



State of Wisconsin  
Governor Scott Walker

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**Department of Agriculture, Trade and Consumer Protection**  
Ben Brancel, Secretary

**DATE:** September 8, 2017

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

**FROM:** Jeff Lyon, Interim Secretary  
Steve Ingham, Division of Food & Recreational Safety Administrator

**SUBJECT: ATCP 70, Food Processing Plants**

**PRESENTED BY:** Steve Ingham

**REQUESTED ACTION:**

At the September 21, 2017 Board meeting, the Department of Agriculture, Trade and Consumer Protection ("DATCP") will ask the Board to authorize public hearings on a proposed rule (copy attached) related to Food Processing Plants.

This rule repeals and recreates ATCP 70, "Food Processing Plants." This proposed rule is necessary to update Wisconsin's food processing standards and incorporate new federal requirements designed to improve the nation's food safety system, to update and coordinate references to food processing in retail food establishments as well as deal with products not currently being inspected under state and federal meat inspection programs, to address vending machine and micro-market commissaries, and to modernize and clarify Wisconsin's standards for food processing.

The proposed rule also specifically incorporates the federal Food and Drug Administration's (FDA's) new 21 CFR 117, that will allow the department to continue doing contract inspections and work with the FDA in implementing the new Food Safety Modernization Act (FSMA) without going through the lengthy and complicated process of becoming "credentialed" by the FDA and performing inspections under FDA authority. That process would diminish local control of DATCP's program and require that all records generated during contract inspections would be the property of the FDA and subject to their rules on handling and access.

**SUMMARY:**

***Background***

DATCP has, on a fairly regular basis, amended or re-created this rule in order to keep pace with changes in industry as well as the FDA's regulatory philosophy. In this rule revision, DATCP has been especially cognizant of clarifications necessitated by the merger between the DATCP's Division of Food Safety and the Department of Health Services' (DHS) Food Safety and Recreational Licensing Section (FSRL) which occurred in July of 2016. In the wake of this merger, as DATCP continues to seek better ways to serve our stakeholders,

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in particular, and Wisconsin residents, generally, DATCP will continue to advance improvements to Wisconsin's administrative rules and statutory framework.

One major change in implementing this merger concerns the evaluation of the food processing and wholesaling (activities regulated by ATCP 70) operations of persons holding retail food establishment licenses. It should be noted that provisions of ATCP 70 related to these activities will impact restaurants currently licensed as retail food establishments. For the first time, this rule spells out definitions for "wholesale" and "retail." This rule requires retail food establishment license holders, exempted from the requirement of holding an additional food processing plant license, to still meet safe food manufacturing requirements included in ATCP 70.

### ***Rule Content***

#### **Incorporation by reference of 21 CFR 117:**

DATCP has updated ATCP 70 with the incorporation by reference of provisions of Federal regulations that implement the requirements of FSMA. This involves multiple subparts of the recently created 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, formerly 21 CFR 110, *Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding, Human Food*, pertaining to preventive food safety systems that have already been referenced in chs. ATCP 65 (Milk and Milk Products) and 71 (Food Warehouses and Milk Distributors). Since the majority of Wisconsin food facilities, already subject to this federal rule, are licensed as food processing plants, this proposed rule includes similar referencing for the sake of consistency. This revision also clearly articulates the requirements for Wisconsin-licensed food processing plants that are not subject to the federal rule.

#### **Restaurants now licensed as retail food establishments:**

In July of 2016, when DATCP's Division of Food Safety merged with DHS' FSRL to form the new Division of Food and Recreational Safety ("DFRS"), a merger of the two food safety regulatory systems became necessary. For example, restaurant operators were not allowed to wholesale food pursuant to the DHS regulation, while retail food establishment operators, pursuant to DATCP's authority, could engage in a limited amount of wholesaling. At present, restaurant operators are now licensed as retail food establishments and now enjoy a limited ability to wholesale food. The new ATCP 70 clarifies both the exemption from the requirement to hold a food processing plant license as well as the requirements for food processing and subsequent wholesaling now allowed in licensed retail food establishments. The new ATCP 70 also incorporates, for the first time, specific definitions for wholesaling and retailing concomitantly being incorporated into ATCP 75 (Retail Food Establishments) and ATCP 55 (Meat and Meat Food Products). DATCP expects these updates to promote clarity, uniformity, and improved guidance to food businesses in Wisconsin.

#### **Food processing plant license exemptions:**

In addition, the new ATCP 70 contains language designed to specifically clarify the responsibilities for operators of retail food establishments. Besides the afore-mentioned exemption from the requirement of holding a food processing plant license, operators will better understand their duty to follow the safety, processing, and labeling requirements in ATCP 70 for the production of food for wholesaling. These provisions not only level the playing field for industry, but, more importantly, also ensure that certain ATCP 70 requirements are in place

to ensure food safety. Examples of such requirements include provisions for a written recall plan and a written food safety plan for facilities subject to FSMA rules.

**New requirements to hold a retail license:**

In revising this rule, DATCP sought to eliminate duplication, improve regulatory transparency, and, to the extent possible, ensure that food businesses are not required to hold multiple licenses, except when completely necessary. In doing so, DATCP never relinquishes its public health mission or compromises its directive to ensure that food is produced safely and pursuant to some responsible form of inspection. In some cases, such as meat establishments that produce some products under a state license or a federal grant of inspection and other products separate from that inspection, businesses will be allowed to obtain a retail food establishment license from the state or local agency with jurisdiction in that area (in addition to the state meat establishment license or federal grant of meat inspection). This ensures that those business will be allowed to sell product at retail that was not produced under either the federal or state meat inspection programs because those programs are not allowed to inspect and regulate retail food establishment operations.

**Food processing plants that are located in residences:**

Another substantive change is to end the licensing of food processing plants that are located in homes after the date this rule becomes effective. It should be noted that food processing plants currently located in residences will not be able to expand their facilities after the effective date of this rule. This rule also requires that food processing plants that are currently located in residential or commercial buildings must have a door that opens to the outside or into a community space.

**Adoption of the Model Ordinance for Marine Shellfish:**

Further, the rule adopts the Model Ordinance for Molluscan Shellfish, now *Marine Shellfish*, which replaces all of s. ATCP 70.21, except for the section on illnesses and outbreaks associated with shellfish. This modification will keep the State's regulations current with the national rules on shellfish processing and marketing.

**Other clarifications, changes, and additions:**

- This rule addresses requirements for vending machines, micro-markets, and the commissaries for these entities, as well as in the new ch. ATCP 75, and the Appendix to ATCP 75, *The Wisconsin Food Code*, to ensure consistency and clarity in requirements for both the food processing part of the operation and the retail food business.
- This rule clarifies extended runs and waivers allowing those runs, while clarifying and expanding the list of food processing activities during which daily cleaning and sanitizing are not required.
- This rule clarifies that filing and obtaining process-authority approval for processes used in the making of acidified or low acid canned foods is mandatory.
- This rule expands the ability of food processing plants to obtain waivers or variances from DATCP for non-standardized and innovative processing and procedural activities. Prior to this revision, these waivers and variances could only be obtained by food processing plants for structural and equipment issues.

- This rule updates and clarifies the language dealing with the standards and testing of operations water and ingredient water used in the various bottling and processing operations in Wisconsin, and finished product sampling and analysis for bottling establishments.
- The new rule also expands the scope of the bottling rules to cover more than just bottled water and soda to match the expansion of this rapidly changing and innovative segment of the bottling industry.
- This rule generally updates and clarifies definitions, licensing requirements and exemptions, as well as exempt wholesaling requirements and limitations, to keep pace with industry and regulatory needs.
- This rule removes the lower sales limit of \$25,000 on persons who must pay the canning surcharge to reflect the very real need of DATCP's staff to provide extensive information, consultation, and service to persons manufacturing canned foods.
- This rule will be consistent with the Retail Food Establishment and Meat Inspection rules to ensure consistency throughout food processing businesses of all types and a regulatory presence for all foods, regardless of where they are produced. This is in keeping with the scope of ch. 97, Stats., requiring the Department to regulate food safety wherever that food is produced, stored, or offered for sale.
- The proposed rule protects the consistent quality of the Wisconsin "brand" by removing many of the long-expired "Grandfather Clause" dates in the existing rule and replacing them with language about gaining compliance for structural standards in existing buildings and updating the expectations for structural standards in new plants. Most significantly, the proposed rule promotes consistent food safety by not allowing a food processing plant in a residence to be licensed after the effective date of this rule.

### ***Fiscal Impact***

No new staff will be required for DATCP to enforce the proposed rule. This rule replaces one that is already in effect, so DATCP will train staff in the new requirements, and the new requirements will be enforced as part of the normal inspection.

### ***Business Impact***

The businesses affected by this rule run the gamut from very small to very large operations. The businesses range from one- and two-person popcorn wholesalers to multi-national corporations that are on the cutting edge of food science. DATCP's challenge is to write and then enforce applicable and consistent requirements that do not penalize either end of this range of business types.

If the proposed rule is adopted, some small food processing plants may incur immediate costs to meet the requirement to have a door that opens to the outside rather than to a residential vestibule. There is also a potential cost for a small number of businesses that have not upgraded their facilities since the "grandfather clauses" were put in place over thirty years ago. They will now need to upgrade warewashing and handwashing sinks or provide a non-residential restroom for the facility. Another cost that may be incurred by a few very small businesses is the \$320 canning surcharge, which currently is not assessed for food processing plants manufacturing and selling less than \$25,000 of food per year. DATCP's Manufactured Food Specialists spend a disproportionate amount of time working with very small canning businesses, and this surcharge recoups these

costs. The service provided by DATCP is comparable to that of consultants who are not economically available to operations in the < \$25,000/year category.

Much of the focus of the proposed rule revision is on clarification and the updating of existing regulations such as the various exemptions from a food processing plant license, and the clarification of various record-keeping requirements.

A positive impact of this rule revision on all classes of business is the expanded ability of food processing plants to apply for processing or procedural waivers. This will potentially allow for the use of new and innovative techniques and processes so long as the processor can demonstrate that food safety is not compromised.

No economic impact comments were received during the August 8 – September 7, 2017, comment period. However, meat establishments that produce some products under a state license or a federal grant of inspection, as well as other products separate from that inspection, may be required to hold a retail food establishment license from the state or local agency with jurisdiction in that area in addition to holding the state meat establishment license or federal grant of meat inspection. Allowing these meat establishments to also hold a retail food establishment license will make it possible for them to retail the unique meat and poultry products that the state is known for because those products will now be produced under inspection. This additional oversight more closely meets consumer expectations and provides a level playing field between these establishments and other, non-meat inspection establishments that also produce the same types of meat and poultry products for sale at retail. These other, non-meat inspection establishments have always been subject to licensing and regulation by the state or local food inspection system.

### ***Environmental Impact***

This rule will have no environmental impact.

### ***Federal and Surrounding State Programs***

#### **Federal Programs**

A major objective was to include the updated language in *21 CFR 117* which replaced *21 CFR 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding for Human Food*, and is the cornerstone of the regulations implementing FSMA. ATCP 70.04 was specifically inserted to address this issue, and definitions for “facility” and “qualified facility” were also inserted to facilitate the department’s implementation of those federal requirements.

Current language on the molluscan shellfish program was deleted in order to adopt the federal *Model Ordinance* in order to provide that segment of the Wisconsin food industry regulatory consistency during interstate commerce.

### **Surrounding State Programs**

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

### *Next Steps*

If the Board authorizes public hearings on this rule, the department will refer a copy to the Legislative Council Rules Clearinghouse that will publish a hearing notice in the Wisconsin Administrative Register. DATCP will hold public hearings on the dates and at the locations specified in the hearing notice. The hearing dates and locations have not yet been determined.

Following the public hearings, DATCP will prepare the final draft rule which will be presented for the Board's consideration and then transmitted to the Governor for written approval. If approved, the final draft rule will be submitted to the Legislature for review by the appropriate legislative committees. If the Legislature takes no action to stop the rule, the Secretary will sign the final rulemaking order and transmit it for publication. If all goes as planned, the rule would become effective in 2018.

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

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

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

This rule repeals and recreates ATCP 70, “Food Processing Plants.” This rule is necessary to update Wisconsin’s food processing standards and incorporate new federal requirements designed to improve the nation’s food safety system, to update and coordinate references to food processing in retail food establishments (as well as deal with products not currently being inspected in state and federal meat establishments), to address vending machine and micro-market commissaries, and to modernize and clarify Wisconsin’s standards for food processing.

***Statutes Interpreted***

Statutes Interpreted: ss. 97.20, Stats., “Dairy Plants;” 97.29, Stats., “Food processing plants;” 97.30, Stats., “Retail food establishments;” 97.34, Stats., “Bottled drinking water and soda water beverage; standards; sampling and analysis;” 97.42, Stats., “Compulsory Inspection of livestock or poultry, and meat or poultry products;” 97.605, “Lodging and vending licenses,” and 97.61, Stats., “Vending machine commissary outside the state.”

***Statutory Authority***

Statutory Authority: ss. 93.07 (1), 97.09 (4), 97.20 (4), 97.29 (5), Stats.

***Explanation of Statutory Authority***

The Wisconsin Department of Agriculture, Trade and Consumer Protection (“DATCP”) has broad general authority, under s. 93.07 (1), Stats., to adopt rules to implement programs under its jurisdiction. DATCP also has general authority under s. 97.09 (4), Stats., to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. DATCP has specific authority, under s. 97.29 (5) to adopt rules establishing fees, setting facility construction and maintenance standards, setting standards for the design, installation, maintenance, and

cleaning of equipment and utensils, personnel sanitation, food handling and storage, sanitary production and processing of food, food sources, and labels.

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

With DATCP's Division of Food Safety merger with the Department of Health Services' (DHS') Food Safety and Recreational Licensing ("FSRL") Section to form the new Division of Food and Recreational Safety ("DFRS"), DATCP's authority, pursuant to ch. 97, Stats., currently includes responsibilities for the related administrative rules covering all retail food establishments, including restaurants, dairy plants, warehouses, and meat and poultry processing.

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

DATCP has updated ATCP 70 with the incorporation by reference of provisions of Federal regulations that implement the requirements of the federal Food Safety Modernization Act (FSMA). This involves multiple subparts of the recently created 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, formerly 21 CFR 110, *Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding, Human Food*, pertaining to preventive food safety systems that have already been referenced in chs. ATCP 65 (Milk and Milk Products) and ATCP 71 (Food Warehouses and Milk Distributors). Since the majority of Wisconsin food facilities, already subject to this federal rule, are licensed as food processing plants, this proposed rule includes similar referencing for the sake of consistency. This revision also ensures that the requirements for Wisconsin-licensed food processing plants, not subject to the federal rule, are clearly articulated.

With DATCP's Division of Food Safety merger with DHS' FSRL to form the new Division of Food and Recreational Safety ("DFRS"), a merger of the two food safety regulatory systems became necessary. A major change involving food processing plants is the fact that restaurant operators were not allowed to wholesale food under DHS regulation, while retail food establishment operators, under DATCP's authority, could engage in a limited amount of wholesaling. At present, restaurant operators are now licensed as retail food establishments and therefore now enjoyed a limited ability to wholesale food. The new ATCP 70 clarifies both the exemption from the requirement to hold a food processing plant license as well as the requirements for food processing and subsequent wholesaling now allowed in licensed retail food establishments. The new ATCP 70 also incorporates, for the first time, specific definitions for wholesaling and retailing concomitantly being incorporated into ATCP 75 (Retail Food Establishments) and ATCP 55 (Meat and Meat Food Products). DATCP expects these updates to promote clarity, uniformity, and improved guidance to food businesses in Wisconsin.

In addition, the new ATCP 70 contains language designed to specifically clarify the responsibilities for operators of retail food establishments. Besides the afore-mentioned exemption from the requirement of holding a food processing plant license, operators will better understand their duty to follow the safety, processing, and labeling requirements in ATCP 70 for the production of food for wholesaling. These provisions not only level the playing field for industry, but, more importantly, also ensure that certain ATCP 70 requirements are in place to ensure food safety. Examples of such requirements include provisions for a written recall plan and a written food safety plan for facilities subject to FSMA rules.



In revising this rule, DATCP sought to eliminate duplication, improve regulatory transparency, and, to the extent possible, ensure that food businesses are not required to hold multiple licenses, except when completely necessary. In doing so, DATCP never relinquishes its public health mission or compromises its directive to ensure that food is produced safely and pursuant to some responsible form of inspection. In some cases, such as meat establishments that produce some products under a state license or a federal grant of inspection and other products separate from that inspection, businesses will be allowed to obtain a retail food establishment license from the state or local agency with jurisdiction in that area, in addition to the state meat establishment license or federal grant of meat inspection. This ensures that those businesses will be allowed to sell product at retail that was not produced under either the federal or state meat inspection programs because those programs are not allowed to inspect and regulate retail operations.

Another substantive change is to end the licensing of food processing plants that are located in homes after the date this rule becomes effective. It should be noted that food processing plants currently located in residences will not be able to expand their facilities after the effective date of this rule. This rule also requires that food processing plants that are currently located in residential or commercial buildings must have a door that opens to the outside or into a community space.

Further, the rule adopts the Model Ordinance for Molluscan Shellfish, now *Marine Shellfish*, which replaces all of s. ATCP 70.21, except the section on illnesses and outbreaks associated with shellfish. This modification will keep the state's regulations current with the national rules on shellfish processing and marketing.

Other clarifications, changes, and additions are as follow:

- This rule addresses requirements for vending machines, micro-markets, and the commissaries for both of these entities, as well as in the new ch. ATCP 75, and the Appendix to ATCP 75, *The Wisconsin Food Code*, to ensure consistency and clarity in requirements for both the food processing part of the operation and the retail food business.
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- This rule updates and clarifies the language dealing with the standards and testing of operations water and ingredient water used in the various bottling and processing operations in Wisconsin, and finished product sampling and analysis for bottling establishments.
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- The proposed rule protects the consistent quality of the Wisconsin "brand" by removing many of the long-expired "Grandfather Clause" dates in the existing rule and replacing them with language about gaining compliance for structural standards in existing buildings and updating the expectations for structural standards in new plants. Most significantly, the proposed rule promotes consistent food safety by not allowing a food processing plant in a residence to be licensed after the effective date of this rule.

### *Federal and Surrounding State Programs*

#### **Federal Programs**

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#### **Surrounding State Programs**

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### *Data and Analytical Methodologies*

In order to identify potential changes to the rule, DATCP reviewed recent changes in FDA regulations and guidelines such as the rules implementing FSMA; Wisconsin statutes and rules for food processing plants, retail food establishments, meat establishments, and dairy plants; and current industrial practices.

### ***Material Incorporated by Reference***

21 CFR 117, Current Good Manufacturing Practice, Hazard Analysis and Risk based Preventive Controls for Human Food.

21 CFR 108, Emergency Permit Control (Canning Process Filing Requirements).

21 CFR 113, Thermally Processed Low-acid foods packaged in hermetically sealed containers (Canning).

21 CFR 114, Acidified Foods (Canning).

21 CFR 120, Hazard Analysis and Critical Control Point (HACCP) Systems (Juice HACCP).

21 CFR 123, Fish and Fishery Products (Seafood HACCP).

National Shellfish Sanitation Program – Guide for the Control of Molluscan Shellfish, Model Ordinance.

### ***Effect on Small Business***

The businesses affected by this rule run the gamut from very small to very large operations. The businesses range from one- and two-person popcorn wholesalers to multi-national corporations that are on the cutting edge of food science. The Department's challenge is to write and then enforce applicable and consistent requirements that do not penalize either end of this range of business types.

If the proposed rule is adopted, some small food processing plants may incur immediate costs to meet the requirement to have a door that opens to the outside rather than to a residential vestibule. There is also a potential cost for a small number of businesses that have not upgraded their facilities since the "grandfather clauses" were put in place over thirty years ago. They will now need to upgrade warewashing and handwashing sinks or provide a non-residential restroom for the facility. Another cost that may be incurred by a few very small businesses is the \$320 canning surcharge, which currently is not assessed for food processing plants manufacturing and selling less than \$25,000 of food per year. The Department's Manufactured Food Specialists spend a disproportionate amount of time working with very small canning businesses, and this surcharge recoups these costs. The service provided by the Department is comparable to that of consultants who are not economically available to operations in the <\$25,000/year category.

Much of the focus of the proposed rule revision is on clarification and the updating of existing regulations such as the various exemptions from a food processing plant license, and the clarification of the various record-keeping requirements.

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8	<b>Subchapter II. General Requirements</b>	
9	ATCP 70.06	Food processing plants; licensing; fees.
10	ATCP 70.08	Construction and maintenance.
11	ATCP 70.10	Personnel standards.
12	ATCP 70.12	Equipment and utensils.
13	ATCP 70.14	Cleaning and Sanitizing Equipment and Utensils: General
14	ATCP 70.16	Cleaning and Sanitizing Equipment: Exemptions
15	ATCP 70.18	Obtaining Approval of Alternative Cleaning and Sanitizing Frequency
16	ATCP 70.20	Water supply.
17	ATCP 70.22	Food ingredients.
18	ATCP 70.24	Food handling and storage.
19	ATCP 70.26	Food packaging and labeling.
20	ATCP 70.28	Sanitizers and sanitizing methods.
21	ATCP 70.30	Ready-to-eat foods; reporting pathogens and toxins.
22	ATCP 70.32	Recall plan.
23	<b>Subchapter III. Canning Operations; Supplementary Requirements</b>	
24	ATCP 70.34	General.
25	ATCP 70.36	Low-acid foods packaged in hermetically sealed containers.
26	ATCP 70.38	Acidified foods.
27	ATCP 70.40	Facilities and equipment; cleaning.

28       ATCP 70.42       Handling raw agricultural commodities and by-products.

29       **Subchapter IV. Fish Processing Plants; Marine Shellfish Plants; Supplementary**  
30 **Requirements.**

31       ATCP 70.44       Fish processing.

32       ATCP 70.46       Labeling and sale of smoked fish.

33       ATCP 70.48       Fish roe.

34       ATCP 70.50       Marine molluscan shellfish processing.

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

36       ATCP 70.52       Bottling establishments; general.

37       ATCP 70.54       Returnable and single-service bottles.

38       ATCP 70.56       Bottled Water Product sampling; recordkeeping; reports.

39       ATCP 70.58       Labeling bottled products.

40       **Subchapter VI. Juice and Juice HACCP**

41       ATCP 70.60       Juice HACCP

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

43       ATCP 70.62       Effect of rules on local ordinances.

44       **Subchapter VIII. Variances**

45       ATCP 70.64       Variances

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

49       **Subchapter I. Scope and Definitions**

50       **ATCP 70.01 Scope.** This chapter applies to all food processing plants as defined in s. ATCP  
51 70.02 (23), regardless of whether the food processing plant is subject to licensing under s. 97.29,  
52 Stats., or this chapter, and all retail food establishments, as defined in s. 97.30 (1) (c), Stats.,  
53 performing food processing operations, as defined in ATCP 70.02 (22).

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

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

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

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

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

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

67       (6) "Bottling establishment" means any place where drinking water, soda water beverage, or  
68 alcohol beverage is manufactured or bottled for sale. "Bottling establishment" does not include a  
69 retail establishment engaged in the preparation and sale of beverages under a license issued under

70 s. 125.26 or 125.51, Stats., a retail food establishment under a license issued under s. 97.30, Stats.,  
71 or other license issued under s. 97.605, Stats.

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

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

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

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

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

88 (12) "Critical control point" means a point in food processing at which a failure to monitor a  
89 food safety parameter such as pH, temperature, time, or water activity ( $a_w$ ), or a failure to control



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

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

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

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

98 (16) "Fish" means fresh or saltwater finfish; crustaceans; forms of aquatic life other than birds  
99 or mammals including but not limited to, alligators, frogs, aquatic turtles, jellyfish, sea cucumber,  
100 and sea urchin, and their roe, and all mollusks, if intended for human consumption.

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

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

105 (19) "Food" means:

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

107 (b) Chewing gum.

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

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

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

115       **(22)** "Food processing" means the manufacture or preparation of food for sale through the  
116 process of canning, extracting, fermenting, distilling, pickling, freezing, baking, drying, smoking,  
117 grinding, cutting, mixing, coating, stuffing, packing, bottling or packaging, or through any other  
118 treatment or preservation process. 0163"Food processing" includes the activities of a bakery,  
119 confectionary, vending machine commissary licensed under s. 97.605, Stats., or bottling  
120 establishment, and also includes the receipt and salvaging of distressed food for sale or use as  
121 food. It also includes the packaging of seeds that have been harvested, and dried after the harvest  
122 for sale as food. These seeds include, but are not limited to unpopped popcorn whether shelled or  
123 on the cob, black beans, wild rice, sunflower seeds, pumpkin seeds, and soybeans. "Food  
124 processing" does not include any of the following:

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

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

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

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

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

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

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

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

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

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

148       **(23)** "Food processing plant" means any place where food processing is conducted. "Food  
149 processing plant" does not include any personal residence or building used as a personal domicile,  
150 mobile establishment, establishment subject to the requirements of s. 97.30, Stats., or any  
151 restaurant or other establishment holding a license under s. 97.605, Stats., to the extent that the  
152 activities of that establishment are covered by s. 97.30, Stats., or the license under s. 97.605, Stats.

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

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

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

162       (b) Treated with smoke or smoke flavoring to give it a smoked flavor.

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

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

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

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

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

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

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

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

184       **(33)** "Potentially hazardous food" also means "TCS (time/temperature controlled for safety)  
185 Food", and has the meaning given in ch. ATCP 75 Appendix (Wisconsin Food Code), section 1-  
186 201.10 (B).

187       **(34)** "Processed fish" means fish that is preserved for human consumption by means of hot or  
188 cold smoking, curing, salting, drying, marinating, pickling, fermenting, or related processes.

189 "Processed fish" does not include fish processed in accordance with s. ATCP 70.30 or 70.32.

190 (35) "Qualified facility" has the meaning given in 21 CFR 117.3.

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

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

195 (38) "Retail" means the sale of food or food products to any consumer who will not re-sell it,  
196 but will consume it or provide it for consumption by his/her immediate family, or non-paying  
197 guests.

198 (39) "Roe" means fish eggs, including fish eggs that are still enclosed in the ovarian  
199 membrane.

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

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

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

204 (c).

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

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

208 (41) "Salt content" or "salt in the water phase," means the percent salt (sodium chloride) as

209 determined by the method described in sections 18.034 and 18.035 of the *Official Methods of*

210 *Analysis*, multiplied by 100 and divided by the sum of the percent salt (sodium chloride) and the

211 percent moisture in the finished product as determined by the method described in section 24.002  
212 of the *Official Methods of Analysis*.

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

217 (43) "Single service article" means any utensil or food package, or any part of a utensil or food  
218 package, which is designed to be used only once prior to disposal.

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

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

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

231 (47) “Wholesale” means the sale of any food to a person or commercial entity who will either  
232 re-sell it or use it as an ingredient in a product that will be then offered for sale. “Wholesale” also  
233 means the transfer of food from the point of production to another location for sale during which  
234 control of the food is relinquished.

235 **ATCP 70.04 Federal requirements. (1) QUALIFIED FACILITIES.** A food processing plant  
236 which is also a qualified facility shall comply with the requirements of this chapter and applicable  
237 requirements of 21 CFR 117.

238 **(2) FACILITIES.** A food processing plant that is a facility, but is not a qualified facility, shall  
239 meet the requirements of this chapter and applicable requirements of 21 CFR 117.

## 240 **Subchapter II. General Requirements**

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

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

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



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

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

256 (c) For a food processing plant that has an annual production of at least \$25,000 but less than  
257 \$250,000, and is not engaged in processing potentially hazardous food or in canning, an annual  
258 license fee of \$160.

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

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

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

266 **Note:** The treatment of subs. (2m) and (2n) first applies to applications for new licenses that are filed on  
267 or after February 1, 1998 and to renewals of food processing plant licenses which expire on March 31,  
268 1998.

269 **(5) SURCHARGE FOR OPERATING WITHOUT A LICENSE.** An applicant for a license under sub. (1)  
270 shall pay a license fee surcharge of \$100 if the department determines that, within one year prior to  
271 submitting the license application, the applicant operated the food processing plant without a

272 license in violation of sub. (1). Payment of this license fee surcharge does not relieve the applicant  
273 of any other civil or criminal liability which results from the unlicensed operation of the food  
274 processing plant, but does not constitute evidence of a violation of any law.

275 (6) REINSPECTION FEE. (a) If the department reinspects a food processing plant because the  
276 department has found a violation of ch. 97, Stats., or this chapter, on a regularly scheduled  
277 inspection, the department shall charge the food processing plant operator the reinspection fee  
278 specified under par. (b). A reinspection fee is payable when the reinspection is completed, and is  
279 due upon written demand from the department. The department may issue a demand for payment  
280 when it issues a license renewal application form to a food processing plant operator.

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

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

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

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

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

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

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

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

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

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

311       **(9) PRE-LICENSE INSPECTION.** The department may inspect a food processing plant, as the  
312 department deems necessary, before issuing a license for the food processing plant. The

313 department may not issue a license or temporary license for a new food processing plant until the  
314 department inspects the new food processing plant for compliance with this chapter. A previously  
315 licensed food processing plant may not be considered a new food processing plant under this  
316 subsection solely because of a change of ownership.

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

321 **(11) LICENSE EXEMPTIONS.** A food processing plant license is not required under s. 97.29,  
322 Stats., or this section for:

323 (a) A retail food establishment which is engaged in food processing if all of the following  
324 apply:

325 1. The retail food establishment is licensed by the department under s. 97.30, Stats., or by an  
326 agent as defined in s. ATCP 74, under ss. 97.30 and 97.41, Stats.

327 2. Wholesale receipts from food processing operations at the retail food establishment  
328 comprise no more than 25% of gross annual food sales from the retail food establishment. If a  
329 licensed retail food establishment is also licensed as a dairy plant under s. 97.20, Stats., or as a  
330 meat establishment under s. 97.42, Stats., sales of dairy or meat products processed at the  
331 establishment shall be excluded from the calculation of food sales receipts under this subdivision.

332 3. The retail food establishment is not engaged in canning of food products, does not engage  
333 in juice processing subject to requirements of 21 CFR 120, does not engage in any fish or fishery

334 products processing subject to requirements of 21 CFR 123, does not process smoked fish, and  
335 does not manufacture and bottle a beverage containing alcohol in excess of 2% if the product is  
336 liquid or 0.5% as an ingredient.

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

339 1. The retail food establishment does not process food for wholesale distribution in excess of  
340 25% of total food sales, is not engaged in canning of food products, does not engage in juice  
341 processing subject to requirements of 21 CFR 120, does not engage in any fish or fishery products  
342 processing subject to requirements of 21 CFR 123, and does not manufacture or bottle beverages  
343 containing alcohol in excess of 2% if the product is liquid or 0.5% as an ingredient for sale to  
344 anyone other than the ultimate consumer, except for beer brewed and sold under the provisions in  
345 s. 125.295, Stats..

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

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

350 1. Receipts from non-dairy food processing operations at that location comprise no more than  
351 25% of gross annual dairy and non-dairy food sales from that location.

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

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

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

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

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

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

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

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

371 4. The processor registers with the department before engaging in any processing activities  
372 under this paragraph in any license year ending March 31. A registration expires at the end of the  
373 license year. A processor shall register in writing on a form provided by the department, or shall  
374 register online at <http://datcp.wi.gov>. The registration shall include information reasonably

375 required by the department, including the registrant's name and address and information related to  
376 the nature, location, and scope of the registrant's processing activities and product sales. There is  
377 no fee to register, and the registrant is not required to hold a registration certificate from the  
378 department.

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

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

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

387 1. Reshipping marine molluscan shellfish, provided that the licensed warehouse operator holds  
388 a licensee dealer certification as required by FDA's *Guide for the Control of Molluscan Shellfish*,  
389 *The Model Ordinance*, that annual inventory value of molluscan shellfish repacked at the licensed  
390 warehouse does not exceed 25% of the gross annual inventory value of the food warehouse, and  
391 the licensed food warehouse meets all of the applicable requirements of s. ATCP 70.21.

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

394 3. Combining two or more food items that are already individually packaged and labeled for  
395 retail sale into a combination package for retail sale, if the label on each individual item inside the  
396 combination package remains visible or if the package of combined items is labeled for retail sale.

397 All packaging and labels shall comply with s. ATCP 70.24.

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

402 (g) Exemption from a food processing plant license under this section does not exempt retail  
403 food establishments, whether serving or not serving meals, but also performing activities normally  
404 licensed under this chapter, from the requirements of this chapter except for holding the license.

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

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

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

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

417 **ATCP 70.08 Construction and maintenance. (1) CONSTRUCTION AND MAINTENANCE;**  
418 **GENERAL.** The operator shall soundly construct and maintain in a clean and sanitary condition all



419 buildings, facilities, and equipment used in food processing operations. The interior and exterior  
420 portions of a food processing plant, and the premises on which the food processing plant is located,  
421 shall be kept free of unhealthful or unsanitary conditions, and shall be maintained in compliance  
422 with this chapter.

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

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

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

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

430 2. Floors, walls, and ceilings in a food processing plant shall be kept clean and in good repair.

431 **(3)** A licensed food processing plant that is not a strictly seasonal business, e.g., an orchard or a  
432 maple sap processing facility, and that has ceased to operate continuously for more than 30 days at  
433 any time after the effective date of this rule, or has been structurally remodeled or altered in a  
434 manner which results in structural changes to a processing area, or a plant that has added product  
435 lines or processes after the effective date of this rule, shall be subject to current licensed plant  
436 requirements including, but not limited to:

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

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

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

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

449 (b) If a retail establishment serving meals also engages in food processing, under the  
450 exemption in 70.06 (11) (a) or (b), that processing shall only be done in specifically designated  
451 areas and not in areas accessible to the public such as the retail area of a grocery store or the dining  
452 room of a restaurant.

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

457 (b) A food processing plant issued a license, after the date this rule is effective, is required to  
458 have a direct exterior entrance or a direct entrance from a common space or hallway if the food  
459 processing plant is located within a shared, non-residential building.

460 (c) After the effective date of this rule, no license shall be granted to a new food processing  
461 plant that consists of designated space in a building or in a garage attached to a building that is  
462 otherwise used as a residence.

463 (d) Food processing plants currently located in spaces existing in residential buildings or the  
464 attached garages of residential buildings may not be expanded or rebuilt following the effective  
465 date of this rule.

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

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

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

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

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

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

490       **(8) TOILET FACILITIES.** (a) The licensee shall provide sanitary toilets meeting applicable state  
491 and local regulations in sufficient number to accommodate employees. The toilets shall be located  
492 in toilet rooms meeting the requirements of this section, for any facility constructed or licensed  
493 after the effective date of this rule. Toilet rooms and fixtures shall be easily cleanable, and shall be  
494 kept clean and in good repair. Non-contiguous toilet facilities, serving facilities licensed prior to  
495 the effective date of this rule, shall be conveniently adjacent and accessible to the facility, and  
496 meet all applicable state and local regulations for unattached or portable toilet rooms.

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

498 (c) Handwashing facilities shall be located in or adjacent to every toilet room. Handwashing  
499 facilities serving toilet rooms shall include hot and cold running water, soap in a soap dispenser,  
500 and a sanitary single-service means of drying the hands. A sign directing employees to wash their  
501 hands shall be prominently posted in every toilet room used by employees. Handwashing facilities  
502 serving a toilet room shall comply with all of the following requirements if they are installed after  
503 the effective date of this rule, or if they are located in a food processing plant that is initially  
504 licensed or licensed to a new operator after the effective date of this rule:

505 1. The facility shall be served by hot and cold running water provided through a mixing valve  
506 or combination faucet, or by potable tempered water.

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

510 (d) The faucets of a handwashing sink in a licensed, non-seasonal food processing plant that  
511 has ceased to operate continuously for more than 30 days at any time after the effective date of this  
512 rule, or located on a sink in an area that has been structurally remodeled or altered in a manner  
513 which results in structural changes to a processing area, or located in a plant that adds more  
514 complex food processing after the effective date of this rule, shall be subject to current licensed  
515 plant requirements including, but not limited to, the requirements in pars. (c) 1. and 2, (e) and (f).

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

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

521 (9) LOCKER AND LINEN FACILITIES. The licensee shall provide lockers or comparable facilities  
522 for employees to store clothing and other personal items. The locker facility shall not be in food  
523 processing or food storage areas, or in areas where food, packages, equipment, or utensils are  
524 cleaned or stored. Protective clothing worn during processing shall be stored in an orderly and  
525 sanitary manner. Soiled linen and clothing shall be kept in non-absorbent containers or laundry  
526 bags until removed for laundering. Soiled linen and clothing shall be removed as often as  
527 necessary to prevent unsanitary conditions.

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

534 (b) A handwashing sink serving a food processing area shall comply with all of the following  
535 requirements if it is installed after the effective date of this rule, or if it is located in a food  
536 processing plant that is initially licensed or licensed to a new operator after the effective date of  
537 this rule:

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

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

541 3. It shall not be hand operated.

542 (c) A handwashing sink in a non-seasonal licensed food processing plant that has ceased to  
543 operate continuously for more than 30 days at any time after the effective date of this rule, or  
544 located in an area that has been structurally remodeled or altered in a manner which results in  
545 structural changes to a processing area, or located in a plant that adds more complex food  
546 processing after the effective date of this rule, shall comply with the requirements as referenced in  
547 sub. (b) 1-3.

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

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

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

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

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

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

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

573 **(12) EXTERIOR PREMISES.** The premises surrounding a food processing plant shall be well  
574 drained and shall be kept in a clean and orderly condition. The premises shall be kept free of  
575 accumulations of garbage and refuse, potential vermin harborages, and other potential health  
576 nuisances. Driveways and parking lots shall be surfaced or maintained to minimize airborne dust  
577 and dirt.

578 **(13) PLUMBING SYSTEM AND SEWAGE DISPOSAL.** Sewage and waste materials from a food  
579 processing plant shall be removed in a sanitary manner, in compliance with applicable state and



580 local regulations. All plumbing, plumbing fixtures, and equipment shall be designed, installed,  
581 and maintained to prevent backflow, back siphonage, and cross-connections.

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

584 **(14) GARBAGE AND REFUSE DISPOSAL.** Garbage and refuse shall not be allowed to accumulate  
585 in or around a food processing plant. Garbage and refuse shall be removed as often as necessary to  
586 maintain the premises in a clean and sanitary condition. Garbage storage areas shall be  
587 constructed and maintained so that they do not attract or harbor insects, rodents, or other animals.  
588 Garbage and refuse shall be held in durable, leakproof, easily cleanable, and pest-resistant  
589 containers. Containers shall be kept covered with tight-fitting lids, and shall be cleaned when  
590 necessary to prevent insanitary conditions. Garbage and refuse shall not be burned on the  
591 premises, except in compliance with state and local laws. Garbage and refuse shall not be burned  
592 on the premises if burning may contaminate food.

593 **(15) CONTROL OF PESTS.** The licensee shall take effective measures, as necessary, to control  
594 insects, rodents, and other pests in a food processing plant. Pesticides and other hazardous  
595 substances shall not be stored or used in a manner which may contaminate food, or which may  
596 constitute a hazard to employees or the public. Pesticides shall not be stored, handled, or used in a  
597 manner inconsistent with label directions, or in a negligent manner.

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

600 **(16) CONSTRUCTION; PLAN REVIEW.** Before a food processing plant is constructed,  
601 substantially reconstructed, or extensively altered, the new operator or licensee shall notify the

602 department in writing. Plans and specifications for the construction, reconstruction, or alteration  
603 may be submitted to the department for review before the work is begun. Plans and specifications  
604 shall be available for review by the department upon request.

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

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

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

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

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

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

622 3. Properly stored until used.

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

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

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

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

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

- 640 1. The individuals or positions responsible for implementing the training, maintaining training  
641 records, and ensuring compliance with training requirements.
- 642 2. The content of the training, including the written procedures required under par. (d).
- 643 3. The form of initial training, and the form and frequency of follow-up training if any.

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

646 5. Procedures to evaluate training effectiveness.

647 (f) The operator of a food processing plant shall review the training program under par. (e) at  
648 least annually.

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

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

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

664 (a) One or more reportable symptoms of communicable disease as defined in ch. ATCP  
665 75 Appendix, 2-201.11 (A).

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

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

669 (5) FOOD CONTAMINATION. No person who has received a reportable diagnosis of  
670 communicable disease, as defined in ch. ATCP 75 Appendix, *The Wisconsin Food Code*,  
671 2-201.11 (A) (2), may work in a food processing plant in any capacity that may contaminate  
672 food products.

673 (6) CONSUMPTION OF FOOD, BEVERAGES, AND TOBACCO. No person may consume food,  
674 beverages, or tobacco in any food processing area, or in any area where food processing equipment  
675 or utensils are cleaned or stored. Employees may not consume food, beverages, or tobacco except  
676 in designated areas which are separated from food processing areas. This subsection does not  
677 prohibit a sanitary water fountain in a processing area, nor does it prohibit on-line quality control  
678 sampling in accordance with written quality control procedures written and followed by the food  
679 processing plant operator.

680 **ATCP 70.12 Equipment and utensils. (1) CONSTRUCTION AND MAINTENANCE; GENERAL.**  
681 Equipment and utensils shall be of sanitary design and construction. Equipment and utensils shall  
682 be readily accessible for cleaning and inspection and shall be constructed so that they can be easily  
683 cleaned. Equipment and utensils shall be kept clean and in good repair.

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

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

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

702       **(4) LOCATION AND INSTALLATION OF EQUIPMENT.** Equipment which cannot be easily moved  
703 shall be installed in a manner which prevents liquid or debris from accumulating under or around  
704 the equipment. Equipment shall be installed so that there is adequate clearance on all sides for

705 cleaning and maintenance. This does not apply to that portion of a tank or container which is  
706 designed and installed to protrude into or through the wall or ceiling of a food processing plant.  
707 Air intake vents for food or ingredient storage containers shall be located in processing areas or  
708 shall be properly filtered.

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

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

718 **ATCP 70.14 Cleaning and Sanitizing Equipment and Utensils. (1) GENERAL.** Except as  
719 provided in s. ATCP 70.16, the food processing plant operator shall do all of the following.

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

722 (b) Except as provided in par. (c), (d) and (e), clean and sanitize all food contact surfaces of  
723 equipment and utensils after each day's use, and before any change in use that may cross-  
724 contaminate food with major food allergens or other contaminants.

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

727 (d) Clean and sanitize all food contact surfaces of equipment used for the distillation of alcohol  
728 products, such as distilled spirits, after each distillation batch.

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

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

740 **(3) CLEANING COMPOUNDS, DETERGENTS, AND SANITIZERS: STORAGE AND LABELING.**

741 Cleaning compounds, detergents, and sanitizers used in a food processing plant shall be clearly  
742 labeled. When they are not being used, they shall be stored in designated areas and in an  
743 appropriate manner so that they do not contaminate food products, ingredients, equipment, or  
744 utensils.



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

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

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

753 **ATCP 70.16 Cleaning and Sanitizing Equipment and Utensils; Exemptions. (1)**

754 APPROVAL REQUIRED FOR AN ALTERNATIVE CLEANING AND SANITIZING FREQUENCY. Except as  
755 provided in s. ATCP 74.16 (2), if a food processing plant operator seeks to clean and sanitize  
756 equipment and utensils at a frequency other than that required in s. ATCP 70.14 (1) because the  
757 equipment and utensils are used with food products, processes, or conditions reducing the risk of  
758 foodborne illness, the food processing plant operator shall submit an alternate cleaning and  
759 sanitizing procedure in compliance with s. ATCP 70.18 to the department for written approval.

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

763 (b) Upon review, the department will issue a letter of approval applicable for not more than  
764 five years that is to be maintained on file at the food processing facility.

765 (c) If changes are planned for the product or any process that affects the food safety validation  
766 factors of that product, the operator shall inform the department in writing prior to making those  
767 changes.

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

774 (a) Drying equipment.

775 (b) Cloth-collector systems.

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

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

778 (e) Food contact surfaces of equipment used solely to process foods or food ingredients with  
779 low water activity ( $\leq 0.85$ ), or foods which are considered non-PHF/non-TCS foods based on  
780 Table A or Table B in Section 2 of ATCP 75 Appendix, (Time/Temperature Control for Safety  
781 Food), such as chocolate, fats and oils, liquid nutritive sweeteners, peanut butter, or similar foods.

782 (f) Ice makers maintained in a cold/frozen state. A food processing plant operator shall clean  
783 and sanitize the ice maker in accordance with ice maker manufacturer instructions for cleaning, or  
784 shall clean and sanitize using a validated cleaning process.

785 (g). Food contact surfaces of equipment used for brewing or fermentation of alcoholic  
786 beverages, such as brewing of beer or wine fermentation. A food processing plant operator shall  
787 clean and sanitize equipment used following each brewing or fermentation batch.

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

791 (i) Equipment used for food fermentations, such as the manufacture of sauerkraut or cucumber  
792 pickles; development of one or more pure bacterial cultures, and development of starter cultures. A  
793 food processing plant operator shall clean and sanitize all equipment following each fermentation  
794 batch.

795 (j) Equipment used for processing of products with a natural  $\text{pH} \leq 4.0$ . A food processing plant  
796 operator shall clean and sanitize all equipment at the end of a continuous operation, not to exceed  
797 30 days (720 hours).

798 (k) Equipment used for maple syrup processing. A food processing plant operator shall clean  
799 and sanitize all equipment at the end of a continuous operation, not to exceed 40 days (960 hours).

800 (m) Equipment used for bottled water processing. A food processing plant operator shall clean  
801 and sanitize all equipment at the end of a continuous operation, not to exceed 30 days (720 hours).

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

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

804 A food processing plant operator may submit a written request for the department to approve

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

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

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

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

817 (d) A written statement, by the food processing plant operator, that the alternative cleaning  
818 and sanitizing procedure has been determined by competent authority (e.g., a process authority, or  
819 is validated by a published or unpublished, peer-reviewed article, challenge studies, or regulatory  
820 standards) and determined to be effective in preventing food contamination and ensuring the  
821 microbiological safety of food. The written statement shall be based on the structure of a written  
822 plan under subd. 5.

823 (e) A written plan used to ensure that the alternative cleaning and sanitizing procedure will be  
824 effective in preventing food contamination and ensuring the microbiological safety of food shall  
825 identify and assess foreseeable hazards, identify critical control points, identify critical safety

826 parameters and limits, and identify monitoring procedures and controls to ensure that the  
827 procedure is effective and appropriately implemented.

828 (f) The department may approve a proposal for an alternative cleaning and sanitizing  
829 procedure that does not comply with sub. (a), if the department believes that the procedure will be  
830 effective in preventing food contamination and ensuring the microbiological safety of food. The  
831 department shall give its approval in writing.

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

836 (3) QUALIFICATIONS, LIMITS, AND WITHDRAWAL OF DEPARTMENT APPROVAL. The department  
837 may qualify or limit its approval under sub. (2), as deemed appropriate. The department may  
838 withdraw its approval for cause, including obtaining information that casts doubt on the efficacy or  
839 consistent implementation of the approved procedure or when changes are made that could affect  
840 the validity of the procedures or process.

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

844 (5) OPERATION OF AN ALTERNATIVE CLEANING AND SANITIZING FREQUENCY. A food  
845 processing plant operator that implements an alternative cleaning and sanitizing procedure  
846 approved under sub. (2) shall do all of the following:

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

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

851 (c) Collect and retain data and records to document, on a continuing basis, the implementation  
852 and efficacy of the approved procedure. The operator shall retain the data and records for at least  
853 90 days, and shall make them available upon request for inspection and copying by the  
854 department.

855 **ATCP 70.20 Water supply. (1) OPERATIONS WATER.** (a) Operations water, other than  
856 water reclaimed according to sub. (3), shall be obtained from a source that complies with ch. NR  
857 811, for municipal water systems, or NR 812, for private or non-community water systems.

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

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

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

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

870 1. Washing subsequent deliveries of raw fruit or vegetables at the processing plant if the fruit  
871 or vegetable will undergo canning.

872 2. Flushing floors and gutters in the receiving areas for raw fruit or vegetables in the  
873 processing plant.

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

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

886 (c) If ingredient water is obtained from a privately owned water system, it shall be sampled by  
887 the operator not less than once every twelve months, and be tested at a laboratory, certified to  
888 perform the appropriate tests, under ch. ATCP 77.

889 (d) A food processing plant operator shall keep on file, for at least five years, the results of all  
890 microbiological and other tests conducted on ingredient water sampled at the food processing plant

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

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

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

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

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

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



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

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

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

918 8. The food processing plant operator tests the reclaimed water for compliance with subd. 1-4  
919 above at least once during any 6 month interval. The operator shall test the reclaimed water daily  
920 for 14 working days after the department approves the reclamation system under subd. 1., and for  
921 at least 7 working days after any repairs or alterations to the system.

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

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

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

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

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

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

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

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

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

952 7. There are no cross-connections between reclaimed water lines and any public or private  
953 water system, except for lines with backflow preventers that meet the requirements of chs. SPS  
954 382 and 384.

955 8. The reclaimed water, if held for more than twenty-four (24) hours, is at all times held at a  
956 temperature of at least 145°F. (63° C.) or is chemically treated under subd. 4 to suppress bacterial  
957 growth.

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

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

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

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

971 **(4) WATER TREATMENT.** (a) A food processing plant operator may not use any chemical to  
972 suppress bacterial growth in water, or to prevent off-tastes or odors in water, unless that chemical  
973 is approved for that purpose by the federal Environmental Protection Agency (EPA). Neither the  
974 chemical as applied, nor any compound produced by the chemical application, may adulterate food  
975 in the food processing plant in which it was used.

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

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

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

- 987 1. Obtained from a source that complies with ch. NR 811 or 812, as applicable.
- 988 2. Bacteriologically safe.
- 989 3. Protected from contamination.
- 990 4. Tested by the food processing plant operator for compliance with subd. 2 above at 6 month  
991 intervals.

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

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

997           **(6) WATER AND POTABLE LIQUIDS TRANSPORTED IN BULK.** (a) Water transported to a food  
998 processing plant in a bulk tanker or bulk container, for use as an ingredient or in other plant  
999 operations, shall be potable and shall be obtained from a source that complies with ch. NR 811 or  
1000 812.

1001           (b) Whenever potable water or another potable liquid is transported to or from a food  
1002 processing plant in a bulk tanker or bulk container, it shall be loaded, transported, and unloaded in  
1003 a sanitary manner that prevents contamination. The bulk tanker or bulk container shall be  
1004 thoroughly cleaned and sanitized before being filled. Suitable pumps, hoses, and fittings shall be  
1005 used to transfer potable water and potable liquids to and from bulk tankers and bulk containers  
1006 shall be cleaned and sanitized prior to use.

1007           (c) Whenever potable water or another potable liquid is transported to or from a food  
1008 processing plant in a bulk tanker or bulk container, the bulk tanker or bulk container and each of  
1009 its fittings and equipment shall meet all of the following requirements:

1010           1. It shall be properly constructed and maintained to prevent contamination of the potable  
1011 water or potable liquid. Food contact surfaces shall comply with s. ATCP 70.12 (2).

1012           2. It shall be cleaned, sanitized, and inspected on a routine basis.

1013           3. It may not be used to transport materials that may contaminate potable water or potable  
1014 liquid that is subsequently transported in the bulk tanker or bulk container.

1015           4. It shall be effectively sealed to protect the potable water or potable liquid from  
1016 contamination during transit.

1017           **Note:** Effective sealing systems include manhole cover gaskets and seals.

1018 5. It shall be properly stored and serviced to prevent contamination. When not in use, pumps,  
1019 hoses, and fittings shall be properly maintained, capped, stored, and protected from contamination.

1020 (7) CULINARY STEAM. Water used to produce culinary steam shall be potable. Water  
1021 reclaimed from food processing operations may not be used to produce culinary steam unless it  
1022 complies with sub. (3) (a) or (b). In boilers used to produce culinary steam, boiler water additives  
1023 shall comply with 21 CFR 173.310.

1024 (8) ICE. Ice used to cool or maintain the temperature of foods shall be made from potable  
1025 water. Ice used to cool or maintain the temperature of ready-to-eat foods shall not have been  
1026 previously used for any other purpose. Ice shall be received, handled, and stored in a manner to  
1027 prevent contamination or adulteration. Any ice which is not made on site shall be inspected upon  
1028 receipt, and rejected if it is delivered in a way that has not adequately protected the ice from  
1029 contamination.

1030 **ATCP 70.22 Food ingredients. (1) GENERAL.** Food ingredients shall be safe, wholesome,  
1031 and unadulterated, and shall comply with applicable standards of identity under s. 97.09, Stats.  
1032 Raw agricultural commodities and other food ingredients shall be segregated and examined as  
1033 necessary to determine whether they are clean and fit for processing. Processed foods and dairy  
1034 products which are used as food ingredients shall be obtained from sources which comply with  
1035 applicable licensing and inspection requirements.

1036 (2) EGGS AND EGG PRODUCTS. Only clean whole eggs, pasteurized eggs in liquid, frozen or  
1037 dry form, or pasteurized egg products may be used in food processing. Eggs and egg products

1038 may be pasteurized during processing. Clean whole eggs shall be equivalent to USDA Grade B or  
1039 better with shells intact.

1040 **ATCP 70.24 Food handling and storage. (1) GENERAL.** Food shall be protected from  
1041 contamination and decomposition while being processed, handled, conveyed, or held at a food  
1042 processing plant. Food shall be processed and held in a manner which keeps the food in a safe,  
1043 wholesome, and unadulterated condition. Potentially hazardous foods shall be processed and held  
1044 at temperatures, or in a manner, which minimizes the potential for growth of undesirable  
1045 microorganisms.

1046 **(2) FOOD STORAGE.** Food storage areas shall be maintained in a clean, sanitary, and orderly  
1047 condition, free from conditions which may result in the adulteration of food. Potentially hazardous  
1048 foods shall be stored at safe temperatures. Storage areas shall be constructed and maintained so  
1049 that waste water and other waste liquids do not drain into, or accumulate in, any storage area.  
1050 Food shall not be stored in a manner which may attract or harbor pests.

1051 **(3) FOOD PROCESSING. (a)** Food processing shall be conducted under appropriate conditions  
1052 and controls to minimize the potential for growth of undesirable microorganisms, or the  
1053 contamination of food.

1054 **Note:** One way to comply with this requirement is to follow a HACCP plan which monitors and  
1055 controls food safety variables at critical control points in the manufacturing process. Monitoring and  
1056 controlling food safety variables such as time, temperature, humidity, water activity ( $a_w$ ), pH, pressure, and  
1057 flow rate at critical control points can ensure that mechanical breakdowns, time delays, temperature  
1058 fluctuations, and other conditions do not contribute to the decomposition or contamination of food.

1059 (b) If potentially hazardous food is heated, refrigerated, or frozen in the course of processing,  
1060 the internal temperature of the food shall be accurately monitored, as necessary, to ensure that safe  
1061 temperatures are promptly attained and maintained.

1062 (c) Any testing and monitoring done to minimize the potential for growth of undesirable  
1063 microorganisms, or the contamination of food during processing and storage as required in  
1064 paragraph (3) of this section shall be recorded, the records shall be maintained on site for one year,  
1065 and shall be made available to the department or its agents on request for copying or  
1066 photographing.

1067 (d) Potentially hazardous frozen foods, if thawed for processing, shall be thawed by one of the  
1068 following methods:

1069 1. By placing the frozen food in a refrigerated space at a temperature of not more than 41°F.  
1070 (5°C.).

1071 2. Placing under potable running water, at a temperature of not more than 70°F. (21°C.), for  
1072 no more time than is needed to thaw the food. Water velocity shall be sufficient to agitate loose  
1073 particles and drain or float them away from the food being thawed.

1074 3. In a microwave oven if the food is fully cooked in the microwave oven, or if cooking is  
1075 immediately completed in another cooking facility.

1076 4. In any cooking facility, as part of the process by which the food is fully cooked.

1077 **(4) BULK FLOUR HANDLING SYSTEMS.** (a) Food contact surfaces of bulk flour handling  
1078 equipment shall comply with the provisions of s. ATCP 70.12 (2). Pneumatic systems using  
1079 storage bins constructed of semi-permeable cloth material are exempt from the requirement that



1080 surfaces be smooth and nonabsorbent, provided the surfaces can be effectively cleaned.  
1081 Attachment mechanisms for holding inspection port covers, access doors, delivery pipe caps, or  
1082 other removable accessories shall have no loose parts. Delivery pipe caps shall be kept in place,  
1083 and secured against removal, except when a bulk flour handling system is in use. Outside  
1084 installations shall be watertight or suitably covered to prevent entry of water and foreign material.

1085 (b) Intake air used in pneumatic flour handling systems shall be filtered to exclude particles of  
1086 50 microns or larger. Air discharged from the system shall be filtered so that no visible dust  
1087 escapes. Filters shall be readily removable for cleaning or replacement. Straight runs of  
1088 pneumatic conveyors shall comply with the provisions of s. ATCP 70.12 (1), except that piping  
1089 which is self-purging is exempt from accessibility requirements.

1090 (5) RAW INGREDIENTS AND FINISHED PRODUCTS; SEPARATE HANDLING. Effective measures  
1091 shall be taken to prevent cross contamination between raw ingredients and finished food products.  
1092 Raw ingredients shall not be handled simultaneously with finished products in any part of a food  
1093 processing plant if either the raw materials or the finished products are uncovered or unprotected,  
1094 and if the handling may result in contamination.

1095 (6) SALVAGING DISTRESSED FOOD. (a) In this subsection:

1096 1. "Distressed food" means processed food exposed to a fire, flood, transportation accident,  
1097 refrigeration breakdown, or other unusual condition which may affect its safety or suitability as  
1098 human food. "Distressed food" does not include food or food packages damaged during normal  
1099 conditions of food and food product handling, transit, or storage.

1100 2. "Reconditioned food" means packaged distressed food which is distributed or offered for  
1101 sale as human food after its package is repaired or relabeled without being opened.

1102 3. "Reprocessed food" means distressed food that is subsequently processed in accordance  
1103 with the requirements under this chapter and distributed or offered for sale as human food.

1104 (b) A food processing plant operator shall notify the department within 3 days after the  
1105 operator takes possession of any distressed food, or within 3 days after food in the operator's  
1106 custody becomes distressed food. The operator shall notify the department before the operator  
1107 reprocesses or reconditions the distressed food.

1108 (c) A food processing plant operator shall identify distressed food as such, and shall separate it  
1109 from other food. No operator may store distressed food in a processing area, or under conditions  
1110 which may lead to the contamination of other food, equipment, utensils, or packaging materials.

1111 (d) No food processing plant operator may do either of the following:

1112 1. Reprocess for sale, as human food, any distressed food which is unwholesome or  
1113 adulterated.

1114 2. Offer for sale, sell, or distribute food in packages that are damaged to such an extent that the  
1115 food may have been exposed or subjected to possible contamination, including packages with  
1116 bulging ends, ruptures, hairline fractures, breakage along critical seams, or openings which may  
1117 have exposed food to contamination.

1118 (e) No food processing plant operator may sell or distribute reprocessed or reconditioned food  
1119 at wholesale unless the operator gives the purchaser or recipient written notice that the food is  
1120 reprocessed or reconditioned. The notice shall also include the name and address of the person

1121 who reprocessed or reconditioned the distressed food. The notice may be included on an invoice,  
1122 bill of lading, or other documentation of the sale or distribution of the food.

1123 (f) A food processing plant operator shall keep, for the period of time set forth in 21 CFR  
1124 117.315, all of the following records related to distressed food handled by that operator:

1125 1. A description of the distressed food, including the type of food, the package or container  
1126 style, and the amount of the food.

1127 2. The source of the distressed food, or the conditions which caused it to become distressed  
1128 food.

1129 3. The date on which the operator received the distressed food.

1130 4. The nature of any reprocessing or reconditioning which the operator performed on the  
1131 distressed food.

1132 5. The final disposition of the distressed food if the distressed food was not sold directly at  
1133 retail. That record shall include the name and address of the person, such as the food wholesaler,  
1134 food distributor, waste disposal firm or waste disposal site operator, to whom the food processing  
1135 plant operator delivered the food.

1136 (7) FOOD IRRADIATION. Irradiation in the production, processing and handling of food shall  
1137 comply with applicable federal regulations under 21 CFR 179.

1138 **Note:** Copies of 21 CFR 179 are on file with the department and the legislative reference bureau.

1139 (8) EGG CLEANING AND STORAGE. Cleaning and storage of eggs shall be done in compliance  
1140 with the requirements of s. ATCP 88.20.

1141       **ATCP 70.26 Food packaging and labeling. (1) GENERAL.** Food packages shall be of  
1142 sanitary design and construction, so as to protect food contents from reasonably foreseeable risks  
1143 of contamination. Food packages shall be clean, sanitary, and free of any extraneous or deleterious  
1144 substance. Food shall not be sold or distributed in packages which are damaged to the extent that  
1145 food contents may be adulterated as a result of the damage. A sealed food package is damaged  
1146 within the meaning of this subsection if the package or seal is broken or bulged.

1147       **(2) CLEANING AND SANITIZING RETURNABLE FOOD PACKAGES.** Returnable or multi-use food  
1148 packages, including returnable bottles, shall be effectively cleaned and sanitized before being  
1149 reused. Cleaning and sanitizing processes shall remove all extraneous matter and potential  
1150 adulterants from a food package before the food package is reused. Sanitizing methods shall  
1151 comply with s. ATCP 70.28. No food package may be reused unless it is specifically designed and  
1152 constructed for that purpose.

1153       **(3) INSPECTION OF RETURNABLE FOOD PACKAGES.** Returnable or multi-use packages, after  
1154 being cleaned and sanitized, shall be inspected before being reused. Inspection shall be adequate  
1155 to detect extraneous material and visible adulterants, and any damage to product contact surfaces.  
1156 Inspection shall be performed on surfaces lighted in compliance with s. ATCP 70.08 (6) (b).

1157       **(4) SINGLE-SERVICE FOOD PACKAGES.** Single-service food packages, including bottle caps and  
1158 other single-service articles used to package food, shall be made from clean, sanitary materials.  
1159 Single-service food packages shall be clean and sanitary at the time of use. Single service food  
1160 packages shall be protected from contamination prior to use, and shall be handled in a sanitary

1161 manner. Single-service food packages, including single-service bottles and bottle caps, shall not  
1162 be re-used.

1163 **(5) FOOD PACKAGE LABELING.** Packaged food shall be packaged and labeled according to all  
1164 of the following, as applicable:

1165 (a) 21 CFR 101.

1166 (b) Section 97.09, Stats., and federal regulations incorporated by reference in s. 97.09, Stats.

1167 (c) Chapter ATCP 90.

1168 (d) Chapter ATCP 75 Appendix, *Wisconsin Food Code* section 3-201.11(C).

1169 (e) If the packaged food contains a major food allergen, the ingredient statement on the  
1170 package shall disclose the common name of the major food allergen. The disclosure shall be  
1171 equivalent in size and prominence to the rest of the ingredient statement. If an allergen originates  
1172 from fish, crustacean shellfish, or tree nuts, the disclosure shall include the common name of the  
1173 source species.

1174 **Note:** For example, if a food product includes an allergen that originates from fish, the ingredient  
1175 statement must disclose the common name such as bass, flounder, or cod. If the allergen originates from  
1176 crustacean shellfish, the ingredient statement must disclose the common name such as crab, lobster, or  
1177 shrimp. If the allergen originates from tree nuts, the ingredient statement must disclose the common name  
1178 such as almond, pecan, walnut, or coconut.

1179 **(6) EGG PACKAGING AND LABELING.** The packaging and labeling of eggs shall be done in  
1180 compliance with the requirements of ss. ATCP 88.32, 88.34, and 88.38.

1181 **ATCP 70.28 Sanitizers and sanitizing methods. (1) SANITIZING METHODS.** All returnable  
1182 or multi-use food packages, and all food contact surfaces of equipment and utensils used to handle  
1183 foods, shall be effectively sanitized prior to each use.

1184 (1m) The food processing plant operator shall use only chemical sanitizers that comply with  
1185 21 CFR 178.1010, are registered with the U.S. environmental protection agency, are applied  
1186 according to manufacturer's instructions, labeled for use in food processing plants on food contact  
1187 surfaces and, when used appropriately, do not leave residue on the food contact surface.

1188 (2) BAKING AND COOKING CONTAINERS; EXEMPTION. Subsection (1) does not apply to baking  
1189 and cooking containers if heating time and temperature combinations meet industry standards and  
1190 are adequate to destroy pathogenic microorganisms, provided that the containers are cleaned,  
1191 stored, and used in a manner which prevents contamination of food.

1192 (3) SANITIZERS; MAXIMUM CONCENTRATIONS. The food processing plant operator shall use  
1193 sanitizers and cleaning compounds so no toxic residue is left on any food contact surface.  
1194 Sanitizing solutions shall not exceed the maximum concentrations established by the food and  
1195 drug administration, United States department of health and human services, under 21 CFR  
1196 178.1010. A test kit or other device that measures the concentration of sanitizing solutions in parts  
1197 per million shall be used as necessary to ensure compliance with this subsection.

1198 **Note:** Copies of 21 CFR 178.1010 are on file with the department and the legislative reference bureau.

1199 (4) SANITIZERS; DEPARTMENT APPROVAL. (a) Sanitizers approved by the EPA and labeled for  
1200 use on food contact surfaces are also accepted by the department for use according to their labels.  
1201 The department may approve other sanitizers and sanitizing methods that it finds to be safe and  
1202 effective for the purpose used.

1203 (b) The department may deny or withdraw approval of any sanitizer or sanitizing method if the  
1204 department determines that the sanitizer or sanitizing method is not safe or effective for the

1205 purpose or under the conditions used, or that it adversely affects the sanitary characteristics of  
1206 equipment, utensils or food packages.

1207 **ATCP 70.30 Ready-to-eat foods; reporting pathogens and toxins. (1) REQUIREMENT.**

1208 Except as provided under sub. (2), a food processing plant operator shall report to the department  
1209 the results of any microbiological test or laboratory analysis which indicates that any ready-to-eat  
1210 food produced by that operator contains pathogenic organisms, toxins resulting from the growth of  
1211 pathogenic organisms, or any other adulterant capable of causing disease or injury if ingested. The  
1212 operator shall report to the department within 24 hours after the operator obtains the test results.  
1213 The operator may report orally, electronically, or in writing.

1214 **Note:** The Department's emergency phone number is (608) 224-4714. The general number is (608)  
1215 224-4700, and the FAX number is (608) 224-4710.

1216 **(2) EXEMPTION.** A food processing plant operator is not required to report test results under  
1217 sub. (1) if all of the following apply:

1218 (a) The ready-to eat-food is identified by a product code or production lot number.

1219 (b) The food processing plant operator has not yet sold or distributed any of the ready-to-eat  
1220 food represented by the product code or production lot number under par. (a), but retains direct  
1221 control over all of that ready-to-eat food.

1222 **ATCP 70.32 Recall plan. (1) PLAN REQUIRED.** A food processing plant operator shall have  
1223 a written plan for identifying and recalling food produced at that plant, should a food recall  
1224 become necessary. The operator shall update the plan as necessary, and shall make it available to  
1225 the department for inspection and copying upon request.

1226 **(2) PLAN CONTENTS.** A plan, under sub. (1), shall do all of the following:

- 1227 (a) Identify key individuals or positions that are responsible for planning, approving, and  
1228 implementing recalls on behalf of the food processing plant operator.
- 1229 (b) Identify key individuals or entities to be contacted or consulted in connection with a recall.
- 1230 (c) Include procedures for the routine identification, dating, and tracking of food production  
1231 lots, so that affected lots can be identified and distinguished from unaffected lots in the event of a  
1232 recall.
- 1233 (d) Include procedures to enable routine identification, dating, and tracking of food shipments  
1234 from the food processing plant. Tracking shall identify shipment recipients and contents, cross-  
1235 referenced to production lots, so that recipients of affected lots can be contacted in the event of a  
1236 recall.
- 1237 (e) Include procedures for determining the nature and scope of a recall, including affected  
1238 food production lots, shipments, and shipment recipients.
- 1239 (f) Include procedures for identifying and communicating with affected persons, including  
1240 suppliers, food shipment recipients, down-line buyers, consumers, government agencies, and  
1241 others.
- 1242 (g) Identify potential target audiences for recall information, including consumers,  
1243 distributors, and government agencies.
- 1244 (h) Identify potential methods for communicating with target audiences under par. (g).
- 1245 (i) Identify key information, including the identity of the affected food, the reason for the  
1246 recall, and suggested actions to be taken by affected persons, which may need to be communicated  
1247 in the event of a recall.



1248 (3) DEVIATIONS FROM PLAN. Actual recall procedures may deviate from the recall plan under  
1249 sub. (1), as circumstances warrant.

1250 **Subchapter III. Canning Operations; Supplementary Requirements**

1251 **ATCP 70.34 General. (1) APPLICABLE REQUIREMENTS.** Food processing plants engaged in  
1252 canning operations shall comply with applicable provisions of subch. II. Food processing plants  
1253 engaged in canning operations shall also comply with this subchapter and shall file processes, as  
1254 required, with the FDA according to the provisions in 21 CFR 108.

1255 (2) RESTRICTIONS ON SALE, DISTRIBUTION, AND DONATION OF HOME-CANNED FOODS. Home-  
1256 canned low-acid or acidified foods may not be donated to charitable organizations, food banks,  
1257 food pantries, or other non-profit organizations that will distribute or sell the home-canned foods.  
1258 The individual canning processor may not sell the home-canned foods at a food bank or food  
1259 pantry, or on behalf of a charitable or non-profit organization, unless exempted by statute or rule.

1260 **ATCP 70.36 Low-acid foods packaged in hermetically sealed containers.** The operator  
1261 of a food processing plant that processes and packages low-acid foods in hermetically sealed  
1262 containers shall comply with applicable federal regulations under 21 CFR 108.35 (c) and 21 CFR  
1263 113.

1264 **Note:** Section ATCP 70.13 applies to all low-acid foods processed and packaged in hermetically sealed  
1265 containers, including thermally processed and aseptically processed low-acid foods.

1266 **ATCP 70.38 Acidified foods.** Persons who process acidified foods shall comply with  
1267 applicable federal regulations under 21 CFR 108.25 (c) and 21 CFR 114.

1268 **Note:** Copies of 21 CFR 114 are on file with the department and the legislative reference bureau.

1269       **ATCP 70.40 Facilities and equipment; cleaning. (1)** EQUIPMENT DESIGN, CONSTRUCTION,  
1270 AND ACCESSIBILITY. The operator, of a food processing plant facility handling raw agricultural  
1271 commodities to prepare the commodities for canning, shall use product-handling equipment that is  
1272 kept clean and in good repair and is designed and constructed in a way that allows easy  
1273 accessibility for maintenance and cleaning.

1274       **(2)** EQUIPMENT, WATER, AND SUPPLIES USED FOR CLEANING. The food processing plant  
1275 operator of a canning facility shall use cleaning equipment that is adequate and in good repair, and  
1276 shall provide ample supplies of water and steam or other approved cleaning and sanitizing  
1277 materials for cleaning purposes at the facility.

1278       **(3)** CLEANING REQUIREMENTS FOR EQUIPMENT USED TO PROCESS FOOD BEFORE THERMAL  
1279 PROCESSING. The food processing plant operator at a canning facility shall clean equipment used  
1280 to process food before thermal processing, in accordance with a written plan kept at the canning  
1281 facility and made available to the department for review upon request. The written plan shall  
1282 include:

1283       (a) A clear and complete description of the affected food processing equipment and utensils,  
1284 including any continuously-operated equipment. The description shall identify sanitary design  
1285 features that are relevant to the proposed cleaning and sanitizing procedures.

1286       (b) The types of food produced with the affected equipment or utensils, the purposes for which  
1287 the food will be used, and the thermal processing conditions to which the food will be subjected.

1288       (c) A clear and complete description of the alternative procedures used to clean and, if  
1289 appropriate, sanitize the equipment, including equipment used to administer the cleaning and

1290 sanitizing treatments, frequency, methods, materials, and relevant process parameters such as time  
1291 and temperature. The description shall include a flow diagram of the cleaning and sanitizing  
1292 procedure.

1293 (d) A written statement, by the food processing plant operator, that the alternative cleaning  
1294 and sanitizing procedure has been determined by competent authority (e.g., a process authority, or  
1295 is validated by a published or unpublished, peer-reviewed article, challenge studies, or regulatory  
1296 standards) and determined to be effective in preventing finished food product contamination and  
1297 ensuring the microbiological safety of food.

1298 (e) Identification of foreseeable hazards, critical control points, critical safety parameters and  
1299 limits, and monitoring procedures and controls to ensure that the procedure is effective and  
1300 appropriately implemented.

1301 **ATCP 70.42 Handling raw agricultural commodities and by-products. (1) PRE-**  
1302 **CANNING OPERATIONS.** Raw agricultural commodities shall be washed, sorted, trimmed as  
1303 necessary, and inspected before being canned. This requirement does not apply to the washing of  
1304 cabbage being prepared to make sauerkraut.

1305 **(2) WASTE HANDLING.** Waste and by-products from canning operations shall be stored and  
1306 handled in a sanitary manner.

1307 **Subchapter IV. Fish Processing Plants; Marine Shellfish Plants; Supplementary**

1308 **Requirements**

1309 **ATCP 70.44 Fish processing. (1) APPLICABLE REGULATIONS.** Fish processing operations  
1310 shall comply with subch. II and 21 CFR 123. Fish processing plant operators shall have and  
1311 operate in accordance with HACCP plans that comply with 21 CFR 123 and address food safety  
1312 hazards that may occur in fish processing. If a fish processing plant produces smoked fish  
1313 products or smoke-flavored fish products, the HACCP plan for that fish processing plant shall  
1314 address potential botulism risks as provided in 21 CFR 123 part B.

1315 **(2) RESTRICTION ON USE OF COLD-PROCESS SMOKED FISH.** Cold-process smoked fish may  
1316 not be used as an ingredient in any other ready-to-eat, potentially hazardous food.

1317 **ATCP 70.46 Labeling and sale of smoked fish. (1) MANDATORY LABEL INFORMATION.**  
1318 Every package containing smoked fish shall be clearly and conspicuously labeled, on the principal  
1319 display panel of that package, with all of the following information:

1320 (a) The name and address, including the zip code, of the smoked fish processor or distributor.

1321 (b) The name of the product, including the common name of the fish from which the product  
1322 is derived as found in Table 3-2 of the Fourth Edition of Fish and Fishery Products Hazards and  
1323 Controls Guidance.

1324 (c) The net weight of the package contents.

1325 (d) If cold-smoked fish is contained in reduced-oxygen packaging as defined in s. ATCP 70.02  
1326 (22n) and sold or distributed in an unfrozen state, the words “PERISHABLE – KEEP

1327 REFRIGERATED AT OR BELOW 38° F” in conspicuous letters at least the size of those used in  
1328 the food name.

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

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

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

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

1339 (4) REMOVAL OF MISLABELED OR MISHANDLED SMOKED FISH. Food consisting of or containing  
1340 smoked fish shall be immediately removed from sale, and shall be destroyed or treated to render it  
1341 unattractive and unfit for human consumption, if any of the following occurs:

1342 (a) The food package is not labeled with a processing date.

1343 (b) The vacuum-packaged, cold-smoked fish is held, other than for brief periods during  
1344 distribution, at a temperature above 38° F. (3.4° C.) prior to retail sale. This paragraph does not  
1345 apply to a food which the department specifically exempts in writing because it is not a potentially  
1346 hazardous food.

1347       **(5) APPLICABILITY OF SMOKED FISH REGULATIONS IN WISCONSIN.** No smoked fish may be sold,  
1348 distributed, or offered or exposed for sale in this state unless the smoked fish have been processed,  
1349 labeled, and handled in compliance with this subchapter. This subsection applies to every person  
1350 engaged in the sale or distribution of smoked fish in this state, regardless of whether the person  
1351 processes smoked fish in this state.

1352       **ATCP 70.48 Fish roe. (1) REFRIGERATION.** Roe and any attached entrails harvested from  
1353 a fish shall be refrigerated at a temperature of not more than 38° F. (3.4° C.). Processing of dry  
1354 salted roe or salted roe product shall be accomplished under 21 CFR 123.

1355       **(2) HARVESTING AND HANDLING.** Roe and attached entrails, if any, shall be harvested, stored,  
1356 and transported for processing in covered food grade containers. Each container shall be  
1357 conspicuously labeled to indicate when each of the following operations was performed, if that  
1358 operation has been performed:

1359       (a) The roe and attached entrails, if any, were harvested from the fish.

1360       (b) The roe sacks were separated from attached entrails, if any. Roe sacks shall be separated  
1361 from attached entrails within 48 hours after the roe sacks and entrails are harvested from the fish.

1362       (c) The roe was separated from the roe sacks. Roe shall be separated from roe sacks within 72  
1363 hours after the roe sacks are harvested from the fish, unless the roe is processed and packed in roe  
1364 sacks. Roe processed and packed without being separated from roe sacks shall be processed and  
1365 packed within 72 hours after the roe sacks are harvested from the fish.

1366       **(3) RECEIPT FOR PROCESSING.** A fish processing plant operator may not accept for processing  
1367 any roe that has been held, transported, or processed in violation of sub. (1) or (2).

1368 (4) PROCESSING STANDARDS. (a) Roe shall be held and processed according to s. ATCP 70.24

1369 (1).

1370 (b) Processed roe shall contain a minimum of 2.5% salt by weight, as determined by  
1371 quantitative analysis for total salt content.

1372 (c) No fish processing plant personnel may have direct hand contact with finished, ready-to-  
1373 eat roe.

1374 (5) PRODUCT REPRESENTATION. (a) No roe product may be labeled or represented as "caviar"  
1375 unless one of the following applies:

1376 1. The product consists only of the eggs of sturgeon prepared by a salting and separation  
1377 process traditionally associated with the term "caviar."

1378 2. The product consists of roe prepared by a salting and separation process traditionally  
1379 associated with the term "caviar," and the name of the fish species is clearly disclosed with the  
1380 term "caviar" whenever that term is used.

1381 **Note:** For example, a caviar-type product made from whitefish eggs, using the traditional caviar  
1382 process, may not be labeled as "caviar" unless it is labeled as "whitefish caviar." All packaged food  
1383 product labels, including "caviar" labels, must also include a statement of ingredients listed by their  
1384 common or usual names in descending order of prominence (see ATCP 70.10).

1385 (b) No person may misrepresent the identity or value of any roe product by adding a color  
1386 additive to the roe product. This paragraph does not prohibit the use of color additives in roe  
1387 products if all of the following apply:

1388 1. The color additive is approved by the United States food and drug administration.

1389 2. The product includes a conspicuous label disclosure, such as "artificially colored" or "color  
1390 added," which clearly indicates that the product includes a color additive. The disclosure shall  
1391 appear on the product label directly below the product name in type at least one-third the size of  
1392 the type used in the product name.

1393 3. The color additive is included in the ingredient statement on the product label.

1394 **ATCP 70.50 Marine molluscan shellfish processing. (1)** APPLICABLE FEDERAL  
1395 REGULATIONS. Shellfish processing and shipping operations shall comply with subch. II of this  
1396 rule, FDA's *Guide for the Control of Molluscan Shellfish, The Model Ordinance*, and applicable  
1397 sections of 21 CFR 123. Shellfish processing plant operators shall have HACCP plans that  
1398 comply with 21 CFR 123 and address food safety hazards that may occur in shellfish processing.  
1399 If a shellfish processing plant produces smoked shellfish products or smoke-flavored shellfish  
1400 products, the HACCP plan for that fish processing plant shall address potential botulism risks as  
1401 provided in 21 CFR 123 part B.

1402 **(2) ILLNESS OUTBREAKS ASSOCIATED WITH SHELLFISH.** (a) At any time shellfish are  
1403 potentially implicated in an illness outbreak involving at least 2 (two) persons not from the same  
1404 household (or at least one person in the case of paralytic shellfish poisoning), the department shall  
1405 determine whether an epidemiological association exists between the illness and the shellfish  
1406 consumption by reviewing each consumer's food intake history and the shellfish handling  
1407 practices of the consumer and retailer.

1408 (b) When the department has determined an epidemiological association exists between an  
1409 illness outbreak and shellfish consumption, the department shall conduct an investigation of the



1410 outbreak to determine whether the illness is related to the shellfish growing area or to post-harvest  
1411 contamination or mishandling.

1412 (c) Upon completion of the investigation, the department shall notify receiving states and the  
1413 United States food and drug administration of the findings, and take appropriate steps in  
1414 cooperation with the licensee dealer to recall the affected product and, if necessary, inform  
1415 consumers about the outbreak and associated product.

1416 (3) DOCUMENTS ASSOCIATED WITH SHELLFISH PROCESSING. Any documents generated by the  
1417 facility in the course of its operation shall be available to the department within 24 hours of request  
1418 by the department or its agent..

#### 1419 **Subchapter V. Bottling Establishments; Supplementary Requirements**

1420 **ATCP 70.52 Bottling establishments; general.** Bottling establishments shall comply with  
1421 subch. II and this subchapter. Bottling establishments producing bottled water shall comply with  
1422 21 CFR 129.

1423 **ATCP 70.54 Returnable and single-service bottles.** Bottles shall comply with food  
1424 package requirements under s. ATCP 70.26 (1). Returnable bottles shall be cleaned, sanitized, and  
1425 inspected in compliance with s. ATCP 70.26 (2) and (3). Single service bottles shall comply with  
1426 s. ATCP 70.26 (4).

#### 1427 **ATCP 70.56 Bottled water product sampling; record keeping; reports.**

1428 (1) SAMPLING AND ANALYSIS. The operator of a bottled water plant shall collect and analyze  
1429 samples of bottled product for the following contaminants at the following minimum frequency,

1430 and more frequently if necessary, to provide reasonable assurance of compliance with this  
1431 subsection.

1432 (a) A weekly total coliform analysis. Pursuant to 21 CFR 129.80 (g) (1), a positive total  
1433 coliform analysis requires follow-up testing for *E. coli* and, pursuant to 21 CFR 165.110 (b) (2)  
1434 (B), if *E. coli* is present the bottled water will be deemed adulterated.

1435 (b) An annual physical analysis pursuant to 21 CFR 165.110 (b) (3) for turbidity, color and  
1436 odor analysis.

1437 (c) An annual chemical analysis pursuant to 21 CFR 165.110 (b) (4).

1438 (d) An annual radiological analysis pursuant to 21 CFR 165.110 (b) (5).

1439 **(2) REPORTING OF ANALYTICAL RESULTS.** A processor of bottled water shall report the results  
1440 of all required analyses, under sub. (1), to the department, for each license year upon request. If  
1441 the result of any individual analysis exceeds the established enforcement standard, the bottled  
1442 water processor shall submit a copy of that analytical report to the department within 7 days of the  
1443 completion of the analysis.

1444 **ATCP 70.58 Labeling bottled products.** (1) Bottled products shall be labeled according to  
1445 s. ATCP 70.26 (5). Bottled water shall also be labeled according to 21 CFR 165.110. Juice shall  
1446 be labeled according to 21 CFR 120, and any applicable state regulations found in this chapter.

1447 **Subchapter VI. Juice and Juice HACCP**

1448 **ATCP 70.60 Juice and Juice HACCP. (1) APPLICABLE REGULATIONS.** Food processing  
1449 plants producing and packaging or bottling juice shall comply with subch. II and this subchapter.

1450 Food processing plants engaged in juice processing and packaging or bottling shall comply with 21  
1451 CFR 120.

1452 (2) LABELING REQUIREMENTS. A juice label may not misrepresent that juice has been  
1453 pasteurized or has undergone a process equivalent to pasteurization. A juice label may not  
1454 represent as "fresh" any juice that has been treated with ultra-violet light.

1455 **Subchapter VII. Effect of Rules on Local Ordinances**

1456 **ATCP 70.62 Effect of rules on local ordinances. (1) NON-CONFLICTING LOCAL**  
1457 **ORDINANCES PERMITTED.** This chapter does not prohibit or nullify any local government ordinance  
1458 with which it is not in direct conflict as provided in sub. (2).

1459 (2) PRE-EMPTION OF CONFLICTING LOCAL ORDINANCES. If this chapter conflicts directly with  
1460 any local government ordinance, so that it is impossible to comply with one except by violating the  
1461 other, this chapter controls.

1462 (3) DUTY TO COMPLY. Compliance with local government ordinances does not relieve any  
1463 person from the duty of complying with this chapter.

1464 **Subchapter VIII. Variances**

1465 **ATCP 70.64 Variances. (1) ISSUANCE.** The department may issue a written waiver granting  
1466 a variance from a construction, equipment, or processing standard under this section if the  
1467 department finds that the variance is reasonable and necessary under the circumstances, and that it  
1468 will not compromise the purpose served by the construction, equipment, or processing and  
1469 recreational standard. The administrator of the department's division of food and recreational

1470 safety may issue a waiver on behalf of the department. The department shall keep a copy of the  
1471 waiver on file for as long as the waiver remains in effect.

1472 **(2) SUBMISSION OF REQUEST FOR A VARIANCE.** A variance request shall be submitted to the  
1473 department through the sanitarian assigned by the department to inspect the food processing plant,  
1474 and shall include all validation documents as well as a HACCP Plan or FSMA preventive controls  
1475 as applicable if it is for a waiver of accepted processing protocols.

1476 **(3) DURATION AND EXPIRATION.** All waivers granted under this section shall expire in five  
1477 years from the date of issuance or when changes are made that could have an effect on the validity  
1478 of the procedures or process.

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1481       **SECTION 2. EFFECTIVE DATE:** This rule shall take effect on the first day of the month  
1482 following publication in the Wisconsin administrative register, as provided under s. 227.22 (2)  
1483 (intro).

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

WISCONSIN DEPARTMENT OF AGRICULTURE,  
TRADE AND CONSUMER PROTECTION

By \_\_\_\_\_

Jeff Lyon, Interim Secretary

## Wisconsin Department of Agriculture, Trade and Consumer Protection

### Initial Regulatory Flexibility Analysis

**Rule Subject:** Food Processing Plants

**Adm. Code Reference:** ATCP 70

**Rules Clearinghouse #:** Not assigned

**DATCP Docket #:** 17 – R - 05

#### *Rule Background*

DATCP has, on a fairly regular basis, amended or re-created this rule in order to keep pace with changes in industry as well as the FDA's regulatory philosophy. In this rule revision, DATCP has been especially cognizant of clarifications necessitated by the merger between the DATCP's Division of Food Safety and the Department of Health Services' ("DHS") Food Safety and Recreational Licensing Section ("FSRL") which occurred in July of 2016. In the wake of this merger, as DATCP continues to seek better ways to serve our stakeholders in particular and Wisconsin residents generally, DATCP will continue to advance improvements to Wisconsin's administrative rules and statutory framework.

One major change in implementing this merger involved evaluating the food processing and wholesaling (activities regulated by ATCP 70) operations of persons holding retail food establishment licenses. It should be noted that provisions of ATCP 70 related to these activities will impact restaurants, now licensed as retail food establishments. This rule, for the first time, spells out definitions for "wholesale" and "retail." This rule also requires retail food establishment license holders exempted from the requirement of holding an additional food processing plant license to still meet safe food manufacturing requirements in ATCP 70.

#### *Rule Content*

DATCP has updated ATCP 70 with the incorporation by reference of provisions of Federal regulations that implement the requirements of FSMA. This involves multiple subparts of the recently created 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, formerly 21 CFR 110, *Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding, Human Food*, pertaining to preventive food safety systems that have already been referenced in chs. ATCP 65 (Milk and Milk Products) and ATCP 71 (Food Warehouses and Milk Distributors). Since the majority of Wisconsin food facilities, already subject to this federal rule, are licensed as food processing plants, this proposed rule includes similar referencing for the sake of consistency. This revision also clearly articulates the requirements for Wisconsin-licensed food processing plants that are not subject to the federal rule.

In July of 2016, when DATCP's Division of Food Safety merged with DHS' FSRL to form the new Division of Food and Recreational Safety ("DFRS"), a merger of the two food safety regulatory systems became necessary. For example, restaurant operators were not allowed to wholesale food pursuant to the DHS regulation, while retail food establishment operators, pursuant to DATCP's authority, could engage in a limited amount of wholesaling. At present, restaurant operators are now licensed as retail food establishments and now enjoy a limited ability to wholesale food. The new ATCP 70 clarifies both the exemption from the requirement to hold a food processing plant license as well as the requirements for food processing and subsequent wholesaling now allowed in licensed retail food establishments. The new ATCP 70 also incorporates, for the first time, specific definitions for wholesaling and retailing concomitantly being incorporated into ATCP 75 (Retail Food Establishments) and ATCP 55 (Meat and Meat Food Products). DATCP expects these updates to promote clarity, uniformity, and improved guidance to food businesses in Wisconsin.

In addition, the new ATCP 70 contains language designed to specifically clarify the responsibilities for operators of retail food establishments. Besides the afore-mentioned exemption from the requirement of holding a food processing plant license, operators will better understand their duty to follow the safety, processing, and labeling requirements in ATCP 70 for the production of food for wholesaling. These provisions not only level the playing field for industry, but, more importantly, also ensure that certain ATCP 70 requirements are in place to ensure food safety. Examples of such requirements include provisions for a written recall plan and a written food safety plan for facilities subject to FSMA rules.

In revising this rule, DATCP sought to eliminate duplication, improve regulatory transparency, and, to the extent possible, ensure that food businesses are not required to hold multiple licenses, except when completely necessary. In doing so, DATCP never relinquishes its public health mission or compromises its directive to ensure that food is produced safely and pursuant to some responsible form of inspection. In some cases, such as meat establishments that produce some products under a state license or a federal grant of inspection and other products separate from that inspection, businesses will be allowed to obtain a retail food establishment license from the state or local agency with jurisdiction in that area, in addition to the state meat establishment license or federal grant of meat inspection. This ensures that those business will be allowed to sell product at retail that was not produced under either the federal or state meat inspection programs because those programs are not allowed to inspect and regulate retail food establishment operations.

Another substantive change is to end licensing of food processing plants that are located in homes after the date this rule becomes effective. It should be noted that food processing plants currently located in residences will not be able to expand their facilities after the effective date of this rule. This rule also requires that food processing plants that are currently located in residential or commercial buildings must have a door that opens to the outside or into a community space.

Further, the rule adopts the Model Ordinance for Molluscan Shellfish, now *Marine Shellfish*, which replaces all of s. ATCP 70.21, except for the section on illnesses and outbreaks associated with shellfish. This modification will keep the state's regulations current with the national rules on shellfish processing and marketing.

Other clarifications, changes, and additions are as follows:

- This rule addresses requirements for vending machines, micro-markets, and the commissaries for these entities, as well as in the new ch. ATCP 75, and the Appendix to ATCP 75, *The Wisconsin Food Code*, to ensure consistency and clarity in requirements for both the food processing part of the operation and the retail food business.
- This rule clarifies extended runs and waivers allowing those runs, while clarifying and expanding the list of food processing activities during which daily cleaning and sanitizing are not required.
- This rule clarifies that filing and obtaining of process-authority approval for processes used in the making of acidified or low acid canned foods is mandatory.
- This rule expands the ability of food processing plants to obtain waivers or variances from DATCP for non-standardized and innovative processing and procedural activities. Prior to this revision, these waivers and variances could only be obtained by food processing plants for structural and equipment issues.
- This rule updates and clarifies the language dealing with the standards and testing of operations water and ingredient water used in the various bottling and processing operations in Wisconsin, and finished product sampling and analysis for bottling establishments.
- The new rule also expands the scope of the bottling rules to cover more than just bottled water and soda to match the expansion of this rapidly changing and innovative segment of the bottling industry.
- This rule generally updates and clarifies definitions, licensing requirements and exemptions, as well as exempt wholesaling requirements and limitations, to keep pace with industry and regulatory needs.
- This rule removes the lower sales limit of \$25,000 on persons who must pay the canning surcharge to reflect the very real need of DATCP's staff to provide extensive information, consultation, and service to persons manufacturing canned foods.
- This rule will be consistent with the Retail Food Establishment and Meat Inspection rules to ensure consistency throughout food processing businesses of all types and a regulatory presence for all foods, regardless of where they are produced. This is in keeping with the scope of ch. 97, Stats., requiring the Department to regulate food safety wherever that food is produced, stored, or offered for sale.
- The proposed rule protects the consistent quality of the Wisconsin "brand" by removing many of the long-expired "Grandfather Clause" dates in the existing rule and replacing them with language about gaining compliance for structural standards in existing buildings and updating the expectations for structural standards in new plants. Most significantly, the proposed rule promotes



consistent food safety by not allowing a food processing plant in a residence to be licensed after the effective date of this rule.

### ***Small Businesses Affected***

The businesses affected by this rule run the gamut from very small to very large operations. The businesses range from one- and two-person popcorn wholesalers to multi-national corporations that are on the cutting edge of food science. DATCP's challenge is to write and then enforce applicable and consistent requirements that do not penalize either end of this range of business types.

If the proposed rule is adopted, some small food processing plants may incur immediate costs to meet the requirement to have a door that opens to the outside rather than to a residential vestibule. There is also a potential cost for a small number of businesses that have not upgraded their facilities since the "grandfather clauses" were put in place over thirty years ago. They will now need to upgrade warewashing and handwashing sinks or provide a non-residential restroom for the facility. Another cost that may be incurred by a few very small businesses is the \$320 canning surcharge, which currently is not assessed for food processing plants manufacturing and selling less than \$25,000 of food per year. DATCP's Manufactured Food Specialists spend a disproportionate amount of time working with very small canning businesses, and this surcharge recoups these costs. The service provided by DATCP is comparable to that of consultants who are not economically available to operations in the <\$25,000/year category.

Much of the focus of the proposed rule revision is on clarification and the updating of existing regulations, such as the various exemptions from a food processing plant license, as well as the clarification of various record-keeping requirements.

A positive impact of this rule revision on all classes of business is the expanded ability of food processing plants to apply for processing or procedural waivers. This will potentially allow for the use of new and innovative techniques and processes so long as the processor can demonstrate that food safety is not compromised.

### ***Reporting, Bookkeeping and other Procedures***

The proposed rule will not require any additional reporting, bookkeeping, or other procedures.

### ***Professional Skills Required***

The proposed rule does not require any new professional skills by small businesses.

### ***Accommodation for Small Business***

The requirements for food processing are not size-dependent. There is very little room in the regulations for accommodations due to size, but the department has rewritten the language on waivers to allow processors using alternative methods of processing or

cleaning to apply for waivers if they can show equivalent food safety. This may be of use to smaller, traditional processors.

***Conclusion***

The provisions in this proposed rule will benefit Wisconsin's food processing plants and are expected to impose costs for only a few, older small-scale food processing plants, particularly those located in residences.

This rule will not have a significant adverse effect on "small business" and is not subject to the delayed "small business" effective date provided in s. 227.22(2)(e), Stats.

DATCP will, to the maximum extent feasible, seek voluntary compliance with this rule.

Dated this 8th day of September, 2017.

STATE OF WISCONSIN  
DEPARTMENT OF AGRICULTURE,  
TRADE AND CONSUMER PROTECTION

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

## EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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1. Type of Estimate and Analysis

Repeal  Modification

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2. Administrative Rule Chapter, Title and Number

ATCP 70, Food Processing Plants

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3. Date Rule promulgated and/or revised; Date of most recent Evaluation

Most recent corrections made in August 2016

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4. Plain Language Analysis of the Rule, its Impact on the Policy Problem that Justified its Creation and Changes in Technology, Economic Conditions or Other Factors Since Promulgation that alter the need for or effectiveness of the Rule.

DATCP has updated ATCP 70 with the incorporation by reference of provisions of federal regulations that implement the requirements of the Food Safety Modernization Act (FSMA). This involves multiple subparts of the recently created 21 CFR 117, Current Good Manufacturing Practice, Hazard Analysis and Risk based Preventive Controls for Human Food, formerly 21 CFR 110, Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding, Human Food, pertaining to preventive food safety systems that have already been referenced in chs. ATCP 65 (Milk and Milk Products) and 71 (Food Warehouses and Milk Distributors). Since the majority of Wisconsin food facilities already subject to this federal rule are licensed as food processing plants, this proposed rule includes similar referencing for the sake of consistency. This revision also clearly articulates the requirements for Wisconsin-licensed food processing plants that are not subject to the federal rule.

In July of 2016, when DATCP's Division of Food Safety merged with the Department of Health Services' (DHS') Food Safety and Recreational Licenses section to form the new Division of Food and Recreational Safety ("DFRS"), a merger of the two food safety regulatory systems became necessary. Previously, restaurant operators were not allowed to wholesale food pursuant to the DHS regulation, while retail food establishment operators, pursuant to DATCP's authority, could engage in a limited amount of wholesaling. At present, restaurant operators are licensed as retail food establishments and now enjoy a limited ability to wholesale food. The new ATCP 70 clarifies both the exemption from the requirement to hold a food processing plant license as well as the requirements for food processing and subsequent wholesaling now allowed in licensed retail food establishments. For the first time, the new ATCP 70 also incorporates specific definitions for wholesaling and retailing concomitantly being incorporated into ATCP 75 (Retail Food Establishments) and ATCP 55 (Meat and Meat Food Products). DATCP expects these updates to promote clarity, uniformity, and improved guidance to food businesses in Wisconsin.

In addition, the new ATCP 70 contains language designed to specifically clarify the responsibilities for operators of retail food establishments. Besides the afore-mentioned exemption from the requirement of holding a food processing plant license, operators will better understand their duty to follow the safety, processing, and labeling requirements in ATCP 70 for the production of food for wholesaling. These provisions not only level the playing field for industry, but, more importantly, also ensure that certain ATCP 70 requirements are in place to ensure food safety. Examples of such requirements include provisions for a written recall plan and a written food safety plan for facilities subject to FSMA rules.

In revising this rule, DATCP sought to eliminate duplication, improve regulatory transparency, and, to the extent possible, ensure that food businesses are not required to hold multiple licenses, except when completely necessary. In doing so, DATCP never relinquishes its public health mission or compromises its directive to ensure that food is produced safely and pursuant to some responsible form of inspection. In some cases, such as meat establishments that produce some products under a state license or a federal grant of inspection and other products separate from that inspection, businesses will be allowed to obtain a retail food establishment license from the state or local agency with jurisdiction in that area, in addition to the state meat establishment license or federal grant of meat inspection. This

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ensures that those businesses will be allowed to sell product at retail that was not produced under either the federal or state meat inspection programs because those programs are not allowed to inspect and regulate retail food establishment operations.

Another substantive change is to end licensing of food processing plants that are located in homes after the date this rule becomes effective. It should be noted that food processing plants currently located in residences will not be able to expand their facilities after the effective date of this rule. This rule also requires that food processing plants that are currently located in residential or commercial buildings must have a door that opens to the outside or into a community space.

Further, the rule adopts the Model Ordinance for Molluscan Shellfish, now Marine Shellfish, which replaces all of s. ATCP 70.21, except for the section on illnesses and outbreaks associated with shellfish. This modification will keep the State's regulations current with the national rules on shellfish processing and marketing.

Other clarifications, changes, and additions are as follows:

- This rule addresses requirements for vending machines, micro-markets, and the commissaries for these entities in ATCP 70, as well as in the new ch. ATCP 75, and the Appendix to ATCP 75, The Wisconsin Food Code, to ensure consistency and clarity in requirements for both the food processing part of the operation and the retail food business.
- This rule clarifies extended runs and waivers allowing those runs, while clarifying and expanding the list of food processing activities during which daily cleaning and sanitizing are not required.
- This rule clarifies that filing and obtaining of process-authority approval for processes used in the making of acidified or low acid canned foods is mandatory.
- This rule expands the ability of food processing plants to obtain waivers or variances from DATCP for non-standardized and innovative processing and procedural activities. Prior to this revision, these waivers and variances could only be obtained by food processing plants for structural and equipment issues.
- This rule updates and clarifies the language dealing with the standards and testing of operations water and ingredient water used in the various bottling and processing operations in Wisconsin, and finished product sampling and analysis for bottling establishments.
- The new rule also expands the scope of the bottling rules to cover more than just bottled water and soda to match the expansion of this rapidly changing and innovative segment of the bottling industry.
- This rule generally updates and clarifies definitions, licensing requirements and exemptions, as well as wholesaling requirements and limitations, to keep pace with industry and regulatory needs.
- This rule removes the lower sales limit of \$25,000 on persons who must pay the canning surcharge to reflect the very significant public health necessity for DATCP's staff to provide extensive information, consultation, and service to persons manufacturing canned foods.
- This rule will be consistent with the Retail Food Establishment and Meat Inspection rules to ensure consistency throughout food processing businesses of all types and a regulatory presence for all foods, regardless of where they are produced. This is in keeping with the scope of ch. 97, Stats., requiring the Department to regulate food safety wherever that food is produced, stored, or offered for sale.
- The proposed rule protects the consistent quality of the Wisconsin "brand" by removing many of the long-expired "Grandfather Clause" dates in the existing rule and replaces them with language about gaining compliance for structural standards in existing buildings and updating the expectations for structural standards in new plants. Most significantly, the proposed rule promotes consistent food safety by not allowing a new or expanded food processing plant in a residence to be licensed after the effective date of this rule.

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5. Describe the Rule's Enforcement Provisions and Mechanisms

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DATCP has broad general authority, under s. 93.07 (1), Stats., to adopt rules to implement programs under its jurisdiction. DATCP also has general authority under s. 97.09 (4), Stats., to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. DATCP has specific authority, under 97.29 (5) to adopt rules dealing with fees, setting facility construction and maintenance standards, setting rules for the design, installation, maintenance, and cleaning of equipment and utensils, personnel sanitation, food handling and storage, sanitary production and processing of food, food sources and food labeling.

DATCP Environmental Health Sanitarians visit businesses to inspect and license them for safe operation.

6. Repealing or Modifying the Rule Will Impact the Following  
(Check All That Apply)

- State's Economy  
 Local Government Units

- Specific Businesses/Sectors  
 Public Utility Rate Payers  
 Small Businesses

7. Summary of the Impacts, including Compliance Costs, identifying any Unnecessary Burdens the Rule places on the ability of Small Business to conduct their Affairs.

The businesses affected by this rule run the gamut from very small to very large operations. The businesses range from one- and two-person popcorn wholesalers to multi-national corporations that are on the cutting edge of food science. DATCP's challenge is to write and then enforce applicable and consistent requirements that do not penalize either end of this range of business types.

If the proposed rule is adopted, some small food processing plants may incur immediate costs to meet the requirement to have a door that opens to the outside rather than to a residential vestibule. There is also a potential cost for a small number of businesses that have not upgraded their facilities since the "grandfather clauses" were put in place over thirty years ago to upgrade warewashing and handwashing sinks or provide a non-residential restroom for the facility. Another cost that may be incurred by a few very small businesses is the \$320 canning surcharge, which currently is not assessed for food processing plants manufacturing and selling less than \$25,000 of food per year. The Department's Manufactured Food Specialists spend a disproportionate amount of time working with very small canning businesses, and this surcharge recoups these costs. The service provided by the Department is comparable to that of consultants who are not economically available to operations in the < \$25,000/year category.

Much of the focus of the proposed rule revision is on clarification and the updating of existing regulations such as the various exemptions from a food processing plant license, and the clarification of various record-keeping requirements.

An impact to some meat establishments that produce some products under a state license or a federal grant of inspection, as well as other products separate from that inspection, may be required to hold a retail food establishment license from the state or local agency with jurisdiction in that area in addition to holding the state meat establishment license or federal grant of meat inspection. This licensing requirement may affect several state-licensed meat establishments, but these same establishments will benefit from concurrent proposed changes in ATCP 55 that remove time-consuming formula and label approval requirements for meat and poultry products only sold at retail.

A positive impact of this rule revision on all classes of business is the expanded ability of food processing plants to apply for processing or procedural waivers. This will potentially allow for the use of new and innovative techniques and processes so long as the processor can demonstrate that food safety is not compromised.

8. List of Small Businesses, Organizations and Members of the Public that commented on the Rule and its Enforcement and a Summary of their Comments.

No economic impact comments were received during the August 8 – September 7, 2017, comment period. Prior to rule drafting, DATCP attended a listening session/discussion with the Midwest Food Products Association and made some changes suggested by this group to the provisions governing extended runs.

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9. Did the Agency consider any of the following Rule Modifications to reduce the impact of the Rule on Small Businesses in lieu of repeal?

- Less Stringent Compliance or Reporting Requirements
- Less Stringent Schedules or Deadlines for Compliance or Reporting
- Consolidation or Simplification of Reporting Requirements
- Establishment of performance standards in lieu of Design or Operational Standards
- Exemption of Small Businesses from some or all requirements
- Other, describe: Expanded ability of food processing plants to apply for processing or procedural waivers. This will potentially allow for the use of new and innovative techniques and processes so long as the processor can demonstrate that food safety is not compromised.

10. Fund Sources Affected

- GPR    FED    PRO    PRS    SEG    SEG-S

11. Chapter 20, Stats. Appropriations Affected

12. Fiscal Effect of Repealing or Modifying the Rule

- |  |   |   |
|--|---|---|
| <input checked="" type="checkbox"/> No Fiscal Effect | <input type="checkbox"/> Increase Existing Revenues | <input type="checkbox"/> Increase Costs                                 |
| <input type="checkbox"/> Indeterminate               | <input type="checkbox"/> Decrease Existing Revenues | <input checked="" type="checkbox"/> Could Absorb Within Agency's Budget |
|  |   | <input type="checkbox"/> Decrease Cost                                  |

13. Summary of Costs and Benefits of Repealing or Modifying the Rule

DATCP will be able to continue to conduct paid contract audits/inspections for the FDA because the rule changes make ATCP 70 compliant with FSMA and 21 CFR 117. Therefore, DATCP staff will not be required to be credentialed by the FDA, saving time and expense.

Wisconsin's food processing industry will continue to be able to produce and sell on a level playing field because they will be compliant with national standards.

All classes of food processing plant business will have the expanded ability to apply for processing or procedural waivers. This will potentially allow for the use of new and innovative techniques and processes so long as the processor can demonstrate that food safety is not compromised.

Updated rules will make it easier and less expensive for industry to operate micro markets.

Updated rules will provide industry with cost savings by clarifying and updating language dealing with water usage.

Some small operations may incur costs in the future because of mandated, phased upgrading of facilities that did not previously meet structural or equipment standards. Some meat establishments may incur the cost of a retail food establishment license and the associated annual inspection.

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

- Yes    No

15. Long Range Implications of Repealing or Modifying the Rule

DATCP has updated ATCP 70 with the incorporation by reference of provisions of federal regulations that implement the requirements of FSMA so that Wisconsin's food processing industry can produce and sell products on a level playing field with businesses across the country. DATCP will continue to inspect and enforce standards that meet FDA's Manufactured Foods program standards for facilities and equipment.

Long range implications include the continued vigilance of promoting healthy business practices that help businesses to

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grow and that ensure food safety guidelines are met.

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

A major objective was to include the updated language in 21 CFR 117 which replaced 21 CFR 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding for Human Food, and is the cornerstone of the regulations implementing FSMA. ATCP 70.04 was specifically inserted to address this issue, and definitions for “facility” and “qualified facility” were also inserted to facilitate the department’s implementation of those federal requirements.

Current language on the molluscan shellfish program was deleted in order to adopt the federal Model Ordinance in order to provide that segment of the Wisconsin food industry regulatory consistency during interstate commerce.

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

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

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### 18. Contact Name

Peter Haase, Food and Recreational Safety Bureau Director

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### 19. Contact Phone Number

(608) 224-4711

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