| 1 | Clearinghouse Rule 09-009 |                               |
|---|---------------------------|-------------------------------|
|   | DATCP Docket No. 06-R-07  | <b>Proposed Hearing Draft</b> |
|   | Rules Clearinghouse No    | October 29, 2008              |
|   |                           |                               |

## 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) and 70.26(5); *to renumber and amend*
- 5 ATCP 70.02(17m); *to amend* ATCP 70.02(6), (16)(d), (17) and (20),
- 6 70.03(7)(b)(intro.), 70.04(7)(b)(intro.), 70.06(3), 70.08(2) and 70.13; to repeal and
- 7 *recreate* ATCP 70.02(22), (22n) and (23), 70.04(9)(b), 70.06(7), 70.07(3), 70.10(title),
- 8 70.11(4), 70.13(note), 70.18, 70.19, 70.20, and 70.26(3) and (4); and *to create* ATCP
- **9** 70.02(18m), (19m), (22m) and (22p), 70.05(1m), 70.06(7m), 70.07(5) to (7), 70.10(5),
- 10 70.117, 70.18(note), 70.23, 70.26(5), 70.261, 70.262, and ch. ATCP 70 Appendix A;
- 11 *relating to* food processing plants.

# <u>Analysis Prepared by the Department</u> 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) and 97.34(2)(a) and 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 followup 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 does not dictate the contents of the plan, but it does provide content suggestions in an accompanying note.

- *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 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 smoke 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 updated official methods published by the association of official analytical chemists.
- **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 hazard analysis and critical control point (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 provides guidance on plan contents, but it does not impose specific content requirements.

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. 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 of 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 analysis of the association of official analytical chemists, 18<sup>th</sup> edition revision 2 (2007).

#### Technical Standards Incorporated by Reference

This rule incorporates, by reference, laboratory test methods published in the official methods of analysis of the association of official analytical chemists (AOAC), 18<sup>th</sup> edition revision 2 (2007). Pursuant to s. 227.21, Stats., DATCP will request permission from the attorney general to incorporate the AOAC methods by reference in this rule. Copies will be kept on file with DATCP and the legislative reference bureau.

#### **DATCP** Contact

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

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| 1  | <b>SECTION 1.</b> 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 <u>21 USC 451 to 695 and 21 USC 1031 to 1056</u> <u>21 USC 601 et seq. or 21 USC 451</u>  |
| 9  | <u>et seq</u> .                                                                                 |
| 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.                        |
| 15 | SECTION 2. ATCP 70.02(17m) is renumbered (17g) and amended to read:                             |
| 16 | ATCP 70.02(17g) "Hazard analysis and critical control point plan" or "HACCP                     |
| 17 | plan" means a food processing plan under which a food processing plant operator                 |
| 18 | effectively prevents, controls, or eliminates food safety hazards by monitoring food            |
| 19 | safety variables at critical control points, and by controlling those variables within critical |
| 20 | limits.                                                                                         |
| 21 | SECTION 3. ATCP 70.02(18m) and (19m) are created to read:                                       |

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

(19m) "Major food allergen" means milk, eggs, fish, crustacean shellfish, tree
nuts, wheat, peanuts and soybeans. "Major food allergen" includes any food or food
ingredient, other than highly refined oil or an ingredient derived from highly refined oil,
which contains protein derived from milk, eggs, fish, crustacean shellfish, tree nuts,
wheat, peanuts or soybeans. "Major food allergen" does not include a food that is
exempt under the petition or notification process specified in the food allergen labeling
and consumer protection act of 2004 (Public Law 108-282).

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

ATCP 70.02(20) "Official methods of analysis" means the official methods of
 analysis of the association of official analytical chemists, 14<sup>th</sup> edition (1984) <u>18<sup>th</sup> edition</u>

15 <u>revision 2 (2007)</u>.

16 SECTION 5. ATCP 70.02(22) is repealed and recreated to read:

- 17 ATCP 70.02(22) "Potentially hazardous food" has the meaning given in ch.
- 18 ATCP 75 Appendix (Wisconsin Food Code), s. 1-201.10(B)(66).
- **SECTION 6.** ATCP 70.02(22m) is renumbered (22g).
- 20 SECTION 7. ATCP 70.02(22m) is created to read:
- ATCP 70.02(22m) "Ready-to-eat food" has the meaning given in ch. ATCP 75
- 22 Appendix (Wisconsin Food Code), s. 1-201.10(B)(71).
- 23 SECTION 8. ATCP 70.02(22n) is repealed and recreated to read:

| 1  | ATCP 70.02(22n) "Reduced oxygen packaging" has the meaning given in ch.                          |
|----|--------------------------------------------------------------------------------------------------|
| 2  | ATCP 75 Appendix (Wisconsin Food Code), s. 1-201.10(B)(72).                                      |
| 3  | <b>SECTION 9.</b> ATCP 70.02(22p) is created to read:                                            |
| 4  | ATCP 70.02(22p) "Roe" means fish eggs, including fish eggs that are still                        |
| 5  | enclosed in the ovarian membrane.                                                                |
| 6  | <b>SECTION 10.</b> ATCP 70.02(23) is repealed and recreated to read:                             |
| 7  | ATCP 70.02(23) "Safe temperatures" for potentially hazardous foods means one                     |
| 8  | of the following:                                                                                |
| 9  | (a) Temperatures at or above 135° F. (57° C.) for heated foods.                                  |
| 10 | (b) Temperatures at or below 41°F. (5°C.) for refrigerated foods, except as                      |
| 11 | provided in par. (c).                                                                            |
| 12 | (c) Temperatures at or below 38°F. (3.4°C.) for refrigerated fish or fish products.              |
| 13 | (d) Temperatures that maintain frozen food in a constantly frozen condition.                     |
| 14 | SECTION 11. ATCP 70.03(7)(b)(intro.) is amended to read:                                         |
| 15 | ATCP 70.03(7)(b) A restaurant holding a permit under s. 50.51 254.64, Stats., if                 |
| 16 | any of the following applies:                                                                    |
| 17 | SECTION 12. ATCP 70.04(7)(b)(intro.) is amended to read:                                         |
| 18 | ATCP 70.04(7)(b) Handwashing facilities shall be located in or adjacent to every                 |
| 19 | toilet room. Handwashing facilities serving toilet rooms shall include hot and cold              |
| 20 | running water, soap in a soap dispenser, and a sanitary single-service means of drying the       |
| 21 | hands. A sign directing employees to wash their hands shall be prominently posted in             |
| 22 | every toilet room used by employees. If handwashing are installed after June 30, 1989,           |
| 23 | the facilities shall comply with the following requirements. <u>Handwashing facilities</u><br>10 |

| 1  | serving toilet rooms shall comply with all of the following requirements if they are           |
|----|------------------------------------------------------------------------------------------------|
| 2  | installed after [legislative reference bureau inserts effective date of this rule], or if they |
| 3  | are located in a food processing plant that is initially licensed or licensed to a new         |
| 4  | operator after [legislative reference bureau inserts effective date of this rule]:             |
| 5  | <b>SECTION 13.</b> ATCP 70.04(9)(b) is repealed and recreated to read:                         |
| 6  | ATCP 70.04(9)(b) A handwashing sink serving a food processing area shall                       |
| 7  | comply with all of the following requirements if it is installed after [legislative reference  |
| 8  | bureau inserts effective date of this rule], or if it is located in a food processing plant    |
| 9  | that is initially licensed or licensed to a new operator after [legislative reference bureau   |
| 10 | inserts effective date of this rule]:                                                          |
| 11 | 1. It shall be located in the processing area.                                                 |
| 12 | 2. It shall be served by hot and cold running water provided under pressure                    |
| 13 | through a mixing valve or combination faucet, or by potable and tempered water.                |
| 14 | 3. It shall be of a type that is not hand operated. If a self-closing or metering              |
| 15 | faucet is used, that faucet shall provide a flow of water for at least 15 seconds without      |
| 16 | any need to reactivate of the faucet.                                                          |
| 17 | 4. It may not be used to clean, sanitize, or store equipment or utensils.                      |
| 18 | <b>SECTION 14.</b> ATCP 70.05(1m) is created to read:                                          |
| 19 | ATCP 70.05(1) HAND CONTACT WITH FOOD. (a) Except as provided in par. (b),                      |
| 20 | individuals engaged in food processing or handling may not contact ready-to-eat food           |
| 21 | with their bare hands but shall use suitable food handling aids such as deli-tissue,           |
| 22 | 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.                                        |

6. The frequency with which the training program will be reviewed and, if
 necessary, updated. The training program shall be reviewed 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 15. 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 16.** 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 17. ATCP 70.06(7m) is created to read:                                            |

| 1  | ATCP 70.06(7m) Alternative cleaning and sanitizing procedures. (a)                           |
|----|----------------------------------------------------------------------------------------------|
| 2  | The department may approve alternative cleaning and sanitizing procedures that do not        |
| 3  | comply with sub. $(7)(a)$ if the department believes that those procedures will be effective |
| 4  | in preventing food contamination and ensuring the microbiological safety of food. The        |
| 5  | department shall give its approval in writing, based on a written request under par. (e).    |
| 6  | (b) The department shall grant or deny a request under par. (e) within 60 days               |
| 7  | after it receives a complete request, except that the department may give written notice     |
| 8  | extending the action deadline for reasons stated in the notice.                              |
| 9  | (c) The department may qualify or limit its approval under par. (a), as it deems             |
| 10 | appropriate. The department may withdraw its approval for cause, including information       |
| 11 | that casts doubt on the efficacy or faithful implementation of the approved procedure.       |
| 12 | (d) A food processing plant operator that implements an alternative cleaning and             |
| 13 | sanitizing procedure approved under par. (a) shall do all of the following:                  |
| 14 | 1. Control and monitor to ensure that the procedure is faithfully implemented as             |
| 15 | approved, and is effective in preventing food contamination and ensuring the                 |
| 16 | microbiological safety of food.                                                              |
| 17 | 2. Promptly notify the department of any material deviation from the approved                |
| 18 | procedure, and any information that casts doubt on the efficacy of the procedure.            |
| 19 | 3. Collect and retain data and records to document, on a continuing basis, the               |
| 20 | faithful implementation and efficacy of the approved procedure. The operator shall retain    |
| 21 | the data and records for at least 90 days, and shall make them available upon request for    |
| 22 | inspection and copying by the department.                                                    |

(e) A food processing plant operator may ask the department to approve
 alternative cleaning and sanitizing procedures under par. (a). The operator shall submit
 the request in writing. The request shall include all of the following, and any other
 information required by the department:
 1. A clear and complete description of the affected food processing equipment

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

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

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

4. A certification, by the food processing plant operator, that the alternative
cleaning and sanitizing procedure will be effective in preventing food contamination and
ensuring the microbiological safety of food. The certification shall be based on a
HACCP plan under subd. 5.

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

| 1  | foreseeable hazards, identify critical control points, identify critical safety parameters and |
|----|------------------------------------------------------------------------------------------------|
| 2  | limits, and identify monitoring procedures and controls to ensure that the procedure is        |
| 3  | effective.                                                                                     |
| 4  | <b>SECTION 18.</b> ATCP 70.07(3) is repealed and recreated to read:                            |
| 5  | ATCP 70.07(3) RECLAIMED WATER. Water reclaimed from food processing                            |
| 6  | operations may not be used as potable water or reused for any purpose in a food                |
| 7  | processing plant, except that:                                                                 |
| 8  | (a) Water reclaimed from a heat exchanger process, from a compressor cooling                   |
| 9  | water, or from the condensation of food products may be used as ingredient water or for        |
| 10 | any other purpose if all of the following apply:                                               |
| 11 | 1. The water is reclaimed by means of evaporation, reverse osmosis or ultra-                   |
| 12 | filtration, or is reclaimed from a heat exchanger process.                                     |
| 13 | 2. The department pre-inspects and pre-approves the reclamation system, and                    |
| 14 | pre-approves any chemical treatment of the reclaimed water.                                    |
| 15 | 3. The reclaimed water has less than 1 coliform bacterium per 100 ml. of water.                |
| 16 | 4. The standard plate count of the reclaimed water does not exceed 500 per ml.                 |
| 17 | of water and meets the bacteriological standards under s. NR 809.30.                           |
| 18 | 5. The water, if reclaimed from the condensation of food products, has a                       |
| 19 | standard turbidity of less than 5 units, or organic content less than 12 mg. per liter as      |
| 20 | measured by the chemical oxygen demand or permanganate-consumed test. The food                 |
| 21 | processing plant operator shall use an automatic fail-safe monitoring device to identify,      |

and automatically divert to a waste water system, any reclaimed water that fails to
 comply with this subdivision.

3 6. The reclaimed water is of satisfactory organoleptic quality and has no off-4 odors, off-flavors or slime formations. The food processing plant operator shall sample 5 and organoleptically test reclaimed water at weekly intervals. 6 7. Chemical treatment of the reclaimed water, if any, complies with sub. (4). 7 8. The reclaimed water is stored in a properly constructed tank. The tank shall 8 be constructed of a material that will not contaminate the water and can be easily cleaned. 9 9. The food processing plant operator tests the reclaimed water for 10 bacteriological and organic content at least semi-annually. The operator shall test the 11 reclaimed water for 14 working days after the department approves the reclamation 12 system under subd. 2., and for at least 7 working days after any repairs or alterations to 13 the system. 14 10. There are no cross-connections between reclaimed water lines and any public 15 or private water system. 16 (b) Water reclaimed from a heat exchanger process or from the condensation of 17 food products may be used to produce culinary steam, to pre-rinse food contact surfaces 18 of equipment or utensils, to prepare cleaning solutions, or for purposes involving no 19 contact with food or food contact surfaces, if the water complies with par. (a) or if all of 20 the following apply: 21 1. The water is reclaimed by means of evaporation, reverse osmosis or ultra-

22 filtration, or is reclaimed from a heat exchanger process.

2. The department pre-inspects and pre-approves the reclamation system, and
 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 an organic content less than 12 mg. per liter, or an organic content less than 12 mg.    |
| 6  | per liter as measured by the chemical oxygen demand or permanganate-consumed test.            |
| 7  | The food processing plant operator shall use an automatic fail-safe monitoring device to      |
| 8  | identify, and automatically divert to a waste water system, any reclaimed water that fails    |
| 9  | to comply with this subdivision.                                                              |
| 10 | 4. The reclaimed water is of satisfactory organoleptic quality and has no off-                |
| 11 | odors, off-flavors or slime formations. The food processing plant operator shall sample       |
| 12 | and organoleptically test reclaimed water at weekly intervals.                                |
| 13 | 5. Chemical treatment of the reclaimed water, if any, complies with sub. (4).                 |
| 14 | 6. The reclaimed water is stored in a properly constructed tank. The tank shall be            |
| 15 | constructed of a material that will not contaminate the water and can be easily cleaned.      |
| 16 | 7. There are no cross-connections between reclaimed water lines and any public                |
| 17 | or private water system, except for lines with backflow preventers that meet the              |
| 18 | requirements of chs. Comm 82 and 84.                                                          |
| 19 | 8. The reclaimed water is used only on the day that it is reclaimed, except that              |
| 20 | reclaimed water may be stored for later use if it is automatically maintained at a            |
| 21 | temperature of not less than 145 ° F. (63° C.), or is chemically treated under subd. 5. to    |
| 22 | suppress bacterial propagation.                                                               |

- 9. Distribution lines and hose stations used to distribute the reclaimed water are
   clearly identified as "limited-use reclaimed water."
- 3 10. The food processing plant operator posts clear instructions for the use of the 4 reclaimed water. The operator shall post the instructions so that they will be seen and 5 understood by persons using the reclaimed water. The instructions shall disclose the 6 limited purposes for which the reclaimed water may be used. 7 11. Water lines distributing the reclaimed water are not permanently connected to 8 food product vessels. If a water line is temporarily connected to a food product vessel, 9 there shall be an atmospheric break and automatic controls to prevent the reclaimed water 10 from contacting food products. 11 **SECTION 19.** ATCP 70.07(5) to (7) are created to read: 12 ATCP 70.07(5) RE-CIRCULATED WATER SYSTEMS. (a) Re-circulated water used 13 in a cooler or heat exchanger shall be all of the following if there is any possibility that 14 the re-circulated water may come in contact with any food product or food contact 15 surface: 16 1. Obtained from a source that complies with ch. NR 811 or NR 812, as 17 applicable. 18 2. Bacteriologically safe. 19 3. Protected from contamination.
- 20
  - 4. Tested by the food processing plant operator at least semiannually.

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

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

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

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

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

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

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

1 3. It may not be used to haul non-food products such as toxic materials,

2 petroleum products, or other harmful substances.

- 3 4. It shall be effectively sealed to protect the potable water or potable liquid from4 contamination during transit.
- 5 **NOTE:** Effective sealing systems include manhole cover gaskets and seals.
- 5. It shall be properly stored and serviced to prevent contamination. When not in
  use, pumps, hoses and fittings shall be properly maintained, capped, stored, and protected
  from contamination.
- 9 (7) CULINARY STEAM. (a) Water used to produce culinary steam shall be potable.
- 10 Water reclaimed from food processing operations may not be used to produce culinary

11 steam unless it complies with sub. (3)(a) or (b). In boilers used to produce culinary

12 steam, boiler water additives shall comply with 21 CFR 173.310.

13 SECTION 20. ATCP 70.08(2) is amended to read:

14 ATCP 70.08(2) EGGS AND EGG PRODUCTS. Only clean whole eggs, pasteurized

15 eggs in liquid, frozen or dry form, or pasteurized egg products may be used in food

16 processing. Eggs and egg products may be pasteurized during processing. Clean whole

17 eggs shall be equivalent to USDA Grade B or better with shells intact-and without cracks
18 and checks.

**SECTION 21.** ATCP 70.10(title) is repealed and recreated to read:

- 20 ATCP 70.10 Food packaging and labeling.
- 21 SECTION 22. ATCP 70.10(5) is created to read:

| 1                                            | ATCP 70.10(5) FOOD PACKAGE LABELING. Packaged food shall be packaged and                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2                                            | labeled according to all of the following, as applicable:                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 3                                            | (a) 21 CFR 101.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 4                                            | (b) Section 97.09, Stats., and federal regulations incorporated by reference in s.                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 5                                            | 97.09, Stats.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 6                                            | (c) Chapter ATCP 90.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 7                                            | (d) Chapter ATCP 75 Appendix, Wisconsin Food Code s. 3-201.11(C).                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 8                                            | (e) If the packaged food contains a major food allergen, or protein from a major                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 9                                            | food allergen, the ingredient statement on the package shall disclose the common name of                                                                                                                                                                                                                                                                                                                                                                                                            |
| 10                                           | the major food allergen. The disclosure shall be equivalent in size and prominence to the                                                                                                                                                                                                                                                                                                                                                                                                           |
| 11                                           | rest of the ingredient statement. If an allergen originates from fish, crustacean shellfish                                                                                                                                                                                                                                                                                                                                                                                                         |
| 12                                           | or tree nuts, the disclosure shall include the common name of the source species.                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 13<br>14<br>15<br>16<br>17<br>18<br>19<br>20 | <i>NOTE:</i> For example, if a food product includes an allergen that originates from fish, the ingredient statement must disclose the common species name such as bass, flounder or cod. If the allergen originates from crustacean shellfish, the ingredient statement must disclose the common species name such as crab, lobster or shrimp. If the allergen originates from tree nuts, the ingredient statement must disclose the common species name such as almond, pecan, walnut or coconut. |
| 20<br>21                                     | <b>SECTION 23.</b> ATCP 70.11(4) is repealed and recreated to read:                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 22                                           | ATCP 70.11(4) SANITIZERS; DEPARTMENT APPROVAL. (a) Sanitizers                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 23<br>24                                     | approved under ch. ATCP 75 Appendix, Wisconsin Food Code s. 4-501.114 are also                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 25                                           | approved by the department for purposes of sub. (1)(e). The department may approve                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 26                                           | other sanitizers and sanitizing methods that it finds to be safe and effective for the                                                                                                                                                                                                                                                                                                                                                                                                              |
| 27                                           | purpose used.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

| 1                                                                    | (b) The department may deny or withdraw approval of any sanitizer or sanitizing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2                                                                    | method approved under par. (a), regardless of whether that sanitizer or sanitizing method                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 3                                                                    | is approved by any other state or federal agency, if the department determines that the                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| U                                                                    | is approved by any basic state of rederar agency, if the department determines that the                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 4                                                                    | sanitizer or sanitizing method is not safe or effective for the purpose or under the                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 5                                                                    | conditions used, or that it adversely affects the sanitary characteristics of equipment,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 6                                                                    | utensils or food packages.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 7                                                                    | SECTION 24. ATCP 70.11(4)(note) is repealed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 8                                                                    | SECTION 25. ATCP 70.117 is created to read:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 9                                                                    | ATCP 70.117 Recall plan. A food processing plant operator shall have a written                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 10                                                                   | plan for identifying and recalling food produced at that plant, should a food recall become                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 11                                                                   | necessary. The operator shall update the plan as necessary, and shall make it available to                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 12                                                                   | the department for inspection and copying upon request.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 13<br>14<br>15<br>16<br>17<br>18<br>19<br>20                         | <i>NOTE:</i> Section ATCP 70.117 requires a food processing plant operator to have written recall plan, but does not dictate the contents of that plan or prohibit variations from the plan in the event of an actual recall (based, for example, unexpected circumstances that were not fully anticipated by the plan). The operator determines the plan contents and ultimate recall procedures. However, the plan should normally do all of the following things, among others:                                                                                                                                                                                                                                                                                                            |
| 21<br>22<br>23<br>24<br>25<br>26<br>27<br>28<br>29<br>30<br>31<br>32 | <ul> <li>Identify key individuals or positions that are responsible for planning, approving and implementing recalls.</li> <li>Identify key individuals or entities to be contacted or consulted in connection with a recall.</li> <li>Ensure routine identification, dating and tracking of food production lots, so that that affected lots can be identified (and distinguished from unaffected lots) in the event of a recall.</li> <li>Ensure routine identification, dating and tracking of food shipments from the food processing plant. Tracking should identify shipment recipients and contents (cross-referenced to production lots), so that recipients of affected lots can be contacted in the event of a recall (without troubling recipients of unaffected lots).</li> </ul> |

| 1<br>2<br>3                                        | • Spell out procedures for determining the nature and scope of a recall, including affected food production lots, shipments, and shipment recipients.                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4<br>5<br>6<br>7<br>8<br>9<br>10<br>11<br>12<br>13 | <ul> <li>Spell out plans and procedures for identifying and communicating with affected persons, including suppliers, food shipment recipients, down-line buyers, consumers, government agencies and others. The plan should identify possible target audiences, communication methods, and key messages. Key messages may include, for example, identification of the affected food, the reason for the recall, the nature of the food safety risk, the nature and scope of the recall, suggested actions to be taken by affected persons, and key recall terms and conditions.</li> </ul> |
| 14                                                 | SECTION 26. ATCP 70.13 is amended to read:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 15                                                 | ATCP 70.13 Thermally processed low-acid Low-acid foods packaged in                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 16                                                 | hermetically sealed containers. Persons who thermally process and package low-acid                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 17                                                 | foods in hermetically sealed containers shall comply with applicable federal regulations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 18                                                 | under 21 CFR 113.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 19                                                 | <b>SECTION 27.</b> ATCP 70.13(note) is repealed and recreated to read:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 20<br>21<br>22                                     | <i>NOTE:</i> Section ATCP 70.13 applies to all low-acid foods processed and packaged in hermetically sealed containers, including thermally processed and aseptically processed low-acid foods.                                                                                                                                                                                                                                                                                                                                                                                             |
| 23<br>24                                           | SECTION 28. ATCP 70.18 is repealed and recreated to read:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 25                                                 | ATCP 70.18 Fish processing. (a) Fish processing operations shall comply with                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 26                                                 | subch. II and 21 CFR 123.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 27                                                 | SECTION 29. ATCP 70.18(note) is created to read:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 28<br>29<br>30<br>31<br>32<br>33<br>34<br>35       | <i>NOTE:</i> Federal regulations under 21 CFR 123 require fish processing plant operators to prepare HACCP plans to address foreseeable hazards associated with fish processing operations. 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, in their HACCP plans, relevant operations contained in <i>Appendix A</i> to this chapter.                   |

| 1<br>2 | (b) Processed fish shall immediately be refrigerated to a temperature of $38^{\circ}F(3^{\circ})$ |  |
|--------|---------------------------------------------------------------------------------------------------|--|
| 3      | C) or below, and shall be kept at or below that temperature until sold to consumers at            |  |
| 4      | retail, unless one of the following applies:                                                      |  |
| 5      | 1. The fish are salted fish and have a salt content of at least 20%.                              |  |
| 6      | 2. The fish are frozen immediately after processing, and kept frozen until sold to                |  |
| 7      | consumers at retail.                                                                              |  |
| 8      | SECTION 30. ATCP 70.185 is repealed.                                                              |  |
| 9      | SECTION 31. ATCP 70.19 and 70.20 are repealed and recreated to read:                              |  |
| 10     | ATCP 70.19 Labeling and sale of smoked fish. (1) Every food package                               |  |
| 11     | containing smoked fish shall be clearly and conspicuously labeled, on the principal               |  |
| 12     | display panel of that package, with all of the following information:                             |  |
| 13     | (a) The name and address of the smoked fish processor or distributor.                             |  |
| 14     | (b) The name of the product, including the common species name of the fish                        |  |
| 15     | from which the product is derived.                                                                |  |
| 16     | (c) The net weight of the package contents.                                                       |  |
| 17     | (d) If smoked fish contained in the package are sold or distributed in an unfrozen                |  |
| 18     | state, the words "PERISHABLE - KEEP REFRIGERATED AT OR BELOW 38° F" in                            |  |
| 19     | conspicuous letters at least the size of those used in the food name.                             |  |
| 20     | (e) If smoked fish contained in the package are sold or distributed in a frozen                   |  |
| 21     | state, the words "PERISHABLE-KEEP FROZEN PRIOR TO USE" in conspicuous                             |  |
| 22     | letters at least the size of those used in the food name.                                         |  |
| 23     | (f) The processing date of the smoked fish.                                                       |  |

| 1  | (2) Smoked fish processed on different dates may not be commingled in the same                       |
|----|------------------------------------------------------------------------------------------------------|
| 2  | container, either at the processing plant or while the fish are being stored, distributed or         |
| 3  | offered for sale at wholesale or retail.                                                             |
| 4  | (3) No person may misrepresent a smoked fish processing date, or sell or                             |
| 5  | distribute smoked fish under any processing date other than the original processing date             |
| 6  | stated by the processor.                                                                             |
| 7  | (4) Food consisting of or containing smoked fish shall be immediately removed                        |
| 8  | from sale, and shall be destroyed or treated to render it unattractive and unfit for human           |
| 9  | consumption, if any of the following occurs:                                                         |
| 10 | (a) The food package is not labeled with a processing date.                                          |
| 11 | (b) The food is held at a temperature above $38^{\circ}$ F. (3.4 $^{\circ}$ C.) at any time prior to |
| 12 | retail sale. This paragraph does not apply to a food which the department specifically               |
| 13 | exempts in writing because it is not a potentially hazardous food.                                   |
| 14 | (5) No smoked fish may be sold, distributed, or offered or exposed for sale in this                  |
| 15 | state unless the smoked fish have been processed, labeled and handled in compliance                  |
| 16 | with this subchapter. This subsection applies to every person engaged in the sale or                 |
| 17 | distribution of smoked fish in this state, regardless of whether the person processes                |
| 18 | smoked fish in this state.                                                                           |
| 19 | (6) Smoked fish may not be sold or distributed in a frozen state unless the fish are                 |
| 20 | frozen at the smoked fish processing plant and kept frozen until sold at retail. Frozen              |
| 21 | smoked fish may not be thawed for sale in an unfrozen state.                                         |

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

| 3  | ATCP 70.20 Fish roe. (1) REFRIGERATION. Roe and any attached entrails                        |
|----|----------------------------------------------------------------------------------------------|
| 4  | harvested from a fish shall at all times be refrigerated at a temperature of not more than   |
| 5  | 38° F. (3.4° C.), except that processing areas used to dry salted roe or salted roe product  |
| 6  | may be kept at a temperature of not more than 50° F. (10° C.).                               |
| 7  | (2) HARVESTING AND HANDLING. Roe and attached entrails, if any, shall be                     |
| 8  | harvested, stored and transported for processing in covered food grade containers. Each      |
| 9  | container shall be conspicuously labeled to indicate when each of the following              |
| 10 | operations was performed, if that operation has been performed:                              |
| 11 | (a) The roe and attached entrails, if any, were harvested from the fish.                     |
| 12 | (b) The roe sacks were separated from attached entrails, if any. Roe sacks shall             |
| 13 | be separated from attached entrails within 48 hours after the roe sacks and entrails are     |
| 14 | harvested from the fish.                                                                     |
| 15 | (c) The roe was separated from the roe sacks. Roe shall be separated from roe                |
| 16 | sacks within 72 hours after the roe sacks are harvested from the fish, unless the roe is     |
| 17 | processed and packed in roe sacks. Roe processed and packed in roe sacks shall be            |
| 18 | processed and packed within 72 hours after the roe sacks are harvested from the fish.        |
| 19 | (3) RECEIPT FOR PROCESSING. A fish processing plant operator may not accept                  |
| 20 | for processing any roe that has been held, transported or processed in violation of sub. (1) |
| 21 | or (2).                                                                                      |

| 1 | (4) PROCESSING STANDARDS. (a) Roe shall be held and processed according to s. |
|---|-------------------------------------------------------------------------------|
| 2 | ATCP 70.09(1).                                                                |

- 3 (b) Processed roe shall contain a minimum of 2.5% salt by weight, as determined4 by quantitative analysis for total salt content.
- 5 (c) No fish processing plant personnel may have direct hand contact with
- 6 finished, ready-to-eat roe.
- 7 (5) PRODUCT REPRESENTATION. (a) No roe product may be labeled or
- 8 represented as "caviar" unless one of the following applies:
- 9 1. The product consists only of the eggs of sturgeon prepared by a salting and
- 10 separation process traditionally associated with the term "caviar."
- 1 2. The product consists of roe prepared by a salting and separation process
- 12 traditionally associated with the term "caviar," and the name of the fish species is clearly
- 13 disclosed with the term "caviar" whenever that term is used.
- *NOTE:* For example, a caviar-type product made from whitefish eggs, using the traditional caviar process, may not be labeled as "caviar" unless it is labeled as "whitefish caviar." All packaged food product labels, including "caviar" labels, must also include a statement of ingredients listed by their common or usual names in descending order of prominence (see ATCP 70.10).
- 21 (b) No person may misrepresent the identity or value of any roe product by
- 22 adding a color additive to that roe product.
- **SECTION 32.** ATCP 70.21 and 70.22 are repealed.
- 24 SECTION 33. ATCP 70.23 is repealed and recreated to read:
- 25 ATCP 70.23 Bottling establishments; general. Bottling establishments shall
- 26 comply with subchapter II and this subchapter. Bottling establishments producing bottled

water shall comply with 21 CFR 129. Bottling establishments engaged in juice
 processing shall comply with 21 CFR 120.

SECTION 34. ATCP 70.225 is repealed.
SECTION 35. ATCP 70.26(3) and (4) are repealed and recreated to read:
ATCP 70.26(3) The operator of a bottling establishment shall collect and analyze
representative samples of bottled product to provide reasonable assurance of compliance
with sub. (2). For contaminant types identified in sub. (4), the operator shall collect and
test samples at no less than the frequency required under sub. (4).

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

| CONTAMINANT                                   | TEST FREQUENCY                                                                                                                                                                                                                                                                             |
|-----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Bacteria                                      | Monthly, except that bottled water shall be tested weekly per 21 CFR 129.80(g)(1).                                                                                                                                                                                                         |
| Nitrate                                       | Quarterly                                                                                                                                                                                                                                                                                  |
| Volatile Organics<br>Pesticides<br>Inorganics | <ul> <li>Every 3 years, except that the following tests shall be performed annually:</li> <li>Tests on bottled water, per 21 CFR 129.80(g)(2).</li> <li>Tests for any contaminant found in any sample in excess of the legal limit for that contaminant under s. ATCP 70.07(2).</li> </ul> |
| Radionuclides                                 | <ul> <li>Every 5 years, except that the following tests shall be performed annually:</li> <li>Tests on bottled water, per 21 CFR 129.80(g)(2).</li> <li>Tests for any contaminant found in any sample in excess of the legal limit for that contaminant under s. ATCP 70.07(2).</li> </ul> |

- 1 SECTION 36. ATCP 70.26(4)(note) is repealed.
- **SECTION 37.** ATCP 70.26(5) is renumbered (6).

**SECTION 38.** ATCP 70.26(5) is created to read:

| 2       | ATCP 70.26(5) Notwithstanding subsections (3) and (4), if the operator of a             |
|---------|-----------------------------------------------------------------------------------------|
| 3       | bottling establishment obtains ingredient water from a municipal source that complies   |
| 4       | with sub. (2), the operator is not required to test bottled product for any contaminant |
| 5       | other than bacteria unless one of the following applies:                                |
| 6       | (a) The operator has reason to suspect that the contaminant may be present in that      |
| 7       | ingredient water or in the bottled product.                                             |
| 8<br>9  | (b) Testing is required under 21 CFR 129.80(g) for bottled water.                       |
| 9<br>10 | SECTION 39. ATCP 70.261 and 70.262 are created to read:                                 |
| 11      | ATCP 70.261 Water and potable liquids transported in bulk. (1) Water                    |
| 12      | transported to a bottling establishment in a bulk tank or bulk container, for use as an |
| 13      | ingredient or in other plant operations, shall comply with s. ATCP 70.07(6)(a).         |
| 14      | (2) The operator of the bottling establishment operator shall collect at least          |
| 15      | weekly, and analyze for coliform bacteria and heterotrophic plate count, representative |
| 16      | samples of bulk ingredient water shipments received from each shipment source. If the   |
| 17      | operator receives bulk ingredient water shipments from any source less than weekly, the |
| 18      | operator shall collect and analyze a representative sample from each shipment from that |
| 19      | source.                                                                                 |
| 20      | (3) Whenever potable water or another potable liquid is transported in a bulk tank      |
| 21      | or bulk container to or from a bottling establishment:                                  |
| 22      | (a) The potable water or potable liquid shall be loaded, transported and unloaded       |
| 23      | in compliance with s. ATCP 70.07(6)(b).                                                 |

| 1  | (b) The bulk tank or bulk container, and each of its appurtenances, shall comply         |  |
|----|------------------------------------------------------------------------------------------|--|
| 2  | with s. ATCP 70.07(6)(c).                                                                |  |
| 3  | (4) An operator of a bottling establishment shall make a record of each bulk             |  |
| 4  | shipment under this section, and shall keep that record for at least 2 years. The record |  |
| 5  | shall include all of the following:                                                      |  |
| 6  | (a) The name and address of the person sending, and the person receiving, the            |  |
| 7  | shipment contents.                                                                       |  |
| 8  | (b) The name and address of the transport vehicle owner, and the name of the             |  |
| 9  | individual operator of the transport vehicle.                                            |  |
| 10 | (c) The identification number of the transport vehicle, if an identification number      |  |
| 11 | is publicly displayed on that vehicle.                                                   |  |
| 12 | (d) The date on which the shipment was received at, or shipped from, the bottling        |  |
| 13 | establishment.                                                                           |  |
| 14 | (e) The following information if the shipment originated from the bottling               |  |
| 15 | establishment:                                                                           |  |
| 16 | 1. The date on which the bulk tank or container was last cleaned and sanitized           |  |
| 17 | prior to the shipment.                                                                   |  |
| 18 | 2. The name and concentration of the sanitizer used to sanitize the bulk tank or         |  |
| 19 | container.                                                                               |  |
| 20 | (f) Laboratory results under sub. (2), if any.                                           |  |
| 21 | ATCP 70.262 Labeling bottled products. (1) Bottled products shall be labeled             |  |
| 22 | according to s. ATCP 70.10(5). Bottled water shall also be labeled according to 21 CFR   |  |
| 23 | 165.110.                                                                                 |  |

| 1 | (2) A juice label may not misrepresent that juice has been pasteurized. A juice             |
|---|---------------------------------------------------------------------------------------------|
| 2 | label may not represent as "fresh" any juice that has been treated with ultra-violet light. |
| 3 | SECTION 40. Appendix A to ch. ATCP 70 is created in the form attached.                      |
| 4 | SECTION 41. EFFECTIVE DATE: This rule takes effect on the first day of the                  |
| 5 | month following publication in the Wisconsin administrative register, as provided under     |
| 6 | s. 227.22(2) (intro.), Stats.                                                               |

Dated this \_\_\_\_\_\_, \_\_\_\_,

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 plans (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  $38 \degree F$ . ( $3^{\circ}$  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  $145^{\circ}$  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 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.