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(FORM UPDATED: 08/11/2010)

## WISCONSIN STATE LEGISLATURE ... PUBLIC HEARING - COMMITTEE RECORDS

### 2009-10

(session year)

### Joint

(Assembly, Senate or Joint)

### Committee for Review of Administrative Rules ...

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#### INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

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  - (**ab** = Assembly Bill)                      (**ar** = Assembly Resolution)                      (**ajr** = Assembly Joint Resolution)
  - (**sb** = Senate Bill)                              (**sr** = Senate Resolution)                              (**sjr** = Senate Joint Resolution)
- Miscellaneous ... **Misc**

\* Contents organized for archiving by: Stefanie Rose (LRB) (June 2012)



State of Wisconsin  
Jim Doyle, Governor

Senator Jim Holperin  
JCRAR Co-Chair  
409 South, State Capitol

Department of Agriculture, Trade and  
Consumer Protection  
Rod Nilsestuen, Secretary

## PUBLIC NOTICE

### FINAL DRAFT RULE TO LEGISLATURE

The Department of Agriculture, Trade and Consumer Protection announces that it is submitting the following rule for legislative committee review, pursuant to s. 227.19, Stats.:

CLEARINGHOUSE RULE #: **09-009**  
SUBJECT: **Food Processing Plants**  
ADM. CODE REFERENCE: **ATCP 70**  
DATCP DOCKET #: **06-R-07**

Dated this 27 day of May, 2009.

STATE OF WISCONSIN  
DEPARTMENT OF AGRICULTURE, TRADE AND  
CONSUMER PROTECTION

By Randy Romani for Rod Nilsestuen  
Rodney J. Nilsestuen  
Secretary

*Agriculture generates \$51.5 billion for Wisconsin*



State of Wisconsin  
Jim Doyle, Governor

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Department of Agriculture, Trade and Consumer Protection  
Rod Nilsestuen, Secretary

**DATE:** May 26, 2009

**TO:** The Honorable Fred Risser  
President, Wisconsin State Senate  
Room 220, South, State Capitol  
PO Box 7882  
Madison, WI 53707-7882

The Honorable Michael Sheridan  
Speaker, Wisconsin State Assembly  
Room 211 West, State Capitol  
PO Box 8953  
Madison, WI 53708-8953

**FROM:** Rodney J. Nilsestuen, Secretary *Rod Nilsestuen*  
Department of Agriculture, Trade and Consumer Protection

**SUBJECT:** **Food Processing Plants; Final Draft Rule** (*Clearinghouse Rule #09-009*)

The Department of Agriculture, Trade and Consumer Protection ("DATCP") is transmitting this final draft rule for legislative committee review, as provided in s. 227.19(2) and (3), Stats. DATCP will publish notice of this referral in the Wisconsin Administrative Register, as provided in s. 227.19(2), Stats.

### ***Background***

The Department of Agriculture, Trade and Consumer Protection ("DATCP") administers Wisconsin food safety programs. Among other things, DATCP licenses and inspects wholesale food processing plants. DATCP has adopted food processing plant rules under ch. ATCP 70, Wis. Adm. Code.

This rule updates current food processing plant rules. This rule applies to wholesale food processing plants *other than* dairy plants and meat processing plants. This rule does *not* apply to food warehouses (except those included in food processing plants) or retail food establishments.

Food processing is constantly changing, and it is important to keep rules up-to-date with current food technology and food safety concerns. Modern regulation emphasizes hazard analysis and critical control point (HACCP) systems to identify and control food safety hazards. Disease outbreaks in other states have also underlined the importance of food identification, tracking, recordkeeping and recall plans. DATCP also strives to keep its rules reasonably consistent with federal rules, to ensure a seamless national system of regulation.

*Agriculture generates \$51.5 billion for Wisconsin*

### *Rule Contents*

This rule updates current DATCP rules and harmonizes them with current federal rules. This rule does all of the following:

- ***Definitions.*** This rule harmonizes current definitions with federal rules and Wisconsin retail food rules under ch. ATCP 75 (Model Food Code).
- ***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 establish written policies and procedures, and an employee training program, to prevent food contamination from bare-hand contact. Requirements are consistent with current retail food rules under ATCP 75 (Model Food Code).
- ***Cleaning and sanitizing procedures.*** This rule updates and clarifies current requirements for cleaning and sanitizing food processing equipment and utensils, and it 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 establishes general content standards, but allows operators to determine plan specifics. Actual recall procedures may deviate from advance plans, as circumstances warrant.
- **Low-acid food packaged in hermetically sealed containers.** This rule clarifies that low-acid food packaged in hermetically sealed containers (including aseptically processed food as well as thermally processed food) must be processed according to federal rules under 21 CFR 113.
- **Fish processing; general.** This rule repeals and recreates current rules related to fish processing, in order to make the rules consistent with federal rules under 21 CFR 123.
  - Under federal rules and this rule, fish processors must have a 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, but shelf-life will be based on the HACCP plan per federal rules).
  - This rule updates and clarifies current rules related to processing, labeling and sale of fish eggs (roe). This rule applies to all fish roe, not just “caviar.” This rule clarifies current labeling requirements related to processed fish roe. A fish roe product, other than a sturgeon roe product, may not be labeled as “caviar” unless the name of the fish species is also disclosed (e.g., “whitefish caviar”).
- **Bottling establishments.** This rule updates and clarifies current rules related to bottling establishments.
  - Bottling establishments producing bottled water must comply with federal rules under 21 CFR 129.
  - Bottling establishments engaged in juice processing must comply with federal rules under 21 CFR 120.

- This rule updates and clarifies current product testing requirements, including test frequencies, and harmonizes current requirements with applicable federal rules. Operators who obtain ingredient water from municipal sources are exempt from some, but not all, testing requirements.
  - This rule regulates the transportation and handling of water and other potable liquids transported to or from a bottling establishment (see above). If ingredient water is transported to a bottling establishment in bulk, the operator must test the ingredient water at least weekly for coliform bacteria and heterotrophic plate count. An operator must keep records of bulk shipments.
  - Labeling of bottled products must comply with general food labeling standards (see above). Bottled water labeling must also comply with specific federal requirements under 21 CFR 165.110. A juice label may not misrepresent that juice has been pasteurized. A juice label may not represent as “fresh” any juice that has been treated with ultra-violet light.
- **Lab test methods.** This rule updates required laboratory methods for food safety tests, based on the latest methods published by AOAC International and the American Public Health Association.
  - **Organizational and technical drafting changes.** This rule makes other organizational, technical and drafting changes to update and clarify current rules.

### ***Public Hearings***

DATCP held 3 public hearings on this rule (hearings were extensively publicized). DATCP held the hearings on March 3, 2009 in Eau Claire, on March 12, 2009 in Appleton, and on March 13, 2009, in Madison. Twenty-five persons attended the hearings (3 in Eau Claire, 12 in Appleton and 10 in Madison).

- Seventeen persons registered no position, and did not comment on the proposal.
- Three persons registered in support, but did not comment.
- Three persons registered general concerns about provisions related to reclaimed and re-circulated water, but did not provide any specific comments.
- One person registered in opposition, but did not comment.
- Only one person registered to speak. Nick George, representing the Midwest Food Processors Association, expressed concerns about proposed rule provisions related to reclaimed and re-circulated water.

DATCP received subsequent written comments from Nick George on behalf of the Midwest Food Processors Association (comments were directed mainly at rule provisions related to reclaimed and re-circulated water). DATCP staff also met with Mark Collins from McCain Foods USA, Inc., to discuss proposed rule provisions related to reclaimed and re-circulated water. A more complete hearing summary is attached as *Appendix A*.

### *Changes from the Hearing Draft*

- In response to comments from McCain Foods and the Midwest Food Processors Association, DATCP modified provisions related to reclaimed and re-circulated water. The modifications clarify DATCP intent, and meet the needs of food processing plants that routinely and safely use reclaimed and re-circulated water in their processing operations.
- DATCP made several editorial and structural changes suggested by the Legislative Council Rules Clearinghouse.
- DATCP made a substantive change to the section on caviar and fish eggs in response to a question posed by the Rules Clearinghouse.
- DATCP added a provision referencing the current food processing plant license fee surcharge under s. 97.29(3)(d), Stats., for plant operators found operating without a license. This is a purely technical change. It does not add a new surcharge, or change the amount of the existing statutory surcharge, but merely references the statutory surcharge that already exists (so that readers of the rule will be aware of that surcharge).

### *Response to Rules Clearinghouse Comments*

DATCP modified the final draft rule to address all of the Rules Clearinghouse Comments except the following:

- *Comment 2.k:* Comment applies to future rules.
- *Comment 5.a:* Adopted some but not all of the grammatical suggestions. Explained the "HACCP" acronym earlier in the rule preface.
- *Comment 5.c:* We assume that the Rules Clearinghouse question refers to s. ATCP 70.06(7)(c), not (6)(c). Tanks should be inspected more often if necessary for food safety. There are many potential circumstances that might warrant more frequent inspection (not all can be listed).

### ***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 it makes the rules consistent with other federal and state rules. These changes will eliminate inconsistent and duplicative regulation, and that will make it easier for food processors to comply. For the most part, 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 cost 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. Actual recall procedures may deviate from advance plans, as circumstances warrant.
- This rule incorporates current state and federal labeling requirements for processed food, including current federal requirements related to disclosure of major allergens. This rule may prompt food processors to review their labels for compliance with current law, but it does not add any major new labeling requirements.
- This rule requires food processors to keep certain records related to food processing operations, to help ensure food safety. Since the recordkeeping requirements are consistent with normal business practices, 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 provide training and assistance to affected small businesses. The University of Wisconsin-Extension may offer seminars and training sessions at modest cost.
- This rule will promote food safety, for the benefit of consumers *and* food processors. This rule will clarify current regulations, and make them more consistent. That will facilitate compliance by food processors. This rule will not have a significant adverse impact on small businesses (or other businesses), and it is not subject to the delayed small business effective date under s. 227.22(2)(e), Stats.

### *Federal and Surrounding State Regulation*

#### **Federal Regulation**

At the federal level, the United States Food and Drug Administration (FDA) is primarily responsible for regulating food processing plants. Wholesale food processors must register with FDA, but FDA does not license those food processors. 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, certain FDA regulations related to food labeling, canning operations, juice processing, fish processing and bottled water.

#### **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.

### *Environmental Impact*

This rule will not have a significant impact on the environment.

*Appendix A*  
*Summary of Hearing Testimony*

DATCP held 3 public hearings on this rule (hearings were extensively publicized). DATCP held the hearings on March 3, 2009 in Eau Claire, on March 12, 2009 in Appleton, and on March 13, 2009, in Madison. Twenty-five persons attended the hearings (3 in Eau Claire, 12 in Appleton and 10 in Madison).

- Seventeen persons registered no position, and did not comment on the proposal:
  1. Vern Winker, Blue Mounds (DairyFood USA, Inc.).
  2. Marvin Studzinski, Madison (Arctic Glacier, Inc.).
  3. Kelly Stidhum, Menomonie Falls (Arctic Glacier, Inc.).
  4. Dave Aggen, Manitowoc (Lakeside Foods, Inc.).
  5. Ben Scherwitz, Janesville? (Seneca Foods).
  6. Jim Farah, Green Bay (Meat Processors, Inc.).
  7. Chris Weichman, New Berlin (Wisconsin Glacier Springs).
  8. Bob Lace, Neenah (Collen's Tough Times)
  9. Samantha Clark, Fond du Lac
  10. Don Hartwig, Shawano (Twig's Beverage, Inc.).
  11. Michael Thurber, Lakewood (Thurber Distr., Inc.).
  12. Larry Osegard, Neillsville.
  13. Brad Legreid, Middleton (WI Dairy Products Assn.)
  14. Paul France, Two Rivers (Riverside Foods, Inc.).
  15. Guy Wisniewski, Antigo (DATCP).
  16. Herby Radmann, Menomonie (Bullfrog's Eat My Fish Farm).
  17. Jennifer Hall, Madison (Porchlight Products).
  
- Three persons registered in support, but did not comment:
  1. Michelle Roberts, Appleton (City of Appleton Health Department).
  2. Tim Mirkes, Appleton (City of Appleton Health Department).
  3. Tom Keel, Reedsburg (DATCP).
  
- Three persons registered general concerns about provisions related to reclaimed and re-circulated water, but did not provide any specific comments.
  1. Dave Vogl, Rochelle, IL (Del Monte, Midwest Food Processors Association).
  2. Steve Schuh, Darien (Birds Eye Foods).
  3. Sandra Welles, Darien (Birds Eye Foods).

The Honorable Fred Risser  
The Honorable Michael Sheridan  
May 26, 2009  
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- One person registered in opposition, but did not comment:
  1. Michael Yauser, Two Rivers (Riverside Foods, Inc.).
- Only one person registered to speak. Nick George, representing the Midwest Food Processors Association, expressed concerns about proposed rule provisions related to reclaimed and re-circulated water.

DATCP received subsequent written comments from Nick George on behalf of the Midwest Food Processors Association (comments were directed mainly at rule provisions related to reclaimed and re-circulated water). DATCP staff also met with Mark Collins from McCain Foods USA, Inc., to discuss proposed rule provisions related to reclaimed and re-circulated water.

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

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

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

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

***Statutes Interpreted***

Statutes interpreted: ss. 97.02, 97.03, 97.09, 97.10, 97.29  
and 97.34, Stats.

### *Statutory Authority*

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

### *Explanation of Statutory Authority*

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

### *Related Rules or Statutes*

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

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

### *Rule Contents*

This rule does all of the following:

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

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

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

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

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

#### ***Fiscal Impact***

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

#### ***Business Impact***

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

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

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

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

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

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

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

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

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

## *Federal and Surrounding State Regulation*

### **Federal Regulation**

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

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

### **Surrounding State Regulation**

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

### *Data and Analytical Methodologies*

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

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

### *Technical Standards Incorporated by Reference*

This rule incorporates the following technical standards by reference:

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

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

***DATCP Contact***

Questions about this rule may be directed to:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 5 1. The individuals or positions authorized to contact ready-to-eat food with bare  
6 hands.
- 7 2. The specific tasks for which bare-hand contact is authorized.
- 8 3. The types of ready-to-eat food that may be contacted with bare hands.
- 9 4. The procedures that authorized individuals are required to follow in order to  
10 prevent food contamination from bare-hand contact.

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

- 14 1. The individuals or positions responsible for implementing the training,  
15 maintaining training records, and ensuring compliance with training requirements.
- 16 2. The content of the training, including the written procedures required under  
17 par. (b).
- 18 3. The form of initial training, and the form and frequency of follow-up training  
19 if any.
- 20 4. Monitoring and control procedures to ensure that individuals are trained before  
21 they contact ready-to-eat food with bare hands.
- 22 5. Procedures to evaluate training effectiveness.

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

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

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

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

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

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

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

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

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

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

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

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

- 14           1. Drying equipment.
- 15           2. Cloth-collector systems.
- 16           3. Dry product packaging equipment and storage containers.
- 17           4. Equipment used in brining, aging, curing, and dry product blending processes.
- 18           5. Food contact surfaces of equipment used solely to process foods or food  
19 ingredients with low water activity, such as chocolate, fats and oils, liquid nutritive  
20 sweeteners, peanut butter, or similar foods which are not potentially hazardous.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1           **NOTE:** Copies of the *Standard Methods for the Examination of Water and Waste*  
2           *Water*, twenty-first edition (2005), published by the American Public  
3           Health Association (APHA), the American Water Works Association and  
4           the Water Environment Federation, are on file with the department and the  
5           legislative reference bureau. Copies may be obtained by contacting the  
6           “APHA Bookstore” at [www.apha.org/publications/bookstore/](http://www.apha.org/publications/bookstore/).  
7

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

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

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

14           2. Bacteriologically safe.

15           3. Protected from contamination.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 (a) 21 CFR 101.

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

19 (c) Chapter ATCP 90.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Nitrate	Quarterly
Volatile Organics Pesticides Inorganics	<p>Every 3 years, except that the following tests shall be performed annually:</p> <ul style="list-style-type: none"> <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	<p>Every 5 years, except that the following tests shall be performed annually:</p> <ul style="list-style-type: none"> <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 39.** ATCP 70.26(4)(note) is repealed.

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

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

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

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

8  
9

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

By \_\_\_\_\_  
Rodney J. Nilsestuen, Secretary

## Chapter ATCP 70

### APPENDIX A

#### Smoked Fish Processing

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

##### (1) Salting or Brining

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

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

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

- (3) **Hot-Processed Smoked Fish In Reduced Oxygen Packages.** Hot-processed smoked fish packaged in reduced oxygen packages shall be processed as follows:
- (a) Each fish shall be brined under sub. (1) so that the finished smoked fish contains at least 3.5% water-phase salt, except that fish brined with a sodium nitrite solution containing not less than 100 parts per million nor more than 200 parts per million of sodium nitrite may be brined so that the finished smoked fish contains at least 3.0% water-phase salt.
  - (b) Each fish shall be heated so that the entire fish is held at a continuous internal temperature of at least 145 °F. (63 °C.) for at least 30 minutes.
- (4) **Cold-Process Smoked Fish.** Cold-process smoked fish shall be processed as follows:
- (a) Each fish shall be dry salted or brined so that the finished smoked fish contains at least 3.5% water-phase salt, except that:
    - 1. Fish brined with a sodium nitrite solution containing not less than 100 parts per million nor more than 200 parts per million of sodium nitrite may be brined so that the finished smoked fish contains at least 3.0% water-phase salt.
    - 2. Fish which is frozen immediately after smoking, and which remains frozen until sold to consumers at retail, may be brined so that the finished smoked fish contains at least 2.5% water-phase salt. The fish shall be labeled according to s. ATCP 70.19(1)(e).
  - (b) Each fish shall be smoked at a temperature of not more than 90° F. (32° C.) for not more than 20 hours, or at a temperature of not more than 50° F. (10° C.) for not more than 24 hours.
- (5) **Temperature Records.** Every smokehouse shall be equipped with a temperature recording device, which is designed, installed and maintained to make a continuous record of the internal temperatures of smoked fish. The temperature recording device shall record the internal temperature of the loin muscle of fish, which are located in the coldest portion of the smokehouse. For every lot of fish smoked, a fish processing plant operator shall keep a time-temperature recording chart that identifies the specific oven or chamber load and the processing date. Time and temperature records shall be kept on file in the smoked fish processing plant for at least 6 months. Temperature recording devices shall be accurate to within one degree Fahrenheit or 0.5° Celsius.

## Wisconsin Department of Agriculture, Trade and Consumer Protection

### Business Impact Analysis<sup>1</sup>

**Rule Subject:** Food Processing Plants  
**Adm. Code Reference:** ch. ATCP 70  
**Rules Clearinghouse #** 09-009  
**DATCP Docket #:** 06-R-07

#### *Rule Summary*

The Department of Agriculture, Trade and Consumer Protection ("DATCP") licenses and inspects wholesale food processing plants. DATCP has adopted food processing plant rules under ch. ATCP 70, Wis. Adm. Code. This rule updates current DATCP rules and harmonizes them with current federal rules. This rule does all of the following:

- **Definitions.** This rule harmonizes current definitions with federal rules and Wisconsin retail food rules under ch. ATCP 75 (Model Food Code).
- **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 establish written policies and procedures, and an employee training program, to prevent food contamination from bare-hand contact. Requirements are consistent with current retail food rules under ATCP 75 (Model Food Code).
- **Cleaning and sanitizing procedures.** This rule updates and clarifies current requirements for cleaning and sanitizing food processing equipment and utensils, and it 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).

<sup>1</sup> This analysis includes, but is not limited to, a small business analysis ("regulatory flexibility analysis") under s. 227.114, Stats.

- ***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 establishes general content standards, but allows operators to determine plan specifics. Actual recall procedures may deviate from advance plans, as circumstances warrant.
- ***Low-acid food packaged in hermetically sealed containers.*** This rule clarifies that low-acid food packaged in hermetically sealed containers (including aseptically processed food as well as thermally processed food) must be processed according to federal rules under 21 CFR 113.
- ***Fish processing; general.*** This rule repeals and recreates current rules related to fish processing, in order to make the rules consistent with federal rules under 21 CFR 123.
  - Under federal rules and this rule, fish processors must have a 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, but shelf-life will be based on the HACCP plan per federal rules).
  - This rule updates and clarifies current rules related to processing, labeling and sale of fish eggs (roe). This rule applies to all fish roe, not just “caviar.” This rule clarifies current labeling requirements related to processed fish roe. A fish roe product, other than a sturgeon roe product, may not be labeled as “caviar” unless the name of the fish species is also disclosed (e.g., “whitefish caviar”).

- ***Bottling establishments.*** This rule updates and clarifies current rules related to bottling establishments.
  - Bottling establishments producing bottled water must comply with federal rules under 21 CFR 129.
  - Bottling establishments engaged in juice processing must comply with federal rules under 21 CFR 120.
  - This rule updates and clarifies current product testing requirements, including test frequencies, and harmonizes current requirements with applicable federal rules. Operators who obtain ingredient water from municipal sources are exempt from some, but not all, testing requirements.
  - This rule regulates the transportation and handling of water and other potable liquids transported to or from a bottling establishment (see above). If ingredient water is transported to a bottling establishment in bulk, the operator must test the ingredient water at least weekly for coliform bacteria and heterotrophic plate count. An operator must keep records of bulk shipments.
  - Labeling of bottled products must comply with general food labeling standards (see above). Bottled water labeling must also comply with specific federal requirements under 21 CFR 165.110. A juice label may not misrepresent that juice has been pasteurized. A juice label may not represent as “fresh” any juice that has been treated with ultra-violet light.
- ***Lab test methods.*** This rule updates required laboratory methods for food safety tests, based on the latest methods published by AOAC International and the American Public Health Association.
- ***Organizational and technical drafting changes.*** This rule makes other organizational, technical and drafting changes to update and clarify current rules.

### ***Effects on Business***

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

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

This rule requires fish processors and juice processors to implement HACCP plans. But federal rules already require HACCP plans, and there will be no added cost to affected 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.

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

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

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

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

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

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

#### *Accommodation for Small Business*

This rule will make it easier for affected businesses to understand and comply with the rules that apply to them. DATCP will send copies of the rules to all affected businesses and will offer education and training, including education and training during inspections.

Many food processors have already established HACCP and food recall plans, but some processors may need to develop or improve plans to comply with this rule. Some processors may also need to make physical changes in their processing operations. In most cases, the required changes can be readily implemented. Despite a substantial business outreach effort, DATCP received few adverse business comments on this rule.

This rule will not have any significant adverse impacts on small business. DATCP has not exempted small businesses, because the food safety and other requirements under this rule are important for small as well as large businesses. DATCP has already adopted a rule (subch. VII of ch. ATCP 1) that allows DATCP to exercise enforcement discretion for small business.

### *Conclusion*

This rule generally benefits affected business by clarifying current regulatory requirements. This rule will not have any significant adverse impacts on affected businesses. This rule does not increase industry fees. This rule is not subject to the delayed "small business" effective date provided in s. 227.22(2)(e), Stats.

Dated this 27th day of April, 2009

STATE OF WISCONSIN  
DEPARTMENT OF AGRICULTURE,  
TRADE AND CONSUMER PROTECTION

By Steven C. Ingham  
Steven C. Ingham, Administrator  
Division of Food Safety

**FISCAL ESTIMATE**

DOA-2048 N(R10/98)

- ORIGINAL       UPDATED
- CORRECTED       SUPPLEMENTAL

LRB No. and Bill/Adm. Rule No.

09-009 ATCP 70

Amendment No. if Applicable

amending rules

**Food Processing Plants**

**Fiscal Effect**

**State:**  No State Fiscal Effect

Check columns below only if bill makes a direct appropriation or affects a sum certain appropriation

- Indeterminate
- Increase Existing Appropriation       Increase Existing Revenues
- Decrease Existing Appropriation       Decrease Existing Revenues
- Create New Appropriation

- Increase Costs - May be possible to Absorb Within Agency's Budget  Yes  No
- Decrease Costs

**Local:**  No Local Government Costs

- |   |   |   |
|---|---|---|
| <p>1. <input type="checkbox"/> Increase Costs</p> <p><input type="checkbox"/> Permissive      <input type="checkbox"/> Mandatory</p> <p>2. <input type="checkbox"/> Decrease Costs</p> <p><input type="checkbox"/> Permissive      <input type="checkbox"/> Mandatory</p> | <p>3. <input type="checkbox"/> Increase Revenues</p> <p><input type="checkbox"/> Permissive      <input type="checkbox"/> Mandatory</p> <p>4. <input type="checkbox"/> Decrease Revenues</p> <p><input type="checkbox"/> Permissive      <input type="checkbox"/> Mandatory</p> | <p>5. Types of Local Governmental Units Affected:</p> <p><input type="checkbox"/> Towns      <input type="checkbox"/> Villages      <input type="checkbox"/> Cities</p> <p><input type="checkbox"/> Counties      <input type="checkbox"/> Others</p> <p><input type="checkbox"/> School Districts      <input type="checkbox"/> WTCS Districts</p> |
|---|---|---|

**Fund Sources Affected**

- GPR    FED    PRO    PRS    SEG    SEG-S

**Affected Ch. 20 Appropriations**

**Assumptions Used in Arriving at Fiscal Estimate**

**Background**

DATCP will modify the rules concerning food processing plants to make them consistent with current FDA and Wisconsin retail food processing regulations. This update will bring us in line with current recall, labeling, and processing standards and practices mandated by the FDA.

**Impact of the Proposed Rule on State Government**

Though there will be costs to print and distribute copies of the new rule, most of the distribution can actually be done electronically for state staff and the cost of printing "hard" copies can be absorbed by DATCP.

Much of the training can be incorporated into existing district and bureau meetings, and training for industry can be done on an "as-needed" basis during routine inspectional visits, which can also be absorbed by DATCP.

**Impact of the Proposed Rule on Local Governments**

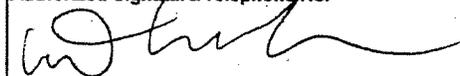
Local governments do not regulate food processors covered under this rule, so there will be no impact on them. Additionally, this rule does not absorb any categories of food processors now under local jurisdiction, so local governments with agent status will not lose any revenue.

**Long-Range Fiscal Implications**

Agency/Prepared by: (Name & Phone No.)

Dept of Agriculture, Trade & Consumer Protection

Authorized Signature/Telephone No.



Date

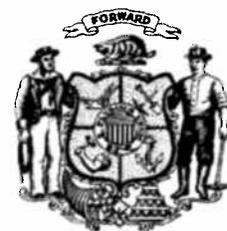
4/29/09

Arthur J. Nass (608) 224-4745

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# WISCONSIN STATE LEGISLATURE





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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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**Ronald Sklansky**  
*Clearinghouse Director*

**Richard Sweet**  
*Clearinghouse Assistant Director*

**Terry C. Anderson**  
*Legislative Council Director*

**Laura D. Rose**  
*Legislative Council Deputy Director*

### CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

#### CLEARINGHOUSE RULE **09-009**

AN ORDER to repeal ATCP 70.11 (4) (note), 70.185, 70.21, 70.22, 70.225, and 70.26 (4) (note); to renumber ATCP 70.02 (22m) and 70.26 (5); to renumber and amend ATCP 70.02 (17m); to amend ATCP 70.02 (6), (16) (d), (17), and (20), 70.03 (7) (b) (intro.), 70.04 (7) (b) (intro.), 70.06 (3), 70.08 (2), and 70.13; to repeal and recreate ATCP 70.02 (22), (22n), and (23), 70.04 (9) (b), 70.06 (7), 70.07 (3), 70.10 (title), 70.11 (4), 70.13 (note), 70.18, 70.19, 70.20, and 70.26 (3) and (4); and to create ATCP 70.02 (18m), (19m), (22m), and (22p), 70.05 (1m), 70.06 (7m), 70.07 (5) to (7), 70.10 (5), 70.117, 70.18 (note), 70.23, 70.26 (5), 70.261, 70.262, and chapter ATCP 70 Appendix A, relating to food processing plants.

Submitted by **DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION**

01-29-2009 RECEIVED BY LEGISLATIVE COUNCIL.

02-23-2009 REPORT SENT TO AGENCY.

RS:DLI

**LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT**

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]  
Comment Attached            YES                             NO
  
2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]  
Comment Attached            YES                             NO
  
3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]  
Comment Attached            YES                             NO
  
4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS  
[s. 227.15 (2) (e)]  
Comment Attached            YES                             NO
  
5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]  
Comment Attached            YES                             NO
  
6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL  
REGULATIONS [s. 227.15 (2) (g)]  
Comment Attached            YES                             NO
  
7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]  
Comment Attached            YES                             NO



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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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*Clearinghouse Director*

**Richard Sweet**  
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**Laura D. Rose**  
*Legislative Council Deputy Director*

### CLEARINGHOUSE RULE 09-009

#### Comments

**[NOTE: All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated September 2008.]**

#### 2. Form, Style and Placement in Administrative Code

- a. The end of the rule preface should include a deadline for the submission of comments to the rule.
- b. In s. ATCP 70.02 (19m), a citation to the U.S. Code should be included.
- c. In the treatment of s. ATCP 70.02 (20), “14<sup>th</sup>” should be replaced with “fourteenth.”
- d. To facilitate further additions to s. ATCP 70.02, possibly avoiding a future renumbering problem similar to the one SECTIONS 6 and 7 of the rule are addressing, s. ATCP 70.02 (22m) should be renumbered s. ATCP 70.02 (22c), and the new definition of “ready-to-eat food” should be numbered s. ATCP 70.02 (22g). For the same reason, ss. ATCP 70.261 and 70.262 should be numbered ss. ATCP 70.263 and 70.267.
- e. Section ATCP 70.04 (9) (b) 4. should be numbered as a separate paragraph from the preceding subdivisions, as it addresses how the equipment is used, while the rest of the rule paragraph addresses the equipment’s design.
- f. Similarly, s. ATCP 70.05 (1m) (e) 6. should be a separate paragraph, phrased in the active voice, as follows: “The operator of a food processing plant shall review the training program under par. (c) at least annually.”
- g. SECTION 14 of the rule creates s. ATCP 70.05 (1m), but then incorrectly numbers it s. ATCP 70.05 (1). The latter should be corrected.

h. In order to present the administrative procedure being created in s. ATCP 70.06 (7m) in chronological order, what is drafted as par. (e) should be the first paragraph of that subsection.

i. Section ATCP 70.07 (5) (intro.) should be rewritten as follows: "If there is any possibility that re-circulated water may come into contact with any food product or food contact surface, the re-circulated water may be used in a cooler or heat exchanger only if all of the following apply:". Each of the following subdivisions should begin with the words "The water is."

j. In s. ATCP 70.10 (5) (e), the phrase ", or protein from a major food allergen," should be omitted, as it is included in the definition of "major food allergen."

k. Section ATCP 70.11 (4) provides that the department may approve other sanitizers and sanitizing methods that it finds to be safe and effective for the purpose used. As these methods are approved, they should be placed in the Administrative Code. [See also s. ATCP 70.19 (4) (b).]

l. SECTION 25 should indicate whether the new s. ATCP 70.117 goes before or after the title to subch. III.

m. It appears that the material in s. ATCP 70.117 (Note) could be incorporated into s. ATCP 70.117 by listing in one subsection required elements of a plan, and authorizing in another subsection an operator to deviate from the plan if necessary, for example, in response to circumstances not fully anticipated in the plan.

n. The following comments relate to the creation of s. ATCP 70.18:

(1) What are numbered pars. (a) and (b) should be numbered subs. (1) and (2).

(2) Section ATCP 70.18 (Note) should be created as part of SECTION 28 of the rule and the current treatment clause of SECTION 29 should be omitted.

(3) If the note is in reference to the entire section, as the treatment clause of SECTION 29 states, it should be placed after the entire section, i.e., after s. ATCP 70.18 (2) (b) (which is incorrectly numbered (b) 2., in the rule). If, on the other hand, it is intended to be in reference to sub. (1), it is in the correct location.

o. The treatment of s. ATCP 70.225 should precede the treatment of s. ATCP 70.23.

p. There is no need to renumber s. ATCP 70.26 (5), if the new subsection is numbered (4m).

q. Section ATCP 70.261 (3) (intro.) should conclude with the phrase "all of the following apply." Similarly, in sub. (4) (e), the phrase "The following" should be replaced by the phrase "All of the following."

#### **4. Adequacy of References to Related Statutes, Rules and Forms**

- a. In the analysis, the list of statutes providing authority for the proposed rules should include a reference to s. 227.11 (2), Stats.
- b. In s. ATCP 70.07 (3) (a) 5. and (b) 3., a cross-reference to the chemical oxygen demand or permanganate-consumed test should be provided.
- c. In s. ATCP 70.07 (6), the notation "ch." should be inserted before the notation "NR."

#### **5. Clarity, Grammar, Punctuation and Use of Plain Language**

- a. In the rule preface discussion of fish processing, the acronym "HACCP" should be spelled out at this point rather than in the rule preface discussion of business impact. Also, the article "a" preceding the acronym should be replaced by the article "an." The entire rule should be reviewed for the correct use of the article "an" preceding the acronym "HACCP." Finally, in the third bulletpoint of the discussion of fish processing in the rule preface, the word "smoke" should be replaced by the word "smoked."
- b. In s. ATCP 70.02 (19m), the definition of "major food allergen" includes an exception for "food that is exempt..." This should indicate from what, and by whom, the food is exempt.
- c. In s. ATCP 70.06 (6) (c), under what conditions would more frequent inspections be necessary?
- d. In s. ATCP 70.06 (7m) (d) 1., what must the plant operator control and monitor?
- e. In s. ATCP 70.07 (3) (a) (intro.), the term, "[w]ater reclaimed...from a compressor cooling water" appears to be incorrect. Should this be "...from the condensation of compressor cooling water," or perhaps "...from a cooling compressor"?
- f. In s. ATCP 70.07 (3) (a) 6. and (b) 4., how does one organoleptically test a sample – by smelling and visually examining the sample? It seems this could be stated more directly; otherwise, the rule should provide a reference to organoleptic testing procedures.
- g. Section ATCP 70.07 (6) (c) 3. prohibits transporting potable liquids in a container that is also used to transport non-food items. It provides examples of non-food items, all of which are toxic or hazardous in nature, giving the impression that the prohibition is limited to such materials. However, the prohibition would apply as well to a container used to transport, for example, clean sand, which is neither toxic nor hazardous, would it not? The examples seem to obscure this, and so the prohibition may be clearer if the examples are omitted.
- h. In s. ATCP 70.117 (Note), it appears that "variations" should be replaced with "deviations." Also, it appears that the word "on" should be inserted before the phrase "unexpected circumstances."
- i. Section ATCP 70.20 (5) (b) states that no person may misrepresent the identity of any roe product by adding a color additive to that product. May a person add color to roe for any

other reason? If not, it would appear that tying this prohibition to the intent of misrepresenting the product's identity creates an unnecessarily difficult enforcement situation for the department. Would the department's intent be accomplished by simply prohibiting the addition of color additives to roe products?

j. In s. ATCP 70.261 (2), the second occurrence of "operator" should be omitted.

k. In the introductory paragraph to ch. ATCP 70 Appendix A, the first occurrence of the word "plans" should be omitted.