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Report From Agency

DATCP Docket No. 06-R-07
Rules Clearinghouse No. 09-009

Final Draft Rule
May 26, 2009

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

2 The Wisconsin department of agriculture, trade and consumer protection proposes the
3 following order *to repeal* ATCP 70.11(4)(note), 70.185, 70.21, 70.22, 70.225 and
4 70.26(4)(note); *to renumber* ATCP 70.02(22m); *to renumber and amend* ATCP
5 70.02(17m); *to amend* ATCP 70.02(6), (16)(d), (17) and (20), 70.03(7)(b)(intro.),
6 70.04(7)(b)(intro.), 70.06(3), 70.08(2) and 70.13; *to repeal and recreate* ATCP
7 70.02(22), (22n) and (23), 70.04(9)(b), 70.06(7), 70.07(3), 70.10(title), 70.11(4),
8 70.13(note), 70.18, 70.19, 70.20, 70.23, and 70.26(3) and (4); and *to create* ATCP
9 70.02(18m), (19m), (20m), (22g) and (22p), 70.05(1m), 70.03(2p), 70.06(7m),
10 70.07(3)(a)5.(note) and (3)(b)3.(note), 70.07(5) to (7), 70.10(5), 70.117, 70.18(note),
11 70.26(4m), 70.261, 70.262, and ch. ATCP 70 *Appendix A*; *relating to* food processing
12 plants.

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

The department of agriculture, trade and consumer protection (DATCP) currently licenses and regulates food processing plants to protect public health and safety. This rule updates current DATCP rules and harmonizes them with current federal rules.

Statutes Interpreted

Statutes interpreted: ss. 97.02, 97.03, 97.09, 97.10, 97.29

and 97.34, Stats.

Statutory Authority

Statutory authority: ss. 93.07(1), 97.09, 97.29(5), 97.34(2)(a) and 227.11(2), Stats.

Explanation of Statutory Authority

DATCP has general authority under 93.07(1) to adopt rules interpreting statutes under its jurisdiction. DATCP is specifically authorized under ss. 97.09, 97.29(5) and 97.34(2)(a) and (c), Stats., to adopt rules to regulate food processing, labeling and distribution.

Related Rules or Statutes

This rule incorporates, by reference, parts or all of the following rules:

- DATCP rules related to retail food establishments (ATCP 75) and fair packaging and labeling (ATCP 90).
- Department of natural resources (DNR) rules related to safe drinking water (NR 809), community water systems (NR 811) and well construction (NR 812).
- Federal rules adopted by the United States food and drug administration (FDA). These include 21 CFR 101 (food labeling), 21 CFR 113 (low-acid food packaged in hermetically sealed containers), 21 CFR 120 (juice processing), 21 CFR 123 (fish processing), 21 CFR 129 (bottled water), and 21 CFR 165.110 (bottled water labeling).

Rule Contents

This rule does all of the following:

- ***Definitions.*** This rule harmonizes current definitions with federal rules, as well as with Wisconsin retail food rules under ch. ATCP 75. For example, this rule creates or modifies definitions of “juice,” “major food allergen,” “potentially hazardous food,” “ready-to-eat food,” “reduced oxygen packaging” and “safe temperatures” to be consistent with other state and federal rules.
- ***Handwashing facilities.*** This rule updates current standards related to handwashing facilities serving toilet rooms and food processing areas. New requirements apply only to facilities installed after the effective date of this rule, to food processing plants initially licensed after the effective date of this rule, or to food processing plants licensed to a new operator after the effective date of this rule.
- ***Hand contact with ready-to-eat food.*** This rule prohibits bare hand contact with ready-to-eat food, unless bare hand contact is reasonably necessary and does not contaminate food. If a food processing plant operator allows bare-hand contact with

ready-to-eat food, the operator must do all of the following (requirements are consistent with current rules for retail food establishments):

- Establish written policies and procedures related to bare-hand contact. These must identify authorized employees and tasks, affected foods, and the procedures that employees must follow to prevent food contamination from bare-hand contact.
 - Provide advance training to employees who may have bare hand contact with ready-to-eat food. A written training plan must identify responsible training providers, training contents (including operator policies and procedures related to bare-hand contact), the form of initial training, the form and frequency of follow-up training, and measures to ensure that effective training is provided as planned.
 - Keep records to document compliance with bare-hand food handling policies, procedures and training requirements.
- ***Cleaning and sanitizing procedures.*** This rule updates and clarifies current requirements for cleaning and sanitizing food processing equipment and utensils, and creates procedures by which DATCP may authorize alternative procedures and sanitizing materials.
 - ***Reclaimed water.*** This rule updates and clarifies current standards related to use of reclaimed water in food processing plants.
 - ***Re-circulated water systems.*** This rule regulates the use of re-circulated water in coolers and heat exchangers (if there is any possibility that the re-circulated water may come in contact with any food product or food contact surface).
 - ***Water and potable liquids transported in bulk.*** This rule regulates the transportation and handling of water and other potable liquids transported to or from a food processing plant. Transported water must be obtained from a potable source that complies with DNR rules. Bulk tankers must be constructed, maintained, cleaned and sanitized for sanitary operation, and bulk liquids must be loaded and unloaded in a sanitary manner.
 - ***Labeling packaged food.*** This rule incorporates, by reference, current federal and state food packaging and labeling requirements. Among other things, this rule incorporates current federal rules related to disclosure of major food allergens.
 - ***Recall plan.*** Consistent with current federal rules, this rule requires a food processing plant operator to have a written plan for identifying and recalling food produced at the plant, should a food recall become necessary. This rule spells out general content requirements, but allows operators to determine plan specifics. Actual recall procedures may deviate from advance plans, as circumstances warrant.

- ***Low-acid food packaged in hermetically sealed containers.*** This rule clarifies that low-acid food packaged in hermetically sealed containers (including aseptically processed food as well as thermally processed food) must be processed according to federal rules under 21 CFR 113.
- ***Fish processing; general.*** This rule repeals and recreates current rules related to fish processing, in order to make the rules consistent with federal rules under 21 CFR 123.
 - Under federal rules and this rule, fish processors must have a hazard analysis and critical control point (HACCP) plan to identify and control food safety hazards associated with fish processing. Plans must meet federal standards.
 - This rule repeals current required procedures related to smoked-fish processing, in favor of the more flexible HACCP plan approach. However, this rule encourages smoked fish processors to incorporate and adapt the repealed procedures, as appropriate, in their HACCP plans (this rule includes the repealed procedures in an appendix, which processors may consult for guidance).
 - This rule updates and clarifies current rules related to the labeling and sale of smoked fish. Among other things, this rule repeals the current 21-day shelf-life limit on sales of smoked fish (this rule requires a stated shelf-life expiration date for smoked fish, but the shelf-life will be based on the HACCP plan per federal rules).
 - This rule updates and clarifies current rules related to processing, labeling and sale of fish eggs (roe). This rule applies to all fish roe, not just “caviar.” This rule clarifies current labeling requirements related to processed fish roe. A fish roe product, other than a sturgeon roe product, may not be labeled as “caviar” unless the name of the fish species is also disclosed (e.g., “whitefish caviar”).
- ***Bottling establishments.*** This rule updates and clarifies current rules related to bottling establishments:
 - Bottling establishments producing bottled water must comply with federal rules under 21 CFR 129.
 - Bottling establishments engaged in juice processing must comply with federal rules under 21 CFR 120.
 - This rule updates and clarifies current product testing requirements, including test frequencies, and harmonizes current requirements with applicable federal rules. Operators who obtain ingredient water from municipal sources are exempt from some, but not all, testing requirements.

- This rule regulates the transportation and handling of water and other potable liquids transported to or from a bottling establishment (see above). If ingredient water is transported to a bottling establishment in bulk, the operator must test the ingredient water at least weekly for coliform bacteria and heterotrophic plate count. An operator must keep records of bulk shipments.
- Labeling of bottled products must comply with general food labeling standards (see above). Bottled water labeling must also comply with specific federal requirements under 21 CFR 165.110. A juice label may not misrepresent that juice has been pasteurized. A juice label may not represent as “fresh” any juice that has been treated with ultra-violet light.
- **Lab test methods.** This rule updates required laboratory methods for food safety tests, based on the latest methods published by AOAC International and the American Public Health Association.
- **Fees and surcharges.** This rule does *not* create or modify any food processing plant license fees or surcharges. This rule does add a reference to an *existing* statutory surcharge (s. 97.29(3)(d), Stats.) of \$100 for food processing plant operators found operating without a license. This rule does not change the current statutory surcharge, but merely references it so that readers will be aware of it.
- **Organizational and technical drafting changes.** This rule makes other organizational, technical and drafting changes to update and clarify current rules.

Fiscal Impact

This rule will have no significant fiscal impact on Wisconsin state government and no fiscal impact on local units of government. DATCP will incur some costs to provide information and education to affected businesses. However, DATCP expects to absorb those costs. A complete *fiscal estimate* is attached.

Business Impact

This rule will help Wisconsin food processors to produce safe food products. Food safety regulation is important not only for consumers, but also for the food processors themselves. Food safety problems can harm individual businesses and the overall food industry.

For the most part, this rule merely updates and clarifies current rules and makes the rules consistent with other federal and state rules. These modifications will eliminate inconsistent and duplicative regulation, which will make it easier for food processors to comply. Generally, this rule gives affected food processors more flexibility to design effective food safety systems tailored to their operations. But in some instances, this rule provides definite compliance standards that are not provided by federal rules.

This rule requires fish processors and juice processors to implement HACCP plans. But there will be no added costs to affected businesses because those plans are already required by federal rules. DATCP will help train affected businesses on the implementation of HACCP plans and other food safety measures. The University of Wisconsin-Extension may offer seminars and training sessions at modest cost.

Consistent with current federal rules, this rule requires food processors to have written recall plans. However, this rule gives processors considerable flexibility to design recall plans that are tailored to their operations. This rule establishes general content standards, but it does not impose specific content requirements. Actual recall procedures may vary from advance plans, as circumstances warrant.

This rule incorporates current state and federal labeling requirements for processed food, including current federal requirements related to disclosure of major allergens. This rule may prompt food processors to review their labels for compliance with current law, but it does not add any major new labeling requirements.

This rule requires food processors to keep certain records related to food processing operations to help ensure food safety. Since the recordkeeping requirements are consistent with normal business practice, they will not impose significant new burdens or costs. There are no new professional skills required.

This rule may require some changes in some food processing facilities and operations. But for most food processors, the changes (if any) will not be large or costly. Most food processors are already complying with most of the requirements. New requirements related to hand-washing facilities will apply prospectively to newly installed facilities or newly licensed operations.

Many of the food processing plants affected by this rule are “small businesses.” This rule will not have a significant adverse effect on small businesses, and it will help many small businesses by making food safety regulations clearer and more consistent. This rule does not exempt small businesses, because food safety risks affect small as well as large businesses. DATCP will help train affected businesses on the implementation of HACCP plans and other food safety measures. The University of Wisconsin-Extension may offer seminars and training sessions at modest cost.

This rule will promote food safety for the benefit of consumers *and* food processors. This rule will clarify current regulations, and make them more consistent. That will facilitate compliance by food processors. This rule will not have a significant adverse impact on small businesses (or other businesses), and it is not subject to the delayed small business effective date under s. 227.22(2)(e), Stats.

Federal and Surrounding State Regulation

Federal Regulation

At the federal level, the United States food and drug administration (FDA) is primarily responsible for regulating food processing plants. Wholesale food processing plants are required to register with FDA, but FDA does not license those food processing plants. FDA has established basic food safety standards and requirements for food processing plants, but those standards do not preempt consistent or more rigorous state standards. Most food processing plant inspections are conducted by the states (FDA does few inspections). States generally coordinate their regulatory programs with FDA, and state regulations are based to a considerable degree on federal regulations.

This rule incorporates by reference parts or all of the following FDA regulations: 21 CFR 101 (food labeling), 21 CFR 113 (low-acid food packaged in hermetically sealed containers), 21 CFR 120 (juice processing), 21 CFR 123 (fish processing), 21 CFR 129 (bottled water), and 21 CFR 165.110 (bottled water labeling).

Surrounding State Regulation

Michigan, Minnesota, Illinois and Iowa all regulate and inspect food processing plants. Rules in those states are broadly consistent with this rule and federal rules, although there are a number of specific variations between the states.

Data and Analytical Methodologies

This rule relies, generally, on a large body of generally-accepted scientific information related to food safety hazards (and effective means for preventing or controlling those hazards). That information also provides the basis for federal and state rules that DATCP has incorporated by reference in this rule.

This rule incorporates, by reference, laboratory test methods published in the official methods of AOAC International, 18th edition revision 2 (2007).

Technical Standards Incorporated by Reference

This rule incorporates the following technical standards by reference:

- Various laboratory test methods published in the official methods of analysis of the association of official analytical chemists (AOAC), 18th edition revision 2 (2007).
- *Standard Methods for the Examination of Water and Waste Water*, 21st edition (2005), published by the American Public Health Association (APHA), the American Water Works Association and the Water Environment Federation.

Pursuant to s. 227.21, Stats., DATCP has requested permission from the attorney general to incorporate these technical standards by reference in this rule. Copies will be kept on file with DATCP and the legislative reference bureau.

DATCP Contact

Questions about this rule may be directed to:

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1 **SECTION 1.** ATCP 70.02(6), (16)(d) and (17) are amended to read:

2 ATCP 70.02(6) “Bottling establishment” means any place where drinking water,
3 soda water beverage or alcohol beverage is manufactured or bottled for sale. “Bottling
4 establishment” does not include a retail establishment engaged in the preparation and sale
5 of beverages under a license issued under s. 125.26 or 125.51, Stats., or a restaurant
6 permit or other permit issued under s. ~~50.51~~ 254.64, Stats.

7 (16)(d) Activities inspected by the ~~federal~~ United States department of agriculture
8 ~~under 21 USC 451 to 695 and 21 USC 1031 to 1056~~ 21 USC 601 et seq. or 21 USC 451
9 et seq.

10 (17) “Food processing plant” means any place where food processing is
11 conducted. “Food processing plant” does not include any establishment subject to the
12 requirements of s. 97.30, Stats., or any restaurant or other establishment holding a permit
13 under s. ~~50.51~~ 254.64, Stats., to the extent that the activities of that establishment are
14 covered by s. 97.30, Stats., or the permit under s. ~~50.51~~ 254.64, Stats.

1 **SECTION 2.** ATCP 70.02(17m) is renumbered (17g) and amended to read:

2 ATCP 70.02(17g) “Hazard analysis and critical control point plan” or “HACCP
3 plan” means a food processing plan under which a food processing plant operator
4 effectively prevents, controls, or eliminates food safety hazards by monitoring food
5 safety variables at critical control points, and by controlling those variables within critical
6 limits.

7 **SECTION 3.** ATCP 70.02(18m) and (19m) are created to read:

8 ATCP 70.02(18m) “Juice” means aqueous liquids expressed or extracted from
9 fruits or vegetables, purées of the edible portions of fruits or vegetables, or combinations
10 or concentrates of those liquids or purées, which are used as whole beverages or beverage
11 ingredients.

12 (19m) “Major food allergen” means milk, eggs, fish, crustacean shellfish, tree
13 nuts, wheat, peanuts and soybeans. “Major food allergen” includes any food or food
14 ingredient, other than highly refined oil or an ingredient derived from highly refined oil,
15 which contains protein derived from milk, eggs, fish, crustacean shellfish, tree nuts,
16 wheat, peanuts or soybeans. “Major food allergen” does not include a food that is
17 exempted by the secretary of the United States department of health and human services
18 pursuant to 21 USC 321(qq)(2).

19 **SECTION 4.** ATCP 70.02(20) is amended to read:

20 ATCP 70.02(20) “Official methods of analysis” means the official methods of
21 AOAC International, ~~14th edition (1984)~~ eighteenth edition revision 2 (2007).

22 **SECTION 5.** ATCP 70.02(20m) is created to read:

1 ATCP 70.02(20m) “Organoleptic quality” means quality as assessed by means of
2 sight, smell, touch, or taste.

3 **SECTION 6.** ATCP 70.02(22) is repealed and recreated to read:

4 ATCP 70.02(22) “Potentially hazardous food” has the meaning given in ch.
5 ATCP 75 Appendix (Wisconsin Food Code), s. 1-201.10(B)(66).

6 **SECTION 7.** ATCP 70.02(22m) is renumbered (22c).

7 **SECTION 8.** ATCP 70.02(22g) is created to read:

8 ATCP 70.02(22g) “Ready-to-eat food” has the meaning given in ch. ATCP 75
9 Appendix (Wisconsin Food Code), s. 1-201.10(B)(71).

10 **SECTION 9.** ATCP 70.02(22n) is repealed and recreated to read:

11 ATCP 70.02(22n) “Reduced oxygen packaging” has the meaning given in ch.
12 ATCP 75 Appendix (Wisconsin Food Code), s. 1-201.10(B)(72).

13 **SECTION 10.** ATCP 70.02(22p) is created to read:

14 ATCP 70.02(22p) “Roe” means fish eggs, including fish eggs that are still
15 enclosed in the ovarian membrane.

16 **SECTION 11.** ATCP 70.02(23) is repealed and recreated to read:

17 ATCP 70.02(23) “Safe temperatures” for the holding or storage of potentially
18 hazardous foods means one of the following:

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

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

22 (c) Temperatures at or below 38°F. (3.4°C.) for refrigerated fish or fish products.

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

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SECTION 11m. ATCP 70.03(2p) is created to read:

ATCP 70.03(2p) SURCHARGE FOR OPERATING WITHOUT A LICENSE. An applicant for a license under sub. (1) shall pay a license fee surcharge of \$100 if the department determines that, within one year prior to submitting the license application, the applicant operated the food processing plant without a license in violation of sub. (1). Payment of this license fee surcharge does not relieve the applicant of any other civil or criminal liability which results from the unlicensed operation of the food processing plant, but does not constitute evidence of a violation of any law.

SECTION 12. ATCP 70.03(7)(b)(intro.) is amended to read:

ATCP 70.03(7)(b) A restaurant holding a permit under s. ~~50.51~~ 254.64, Stats., if any of the following applies:

SECTION 13. ATCP 70.04(7)(b)(intro.) is amended to read:

ATCP 70.04(7)(b) Handwashing facilities shall be located in or adjacent to every toilet room. Handwashing facilities serving toilet rooms shall include hot and cold running water, soap in a soap dispenser, and a sanitary single-service means of drying the hands. A sign directing employees to wash their hands shall be prominently posted in every toilet room used by employees. ~~If handwashing are installed after June 30, 1989, the facilities shall comply with the following requirements.~~ Handwashing facilities serving toilet rooms shall comply with all of the following requirements if they are installed after [legislative reference bureau inserts effective date of this rule], or if they

1 are located in a food processing plant that is initially licensed or licensed to a new
2 operator after *[legislative reference bureau inserts effective date of this rule]*:

3 **SECTION 14.** ATCP 70.04(9)(b) is repealed and recreated to read:

4 ATCP 70.04(9)(b) A handwashing sink serving a food processing area shall
5 comply with all of the following requirements if it is installed after *[legislative reference*
6 *bureau inserts effective date of this rule]*, or if it is located in a food processing plant
7 that is initially licensed or licensed to a new operator after *[legislative reference bureau*
8 *inserts effective date of this rule]*:

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

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

12 3. It shall be of a type that is not hand operated. If a self-closing or metering
13 faucet is used, that faucet shall provide a flow of water for at least 15 seconds without
14 any need to reactivate of the faucet.

15 (c) Handwashing sinks may not be used to clean, sanitize, or store equipment or
16 utensils.

17 **SECTION 15.** ATCP 70.05(1m) is created to read:

18 ATCP 70.05(1m) HAND CONTACT WITHFOOD. (a) Except as provided in par. (b),
19 individuals engaged in food processing or handling may not contact ready-to-eat food
20 with their bare hands but shall use suitable food handling aids such as deli-tissue,
21 spatulas, tongs, single-use gloves, or dispensing equipment to avoid bare-hand contact.

1 (b) Individuals may contact ready-to-eat food with their bare hands if that contact
2 is reasonably necessary, and does not contaminate food. The individuals shall be trained
3 in, and shall follow, written policies and procedures to ensure safe use of bare hands.

4 The policies and procedures shall identify all of the following:

5 1. The individuals or positions authorized to contact ready-to-eat food with bare
6 hands.

7 2. The specific tasks for which bare-hand contact is authorized.

8 3. The types of ready-to-eat food that may be contacted with bare hands.

9 4. The procedures that authorized individuals are required to follow in order to
10 prevent food contamination from bare-hand contact.

11 (c) A food processing plant operator shall provide advance training under par. (b)
12 to all individuals who may contact ready-to-eat food with their bare hands. The operator
13 shall have a written training plan that identifies all of the following:

14 1. The individuals or positions responsible for implementing the training,
15 maintaining training records, and ensuring compliance with training requirements.

16 2. The content of the training, including the written procedures required under
17 par. (b).

18 3. The form of initial training, and the form and frequency of follow-up training
19 if any.

20 4. Monitoring and control procedures to ensure that individuals are trained before
21 they contact ready-to-eat food with bare hands.

22 5. Procedures to evaluate training effectiveness.

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

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

7 **SECTION 16.** ATCP 70.06(3) is amended to read:

8 ATCP 70.06(3) C-I-P SYSTEMS. C-I-P systems shall be of sanitary design and
9 construction, and shall be installed and maintained for sanitary operation. A C-I-P
10 system shall be installed and maintained so that cleaning and sanitizing solutions can be
11 circulated throughout all interior product contact surfaces of the system. C-I-P systems
12 shall be equipped with adequate inspection ports or other access points. C-I-P systems
13 shall be self-draining, or shall be capable of being easily and completely drained. A
14 temperature recording device, which accurately records the return temperatures of
15 cleaning and sanitizing solutions ~~on a temperature recording chart~~, shall be installed in all
16 circuits through which cleaning and sanitizing solutions are circulated. Cleaning records
17 shall be kept for at least 90 days after they are created.

18 **SECTION 17.** ATCP 70.06(7) is repealed and recreated to read:

19 ATCP 70.06(7) CLEANING AND SANITIZING EQUIPMENT AND UTENSILS; GENERAL.

20 (a) Except as provided in pars. (b) to (d):

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

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

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

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

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

14 1. Drying equipment.

15 2. Cloth-collector systems.

16 3. Dry product packaging equipment and storage containers.

17 4. Equipment used in brining, aging, curing, and dry product blending processes.

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

21 **SECTION 18.** ATCP 70.06(7m) is created to read:

1 ATCP 70.06(7m) ALTERNATIVE CLEANING AND SANITIZING PROCEDURES. (a) A
2 food processing plant operator may ask the department to approve alternative cleaning
3 and sanitizing procedures under par. (b). The operator shall submit the request in writing.
4 The request shall include all of the following, and any other information required by the
5 department:

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

10 2. The types of food produced with the affected equipment or utensils, the
11 purposes for which the food will be used, and the temperatures at which the food will be
12 prepared, stored and distributed.

13 3. A clear and complete description of the alternative cleaning and sanitizing
14 procedure, including cleaning and sanitizing equipment, frequency, methods, materials,
15 and relevant process parameters such as time and temperature. The description shall
16 include a flow diagram of the cleaning and sanitizing procedure.

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

21 5. A HACCP plan, prepared by qualified personnel, to ensure that the alternative
22 cleaning and sanitizing procedure will be effective in preventing food contamination and

1 ensuring the microbiological safety of food. The HACCP plan shall identify and assess
2 foreseeable hazards, identify critical control points, identify critical safety parameters and
3 limits, and identify monitoring procedures and controls to ensure that the procedure is
4 effective.

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

10 (c) The department shall grant or deny a request under par. (a) within 60 days
11 after it receives a complete request, except that the department may give written notice
12 extending the action deadline for reasons stated in the notice.

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

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

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

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

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

5 **SECTION 19.** ATCP 70.07(3) is repealed and recreated to read:

6 ATCP 70.07(3) RECLAIMED WATER. (a) Water reclaimed from a heat exchanger
7 process, from a compressor cooling unit, from the condensation of food products, or from
8 other food processing plant systems or processes, may be used as ingredient water with
9 department approval if all of the following apply:

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

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

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

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

17 5. The water, if reclaimed from the condensation of food products, has a
18 standard turbidity of less than 5 units or organic content of less than 12 mg. per liter, as
19 measured by the chemical oxygen demand or permanganate-consumed test specified in
20 *Standard Methods for the Examination of Water and Waste Water*, twenty-first edition
21 (2005), published by the American Public Health Association, the American Water
22 Works Association and the Water Environment Federation. The food processing plant

1 operator shall use an automatic fail-safe monitoring device to identify, and automatically
2 divert to a waste water system, any reclaimed water that fails to comply with this
3 subdivision.

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

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

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

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

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

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

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

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

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

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

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

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

19 7. There are no cross-connections between reclaimed water lines and any public
20 or private water system, except for lines with backflow preventers that meet the
21 requirements of chs. Comm 82 and 84.

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

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

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

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

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

17 **SECTION 20.** ATCP 70.07(3)(a)5.(note) is created to read:

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

24 **SECTION 21.** ATCP 70.07(3)(b)3. (note) is created to read:
25

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

7
8 **SECTION 22.** ATCP 70.07(5) to (7) are created to read:

9 ATCP 70.07(5) RE-CIRCULATED WATERSYSTEMS. (a) If re-circulated water used
10 in a cooler or heat exchanger may come in contact with any food product or food contact
11 surface, the re-circulated water shall be all of the following:

12 1. Obtained from a source that complies with ch. NR 811 or NR 812, as
13 applicable.

14 2. Bacteriologically safe.

15 3. Protected from contamination.

16 4. Tested by the food processing plant operator at least semiannually.

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

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

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

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

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

10 1. It shall be properly constructed and maintained to prevent contamination of the
11 potable water or potable liquid. Food contact surfaces shall comply with s. ATCP
12 70.06(2).

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

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

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

18 **NOTE:** Effective sealing systems include manhole cover gaskets and seals.

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

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

5 **SECTION 23.** ATCP 70.08(2) is amended to read:

6 ATCP 70.08(2) EGGS AND EGG PRODUCTS. Only clean whole eggs, pasteurized
7 eggs in liquid, frozen or dry form, or pasteurized egg products may be used in food
8 processing. Eggs and egg products may be pasteurized during processing. Clean whole
9 eggs shall be equivalent to USDA Grade B or better with shells intact ~~and without cracks~~
10 ~~and checks.~~

11 **SECTION 24.** ATCP 70.10(title) is repealed and recreated to read:

12 **ATCP 70.10 Food packaging and labeling.**

13 **SECTION 25.** ATCP 70.10(5) is created to read:

14 ATCP 70.10(5) FOOD PACKAGE LABELING. Packaged food shall be packaged and
15 labeled according to all of the following, as applicable:

16 (a) 21 CFR 101.

17 (b) Section 97.09, Stats., and federal regulations incorporated by reference in s.
18 97.09, Stats.

19 (c) Chapter ATCP 90.

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

21 (e) If the packaged food contains a major food allergen, the ingredient statement
22 on the package shall disclose the common name of the major food allergen. The

1 disclosure shall be equivalent in size and prominence to the rest of the ingredient
2 statement. If an allergen originates from fish, crustacean shellfish or tree nuts, the
3 disclosure shall include the common name of the source species.

4 **NOTE:** For example, if a food product includes an allergen that originates from
5 fish, the ingredient statement must disclose the common species name
6 such as bass, flounder or cod. If the allergen originates from crustacean
7 shellfish, the ingredient statement must disclose the common species name
8 such as crab, lobster or shrimp. If the allergen originates from tree nuts,
9 the ingredient statement must disclose the common species name such as
10 almond, pecan, walnut or coconut.

11
12 **SECTION 26.** ATCP 70.11(4) is repealed and recreated to read:

13 ATCP 70.11(4) SANITIZERS; DEPARTMENT APPROVAL. (a) Sanitizers
14 approved under ch. ATCP 75 Appendix, *Wisconsin Food Code s. 4-501.114* are also
15 approved by the department for purposes of sub. (1)(e). The department may approve
16 other sanitizers and sanitizing methods that it finds to be safe and effective for the
17 purpose used.

18
19 (b) The department may deny or withdraw approval of any sanitizer or sanitizing
20 method approved under par. (a), regardless of whether that sanitizer or sanitizing method
21 is approved by any other state or federal agency, if the department determines that the
22 sanitizer or sanitizing method is not safe or effective for the purpose or under the
23 conditions used, or that it adversely affects the sanitary characteristics of equipment,
24 utensils or food packages.

25 **SECTION 27.** ATCP 70.11(4)(note) is repealed.

26 **SECTION 28.** ATCP 70.117, inserted prior to subch. III, is created to read:

27 **ATCP 70.117 Recall plan.** (1) PLAN REQUIRED. A food processing plant
28 operator shall have a written plan for identifying and recalling food produced at that

1 plant, should a food recall become necessary. The operator shall update the plan as
2 necessary, and shall make it available to the department for inspection and copying upon
3 request.

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

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

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

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

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

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

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

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

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

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

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

8 **SECTION 29.** ATCP 70.13 is amended to read:

9 **ATCP 70.13 ~~Thermally processed low-acid~~ Low-acid foods packaged in**
10 **hermetically sealed containers.** Persons who ~~thermally~~ process and package low-acid
11 foods in hermetically sealed containers shall comply with applicable federal regulations
12 under 21 CFR 113.

13 **SECTION 30.** ATCP 70.13(note) is repealed and recreated to read:

14 **NOTE:** Section ATCP 70.13 applies to all low-acid foods processed and
15 packaged in hermetically sealed containers, including thermally processed
16 and aseptically processed low-acid foods.

17
18 **SECTION 31.** ATCP 70.18 is repealed and recreated to read:

19 **ATCP 70.18 Fish processing.** (1) Fish processing operations shall comply with
20 subch. II and 21 CFR 123. Fish processing plant operators shall have HACCP plans that
21 comply with 21 CFR 123 and address food safety hazards that may occur in fish
22 processing. If a fish processing plant produces smoked fish products or smoke-flavored
23 fish products, the HACCP plan for that fish processing plant shall address potential
24 botulism risks as provided in 21 CFR 123 part B.

1 (2) Processed fish shall immediately be refrigerated to a temperature of 38°F (3°
2 C) or below, and shall be kept at or below that temperature until sold to consumers at
3 retail, unless one of the following applies:

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

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

7 **SECTION 32.** ATCP 70.18(note) is created to read:

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

13
14 **SECTION 33.** ATCP 70.185 is repealed.

15 **SECTION 34.** ATCP 70.19 and 70.20 are repealed and recreated to read:

16 **ATCP 70.19 Labeling and sale of smoked fish.** (1) Every food package
17 containing smoked fish shall be clearly and conspicuously labeled, on the principal
18 display panel of that package, with all of the following information:

19 (a) The name and address of the smoked fish processor or distributor.

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

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

23 (d) If smoked fish contained in the package are sold or distributed in an unfrozen
24 state, the words “PERISHABLE - KEEP REFRIGERATED AT OR BELOW 38° F” in
25 conspicuous letters at least the size of those used in the food name.

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

4 (f) The processing date of the smoked fish.

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

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

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

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

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

18 (5) No smoked fish may be sold, distributed, or offered or exposed for sale in this
19 state unless the smoked fish have been processed, labeled and handled in compliance
20 with this subchapter. This subsection applies to every person engaged in the sale or
21 distribution of smoked fish in this state, regardless of whether the person processes
22 smoked fish in this state.

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

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

6 **ATCP 70.20 Fish roe.** (1) REFRIGERATION. Roe and any attached entrails
7 harvested from a fish shall at all times be refrigerated at a temperature of not more than
8 38° F. (3.4° C.), except that processing areas used to dry salted roe or salted roe product
9 may be kept at a temperature of not more than 50° F. (10° C.).

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

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

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

18 (c) The roe was separated from the roe sacks. Roe shall be separated from roe
19 sacks within 72 hours after the roe sacks are harvested from the fish, unless the roe is
20 processed and packed in roe sacks. Roe processed and packed in roe sacks shall be
21 processed and packed within 72 hours after the roe sacks are harvested from the fish.

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

4 (4) PROCESSING STANDARDS. (a) Roe shall be held and processed according to s.
5 ATCP 70.09(1).

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

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

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

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

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

17 **NOTE:** For example, a caviar-type product made from whitefish eggs, using the
18 traditional caviar process, may not be labeled as “caviar” unless it is
19 labeled as “whitefish caviar.” All packaged food product labels, including
20 “caviar” labels, must also include a statement of ingredients listed by their
21 common or usual names in descending order of prominence (see ATCP
22 70.10).

23
24 (b) No person may misrepresent the identity or value of any roe product by
25 adding a color additive to the roe product. This paragraph does not prohibit the use of
26 color additives in roe products if all of the following apply:

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

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

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

8 **SECTION 35.** ATCP 70.21 and 70.22 are repealed.

9 **SECTION 36.** ATCP 70.225 is repealed.

10 **SECTION 37.** ATCP 70.23 is repealed and recreated to read:

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

15 **SECTION 38.** ATCP 70.26(3) and (4) are repealed and recreated to read:

16 ATCP 70.26(3) The operator of a bottling establishment shall collect and analyze
17 representative samples of bottled product to provide reasonable assurance of compliance
18 with sub. (2). For contaminant types identified in sub. (4), the operator shall collect and
19 test samples at no less than the frequency required under sub. (4).

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

CONTAMINANT	TEST FREQUENCY
Bacteria	Monthly, except that bottled water shall be tested weekly per 21 CFR 129.80(g)(1).

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

1 **SECTION 39.** ATCP 70.26(4)(note) is repealed.

2 **SECTION 40.** ATCP 70.26(4m) is created to read:

1 ATCP 70.26(4m) Notwithstanding subsections (3) and (4), if the operator of a
2 bottling establishment obtains ingredient water from a municipal source that complies
3 with sub. (2), the operator is not required to test bottled product for any contaminant
4 other than bacteria unless one of the following applies:

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

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

8
9

SECTION 41. ATCP 70.261 and 70.262 are created to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 **SECTION 42.** *Appendix A to ch. ATCP 70* is created in the form attached.

2 **SECTION 43. EFFECTIVE DATE:** This rule takes effect on the first day of the
3 month following publication in the Wisconsin administrative register, as provided under
4 s. 227.22(2) (intro.), Stats.

Dated this _____ day of _____, _____.

STATE OF WISCONSIN,
DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By _____
Rodney J. Nilsestuen, Secretary

Chapter ATCP 70

APPENDIX A

Smoked Fish Processing

Federal regulations under 21 CFR 123 require fish processing plant operators to prepare hazard analysis and critical control point (HACCP) plans to address foreseeable hazards associated with fish processing operations (see also ATCP 70.18). Plans must meet minimum standards specified in 21 CFR 123. Under 21 CFR 123, Part B, operators of smoked fish and smoke-flavored fish products must include, in their HACCP plans, steps to address botulism risks. Operators of smoked fish processing plants may wish to include the following *suggested* procedures, as applicable, in their HACCP plans:

(1) Salting or Brining

- (a) Before any fish is smoked, it shall be dry salted or brined so that the amount of water-phase salt in the loin muscle of the finished smoked fish meets applicable requirements under subs. (2) to (4). The fish shall be rinsed with fresh water immediately after it is removed from the salt or brine.
- (b) Throughout the dry salting or brining process under par. (a), fish and brine shall be kept at a temperature of not more than 38 ° F. (3° C.).
- (c) A fish processing plant operator shall test each type of finished smoked fish product at least quarterly, using an official method of analysis, to ensure that the fish contains the amount of salt required under par. (a). The operator shall retain test records at the processing plant for at least 6 months, and shall make the records available to the department for inspection and copying upon request.

(2) Air Packaged Hot-Process Smoked Fish. Air packaged hot-process smoked fish shall be processed as follows:

- (a) Each fish shall be brined under sub. (1), so that the finished smoked fish contains at least 2.5% water-phase salt.
- (b) Each fish shall be heated so that the entire fish is held at a continuous internal temperature of at least 145° F. (63° C.) for at least 30 minutes.

(3) Hot-Processed Smoked Fish In Reduced Oxygen Packages. Hot-processed smoked fish packaged in reduced oxygen packages shall be processed as follows:

- (a) Each fish shall be brined under sub. (1) so that the finished smoked fish contains at least 3.5% water-phase salt, except that fish brined with a sodium nitrite solution containing not less than 100 parts per million nor more than 200 parts per million of sodium nitrite may be brined so that the finished smoked fish contains at least 3.0% water-phase salt.
- (b) Each fish shall be heated so that the entire fish is held at a continuous internal temperature of at least 145 °F. (63 °C.) for at least 30 minutes.

(4) Cold-Process Smoked Fish. Cold-process smoked fish shall be processed as follows:

- (a) Each fish shall be dry salted or brined so that the finished smoked fish contains at least 3.5% water-phase salt, except that:
 - 1. Fish brined with a sodium nitrite solution containing not less than 100 parts per million nor more than 200 parts per million of sodium nitrite may be brined so that the finished smoked fish contains at least 3.0% water-phase salt.
 - 2. Fish which is frozen immediately after smoking, and which remains frozen until sold to consumers at retail, may be brined so that the finished smoked fish contains at least 2.5% water-phase salt. The fish shall be labeled according to s. ATCP 70.19(1)(e).
- (b) Each fish shall be smoked at a temperature of not more than 90° F. (32° C.) for not more than 20 hours, or at a temperature of not more than 50° F. (10° C.) for not more than 24 hours.

(5) Temperature Records. Every smokehouse shall be equipped with a temperature recording device, which is designed, installed and maintained to make a continuous record of the internal temperatures of smoked fish. The temperature recording device shall record the internal temperature of the loin muscle of fish, which are located in the coldest portion of the smokehouse. For every lot of fish smoked, a fish processing plant operator shall keep a time-temperature recording chart that identifies the specific oven or chamber load and the processing date. Time and temperature records shall be kept on file in the smoked fish processing plant for at least 6 months. Temperature recording devices shall be accurate to within one degree Fahrenheit or 0.5° Celsius.