



State of Wisconsin  
Governor Scott Walker

**Department of Agriculture, Trade and Consumer Protection**  
Sheila E. Harsdorf, Secretary

**DATE:** January 11, 2018

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

**FROM:** Sheila Harsdorf, Secretary  
Dr. Steve Ingham, Division of Food and Recreational Safety Administrator

**SUBJECT:** Ch. ATCP 70–Food Processing Plants; Final Draft

**PRESENTED BY:** Dr. Steve Ingham

**REQUESTED ACTION:**

At the January 25, 2018 Board meeting, the Department of Agriculture, Trade and Consumer Protection (“Department”) will ask the Board to approve the final rule (copy attached) related to food processing plants and wholesale food manufacturing.

**SUMMARY:**

***Background***

DATCP has regularly updated Wis. Admin. Code ch. ATCP 70 in order to keep pace with changes in industry as well as the U.S. Food and Drug Administration’s (FDA) regulatory philosophy. In this rule revision, DATCP made clarifications necessitated by the merger between DATCP’s Division of Food Safety and the Department of Health Services’ (“DHS”) Food Safety and Recreational Licensing Section (“FSRL”) that occurred in July 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.

***Rule Content***

DATCP has updated Wis. Admin. Code ch. ATCP 70 with the incorporation by reference of certain federal regulations that implement the requirements of the federal Food Safety Modernization Act (FSMA): Multiple subparts of the recently created 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, formerly known as 21 CFR 110, *Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food*. These federal regulations pertain to preventive food safety systems which have already been referenced in Wis. Admin. Code chs. ATCP 65 (Milk and Milk Products) and ATCP 71 (Food Warehouses and Milk Distributors). Since the majority of

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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 was 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 licensed as retail food establishments and therefore 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 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 new food processing plants that are located in homes. It should be noted that existing food processing plants located in residences will not be able to expand their facilities. 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 Wis. Admin. Code 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 standards for 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 both of these entities, as also done in the new Wis. Admin. Code ch. ATCP 75 and the Appendix to ATCP 75, *The Wisconsin Food Code*, in order 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.
- The rule updates some restrictions on hot-smoked, vacuum-packed fish previously found only in Wisconsin regulations in order to conform with requirements in other states as well as current, science-based United States Food and Drug Administration (FDA) guidance.
- 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 the Department 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, as well as finished product sampling and analysis for bottling establishments.
- This 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, in order 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 time necessary for Department staff to provide extensive information, consultation, and service to persons manufacturing small amounts of canned foods.
- This rule will be consistent with the Retail Food Establishment and Meat and Poultry Products 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 new food processing plant in a residence to be licensed after the effective date of this rule.

### ***Fiscal Impact***

This rule is not anticipated to have a fiscal effect on state resources. It does not require additional staff specifically to enforce the proposed rule. The Department will train staff on the new requirements.

### ***Business Impact***

The Small Business Regulatory Review Board did not issue a report on this rule. No economic impact comments were received during the August 8, 2017 – September 7, 2017 comment period.

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 hinder successful operations by either end of this spectrum.

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 various "grandfather clauses" were put in place over thirty years ago. They may 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 provided by consultants who are not affordable for 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.

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

### ***Environmental Impact***

This rule will have essentially 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 Human Food*, and is the cornerstone of the regulations implementing FSMA. Wis. Admin. Code s. 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 within interstate commerce.

#### **Surrounding State Programs**

Michigan, Iowa, and Minnesota license and regulate food processing facilities within their borders as does Wisconsin. Illinois food processors are regulated only by the United States Food and Drug Administration (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.

### ***Changes from the Hearing Draft***

The Department incorporated all necessary changes suggested by the Legislative Council Rules Clearinghouse.

Changes based on the public hearings and comments sent to the Department are listed in **Appendix A**.

### ***Next Steps***

If the Board and the Governor approve this rule, the Department will transmit the final rule to the Legislature for review by the appropriate legislative committees. If the Legislature approves the rule, the Secretary will sign the final rulemaking order and transmit it for publication.

## Appendix A.

### Public Hearings

The Department held five public hearings around the State. Following the public hearings, the hearing record remained open until December 15, 2017. The following is a summary of the hearing attendees, including those who submitted written comments.

#### Public Hearing Summary

Date and Time	Location
Thursday, November 16, 2017 9:30 a.m. to 3:30 p.m.	Mead Public Library, Rocca Room 710 N. 8 <sup>th</sup> Street, Sheboygan, WI
Wednesday, November 22, 2017 9:30 a.m. to 3:30 p.m.	Division of Public Health Regional Office 2187 N. Stevens Street, Rhinelander, WI
Friday, November 24, 2017 9:00 a.m. to 3:30 p.m.	Prairie Oak State Office Building, Room 106 2811 Agriculture Drive, Madison, WI
Friday, December 1, 2017 9:30 a.m. to 3:30 p.m.	Wisconsin State Office Building, Room 129 718 W. Clairemont Ave., Eau Claire, WI
Friday, December 8, 2017 9:30 a.m. to 3:30 p.m.	Shawano Public Library 128 South Sawyer Street, Shawano, WI

#### List of Comments and Department Response

The following is a complete list of the persons who attended the public hearings or submitted written comments on the proposed rule during the public comment period, the position taken and/or comments submitted by the commenter, and the Department's response.

Commenter #	Name and Address	Position Taken (Support or Opposed)	Method of Commenting and Department Actions Taken
1. 11/27/17	Shawn K. Stevens <b>Representing the Food Industry Council, LLC.</b> 11414 West Park Place, Suite 202 Milwaukee, WI 53224 (920) 698-2561 stevens@foodindustry council.com	Suggested revisions based on the 4 <sup>th</sup> Edition <i>Fish and Fishery Product Hazards and Controls Guidance</i> to the rules involving reduced-oxygen packaged fish products as follow: 1) Request that Wisconsin remove the requirement to hold fish that is reduced-oxygen packaged at or below 38 degrees F., and allow it to be held at 40 degrees F. or below.	<b>Provided Written Comments –</b>  The Department agrees and has amended the sections on Fish in ATCP 70 (Sections 70.44 and 70.46) to reflect the science in the 4 <sup>th</sup> Edition of the <i>Fish and Fishery Products Hazards and Controls Guidance</i> .  The language was amended to account for the lack of hazard in hot-smoked fish and allows industry to use the Guidance document to address reduced-oxygen packing issues. However, language was maintained the 38 degree F. holding temperature as proposed on p. 258 of the Guidance document for raw fish or cold-smoked fish that is reduced-oxygen packaged and held at refrigeration temperatures.
2. 12/1/17	Kristina Burning 57805 North Rd. Eau Claire, WI 54701	None – Present at December 1, 2017 Hearing	Did not wish to testify. Looking for information.

Commenter #	Name and Address	Position Taken (Support or Opposed)	Method of Commenting and Department Actions Taken
3. 12/1/17	Chelsea A. Peabody 100 Colenan St. W Rice Lake, WI 54868 <b>McCain Foods USA, Inc.</b>	None – Present at December 1, 2017 Hearing	Did not wish to testify. Looking for information.
4. 12/1/17	Stephen Bant 2699 23 <sup>rd</sup> Street, Rice Lake, WI 54868 <b>McCain Foods USA, Inc.</b>	Did not wish to speak – Registered as taking no position at December 1 <sup>st</sup> Hearing.	Did not wish to testify. Looking for information.
5. 12/1/17	Corey P. Sukalich 723 Creekwood Lane West Bend, WI 53095 <b>Herbal Symphony (a business) and himself listed as the owner/operator</b>	Spoke – Opposed the proposal  Mr. Sukalich stated he has run his business from his home for 8 years and strongly objects to provisions in the proposed ATCP 70 that would require businesses currently located in homes to : <ol style="list-style-type: none"> <li>1.) Upgrade the facilities to require separation.</li> <li>2.) Not allow currently home-based facilities to expand in the homes.</li> <li>3.) Not allow future businesses to be licensed in homes so that if he moved, he could not be licensed in a home at a new location.</li> </ol> Mr. Sukalich desires an exemption for an unspecified disability or perhaps a dollar/volume - based exemption based on perceived risk of product. He cites possible economic and physical hardship.	<b>Provided Oral Testimony –</b>  The proposed ATCP 70 clarifies the long-standing restriction on home-based businesses that has been the Department’s policy for many years. It further clearly states that no home-based operations will be licensed in the future.  The department’s rationale is based on several issues: <ol style="list-style-type: none"> <li>1) Statewide consistency: Under the former administrative system, different regional districts and Inspectors interpreted and enforced licensing rules inconsistently.</li> <li>2) Sanitation: This rule covers wholesaling, i.e., products that are manufactured for sale at another location. These venues are held to a different standard than retail since the retail customer is unable to see where the product was made and make an informed choice based on observing the conditions.</li> <li>3) Sanitation: The Department’s experience has been that not all of the activities of a home are effectively separated from the production areas, such as access by pets and children, including potential contamination from those pets and children and from persons not involved in the production who might be present.</li> <li>4) Safety and Security – It is not prudent to expose any Department inspector to situations where that inspector might, for example, have to go into a private residence to inspect or use a private bathroom.</li> </ol> No action taken by the Department.
6. 12/1/17	Joy Durbin 723 Crestwood Drive West Bend, WI 53095 <b>Herbal Symphony (a business) and herself</b>	Spoke – Opposed the proposal  Ms. Durbin spoke in favor of allowing small businesses to	<b>Provided Oral Testimony and Brief Written Comment –</b>  The Department’s long-standing position is that lack of funds does not constitute a

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	listed as the owner/operator	<p>operate from the home. She made the following points:</p> <ol style="list-style-type: none"> <li>1) Small businesses operating from the home are a necessary starting point for entrepreneurs in the State of Wisconsin.</li> <li>2) Small businesses are vital to the State's economic growth.</li> <li>3) "Many" of her colleagues started as small businesses from homes.</li> <li>4) Products produced by small, home-based businesses are important to local retailers, co-ops, and local communities in general.</li> <li>5) She fears that eliminating the option of operating from the home will eliminate "mom and pop" stores.</li> <li>6) She cited enthusiastic support from the City of West Bend.</li> <li>7) Suggest she may move out of state if she can no longer expand or license a new business at home.</li> </ol>	<p>valid reason to exempt entrepreneurs from compliance with requirements that exist to promote food safety.</p> <p>The Department does not have a bias against business size and works hard to promote and grow the State's economy.</p> <p>The Department must also be cognizant of the fact that many entrepreneurs as well as the overwhelming majority of established businesses are operating within the parameters of the Department's facility requirements.</p> <p>The Department is also aware that there are businesses who may have been licensed without meeting the requirements that were in place at the time, for a variety of reasons, yet are providing employment and quality products to the people of this state. It is not the Department's position to summarily suspend these businesses, but to work with them to ensure steady progress toward compliance because the Department believes that a successful business will be able to take care of many of these issues in a reasonable amount of time.</p> <p>No action taken by the Department. ATCP 70.08 (4) makes provisions for a processing facility that shares a facility with living quarters if adequate separation can be maintained.</p> <p>ATCP 70.08 does not close existing establishments located in residences, but 70.08(5) (c) and (d) will prohibit expansion of existing plants in residences and prohibit the licensing of plants in residences in the future.</p>
7. 12/15/17	<p>Nickolas George, Jr.  <b>Midwest Food Products Association, Inc.</b>  4600 American Parkway, #210  Madison, WI 53718</p>	<p>Written Comments</p> <p>Mr. George made several Points:</p> <ol style="list-style-type: none"> <li>1) ATCP 70.08 – The requirement for a requisite number of "foot candles" in the lighting section is outdated. He suggests that the words "adequate lighting" be substituted.</li> <li>2) ATCP 70.14 - Cleaning frequencies should not be dictated by regulation. He suggests that because of</li> </ol>	<p><b>Provided Written Comments –</b></p> <ol style="list-style-type: none"> <li>1) The Department believes that using an indefinite word like "adequate" in a rule does not provide sufficient guidance. Lighting parameters were instituted to ensure that processors can see mechanical problems, packaging issues, and other situations that could lead to food adulteration. The "foot candle" unit is still a recognized, measurable standard, and alternative "lux" units are also provided. No change.</li> <li>2) ATCP 70.14 – Cleaning Frequencies:</li> </ol>



Commenter #	Name and Address	Position Taken (Support or Opposed)	Method of Commenting and Department Actions Taken
		<p>Good Manufacturing Practices, Sanitation Standard Operating Procedures, and both internal and third-party audits, the wording in this section should be changed to “as needed to keep the equipment and utensils clean and in a suitable sanitary condition.”</p> <p>3) Under ATCP 70.08, Faucets – He suggests that the 15 second standard for water in an automatic faucet to run does not represent a reasonable time and suggests inserting the wording “until warm water is present”.</p> <p>4) ATCP 70.36, 38, and 40, Canning – He objects to the requirement for a sanitizing step in the case of equipment used in a low-acid canned food operation in addition to the rigorous cleaning steps. The following suggestions are made:</p> <ul style="list-style-type: none"> <li>• Strike the references to “alternative cleaning and sanitizing.” Sanitization should be determined by the processor with input from the 3<sup>rd</sup> party sanitation provider.</li> <li>• The Department’s attention is called to New York State which mandates the use of sanitizers “as necessary”, and to California and Washington where the use of sanitizers is “based on risk by product, targeting certain pathogens in certain segments.”</li> </ul> <p>5) 70.08 (3) MWFPFA understands the rule to require that adding a new piece of equipment would be a sufficient change to</p>	<p>The Department’s position is that the regulations define a commonly-accepted baseline interval for cleaning which industry may lengthen if it can support the extended interval with scientifically valid data. The term “suitable sanitary condition” is not clearly defined and is possibly open to subjective interpretation. No change.</p> <p>3) ATCP 70.08, Faucets. ATCP 70.08 (8) (c) 2. does not mean that the water must be warm but must only run for 15 seconds. The Department agrees with the suggestion that the warm water must be available and already mandates “tempered” water in 70.08 (8) (c) 1. The intent of subdiv. 2. is that the tempered water be available for at least 15 seconds. No change.</p> <p>4) ATCP 70.40 – It is the intent in ATCP 70.40 that cleaning steps as well as any alternative method of cleaning be formulated by competent authority. Sanitizing is not required unless deemed appropriate in the plan written by the authority. The Department has edited the proposed ATCP 70.40 accordingly. The term, “alternative”, in relation to cleaning and sanitizing is not necessarily applicable to a low-acid canned foods plant, which could follow specific requirements in ATCP 70.40. ATCP 70.16 has been edited accordingly.</p> <p>5) The language allowing the “grandfathering” of certain conditions in plants has been removed from the proposed rule. Much of it was 30 years old. Many of these situations have already been corrected by transfers of ownership and remodeling. The Department’s position is that it is in the best interest of sanitary and efficient operation to work with industry to bring outdated facilities into compliance. No change.</p>

Committer #	Name and Address	Position Taken (Support or Opposed)	Method of Commenting and Department Actions Taken
		trigger the upgrading of a “grandfathered” facility. They recommend no change to the current rule which allows certain no-longer-acceptable-conditions to exist if the plant was licensed prior to a certain date.	
8. 11/24/17	Stephanie Mackey DATCP 2811 Agriculture Dr. Madison, WI 53718	Spoke – Suggested a Name Change for Formatting  Suggested we change the chapter title to “Wholesale Food Manufacturing”	<b>Provided Written Comments</b>  The Department made the change for consistency.
9. 10/26/17	Andrea Charney acpc@wi.rr.com	E-mail to department  Ms. Charney cites the expense of starting a business and the high cost of renting commercial kitchen space.  Cites the opportunities available for small producers at a Farmer’s market.	<b>Provided Written Comments</b>  This is a reference to section 70.08 and the prohibition on starting a commercial business in a home.  The Department is aware of the costs of doing business; however, the rules have been enacted in the interest of food safety. As noted next to Commenters 5 and 6, economic stress is not a valid exemption from food safety regulations. No change.
10. 10/27/17	Demetria Lueneburg FDA Minneapolis District Office 250 Marquette Ave., Suite 600 Minneapolis, MN 55401 Demetria.lueneburg@fda.hhs.gov	Provided e-mail giving clarification to a point on alcohol amenability for regulatory purposes.	<b>E-Mail on Alcohol as a food Ingredient</b>  The Department made the change as suggested by FDA: Create “ATCP 70.26 (7), Alcohol in Food” that states: (a) “Alcohol is allowed as an ingredient in a food product and is regulated by this chapter if it is between 1% and 7% by volume, or under 2% in ice cream. It shall be listed in the ingredient statement as “alcohol.” (b) If alcohol is part of an ingredient in another product such as the solvent in a flavoring and is less than 0.5% by volume, then it may be treated as an incidental ingredient. (c) More than 7% alcohol, by volume, falls, in the federal system, under the Alcohol and Tobacco Tax and Trade Bureau (TTB).
11. 12/15/17	Comments during hearing period from multiple department staff.	Discussions on the definition of “wholesaling” in the proposed ATCP 70.02 (47)	<b>Oral Comments –</b>  In order to clarify the Department’s long-standing intent and practice, language was added to the definition of “Wholesale” to ensure that retail food establishments availing themselves of the provisions under ATCP 75 that allow a limited amount of wholesale activity would not be

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			<p>distributing product to outlets they own for re-sale, possibly in other states, without following wholesale requirements for labeling, a written recall plan, and a written plan for manufacturing the product. The wording was changed to include references to distribution as follows:</p> <p>It is the Department's position that, in the interest of both the consuming public and a level playing field for industry, retailers with multiple outlets not be able to manufacture food at a central commissary/kitchen and distribute it to multiple locations or even across state lines without a food processor's license and the controls that go with it.</p>



## 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.

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After 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, a merger of those two food safety regulatory systems became necessary. A major change was 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 licensed as retail food establishments and therefore 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.

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## EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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- This rule removes the lower sales limit of \$25,000 on persons who must pay the canning surcharge to reflect the time necessary for Department staff to provide extensive information, consultation, and service to persons manufacturing small amounts of canned foods.
- This rule will be consistent with the Retail Food Establishment and Meat and Poultry Products 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 new 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

## EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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), Stats., 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 food processing; and food sources and food labeling.

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

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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. The Department's challenge is to write and then enforce applicable and consistent requirements that do not hinder successful operations by either end of this spectrum.

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 various "grandfather clauses" were put in place over thirty years ago. They may 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 provided by consultants who are not affordable for operations in the <\$25,000/year category.

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

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, as well as various non-meat 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, such as grocery stores that 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.

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

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## EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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.

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

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

- No Fiscal Effect       Increase Existing Revenues       Increase Costs  
 Indeterminate       Decrease Existing Revenues       Could Absorb Within Agency's Budget  
 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



## EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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 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 which serves as 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.



# Wisconsin Department of Agriculture, Trade and Consumer Protection

## Final Regulatory Flexibility Analysis

***Rule Subject:*** Food Processing Plants  
***Adm. Code Reference:*** ATCP 70  
***Rules Clearinghouse #:*** 17-073  
***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 U.S. Food and Drug Administration's (FDA) 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 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 certain federal regulations that implement the requirements of the federal Food Safety Modernization Act (FSMA): Multiple subparts of the recently created 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, formerly known as 21 CFR 110, *Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food*. These federal regulations pertain to preventive food safety systems that have already been referenced in Wis. Admin. Code chs. ATCP 65 (Milk and Milk Products) and ATCP 71 (Food Warehouses and Milk Distributors). Since the majority of Wisconsin food facilities are already subject to this federal rule and 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.

DATCP's Division of Food Safety merged with DHS' FSRL to form the new Division of Food and Recreational Safety ("DFRS"). This necessitated the two food safety regulatory systems to merge as well. One issue needed to be reconciled: Restaurant operators were not allowed to wholesale food under the DHS regulation, while retail food establishment operators under DATCP's authority could engage in a limited amount of wholesaling. At present, restaurant operators are licensed as retail food establishments and therefore 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 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 new food processing plants that are located in homes. While existing food processing plants located in residences will continue to operate, they will not be able to expand their facilities. 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 Wis. Admin. Code 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 standards for 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 both of these entities, as also done in the new Wis. Admin. Code ch. ATCP 75 and the Appendix to ATCP 75, *The Wisconsin Food Code*, in order 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.
- The rule updates some restrictions on hot-smoked, vacuum-packed fish previously found only in Wisconsin regulations in order to conform with requirements in other states as well as current, science-based United States Food and Drug Administration (FDA) guidance.
- 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 the Department 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, as well as finished product sampling and analysis for bottling establishments.
- This 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, in order 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 time necessary for Department staff to provide extensive information, consultation, and service to persons manufacturing small amounts of canned foods.
- This rule will be consistent with the Retail Food Establishment and Meat and Poultry Products 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 new 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. The Department’s challenge is to write and then enforce applicable and consistent requirements that do not hinder successful operations by either end of this spectrum.

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 various “grandfather clauses” were put in place over thirty years ago. They may 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 provided by consultants who are not affordable for 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.

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

No economic impact comments were received during the August 8, 2017 – September 7, 2017 comment period. 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 as well as various non-meat 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, such as grocery stores that 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.

### ***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 11<sup>th</sup> day of January, 2018.

STATE OF WISCONSIN  
DEPARTMENT OF AGRICULTURE,  
TRADE AND CONSUMER PROTECTION

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



**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, retitled Wholesale Food Processing. 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), and to address vending machine and micro-market commissaries.

***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), Stats., 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 food processing; and food sources and food labeling.

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

After 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., includes responsibilities for the related administrative rules covering all retail food establishments, including restaurants, dairy plants, food warehouses, and meat and poultry processing.

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

DATCP has updated ATCP 70 with the incorporation by reference of certain federal regulations that implement the requirements of the federal Food Safety Modernization Act (FSMA): Multiple subparts of the recently created 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, formerly known as 21 CFR 110, *Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food*. These federal regulations pertain to preventive food safety systems that have already been referenced in Wis. Admin. Code chs. ATCP 65 (Milk and Milk Products) and ATCP 71 (Food Warehouses and Milk Distributors). Since the majority of Wisconsin food facilities are already subject to this federal rule and 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.

DATCP's Division of Food Safety merged with DHS' FSRL to form the new Division of Food and Recreational Safety ("DFRS"). This necessitated the two food safety regulatory systems to merge as well. One issue needed to be reconciled: Restaurant operators were not allowed to wholesale food under the DHS regulation, while retail food establishment operators under DATCP's authority could engage in a limited amount of wholesaling. At present, restaurant operators are licensed as retail food establishments and therefore 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 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 new food processing plants that are located in homes. While existing food processing plants located in residences will continue to operate, they will not be able to expand their facilities. 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 Wis. Admin. Code 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 standards for 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 both of these entities, as also done in the new Wis. Admin. Code ch. ATCP 75 and the Appendix to ATCP 75, *The Wisconsin Food Code*, in order 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.
- The rule updates some restrictions on hot-smoked, vacuum-packed fish previously found only in Wisconsin regulations in order to conform with requirements in other states as well as current, science-based United States Food and Drug Administration (FDA) guidance.
- 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 the Department 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, as well as finished product sampling and analysis for bottling establishments.
- This 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, in order 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 time necessary for Department staff to provide extensive information, consultation, and service to persons manufacturing small amounts of canned foods.
- This rule will be consistent with the Retail Food Establishment and Meat and Poultry Products 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 new food processing plant in a residence to be licensed after the effective date of this rule.

### ***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 Human Food*, and is the cornerstone of the regulations implementing FSMA. Wis. Admin. Code s. 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 within interstate commerce.

## **Surrounding State Programs**

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

## ***Data and Analytical Methodologies***

In order to identify potential changes to the rule, DATCP reviewed recent changes in FDA regulations 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 Marine 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 hinder successful operations by either end of this spectrum.

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 various "grandfather clauses" were put in place over thirty years ago. They may 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 provided by consultants who are not affordable for 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.

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

No economic impact comments were received during the August 8, 2017 – September 7, 2017 comment period. 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 as well as various non-meat 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, such as grocery stores that 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.

#### ***DATCP Contact***

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

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1 SECTION 1. ATCP 70 is repealed and recreated to read:

2 **Chapter ATCP 70**

3 **WHOLESALE FOOD MANUFACTURING**

4 **Subchapter I. Scope and Definitions**

5 ATCP 70.01 Scope.

6 ATCP 70.02 Definitions.

7 ATCP 70.04 Federal requirements.

8 **Subchapter II. General Requirements**

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.

14 ATCP 70.16 Cleaning and sanitizing equipment and utensils; 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	<b>Subchapter IV. Fish Processing Plants; Marine Shellfish Plants; Supplementary</b>	
30	<b>Requirements</b>	
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	<b>Subchapter V. Bottling Establishments; Supplementary Requirements</b>	
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	<b>Subchapter VI. Juice and Juice HACCP</b>	
41	ATCP 70.60	Juice and 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 (2), Stats., or this chapter, and all retail food establishments, as defined in s. 97.30 (1) (c), Stats.,  
53 performing food processing, 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 sanitizing solution" means a substance or compound approved by the  
57 department for the 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 licensed under s. 97.30 or s. 97.605, Stats.

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

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

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

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

84       **(11)** “Continuous operation” means operating without interruption beyond 24 hours, with no  
85 interruptions after 24 hours longer than a period approved by the department.

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

90       **(13)** “Department” means the state of Wisconsin department of agriculture, trade and  
91 consumer protection.

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

95       **(15)** “Facility” as used in s. ATCP 70.04 has the meaning given in 21 CFR 117.3.

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

99       **(17)** “Fish processing plant” means a food processing plant which produces processed fish or  
100 fishery products.

101       **(18)** “Fishery product” means any human food product in which fish is a characterizing  
102 ingredient.

103       **(19)** “Food” means:

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

105 (b) Chewing gum.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

156       (a) Fully cooked or heat treated, or sold or represented as being fully cooked or heat treated, so  
157       that the internal temperature of the fish has been maintained for at least 30 minutes at not less than  
158       145° F (62.8° C.) or an equivalent process validated for lethality against pathogenic organisms.

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

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

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

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

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

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

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

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

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

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

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

188 "Processed fish" does not include fish processed in accordance with s. ATCP 70.36 or 70.38.

189       **(35)** “Qualified facility” as used in s. ATCP 70.04 has the meaning given in 21 CFR 117.3.

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

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

194       **(38)** “Retail” means selling food or food products directly to any consumer only for  
195 consumption by the consumer or the consumer’s immediate family or non-paying guests.

196       **(39)** “Roe” as used in s. ATCP 70.48 means fish eggs, including fish eggs that are still  
197 enclosed in the ovarian membrane.

198       **(40)** “Safe temperatures” for the holding or storage of potentially hazardous foods means one  
199 of the following as appropriate:

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

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

202       (c).

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

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

206       **(41)** “Salt content” means the percent salt (sodium chloride) as determined by the method  
207 described in sections 18.034 and 18.035 of the *Official Methods of Analysis*, multiplied by 100 and  
208 divided by the sum of the percent salt (sodium chloride) and the percent moisture in the finished



209 product as determined by the method described in section 24.002 of the *Official Methods of*  
210 *Analysis*.

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

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

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

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

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

229 (47) “Wholesale” means the transfer of any food to a person or commercial entity who will  
230 either re-sell it, distribute it, or use it as an ingredient in a product that will be then offered for sale  
231 or distribution. “Wholesale” also means the transfer of food from the point of production to  
232 another location for sale even if the other location is adjacent to the point of production.

233 **ATCP 70.04 Federal requirements.** A food processing plant that is also a facility or a  
234 qualified facility shall comply with the requirements of this chapter and applicable requirements of  
235 21 CFR 117.

## 236 **Subchapter II. General Requirements**

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

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

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

247 (a) For a food processing plant that has an annual production of at least \$25,000 but less than  
248 \$250,000, and is engaged in processing potentially hazardous food or in canning, an annual license  
249 fee of \$400.

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

252 (c) For a food processing plant that has an annual production of at least \$25,000 but less than  
253 \$250,000, and is not engaged in processing potentially hazardous food or in canning, an annual  
254 license fee of \$160.

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

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

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

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

268 **(6) REINSPECTION FEE.** (a) If the department reinspects a food processing plant because the  
269 department has found a violation of ch. 97, Stats., or this chapter, on a regular inspection, the  
270 department shall charge the food processing plant operator the reinspection fee specified under par.

271 (b). A reinspection fee is payable when the reinspection is completed, and is due upon written  
272 demand from the department. The department may issue a demand for payment when it issues a  
273 license renewal application form to a food processing plant operator.

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

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

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

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

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

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

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

290 (8) TEMPORARY LICENSE. (a) The department may issue a temporary license, for a period not  
291 to exceed 30 business days, pending final action on an application for an annual food processing

292 plant license. The department shall grant or deny the annual license application before the  
293 temporary license expires. If the department denies an annual license application before the  
294 applicant's temporary license expires, the temporary license is automatically terminated when the  
295 applicant receives written notice of the denial.

296 (b) The holder of a temporary license may not procure raw agricultural products as defined in  
297 s. 97.01 (14), Stats., from producers, except as specifically authorized by the department in  
298 writing. The department may not authorize a food processing plant operator to procure farm  
299 products from producers unless the food processing plant operator complies with subch. VI of ch.  
300 126, Stats.

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

304 (9) PRE-LICENSE INSPECTION. The department may inspect a food processing plant, as the  
305 department deems necessary, before issuing a license for the food processing plant. The  
306 department may not issue a license or temporary license for a new food processing plant until the  
307 department inspects the new food processing plant for compliance with this chapter. A previously  
308 licensed food processing plant may not be considered a new food processing plant under this  
309 subsection solely because of a change of ownership.

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

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

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

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

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

320 2. Wholesale receipts from food processing operations at the retail food establishment  
321 comprise no more than 25% of gross annual food sales from the retail food establishment. If a  
322 licensed retail food establishment is also licensed as a dairy plant under s. 97.20, Stats., or as a  
323 meat establishment under s. 97.42, Stats., sales of dairy or meat and poultry products processed at  
324 the establishment shall be excluded from the calculation of food sales receipts under this  
325 subdivision.

326 3. The retail food establishment is not engaged in canning of food products, does not engage  
327 in juice processing subject to requirements of 21 CFR 120, does not engage in any fish or fishery  
328 products processing subject to requirements of 21 CFR 123, does not process smoked fish, and  
329 does not manufacture and bottle a beverage containing alcohol in excess of 2% if the product is  
330 liquid or if the alcohol does not constitute more than 0.5% by volume of a product that is used as  
331 an ingredient.

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

334 1. The retail food establishment does not process food for wholesale distribution in excess of  
335 25% of total food sales, is not engaged in canning of food products, does not engage in juice  
336 processing subject to requirements of 21 CFR 120, does not engage in any fish or fishery products  
337 processing subject to requirements of 21 CFR 123, does not process smoked fish, and does not  
338 manufacture or bottle beverages containing alcohol in excess of 2% if the product is liquid or 0.5%  
339 as an ingredient for sale to anyone other than the ultimate consumer, except for beer brewed and  
340 sold under the provisions in s. 125.295, Stats.

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

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

345 1. Receipts from non-dairy food processing operations at that location comprise no more than  
346 25% of gross annual dairy and non-dairy food sales from that location.

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

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

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

353 2. The meat establishment is licensed as a retail food establishment under s. 97.30, Stats., and  
354 not engaged in the canning of food products other than meat or poultry products canned under s.  
355 97.42, Stats., or the production of cold-smoked fish or fishery products.

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

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

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

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

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



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

376 Department of Agriculture, Trade and Consumer Protection  
377 Division of Food and Recreational Safety  
378 P.O. Box 8911  
379 Madison, WI 53708

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

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

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

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

394 4. Manufacturing ice for use in the shipment of foods, or to cool or keep foods cold while in  
395 transit or stored in the warehouse. Ice used for this purpose must meet the standards in s. ATCP

396 70.20 (8). Ice must be made on site in a commercial ice machine and may not be bagged,  
397 distributed or sold separately from food items that it is used to cool.

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

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

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

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

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

413 **ATCP 70.08 Construction and maintenance. (1) CONSTRUCTION AND MAINTENANCE;**  
414 **GENERAL.** The operator shall soundly construct and maintain in a clean and sanitary condition all  
415 buildings, facilities, and equipment used in food processing operations. The interior and exterior

416 portions of a food processing plant, and the premises on which the food processing plant is located,  
417 shall be maintained in a sanitary condition in compliance with this chapter.

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

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

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

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

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

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

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

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

432 **(3) APPLICABILITY OF REQUIREMENTS.** A licensed food processing plant shall be subject to  
433 licensed plant requirements in this section if it ceases to operate continuously for more than 30  
434 days at any time after the effective date of this section ... [LRB inserts date], or has been  
435 structurally remodeled or altered in a manner which results in structural changes to a processing  
436 area, or a plant that has added product lines or processes after the effective date of this section ...

437 [LRB inserts date]. This section does not apply to a licensed food processing plant that closes  
438 because of seasonal natural food production cycles of the food processed by that plant, such as an  
439 orchard or a maple sap processing facility.

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

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

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

454 (b) A food processing plant issued a license after the effective date of this section ... [LRB  
455 inserts date], shall have a direct exterior entrance or a direct entrance from a common space or  
456 hallway if the food processing plant is located within a shared, non-residential building.

457 (c) No license shall be granted to a new food processing plant that consists of designated space  
458 in a building or in a garage attached to a building that is otherwise used as a residence.

459 (d) Food processing plants located in spaces existing in residential buildings or in the attached  
460 garages of residential buildings may not be expanded or rebuilt.

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

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

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

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

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

472 **(7) VENTILATION.** There shall be adequate ventilation in all areas where food is processed,  
473 handled, or stored; in all areas where equipment or utensils are cleaned or sanitized, and in all  
474 dressing rooms, locker rooms, toilet rooms, employee break rooms, and garbage or rubbish storage  
475 areas. Ventilation shall be adequate to remove excessive heat, steam, condensation, vapors,  
476 obnoxious odors, smoke, and fumes. Ventilation systems shall be positioned so that exhaust air is  
477 not vented onto exposed food, or onto clean food packages, equipment, or utensils. Intake fans

478 shall be equipped with filters that are readily removable for cleaning and replacement. Intake  
479 filters shall be capable of removing at least 85% of particulate matter that is 5 microns or larger in  
480 size, or greater than 6 MERV (maximum efficiency reporting value) rating. Exhaust fans, intake  
481 fans, ventilation ducts, and filters shall be kept clean and in good repair, and shall be screened or  
482 louvered to prevent contamination of food by dust, dirt, insects, or other contaminants. Systems  
483 used to ventilate any area of a food processing plant where exposed potentially hazardous food is  
484 handled shall be capable of maintaining positive pressures in that area.

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

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

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

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

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

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

507 (d) The faucets of a handwashing sink in a licensed, non-seasonal food processing plant that  
508 has ceased to operate continuously for more than 30 days at any time after the effective date of this  
509 section ... [LRB inserts date], or located on a sink in an area that has been structurally remodeled  
510 or altered in a manner which results in structural changes to a processing area, or located in a plant  
511 that adds more complex food processing after the effective date of this section ... [LRB inserts  
512 date], shall be subject to licensed plant requirements including the requirements in pars. (c) 1. and  
513 2, (e) and (f).

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

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

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

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

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

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



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

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

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

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

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

557 (c) Drain boards shall be provided in connection with every warewashing sink. Drain boards  
558 shall be large enough to accommodate soiled equipment and utensils prior to washing, and clean  
559 equipment and utensils after they are sanitized. Drain boards shall be located and constructed so

560 that they do not interfere with washing and sanitizing operations. This paragraph does not prohibit  
561 the use of easily movable dish tables as drain boards if the dish tables comply with this paragraph.

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

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

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

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

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

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

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

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

598       **(16) CONSTRUCTION; PLAN REVIEW.** Before a food processing plant is constructed,  
599 substantially reconstructed, or extensively altered, the operator or licensee shall notify the  
600 department in writing. Plans and specifications for the construction, reconstruction, or alteration

601 may be submitted to the department for review before the work is begun. Plans and specifications  
602 shall be available for review by the department upon request.

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

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

607 **ATCP 70.10 Personnel standards. (1) CLEANLINESS.** (a) Persons engaged in food  
608 processing shall maintain a high degree of personal cleanliness, and shall observe good hygienic  
609 practices during all working periods. Persons engaged in food processing shall wash their hands  
610 before 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 (b) Par. (a) does not apply to a maple sap concentration facility licensed as a food processing  
615 plant that is required to meet the provisions of s. ATCP 87.28.

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

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

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

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

624 3. Properly stored until used.

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

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

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

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

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

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

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

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

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

643 2. The content of the training, including the written procedures required under par. (d).

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

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

647 5. Procedures to evaluate training effectiveness.

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

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

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

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

665       (a) One or more reportable symptoms of communicable disease as defined in ch. ATCP  
666 75 Appendix, 2-201.11 (A).

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

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

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

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

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

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

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

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

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



701 cleaning and sanitizing solutions are circulated. Cleaning records shall be kept for at least 90 days  
702 after they are created.

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

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

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

719 **ATCP 70.14 Cleaning and Sanitizing Equipment and Utensils. (1) GENERAL.** Except as  
720 provided in ss. ATCP 70.16 and 70.40, the food processing plant operator shall do all of the  
721 following.

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

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

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

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

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

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

743 (3) CLEANING COMPOUNDS, DETERGENTS, AND SANITIZERS: STORAGE AND LABELING. Cleaning  
744 compounds, detergents, and sanitizers used in a food processing plant shall be clearly labeled.  
745 When they are not being used, they shall be stored in designated areas and in an appropriate  
746 manner so that they do not contaminate food products, ingredients, equipment, or utensils.

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

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

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

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

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

759 APPROVAL REQUIRED FOR AN ALTERNATIVE CLEANING AND SANITIZING FREQUENCY. Except as  
760 provided in sub. (2) or s. ATCP 70.40, if a food processing plant operator seeks to clean and  
761 sanitize equipment and utensils at a frequency other than that required in s. ATCP 70.14 (1)  
762 because the equipment and utensils are used with food products, processes, or conditions reducing  
763 the risk of foodborne illness or presence of major food allergens, then the food processing plant

764 operator shall submit an alternate cleaning and sanitizing procedure, that includes a monitoring and  
765 recording requirement, in compliance with s. ATCP 70.18 to the department for written approval.

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

769 (b) After review by the department, the proposed process may be denied and the department  
770 shall issue a letter of denial. If the alternate cleaning and sanitizing procedure is approved, the  
771 department shall issue a letter of approval applicable for not more than 5 years that is to be  
772 maintained on file at the food processing facility.

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

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

781 (a) Drying equipment.

782 (b) Cloth-collector systems.

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

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

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

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

793 (g) Food contact surfaces of equipment used for brewing or fermentation of alcohol-containing  
794 beverages, such as beer brewing or wine fermentation. A food processing plant operator shall clean  
795 and sanitize equipment used following each brewing or fermentation batch.

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

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

803 (j) Equipment used for processing of products with a natural pH  $\leq 4.0$ . A food processing plant  
804 operator shall clean and sanitize all equipment at the end of a continuous operation, not to exceed  
805 30 days (720 hours).

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

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

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

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

812 A food processing plant operator may submit a written request for the department to approve  
813 alternative cleaning and sanitizing procedures. The request shall include all of the following, and  
814 any other information required by the department:

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

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

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

825 (d) A written statement, by the food processing plant operator, that the alternative cleaning  
826 and sanitizing procedure has been determined by competent authority, such as evaluated by a

827 process authority or validated by a published or unpublished peer-reviewed article, challenge  
828 studies, or regulatory standards, to be effective in preventing food contamination and ensuring the  
829 microbiological safety of food.

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

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

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

843 **(3) QUALIFICATIONS, LIMITS, AND WITHDRAWAL OF DEPARTMENT APPROVAL.** The department  
844 may qualify or limit its approval under sub. (2), as deemed appropriate. The department may  
845 withdraw its approval for cause, including obtaining information that casts doubt on the efficacy or  
846 consistent implementation of the approved procedure or observing changes in operations that could  
847 affect the validity of the procedures or process.

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

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

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

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

858       (c) Collect and retain data and records to document, on a continuing basis, the implementation  
859 and efficacy of the approved procedure. The operator shall retain the data and records for at least  
860 90 days, and shall make them available upon request for inspection and copying by the  
861 department.

862       **ATCP 70.20 Water supply. (1) OPERATIONS WATER.** (a) Operations water, other than  
863 water reclaimed according to sub. (3), shall be obtained from a source that complies with ch. NR  
864 811, for municipal water systems, or ch. NR 812, for private or non-community water systems.

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

867       (c) Operations water sourced from either municipal, private, or non-community water systems  
868 shall comply with the microbiological standards under s. NR 809.30. Operations water from a



869 privately owned water system shall be sampled by the food processing plant operator not less than  
870 once every 12 months and be tested at a laboratory, certified to perform the appropriate tests, under  
871 ch. ATCP 77.

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

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

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

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

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

886 (b) Ingredient water obtained from either municipal, private, or non-community water systems  
887 shall not exceed the maximum contaminant levels set forth in the drinking water standards in ch.  
888 NR 809.07, the microbiological standards under s. NR 809.30, and the health-related enforcement  
889 standards under s. NR 140.10. At the department's request, a food processing plant operator shall

890 provide documentation to the department that the water complies with the microbiological  
891 standards of s. NR 809.30. Documentation may consist of results from tests performed at a  
892 laboratory certified under ch. ATCP 77 for the entity providing the water.

893 (c) If ingredient water is obtained from a privately owned water system, it shall be sampled by  
894 the operator not less than once every 12 months, and be tested at a laboratory, certified to perform  
895 the appropriate tests, under ch. ATCP 77.

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

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

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

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

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

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

911 Federation. The food processing plant operator shall use an automatic fail-safe monitoring device  
912 to identify, and automatically divert to a waste water system, any reclaimed water that fails to  
913 comply with this subdivision.

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

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

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

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

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

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

931 (b) Water reclaimed from a heat exchanger process, from a compressor cooling unit, from the  
932 condensation of food products, or from other food processing plant systems or processes may be

933 used as operations water with department approval if the water complies with par. (a) or if all of  
934 the following apply:

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

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

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

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

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

- 956 5. Chemical treatment of the reclaimed water, if any, complies with sub. (4).
- 957 6. The reclaimed water is stored in a properly constructed tank. The tank shall be constructed  
958 of a material that will not contaminate the water and can be easily cleaned.
- 959 7. There are no cross-connections between reclaimed water lines and any public or private  
960 water system, except for lines with backflow preventers that meet the requirements of chs. SPS  
961 382 and 384.
- 962 8. The reclaimed water, if held for more than 24 hours, is at all times held at a temperature of  
963 at least 145°F. (63° C.) or is chemically treated under sub. (4) to suppress bacterial growth.
- 964 9. Distribution lines and hose stations used to distribute the reclaimed water are clearly  
965 identified as "limited-use reclaimed water."
- 966 10. The food processing plant operator posts clear instructions for the use of the reclaimed  
967 water. The operator shall post the instructions so that they will be seen and understood by persons  
968 using the reclaimed water. The instructions shall disclose the limited purposes for which the  
969 reclaimed water may be used.
- 970 11. Water lines distributing the reclaimed water are not permanently connected to food  
971 product vessels. If a water line is temporarily connected to a food product vessel, there shall be an  
972 atmospheric break and automatic controls to prevent the reclaimed water from contacting food  
973 products.
- 974 (c) Water reclaimed from food processing operations may be used for cleaning or other  
975 purposes but may not be used for any purpose involving contact with food or food contact surfaces  
976 except as provided in par. (a) or (b).

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

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

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

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

- 993       1. Obtained from a source that complies with chs. NR 811 or 812, as applicable.
- 994       2. Bacteriologically safe.
- 995       3. Protected from contamination.
- 996       4. Tested by the food processing plant operator for compliance with subd. 2. at 6 month  
997 intervals.

998 (b) If a re-circulating water system, under par. (a), becomes contaminated, that system may  
999 not be used until it is properly treated and analytical results indicate that the contamination has  
1000 been eliminated.

1001 (c) Freezing point depressants used in re-circulating water systems, under par. (a), shall be  
1002 nontoxic.

1003 **(6) WATER AND POTABLE LIQUIDS TRANSPORTED IN BULK.** (a) Water transported to a food  
1004 processing plant in a bulk tanker or bulk container, for use as an ingredient or in other plant  
1005 operations, shall be potable and shall be obtained from a source that complies with chs. NR 811 or  
1006 812.

1007 (b) Whenever potable water or another potable liquid is transported to or from a food  
1008 processing plant in a bulk tanker or bulk container, it shall be loaded, transported, and unloaded in  
1009 a sanitary manner that prevents contamination. The bulk tanker or bulk container shall be  
1010 thoroughly cleaned and sanitized before being filled. Suitable pumps, hoses, and fittings shall be  
1011 used to transfer potable water and potable liquids to and from bulk tankers and bulk containers  
1012 shall be cleaned and sanitized prior to use.

1013 (c) Whenever potable water or another potable liquid is transported to or from a food  
1014 processing plant in a bulk tanker or bulk container, the bulk tanker or bulk container and each of  
1015 its fittings and equipment shall meet all of the following requirements:

1016 1. It shall be properly constructed and maintained to prevent contamination of the potable  
1017 water or potable liquid. Water contact surfaces shall comply with s. ATCP 70.12 (2).

1018 2. It shall be cleaned, sanitized, and inspected on a routine basis.

1019 3. It may not be used to transport materials that may contaminate potable water or potable  
1020 liquid that is subsequently transported in the bulk tanker or bulk container.

1021 4. It shall be effectively sealed to protect the potable water or potable liquid from  
1022 contamination during transit.

1023 **Note:** Effective sealing systems include manhole cover gaskets and seals.

1024 5. It shall be properly stored and serviced to prevent contamination. When not in use, pumps,  
1025 hoses, and fittings shall be properly maintained, capped, stored, and protected from contamination.

1026 **(7) CULINARY STEAM.** Water used to produce culinary steam shall be potable. Water  
1027 reclaimed from food processing operations may not be used to produce culinary steam unless it  
1028 complies with sub. (3) (a) or (b). In boilers used to produce culinary steam, boiler water additives  
1029 shall comply with 21 CFR 173.310.

1030 **(8) ICE.** Ice used to cool or maintain the temperature of foods shall be made from potable  
1031 water. Ice used to cool or maintain the temperature of ready-to-eat foods shall not have been  
1032 previously used for any other purpose. Ice shall be received, handled, and stored in a manner to  
1033 prevent contamination or adulteration. Any ice which is not made on site shall be inspected upon  
1034 receipt, and rejected if it is delivered in a way that has not adequately protected the ice from  
1035 contamination.

1036 **ATCP 70.22 Food ingredients. (1) GENERAL.** Food ingredients shall be safe, wholesome,  
1037 and unadulterated, and shall comply with applicable standards of identity under s. 97.09, Stats.  
1038 Raw agricultural commodities and other food ingredients shall be segregated and examined as



1039 necessary to determine whether they are clean and fit for processing. Processed foods and dairy  
1040 products which are used as food ingredients shall be obtained from sources which comply with  
1041 applicable licensing and inspection requirements.

1042       **(2) EGGS AND EGG PRODUCTS.** Only clean whole eggs, pasteurized eggs in liquid, frozen or  
1043 dry form, or pasteurized egg products may be used in food processing. Eggs and egg products  
1044 may be pasteurized during processing. Clean whole eggs shall be equivalent to USDA Grade B or  
1045 better with shells intact.

1046       **ATCP 70.24 Food handling and storage. (1) GENERAL.** Food shall be protected from  
1047 contamination and decomposition while being processed, handled, conveyed, or held at a food  
1048 processing plant. Food shall be processed and held in a manner which keeps the food in a safe,  
1049 wholesome, and unadulterated condition. Potentially hazardous foods shall be processed and held  
1050 at temperatures, or in a manner, which minimizes the potential for growth of undesirable  
1051 microorganisms.

1052       **(2) FOOD STORAGE.** Food storage areas shall be maintained in a clean, sanitary, and orderly  
1053 condition, free from conditions which may result in the adulteration of food. Potentially hazardous  
1054 foods shall be stored at safe temperatures. Storage areas shall be constructed and maintained so  
1055 that waste water and other waste liquids do not drain into, or accumulate in, any storage area.  
1056 Food shall not be stored in a manner which may attract or harbor pests.

1057       **(3) FOOD PROCESSING. (a)** Food processing shall be conducted under appropriate conditions  
1058 and controls to minimize the potential for growth of undesirable microorganisms, or the  
1059 contamination of food.

1060       **Note:** One way to comply with this requirement is to follow a HACCP plan which monitors and  
1061 controls food safety variables at critical control points in the manufacturing process. Monitoring and  
1062 controlling food safety variables such as time, temperature, humidity, water activity ( $a_w$ ), pH, pressure, and  
1063 flow rate at critical control points can ensure that mechanical breakdowns, time delays, temperature  
1064 fluctuations, and other conditions do not contribute to the decomposition or contamination of food.

1065       (b) If potentially hazardous food is heated, refrigerated, or frozen in the course of processing,  
1066 the internal temperature of the food shall be accurately monitored, as necessary, to ensure that safe  
1067 temperatures are promptly attained and maintained.

1068       (c) Any testing and monitoring done to minimize the potential for growth of undesirable  
1069 microorganisms or the contamination of food during processing and storage as required in this  
1070 section shall be recorded, the records shall be maintained on site for one year, and shall be made  
1071 available to the department or its agents on request for copying or photographing.

1072       (d) Potentially hazardous frozen foods, if thawed for processing, shall be thawed by one of the  
1073 following methods:

1074       1. By placing the frozen food in a refrigerated space at a temperature of not more than 41°F.  
1075 (5°C.).

1076       2. Placing the frozen food under potable running water, at a temperature of not more than  
1077 70°F. (21°C.), for no more time than is needed to thaw the food. Water velocity shall be sufficient  
1078 to agitate loose particles and drain or float them away from the food being thawed.

1079       3. By microwave heating, if the food is fully cooked in the microwave oven, or if cooking is  
1080 immediately completed in another cooking facility.

1081       4. In any cooking facility, as part of the process by which the food is fully cooked.

1082       **(4) BULK FLOUR HANDLING SYSTEMS.** (a) Food contact surfaces of bulk flour handling  
1083 equipment shall comply with the provisions of s. ATCP 70.12 (2). Pneumatic systems using  
1084 storage bins constructed of semi-permeable cloth material are exempt from the requirement that  
1085 surfaces be smooth and nonabsorbent, provided the surfaces can be effectively cleaned.  
1086 Attachment mechanisms for holding inspection port covers, access doors, delivery pipe caps, or  
1087 other removable accessories shall have no loose parts. Delivery pipe caps shall be kept in place,  
1088 and secured against removal, except when a bulk flour handling system is in use. Outside  
1089 installations shall be watertight or suitably covered to prevent entry of water and foreign material.

1090       (b) Intake air used in pneumatic flour handling systems shall be filtered to exclude particles of  
1091 50 microns or larger. Air discharged from the system shall be filtered so that no visible dust  
1092 escapes. Filters shall be readily removable for cleaning or replacement. Straight runs of  
1093 pneumatic conveyors shall comply with the provisions of s. ATCP 70.12 (1), except that piping  
1094 which is self-purging is exempt from accessibility requirements.

1095       **(5) RAW INGREDIENTS AND FINISHED PRODUCTS; SEPARATE HANDLING.** Effective measures  
1096 shall be taken to prevent cross contamination between raw ingredients and finished food products.  
1097 Raw ingredients shall not be handled simultaneously with finished products in any part of a food  
1098 processing plant if either the raw materials or the finished products are uncovered or unprotected,  
1099 and if the handling may result in contamination.

1100       **(6) SALVAGING DISTRESSED FOOD.** (a) In this subsection:

1101       1. "Distressed food" means processed food exposed to a fire, flood, transportation accident,  
1102 refrigeration breakdown, or other unusual condition which may affect its safety or suitability as

1103 human food. "Distressed food" does not include food or food packages damaged during normal  
1104 conditions of food and food product handling, transit, or storage.

1105 2. "Reconditioned food" means packaged distressed food which is distributed or offered for  
1106 sale as human food after its package is repaired or relabeled without being opened.

1107 3. "Reprocessed food" means distressed food that is subsequently processed in accordance  
1108 with the requirements under this chapter and distributed or offered for sale as human food.

1109 (b) A food processing plant operator shall notify the department within 3 days after the  
1110 operator takes possession of any distressed food, or within 3 days after food in the operator's  
1111 custody becomes distressed food. The operator shall notify the department before the operator  
1112 reprocesses or reconditions the distressed food.

1113 (c) A food processing plant operator shall identify distressed food as such, and shall separate it  
1114 from other food. No operator may store distressed food in a processing area, or under conditions  
1115 which may lead to the contamination of other food, equipment, utensils, or packaging materials.

1116 (d) No food processing plant operator may do either of the following:

1117 1. Reprocess for sale, as human food, any distressed food which is unwholesome or  
1118 adulterated.

1119 2. Offer for sale, sell, or distribute food in packages that are damaged to such an extent that the  
1120 food may have been exposed or subjected to possible contamination, including packages with  
1121 bulging ends, ruptures, hairline fractures, breakage along critical seams, or openings which may  
1122 have exposed food to contamination.

1123 (e) No food processing plant operator may sell or distribute reprocessed or reconditioned food  
1124 at wholesale unless the operator gives the purchaser or recipient written notice that the food is  
1125 reprocessed or reconditioned. The notice shall also include the name and address of the person  
1126 who reprocessed or reconditioned the distressed food. The notice may be included on an invoice,  
1127 bill of lading, or other documentation of the sale or distribution of the food.

1128 (f) A food processing plant operator shall keep, for the period of time set forth in 21 CFR  
1129 117.315, all of the following records related to distressed food handled by that operator:

1130 1. A description of the distressed food, including the type of food, the package or container  
1131 style, and the amount of the food.

1132 2. The source of the distressed food, or the conditions which caused it to become distressed  
1133 food.

1134 3. The date on which the operator received the distressed food.

1135 4. The nature of any reprocessing or reconditioning which the operator performed on the  
1136 distressed food.

1137 5. The final disposition of the distressed food if the distressed food was not sold directly at  
1138 retail. That record shall include the name and address of the person, such as the food wholesaler,  
1139 food distributor, waste disposal firm or waste disposal site operator, to whom the food processing  
1140 plant operator delivered the food.

1141 (7) FOOD IRRADIATION. Irradiation in the production, processing, and handling of food shall  
1142 comply with applicable federal regulations under 21 CFR 179.

1143           **(8) EGG CLEANING AND STORAGE.** Cleaning and storage of eggs shall be done in compliance  
1144 with the requirements of s. ATCP 88.20.

1145           **ATCP 70.26 Food packaging and labeling. (1) GENERAL.** Food packages shall be of  
1146 sanitary design and construction, so as to protect food contents from reasonably foreseeable risks  
1147 of contamination. Food packages shall be clean, sanitary, and free of any extraneous or deleterious  
1148 substance. Food shall not be sold or distributed in packages which are damaged to the extent that  
1149 food contents may be adulterated as a result of the damage. A sealed food package is damaged  
1150 within the meaning of this subsection if the package or seal is broken or bulged.

1151           **(2) CLEANING AND SANITIZING RETURNABLE FOOD PACKAGES.** Returnable or multi-use food  
1152 packages, including returnable bottles, shall be effectively cleaned and sanitized before being  
1153 reused. Cleaning and sanitizing processes shall remove all extraneous matter and potential  
1154 adulterants from a food package before the food package is reused. Sanitizing methods shall  
1155 comply with s. ATCP 70.28. No food package may be reused unless it is specifically designed and  
1156 constructed for that purpose.

1157           **(3) INSPECTION OF RETURNABLE FOOD PACKAGES.** Returnable or multi-use packages, after  
1158 being cleaned and sanitized, shall be inspected before being reused. Inspection shall be adequate  
1159 to detect extraneous material and visible adulterants, and any damage to product contact surfaces.  
1160 Inspection shall be performed on surfaces lighted in compliance with s. ATCP 70.08 (6) (b).

1161           **(4) SINGLE-SERVICE FOOD PACKAGES.** Single-service food packages, including bottle caps and  
1162 other single-service articles used to package food, shall be made from clean, sanitary materials.  
1163 Single-service food packages shall be clean and sanitary at the time of use. Single service food

1164 packages shall be protected from contamination prior to use, and shall be handled in a sanitary  
1165 manner. Single-service food packages, including single-service bottles and bottle caps, shall not  
1166 be re-used.

1167 (5) FOOD PACKAGE LABELING. Packaged food shall be packaged and labeled according to all  
1168 of the following, as applicable:

1169 (a) 21 CFR 101.

1170 (b) s. 97.09, Stats., and federal regulations incorporated by reference in s. 97.09, Stats.

1171 (c) ch. ATCP 90.

1172 (d) ch. ATCP 75 Appendix, *Wisconsin Food Code* section 3-201.11(C).

1173 (e) If the packaged food contains a major food allergen, the ingredient statement on the  
1174 package shall disclose the common name of the major food allergen. The disclosure shall be  
1175 equivalent in size and prominence to the rest of the ingredient statement. If an allergen originates  
1176 from fish, crustacean shellfish, or tree nuts, the disclosure shall include the common name of the  
1177 source species.

1178 **Note:** For example, if a food product includes an allergen that originates from fish, the ingredient  
1179 statement must disclose the common name such as bass, flounder, or cod. If the allergen originates from  
1180 crustacean shellfish, the ingredient statement must disclose the common name such as crab, lobster, or  
1181 shrimp. If the allergen originates from tree nuts, the ingredient statement must disclose the common name  
1182 such as almond, pecan, walnut, or coconut.

1183 (6) EGG PACKAGING AND LABELING. The packaging and labeling of eggs shall be done in  
1184 compliance with the requirements of ss. ATCP 88.32, 88.34, and 88.38.

1185       **(7) ALCOHOL RESTRICTIONS AND LABELING.** If a product contains more than 1.0 % but less  
1186 than 7.0 % alcohol it is regulated by the labeling provisions of this subsection and the alcohol  
1187 would be declared as an ingredient in normal descending order of predominance.

1188       (a) Ice cream containing more than 2.0% alcohol is not regulated by this chapter.

1189       (b) If the alcohol is part of other ingredients such as a flavoring, and it is less than 0.5% of the  
1190 finished product by volume, then it is considered an incidental ingredient.

1191       **ATCP 70.28 Sanitizers and sanitizing methods. (1) SANITIZING METHODS.** All returnable  
1192 or multi-use food packages, and all food contact surfaces of equipment and utensils used to handle  
1193 foods, shall be effectively sanitized prior to each use.

1194       **(1m) CHEMICAL SANITIZERS; REQUIREMENTS.** The food processing plant operator shall use  
1195 only chemical sanitizers that comply with 21 CFR 178.1010, are registered with the U.S.  
1196 environmental protection agency, are applied according to manufacturer's instructions, labeled for  
1197 use in food processing plants on food contact surfaces and, when used appropriately, do not leave  
1198 an unacceptable residue on the food contact surface.

1199       **(2) BAKING AND COOKING CONTAINERS; EXEMPTION.** Sub. (1) does not apply to baking and  
1200 cooking containers if heating time and temperature combinations meet industry standards and are  
1201 adequate to destroy pathogenic microorganisms, provided that the containers are cleaned, stored,  
1202 and used in a manner which prevents contamination of food.

1203       **(3) SANITIZERS; MAXIMUM CONCENTRATIONS.** The food processing plant operator shall use  
1204 sanitizers and cleaning compounds so no toxic or otherwise unacceptable residue is left on any  
1205 food contact surface. Sanitizing solutions shall not exceed the maximum concentrations



1206 established by the food and drug administration, United States department of health and human  
1207 services, under 21 CFR 178.1010. A test kit or other device that measures the concentration of  
1208 sanitizing solutions in parts per million shall be used as necessary to ensure compliance with this  
1209 subsection.

1210 **(4) SANITIZERS; DEPARTMENT APPROVAL.** (a) Sanitizers approved by the U.S. environmental  
1211 protection agency and labeled for use on food contact surfaces are also accepted by the department  
1212 for use according to their labels. The department may approve other sanitizers and sanitizing  
1213 methods that it finds to be safe and effective for the purpose used.

1214 (b) The department may deny or withdraw approval of any sanitizer or sanitizing method if the  
1215 department determines that the sanitizer or sanitizing method is not safe or effective for the  
1216 purpose or under the conditions used, or that it adversely affects the sanitary characteristics of  
1217 equipment, utensils or food packages.

1218 **ATCP 70.30 Ready-to-eat foods; reporting pathogens and toxins. (1) REQUIREMENT.**

1219 Except as provided under sub. (2), a food processing plant operator shall report to the department  
1220 the results of any microbiological test or laboratory analysis which indicates that any ready-to-eat  
1221 food produced by that operator contains pathogenic organisms, toxins resulting from the growth of  
1222 pathogenic organisms, or any other adulterant capable of causing disease or injury if ingested. The  
1223 operator shall report to the department within 24 hours after the operator obtains the test results.

1224 The operator may report orally, electronically, or in writing.

1225 **Note:** The State of Wisconsin's Emergency Management phone number is (800) 943-0003. The general  
1226 number of the Division of Food and Recreational Safety is (608) 224-4700, and its FAX number is (608)  
1227 224-4710.

1228

1229       **(2) EXEMPTION.** A food processing plant operator is not required to report test results under  
1230 sub. (1) if all of the following apply:

1231       (a) The ready-to eat-food is identified by a product code or production lot number.

1232       (b) The food processing plant operator has not yet sold or distributed any of the ready-to-eat  
1233 food represented by the product code or production lot number under par. (a), but retains direct  
1234 control over all of that ready-to-eat food.

1235       **ATCP 70.32 Recall plan. (1) PLAN REQUIRED.** A food processing plant operator shall have  
1236 a written plan for identifying and recalling food produced at that plant, should a food recall  
1237 become necessary. The operator shall update the plan as necessary, and shall make it available to  
1238 the department for inspection and copying upon request.

1239       **(2) PLAN CONTENTS.** A plan, under sub. (1), shall do all of the following:

1240       (a) Identify key individuals or positions that are responsible for planning, approving, and  
1241 implementing recalls on behalf of the food processing plant operator.

1242       (b) Identify key individuals or entities to be contacted or consulted in connection with a recall.

1243       (c) Include procedures for the routine identification, dating, and tracking of food production  
1244 lots, so that affected lots can be identified and distinguished from unaffected lots in the event of a  
1245 recall.

1246       (d) Include procedures to enable routine identification, dating, and tracking of food shipments  
1247 from the food processing plant. Tracking shall identify shipment recipients and contents, cross-  
1248 referenced to production lots, so that recipients of affected lots can be contacted in the event of a  
1249 recall.

1250 (e) Include procedures for determining the nature and scope of a recall, including affected  
1251 food production lots, shipments, and shipment recipients.

1252 (f) Include procedures for identifying and communicating with affected persons, including  
1253 suppliers, food shipment recipients, down-line buyers, consumers, government agencies, and  
1254 others.

1255 (g) Identify potential target audiences for recall information, including consumers,  
1256 distributors, and government agencies.

1257 (h) Identify potential methods for communicating with target audiences under par. (g).

1258 (i) Identify key information, including the identity of the affected food, the reason for the  
1259 recall, and suggested actions to be taken by affected persons, which may need to be communicated  
1260 in the event of a recall.

1261 (3) DEVIATIONS FROM PLAN. Actual recall procedures may deviate from the recall plan under  
1262 sub. (1), as circumstances warrant.

### 1263 **Subchapter III. Canning Operations; Supplementary Requirements**

1264 **ATCP 70.34 General. (1) APPLICABLE REQUIREMENTS.** Food processing plants engaged in  
1265 canning operations shall comply with applicable provisions of subch. II. Food processing plants  
1266 engaged in canning operations shall also comply with this subchapter and shall file processes, as  
1267 required, with the U.S. food and drug administration according to the provisions in 21 CFR 108.

1268 (2) RESTRICTIONS ON SALE, DISTRIBUTION, AND DONATION OF HOME-CANNED FOODS. Home-  
1269 canned low-acid or acidified foods may not be donated to charitable organizations, food banks,  
1270 food pantries, or other non-profit organizations that will distribute or sell the home-canned foods.

1271 The individual canning processor may not sell the home-canned foods at a food bank or food  
1272 pantry, or on behalf of a charitable or non-profit organization, unless exempted by statute or rule.

1273 **ATCP 70.36 Low-acid foods packaged in hermetically sealed containers.** The operator  
1274 of a food processing plant that processes and packages low-acid foods in hermetically sealed  
1275 containers shall comply with applicable federal regulations under 21 CFR 108.35 (c) and 21 CFR  
1276 113.

1277 **Note:** Section ATCP 70.36 applies to all low-acid foods processed and packaged in hermetically sealed  
1278 containers, including thermally processed and aseptically processed low-acid foods.

1279 **ATCP 70.38 Acidified foods.** Persons who process acidified foods shall comply with  
1280 applicable federal regulations under 21 CFR 108.25 (c) and 21 CFR 114.

1281 **ATCP 70.40 Facilities and equipment; cleaning. (1) EQUIPMENT DESIGN, CONSTRUCTION,**  
1282 **AND ACCESSIBILITY.** The operator of a food processing plant facility handling raw agricultural  
1283 commodities to prepare the commodities for canning, shall use product-handling equipment that is  
1284 kept clean and in good repair and is designed and constructed in a way that allows easy  
1285 accessibility for maintenance and cleaning.

1286 **(2) EQUIPMENT, WATER, AND SUPPLIES USED FOR CLEANING.** The operator of a food processing  
1287 plant conducting canning operations shall use cleaning equipment that is adequate and in good  
1288 repair, and shall provide ample supplies of water and steam or other approved cleaning and  
1289 sanitizing materials for cleaning purposes at the facility.

1290 **(3) CLEANING REQUIREMENTS FOR EQUIPMENT USED TO PROCESS FOOD BEFORE THERMAL**  
1291 **PROCESSING.** The food processing plant operator at a canning facility shall clean equipment used  
1292 to process food before thermal processing, in accordance with a written plan kept at the canning

1293 facility and made available to the department for review upon request. The written plan shall  
1294 include:

1295 (a) A clear and complete description of the affected food processing equipment and utensils,  
1296 including any continuously-operated equipment. The description shall identify sanitary design  
1297 features that are relevant to the proposed cleaning and, if deemed appropriate, sanitizing  
1298 procedures.

1299 (b) The types of food produced with the affected equipment or utensils, the purposes for which  
1300 the food will be used, and the thermal processing conditions to which the food will be subjected.

1301 (c) A clear and complete description of the alternative procedures used to clean and, if deemed  
1302 appropriate, sanitize the equipment, including equipment used to conduct these procedures,  
1303 frequency, methods, materials, and relevant process parameters such as time and temperature. The  
1304 description shall include a flow diagram of the alternative procedures.

1305 (d) A written statement, by the food processing plant operator, that the alternative cleaning  
1306 and sanitizing procedures have been determined by competent authority, such as a process  
1307 authority or validated by a published or unpublished, peer-reviewed article, challenge studies, or  
1308 regulatory standards, to be effective in preventing finished food product contamination and  
1309 ensuring the microbiological safety of food.

1310 (e) Identification of foreseeable hazards, critical control points, critical safety parameters and  
1311 limits, and monitoring procedures and controls to ensure that the procedure is effective and  
1312 appropriately implemented.

1313       **ATCP 70.42 Handling raw agricultural commodities and by-products. (1) PRE-**  
1314 CANNING OPERATIONS. Raw agricultural commodities shall be washed, sorted, trimmed as  
1315 necessary, and inspected before being canned. This requirement does not apply to the washing of  
1316 cabbage being prepared to make sauerkraut.

1317       **(2) WASTE HANDLING.** Waste and by-products from canning operations shall be stored and  
1318 handled in a sanitary manner.

1319       **Subchapter IV. Fish Processing Plants; Marine Shellfish Plants; Supplementary**  
1320 **Requirements**

1321       **ATCP 70.44 Fish processing. (1) APPLICABLE REGULATIONS.** Fish processing operations  
1322 shall comply with subch. II and 21 CFR 123. Fish processing plant operators shall have and  
1323 operate in accordance with HACCP plans that comply with 21 CFR 123 and address food safety  
1324 hazards that may occur in fish processing. If a fish processing plant produces smoked fish  
1325 products or smoke-flavored fish products, the HACCP plan for that fish processing plant shall  
1326 address potential botulism risks as provided in 21 CFR 123 part B.

1327       **(2) RESTRICTION ON USE OF COLD-PROCESS SMOKED FISH.** Cold-process smoked fish may  
1328 not be used as an ingredient in any other ready-to-eat, potentially hazardous food.

1329       **ATCP 70.46 Labeling and sale of smoked fish. (1) MANDATORY LABEL INFORMATION.**  
1330 Every package containing smoked fish shall be clearly and conspicuously labeled, on the principal  
1331 display panel of that package, with all of the following information:

1332       (a) The name and address, including the zip code, of the smoked fish processor or distributor.

1333 (b) The name of the product, including the common name of the fish from which the product  
1334 is derived as found in Table 3-2 of the Fourth Edition of *Fish and Fishery Products Hazards and*  
1335 *Controls Guidance*.

1336 **Note:** A copy of the current edition of the *Fish and Fishery Products Hazards and Controls Guidance*,  
1337 may be obtained from the University of Florida Bookstore by calling (800) 226-1764, or it may be  
1338 downloaded from the U.S. food and drug administration website:  
1339 <http://www.fda.gov/Food/GuidanceRegulation/Guidance DocumentsRegulatoryInformation/default.htm/>  
1340

1341 (c) The net weight of the package contents.

1342 (d) If cold-smoked fish is contained in reduced-oxygen packaging and sold or distributed in an  
1343 unfrozen state, the words “PERISHABLE – KEEP REFRIGERATED AT OR BELOW 38° F” in  
1344 conspicuous letters at least the size of those used in the food name.

1345 (e) If smoked fish contained in the package are sold or distributed in a frozen state, the words  
1346 “PERISHABLE — KEEP FROZEN PRIOR TO USE” in conspicuous letters at least the size of  
1347 those used in the food name.

1348 (f) The processing date or processing date code of the smoked fish.

1349 (2) PROHIBITION AGAINST COMMINGLING. Smoked fish processed on different dates or codes  
1350 may not be commingled in the same container, either at the processing plant or while the fish are  
1351 being stored, distributed, or offered for sale at wholesale or retail.

1352 (3) MISREPRESENTATION OF PROCESSING DATE OR PROCESSING DATE CODE PROHIBITED. No  
1353 person may misrepresent a smoked fish processing date or processing date code, or sell or  
1354 distribute smoked fish labeled with any processing date or processing date code other than the  
1355 original date or code affixed by the processor.

1356       **(4) REMOVAL OF MISLABELED OR MISHANDLED SMOKED FISH.** Food consisting of or containing  
1357 smoked fish shall be immediately removed from sale, and shall be destroyed or treated to render it  
1358 unattractive and unfit for human consumption, if any of the following occurs:

1359       (a) The food package is not labeled with a processing date or processing date code.

1360       (b) Vacuum-packaged, cold-smoked fish is held, other than for brief periods during  
1361 distribution, at a temperature above 38° F. (3.4° C.) prior to retail sale. This paragraph does not  
1362 apply to a food which the department specifically exempts in writing because it is not subject to  
1363 spoilage and does not support pathogen growth.

1364       **(5) APPLICABILITY OF SMOKED FISH REGULATIONS IN WISCONSIN.** No smoked fish may be sold,  
1365 distributed, or offered or exposed for sale in this state unless the smoked fish have been processed,  
1366 labeled, and handled in compliance with this subchapter. This subsection applies to every person  
1367 engaged in the sale or distribution of smoked fish in this state, regardless of whether the person  
1368 processes smoked fish in this state.

1369       **ATCP 70.48 Fish roe. (1) REFRIGERATION.** Roe and any attached entrails harvested from  
1370 a fish shall be refrigerated at a temperature of not more than 38° F. (3.4° C.). Processing of dry  
1371 salted roe or salted roe product shall be done in accordance with 21 CFR 123.

1372       **(2) HARVESTING AND HANDLING.** Roe and attached entrails, if any, shall be harvested, stored,  
1373 and transported for processing in covered food grade containers. Each container shall be  
1374 conspicuously labeled to indicate when each of the following operations was performed, if that  
1375 operation has been performed:

1376       (a) The roe and attached entrails, if any, were harvested from the fish.



1377 (b) The roe sacks were separated from attached entrails, if any. Roe sacks shall be separated  
1378 from attached entrails within 48 hours after the roe sacks and entrails are harvested from the fish.

1379 (c) The roe was separated from the roe sacks. Roe shall be separated from roe sacks within 72  
1380 hours after the roe sacks are harvested from the fish, unless the roe is processed and packed in roe  
1381 sacks. Roe processed and packed without being separated from roe sacks shall be processed and  
1382 packed within 72 hours after the roe sacks are harvested from the fish.

1383 **(3) RECEIPT FOR PROCESSING.** A fish processing plant operator may not accept for processing  
1384 any roe that has been held, transported, or processed in violation of sub. (1) or (2).

1385 **(4) PROCESSING STANDARDS.** (a) Roe shall be held and processed according to s. ATCP 70.24  
1386 (1).

1387 (b) Processed roe shall contain a minimum of 2.5% salt by weight, as determined by  
1388 quantitative analysis for total salt content.

1389 (c) No fish processing plant personnel may have direct hand contact with finished, ready-to-  
1390 eat roe.

1391 **(5) PRODUCT REPRESENTATION.** (a) No roe product may be labeled or represented as "caviar"  
1392 unless one of the following applies:

1393 1. The product consists only of the eggs of sturgeon prepared by a salting and separation  
1394 process traditionally associated with the term "caviar."

1395 2. The product consists of roe prepared by a salting and separation process traditionally  
1396 associated with the term "caviar," and the name of the fish species is clearly disclosed with the  
1397 term "caviar" whenever that term is used.

1398       **Note:** For example, a caviar-type product made from whitefish eggs, using the traditional caviar  
1399 process, may not be labeled as “caviar” unless it is labeled as “whitefish caviar.” All packaged food  
1400 product labels, including “caviar” labels, must also include a statement of ingredients listed by their  
1401 common or usual names in descending order of prominence (see s. ATCP 70.26).

1402       (b) No person may misrepresent the identity or value of any roe product by adding a color  
1403 additive to the roe product. This paragraph does not prohibit the use of color additives in roe  
1404 products if all of the following apply:

1405       1. The color additive is approved by the United States food and drug administration.

1406       2. The product includes a conspicuous label disclosure, such as “artificially colored” or “color  
1407 added,” which clearly indicates that the product includes a color additive. The disclosure shall  
1408 appear on the product label directly below the product name in type at least one-third the size of  
1409 the type used in the product name.

1410       3. The color additive is included in the ingredient statement on the product label.

1411       **ATCP 70.50 Marine molluscan shellfish processing. (1) APPLICABLE FEDERAL**  
1412 **REGULATIONS.** Shellfish processing and shipping operations shall comply with subch. II, the U.S.  
1413 food and drug administration’s *Guide for the Control of Marine Shellfish, The Model Ordinance,*  
1414 and applicable sections of 21 CFR 123. Shellfish processing plant operators shall have HACCP  
1415 plans that comply with 21 CFR 123 and address food safety hazards that may occur in shellfish  
1416 processing. If a shellfish processing plant produces smoked shellfish products or smoke-flavored  
1417 shellfish products, the HACCP plan for that fish processing plant shall address potential botulism  
1418 risks as provided in 21 CFR 123 part B.

1419       **(2) ILLNESS OUTBREAKS ASSOCIATED WITH SHELLFISH.** (a) At any time shellfish are  
1420 potentially implicated in an illness outbreak involving at least 2 persons not from the same  
1421 household, or at least one person in the case of paralytic shellfish poisoning, the department shall  
1422 determine whether an epidemiological association exists between the illness and the shellfish  
1423 consumption by reviewing each consumer's food intake history and the shellfish handling  
1424 practices of the consumer and retailer.

1425       (b) When the department has determined an epidemiological association exists between an  
1426 illness outbreak and shellfish consumption, the department shall conduct an investigation of the  
1427 outbreak to determine whether the illness is related to the shellfish growing area or to post-harvest  
1428 contamination or mishandling.

1429       (c) Upon completion of the investigation, the department shall notify receiving states and the  
1430 United States food and drug administration of the findings, and take appropriate steps in  
1431 cooperation with the licensee dealer to recall the affected product and, if necessary, inform  
1432 consumers about the outbreak and associated product.

1433       **(3) DOCUMENTS ASSOCIATED WITH SHELLFISH PROCESSING.** Any documents generated by the  
1434 facility in the course of its operation shall be available to the department within 24 hours of request  
1435 by the department or its agent.

1436       **Subchapter V. Bottling Establishments; Supplementary Requirements**

1437       **ATCP 70.52 Bottling establishments; general.** Bottling establishments shall comply with  
1438 subch. II and this subchapter. Bottling establishments producing bottled water shall comply with  
1439 21 CFR 129.

1440       **ATCP 70.54 Returnable and single-service bottles.** Bottles shall comply with food  
1441 package requirements under s. ATCP 70.26 (1). Returnable bottles shall be cleaned, sanitized, and  
1442 inspected in compliance with ss. ATCP 70.26 (2) and (3). Single service bottles shall comply with  
1443 s. ATCP 70.26 (4).

1444       **ATCP 70.56 Bottled water product sampling; record keeping; reports.**

1445       **(1) SAMPLING AND ANALYSIS.** The operator of a bottled water plant shall collect and analyze  
1446 samples of bottled product for the following contaminants at the following minimum frequency,  
1447 and more frequently if necessary, to provide reasonable assurance of compliance with this  
1448 subsection:

1449       (a) A weekly total coliform analysis. Pursuant to 21 CFR 129.80 (g) (1), a positive total  
1450 coliform analysis requires follow-up testing for *E. coli* and, pursuant to 21 CFR 165.110 (b) (2)  
1451 (B), if *E. coli* is present the bottled water will be deemed adulterated.

1452       (b) An annual physical analysis pursuant to 21 CFR 165.110 (b) (3) for turbidity, color and  
1453 odor analysis.

1454       (c) An annual chemical analysis pursuant to 21 CFR 165.110 (b) (4).

1455       (d) An annual radiological analysis pursuant to 21 CFR 165.110 (b) (5).

1456       **(2) REPORTING OF ANALYTICAL RESULTS.** A processor of bottled water shall report the results  
1457 of all required analyses, under sub. (1), to the department, for each license year upon request. If  
1458 the result of any individual analysis exceeds the established enforcement standard, the bottled  
1459 water processor shall submit a copy of that analytical report to the department within 7 days of the  
1460 completion of the analysis.

1461       **ATCP 70.58 Labeling bottled products.** (1) Bottled products shall be labeled according to  
1462 s. ATCP 70.26 (5). Bottled water shall also be labeled according to 21 CFR 165.110. Juice shall  
1463 be labeled according to 21 CFR 120, and any applicable regulations found in this chapter.

1464       **Subchapter VI. Juice and Juice HACCP**

1465       **ATCP 70.60 Juice and Juice HACCP. (1) APPLICABLE REGULATIONS.** Food processing  
1466 plants producing and packaging or bottling juice shall comply with subch. II and this subchapter.  
1467 Food processing plants engaged in juice processing and packaging or bottling shall comply with 21  
1468 CFR 120.

1469       **(2) LABELING REQUIREMENTS.** A juice label may not misrepresent that juice has been  
1470 pasteurized or has undergone a process equivalent to pasteurization. A juice label may not  
1471 represent as "fresh" any juice that has been treated with ultra-violet light.

1472       **Subchapter VII. Effect of Rules on Local Ordinances**

1473       **ATCP 70.62 Effect of rules on local ordinances. (1) NON-CONFLICTING LOCAL**  
1474 **ORDINANCES PERMITTED.** This chapter does not prohibit or nullify any local government ordinance  
1475 with which it is not in direct conflict as provided in sub. (2).

1476       **(2) PRE-EMPTION OF CONFLICTING LOCAL ORDINANCES.** If this chapter conflicts directly with  
1477 any local government ordinance, so that it is impossible to comply with one except by violating the  
1478 other, this chapter controls.

1479       **(3) DUTY TO COMPLY.** Compliance with local government ordinances does not relieve any  
1480 person from the duty of complying with this chapter.

1481       **Subchapter VIII. Variances**

1482       **ATCP 70.64 Variances. (1) ISSUANCE.** The department may issue a written waiver granting  
1483 a variance from a construction, equipment, or processing standard under this section if the  
1484 department finds that the variance is reasonable and necessary under the circumstances, and that it  
1485 will not compromise the purpose served by the construction, equipment, or processing standards.  
1486 The administrator of the department’s division of food and recreational safety may issue a waiver  
1487 on behalf of the department. The department shall keep a copy of the waiver on file for as long as  
1488 the waiver remains in effect.

1489       **(2) SUBMISSION OF REQUEST FOR A VARIANCE.** A variance request shall be submitted to the  
1490 department through the sanitarian assigned by the department to inspect the food processing plant,  
1491 and shall include all validation documents as well as a HACCP plan required under 21 CFR, parts  
1492 120 or 123, if applicable; or food safety preventive controls plan as required under 21 CFR 117,  
1493 Subpart C, if it is for a waiver of accepted processing protocols.

1494       **(3) DURATION AND EXPIRATION.** All waivers granted under this section shall expire 5 years  
1495 from the date of issuance or when changes are made that could have an effect on the validity of the  
1496 procedures or process.

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1499        **SECTION 2. EFFECTIVE DATE.** This rule shall take effect on the first day of the month  
1500 following publication in the Wisconsin Administrative Register, as provided under s. 227.22 (2)  
1501 (intro.), Stats.

Dated this \_\_\_\_ day of \_\_\_\_\_, 2018.

STATE OF WISCONSIN  
DEPARTMENT OF AGRICULTURE, TRADE  
AND CONSUMER PROTECTION

By \_\_\_\_\_  
Sheila Harsdorf, Secretary

