on the food contact surface when
1190 used appropriately.

1191 **(2) BAKING AND COOKING CONTAINERS; EXEMPTION.** Sub. (1) does not apply to baking and
1192 cooking containers if heating time and temperature combinations meet industry standards and are
1193 adequate to destroy pathogenic microorganisms, provided that the containers are cleaned, stored,
1194 and used in a manner which prevents contamination of food.

1195 **(3) SANITIZERS; MAXIMUM CONCENTRATIONS.** The operator shall use sanitizers and cleaning
1196 compounds so no toxic or otherwise unacceptable residue is left on any food contact surface.
1197 Sanitizing solutions shall not exceed the maximum concentrations established by the food and
1198 drug administration, United States department of health and human services, under 21 CFR
1199 178.1010. A test kit or other device that measures the concentration of sanitizing solutions in parts
1200 per million shall be used as necessary to ensure compliance with this subsection.

1201 **(4) SANITIZERS; DEPARTMENT APPROVAL.** (a) Sanitizers approved by the U.S. environmental
1202 protection agency and labeled for use on food contact surfaces are also accepted by the department
1203 for use according to their labels. The department may approve other sanitizers and sanitizing
1204 methods that it finds to be safe and effective for the purpose used.

1205 (b) The department may deny or withdraw approval of any sanitizer or sanitizing method if the
1206 department determines that the sanitizer or sanitizing method is not safe or effective for the

1207 purpose or under the conditions used, or that it adversely affects the sanitary characteristics of
1208 equipment, utensils or food packages.

1209 **ATCP 70.30 Ready-to-eat foods; reporting pathogens and toxins. (1) REQUIREMENT.**

1210 Except as provided under sub. (2), an operator shall report to the department the results of any
1211 microbiological test or laboratory analysis which indicates that any ready-to-eat food produced by
1212 that operator contains pathogenic organisms, toxins resulting from the growth of pathogenic
1213 organisms, or any other adulterant capable of causing disease or injury if ingested. The operator
1214 shall report to the department within 24 hours after the operator obtains the test results. The
1215 operator may report orally, electronically, or in writing.

1216 **Note:** The State of Wisconsin's Emergency Management phone number is (800) 943-0003. The general
1217 number of the Division of Food and Recreational Safety is (608) 224-4700, and its FAX number is (608) 224-
1218 4710.

1219
1220 **(2) EXEMPTION.** An operator is not required to report test results under sub. (1) if all of the
1221 following apply:

1222 (a) The ready-to eat-food is identified by a product code or production lot number.

1223 (b) The operator has not yet sold or distributed any of the ready-to-eat food represented by the
1224 product code or production lot number under par. (a), but retains direct control over all of that
1225 ready-to-eat food.

1226 **ATCP 70.32 Recall plan. (1) PLAN REQUIRED.** An operator shall have a written plan for
1227 identifying and recalling food produced at that plant, should a food recall become necessary. The
1228 operator shall update the plan as necessary, and shall make it available to the department for
1229 inspection and copying upon request.

1230 **(2) PLAN CONTENTS.** A plan, under sub. (1), shall do all of the following:

1231 (a) Identify key individuals or positions that are responsible for planning, approving, and
1232 implementing recalls on behalf of the operator.

1233 (b) Identify key individuals or entities to be contacted or consulted in connection with a recall.

1234 (c) Include procedures for the routine identification, dating, and tracking of food production
1235 lots, so that affected lots can be identified and distinguished from unaffected lots in the event of a
1236 recall.

1237 (d) Include procedures to enable routine identification, dating, and tracking of food shipments
1238 from the food processing plant. Tracking shall identify shipment recipients and contents, cross-
1239 referenced to production lots, so that recipients of affected lots may be contacted in the event of a
1240 recall.

1241 (e) Include procedures for determining the nature and scope of a recall, including affected food
1242 production lots, shipments, and shipment recipients.

1243 (f) Include procedures for identifying and communicating with affected persons, including
1244 suppliers, food shipment recipients, down-line buyers, consumers, government agencies, and
1245 others.

1246 (g) Identify potential target audiences for recall information, including consumers, distributors,
1247 and government agencies.

1248 (h) Identify potential methods for communicating with target audiences under par. (g).

1249 (i) Identify key information, including the identity of the affected food, the reason for the
1250 recall, and suggested actions to be taken by affected persons, which may need to be communicated
1251 in the event of a recall.

1252 (3) DEVIATIONS FROM PLAN. Actual recall procedures may deviate from the recall plan under
1253 sub. (1), as circumstances warrant.

1254 **Subchapter III. Canning Operations; Supplementary Requirements**

1255 **ATCP 70.34 General. (1) APPLICABLE REQUIREMENTS.** Operators engaged in canning
1256 operations shall comply with applicable provisions of subch. II. Operators engaged in canning
1257 operations shall also comply with this subchapter and shall file processes, as required, with the
1258 U.S. food and drug administration according to the provisions in 21 CFR 108.

1259 (2) RESTRICTIONS ON SALE, DISTRIBUTION, AND DONATION OF HOME-CANNED FOODS. Home-
1260 canned low-acid or acidified foods may not be donated to charitable organizations, food banks,
1261 food pantries, or other non-profit organizations that will distribute or sell the home-canned foods.
1262 The individual canning processor may not sell the home-canned foods at a food bank or food
1263 pantry, or on behalf of a charitable or non-profit organization, unless exempted by statute or rule.

1264 **ATCP 70.36 Low-acid foods packaged in hermetically sealed containers.** The operator of
1265 a food processing plant that processes and packages low-acid foods in hermetically sealed
1266 containers shall comply with applicable federal regulations under 21 CFR 108.35 (c) and 21 CFR
1267 113.

1268 **Note:** Section ATCP 70.36 applies to all low-acid foods processed and packaged in hermetically sealed
1269 containers, including thermally processed and aseptically processed low-acid foods.

1270 **ATCP 70.38 Acidified foods.** Persons who process acidified foods shall comply with
1271 applicable federal regulations under 21 CFR 108.25 (c) and 21 CFR 114.

1272 **ATCP 70.40 Facilities and equipment; cleaning. (1) EQUIPMENT DESIGN, CONSTRUCTION,**
1273 **AND ACCESSIBILITY.** The operator of a food processing plant facility handling raw agricultural
1274 commodities to prepare the commodities for canning, shall use product-handling equipment that is

1275 kept clean and in good repair and is designed and constructed in a way that allows easy
1276 accessibility for maintenance and cleaning.

1277 (2) EQUIPMENT, WATER, AND SUPPLIES USED FOR CLEANING. The operator of a food processing
1278 plant conducting canning operations shall use cleaning equipment that is adequate and in good
1279 repair, and shall provide ample supplies of water and steam or other approved cleaning and
1280 sanitizing materials for cleaning purposes at the facility.

1281 (3) CLEANING REQUIREMENTS FOR EQUIPMENT USED TO PROCESS FOOD BEFORE THERMAL
1282 PROCESSING. The operator at a canning facility shall clean equipment used to process food before
1283 thermal processing, in accordance with a written plan kept at the canning facility and made
1284 available to the department for review upon request. The written plan shall include:

1285 (a) A clear and complete description of the affected food processing equipment and utensils,
1286 including any continuously-operated equipment. The description shall identify sanitary design
1287 features that are relevant to the proposed cleaning and, if deemed appropriate, sanitizing
1288 procedures.

1289 (b) The types of food produced with the affected equipment or utensils, the purposes for which
1290 the food will be used, and the thermal processing conditions to which the food will be subjected.

1291 (c) A clear and complete description of the alternative procedures used to clean and, if deemed
1292 appropriate, sanitize the equipment, including equipment used to conduct these procedures,
1293 frequency, methods, materials, and relevant process parameters such as time and temperature. The
1294 description shall include a flow diagram of the alternative procedures.

1295 (d) A written statement, by the operator, that the alternative cleaning and sanitizing procedures
1296 have been determined by competent authority, such as a process authority or validated by a

1297 published or unpublished, peer-reviewed article, challenge studies, or regulatory standards, to be
1298 effective in preventing finished food product contamination and ensuring the microbiological
1299 safety of food.

1300 (e) Identification of foreseeable hazards, critical control points, critical safety parameters and
1301 limits, and monitoring procedures and controls to ensure that the procedure is effective and
1302 appropriately implemented.

1303 **ATCP 70.42 Handling raw agricultural commodities and by-products. (1) PRE-**
1304 **CANNING OPERATIONS.** Raw agricultural commodities shall be washed, sorted, trimmed as
1305 necessary, and inspected before being canned. This requirement does not apply to the washing of
1306 cabbage being prepared to make sauerkraut.

1307 **(2) WASTEHANDLING.** Waste and by-products from canning operations shall be stored and
1308 handled in a sanitary manner.

1309 **Subchapter IV. Fish Processing Plants; Marine Shellfish Plants; Supplementary**
1310 **Requirements**

1311 **ATCP 70.44 Fish processing. (1) APPLICABLE REGULATIONS.** A fish processing plant
1312 operator shall comply with subch. II and 21 CFR 123. The operator shall have and operate in
1313 accordance with HACCP plans that comply with 21 CFR 123 and address food safety hazards that
1314 may occur in fish processing. If a fish processing plant produces smoked fish products or smoke-
1315 flavored fish products, the HACCP plan for that fish processing plant shall address potential
1316 botulism risks as provided in 21 CFR 123 part B.

1317 **(2) RESTRICTION ON USE OF COLD-PROCESS SMOKED FISH.** Cold-process smoked fish may
1318 not be used as an ingredient in any other ready-to-eat, potentially hazardous food.

1319 **ATCP 70.46 Labeling and sale of smoked fish. (1) MANDATORY LABEL INFORMATION.**

1320 Every package containing smoked fish shall be clearly and conspicuously labeled, on the principal
1321 display panel of that package, with all of the following information:

1322 (a) The name and address, including the zip code, of the smoked fish processor or
1323 distributor.

1324 (b) The name of the product, including the common name of the fish from which the product
1325 is derived as found in Table 3-2 of the Fourth Edition of *Fish and Fishery Products Hazards and*
1326 *Controls Guidance*.

1327 **Note:** A copy of the current edition of the *Fish and Fishery Products Hazards and Controls Guidance*,
1328 may be obtained from the University of Florida Bookstore by calling (800) 226-1764, or it may be
1329 downloaded from the U.S. food and drug administration website:
1330 <http://www.fda.gov/Food/GuidanceRegulation/Guidance DocumentsRegulatoryInformation/default.htm/>

1331
1332 (c) The net weight of the package contents.

1333 (d) If cold-smoked fish is contained in reduced-oxygen packaging and sold or distributed in
1334 an unfrozen state, the words “PERISHABLE – KEEP REFRIGERATED AT OR BELOW 38°
1335 F” in conspicuous letters at least the size of those used in the food name.

1336 (e) If smoked fish contained in the package are sold or distributed in a frozen state, the
1337 words “PERISHABLE — KEEP FROZEN PRIOR TO USE” in conspicuous letters at least the
1338 size of those used in the food name.

1339 (f) The processing date or processing date code of the smoked fish.

1340 **(2) PROHIBITION AGAINST COMMINGLING.** Smoked fish processed on different dates or codes
1341 may not be commingled in the same container, either at the processing plant or while the fish are
1342 being stored, distributed, or offered for sale at wholesale or retail.

1343 **(3) MISREPRESENTATION OF PROCESSING DATE OR PROCESSING DATE CODE PROHIBITED.** No
1344 person may misrepresent a smoked fish processing date or processing date code, or sell or
1345 distribute smoked fish labeled with any processing date or processing date code other than the
1346 original date or code affixed by the processor.

1347 **(4) REMOVAL OF MISLABELED OR MISHANDLED SMOKED FISH.** Food consisting of or containing
1348 smoked fish shall be immediately removed from sale, and shall be destroyed or treated to render it
1349 unattractive and unfit for human consumption, if any of the following occurs:

1350 (a) The food package is not labeled with a processing date or processing date code.

1351 (b) Vacuum-packaged, cold-smoked fish is held, other than for brief periods during
1352 distribution, at a temperature above 38° F. (3.4° C.) prior to retail sale. This paragraph does not
1353 apply to a food which the department specifically exempts in writing because it is not subject to
1354 spoilage and does not support pathogen growth.

1355 **(5) APPLICABILITY OF SMOKED FISH REGULATIONS IN WISCONSIN.** No smoked fish may be sold,
1356 distributed, or offered or exposed for sale in this state unless the smoked fish have been processed,
1357 labeled, and handled in compliance with this subchapter. This subsection applies to every person
1358 engaged in the sale or distribution of smoked fish in this state, regardless of whether the person
1359 processes smoked fish in this state.

1360 **ATCP 70.48 Fish roe. (1) REFRIGERATION.** Roe and any attached entrails harvested from a
1361 fish shall be refrigerated at a temperature of not more than 38° F. (3.4° C.). Processing of dry salted
1362 roe or salted roe product shall be done in accordance with 21 CFR 123.

1363 **(2) HARVESTING AND HANDLING.** Roe and attached entrails, if any, shall be harvested, stored,
1364 and transported for processing in covered food grade containers. Each container shall be
1365 conspicuously labeled to indicate when each of the following operations was performed, if that
1366 operation has been performed:

1367 (a) The roe and attached entrails, if any, were harvested from the fish.

1368 (b) The roe sacks were separated from attached entrails, if any. Roe sacks shall be separated
1369 from attached entrails within 48 hours after the roe sacks and entrails are harvested from the fish.

1370 (c) The roe was separated from the roe sacks. Roe shall be separated from roe sacks within 72
1371 hours after the roe sacks are harvested from the fish, unless the roe is processed and packed in roe
1372 sacks. Roe processed and packed without being separated from roe sacks shall be processed and
1373 packed within 72 hours after the roe sacks are harvested from the fish.

1374 **(3) RECEIPT FOR PROCESSING.** A fish processing plant operator may not accept for processing
1375 any roe that has been held, transported, or processed in violation of sub. (1) or (2).

1376 **(4) PROCESSING STANDARDS. (a)** Roe shall be held and processed according to s. ATCP 70.24
1377 (1).

1378 (b) Processed roe shall contain a minimum of 2.5% salt by weight, as determined by
1379 quantitative analysis for total salt content.

1380 (c) No fish processing plant personnel may have direct hand contact with finished, ready-to-eat
1381 roe.

1382 (5) PRODUCT REPRESENTATION. (a) No roe product may be labeled or represented as "caviar"
1383 unless one of the following applies:

1384 1. The product consists only of the eggs of sturgeon prepared by a salting and separation
1385 process traditionally associated with the term "caviar."

1386 2. The product consists of roe prepared by a salting and separation process traditionally
1387 associated with the term "caviar," and the name of the fish species is clearly disclosed with the
1388 term "caviar" whenever that term is used.

1389 **Note:** For example, a caviar-type product made from whitefish eggs, using the traditional caviar
1390 process, may not be labeled as "caviar" unless it is labeled as "whitefish caviar." All packaged food product
1391 labels, including "caviar" labels, must also include a statement of ingredients listed by their common or
1392 usual names in descending order of prominence (see s. ATCP 70.26).

1393
1394 (b) No person may misrepresent the identity or value of any roe product by adding a color
1395 additive to the roe product. This paragraph does not prohibit the use of color additives in roe
1396 products if all of the following apply:

1397 1. The color additive is approved by the United States food and drug administration.

1398 2. The product includes a conspicuous label disclosure, such as "artificially colored" or "color
1399 added," which clearly indicates that the product includes a color additive. The disclosure shall
1400 appear on the product label directly below the product name in type at least one-third the size of
1401 the type used in the product name.

1402 3. The color additive is included in the ingredient statement on the product label.

1403 **ATCP 70.50 Marine molluscan shellfish processing. (1) APPLICABLE FEDERAL**
1404 **REGULATIONS.** Shellfish processing and shipping operations shall comply with subch. II, the U.S.
1405 food and drug administration's *Guide for the Control of Marine Shellfish, The Model Ordinance,*
1406 and applicable sections of 21 CFR 123. Shellfish processing plant operators shall have HACCP

1407 plans that comply with 21 CFR 123 and address food safety hazards that may occur in shellfish
1408 processing. If a shellfish processing plant produces smoked shellfish products or smoke-flavored
1409 shellfish products, the HACCP plan for that fish processing plant shall address potential botulism
1410 risks as provided in 21 CFR 123 part B.

1411 (2) ILLNESS OUTBREAKS ASSOCIATED WITH SHELLFISH. (a) At any time shellfish are potentially
1412 implicated in an illness outbreak involving at least 2 persons not from the same household, or at
1413 least one person in the case of paralytic shellfish poisoning, the department shall determine
1414 whether an epidemiological association exists between the illness and the shellfish consumption by
1415 reviewing each consumer's food intake history and the shellfish handling practices of the
1416 consumer and retailer.

1417 (b) When the department has determined an epidemiological association exists between an
1418 illness outbreak and shellfish consumption, the department shall conduct an investigation of the
1419 outbreak to determine whether the illness is related to the shellfish growing area or to post-harvest
1420 contamination or mishandling.

1421 (c) Upon completion of the investigation, the department shall notify receiving states and the
1422 United States food and drug administration of the findings, and take appropriate steps in
1423 cooperation with the licensee dealer to recall the affected product and, if necessary, inform
1424 consumers about the outbreak and associated product.

1425 (3) DOCUMENTS ASSOCIATED WITH SHELLFISH PROCESSING. Any documents generated by the
1426 facility in the course of its operation shall be available to the department within 24 hours of request
1427 by the department or its agent.

1428 **Subchapter V. Bottling Establishments; Supplementary Requirements**

1429 **ATCP 70.52 Bottling establishments; general.** Bottling establishments shall comply with
1430 subch. II and this subchapter. Bottling establishments producing bottled water shall comply with
1431 21 CFR 129.

1432 **ATCP 70.54 Returnable and single-service bottles.** Bottles shall comply with food package
1433 requirements under s. ATCP 70.26 (1). Returnable bottles shall be cleaned, sanitized, and
1434 inspected in compliance with ss. ATCP 70.26 (2) and (3). Single service bottles shall comply with
1435 s. ATCP 70.26 (4).

1436 **ATCP 70.56 Bottled water product sampling; record keeping; reports.**

1437 **(1) SAMPLING AND ANALYSIS.** The operator of a bottled water plant shall collect and analyze
1438 samples of bottled product for the following contaminants at the following minimum frequency,
1439 and more frequently if necessary, to provide reasonable assurance of compliance with this
1440 subsection:

1441 (a) A weekly total coliform analysis. Pursuant to 21 CFR 129.80 (g) (1), a positive total
1442 coliform analysis requires follow-up testing for *E. coli* and, pursuant to 21 CFR 165.110 (b) (2)

1443 (B), if *E. coli* is present the bottled water will be deemed adulterated.

1444 (b) An annual physical analysis pursuant to 21 CFR 165.110 (b) (3) for turbidity, color and
1445 odor analysis.

1446 (c) An annual chemical analysis pursuant to 21 CFR 165.110 (b) (4).

1447 (d) An annual radiological analysis pursuant to 21 CFR 165.110 (b) (5).

1448 **(2) REPORTING OF ANALYTICAL RESULTS.** A processor of bottled water shall report the results
1449 of all required analyses, under sub. (1), to the department, for each license year upon request. If
1450 the result of any individual analysis exceeds the established enforcement standard, the bottled

1451 water processor shall submit a copy of that analytical report to the department within 7 days of the
1452 completion of the analysis.

1453 **ATCP 70.58 Labeling bottled products.** (1) Bottled products shall be labeled according to
1454 s. ATCP 70.26 (5). Bottled water shall also be labeled according to 21 CFR 165.110. Juice shall
1455 be labeled according to 21 CFR 120, and any applicable regulations found in this chapter.

1456 **Subchapter VI. Juice and Juice HACCP**

1457 **ATCP 70.60 Juice and Juice HACCP.** (1) APPLICABLE REGULATIONS. Food processing plants
1458 producing and packaging or bottling juice shall comply with subch. II and this subchapter. Food
1459 processing plants engaged in juice processing and packaging or bottling shall comply with 21 CFR
1460 120.

1461 (2) LABELING REQUIREMENTS. A juice label may not misrepresent that juice has been
1462 pasteurized or has undergone a process equivalent to pasteurization. A juice label may not
1463 represent as "fresh" any juice that has been treated with ultra-violet light.

1464 **Subchapter VII. Effect of Rules on Local Ordinances**

1465 **ATCP 70.62 Effect of rules on local ordinances.** (1) NON-CONFLICTING LOCAL
1466 ORDINANCES PERMITTED. This chapter does not prohibit or nullify any local government ordinance
1467 with which it is not in direct conflict as provided in sub. (2).

1468 (2) PRE-EMPTION OF CONFLICTING LOCAL ORDINANCES. If this chapter conflicts directly with
1469 any local government ordinance, so that it is impossible to comply with one except by violating
1470 the other, this chapter controls.

1471 (3) DUTY TO COMPLY. Compliance with local government ordinances does not relieve any
1472 person from the duty of complying with this chapter.

1473 **Subchapter VIII. Variances**

1474 **ATCP 70.64 Variances. (1) ISSUANCE.** The department may issue a written waiver granting
1475 a variance from a construction, equipment, or processing standard under this section if the
1476 department finds that the variance is reasonable and necessary under the circumstances, and that it
1477 will not compromise the purpose served by the construction, equipment, or processing standards.
1478 The administrator of the department’s division of food and recreational safety may issue a waiver
1479 on behalf of the department. The department shall keep a copy of the waiver on file for as long as
1480 the waiver remains in effect.

1481 **(2) SUBMISSION OF REQUEST FOR A VARIANCE.** A variance request shall be submitted to the
1482 department through the sanitarian assigned by the department to inspect the food processing plant,
1483 and shall include all validation documents as well as a HACCP plan required under 21 CFR, parts
1484 120 or 123, if applicable; or food safety preventive controls plan as required under 21 CFR 117,
1485 Subpart C, if it is for a waiver of accepted processing protocols.

1486 **(3) DURATION AND EXPIRATION.** All waivers granted under this section shall expire 5 years
1487 from the date of issuance or when changes are made that could have an effect on the validity of the
1488 procedures or process.

1489 **SECTION 2. EFFECTIVE DATE.** This rule shall take effect on the first day of the month
1490 following publication in the Wisconsin Administrative Register, as provided under s. 227.22 (2)
1491 (intro.), Stats.

Dated this _____ day of _____, 2019.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE, TRADE
AND CONSUMER PROTECTION

By _____
Department Secretary