



State of Wisconsin
Governor Scott Walker

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

DATE: November 6, 2018

TO: Board of Agriculture, Trade and Consumer Protection

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

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 (“DATCP” or the “Department”) will ask the Board of Agriculture, Trade and Consumer Protection 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, 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

The proposed rule updates Wis. Admin. Code ch. ATCP 70 by adopting certain federal regulations that implement the requirements of the federal Food Safety Modernization Act (“FSMA”). Specifically, the revised rule incorporates multiple subparts of the recently issued 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, that has superseded 21 CFR 110, *Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food*.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 federally-registered food facilities are already

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subject to this federal rule and licensed as food processing plants, this rule features similar referencing for the sake of consistency. This revision also ensures that the requirements for Wisconsin-licensed food processing plants, which are not subject to the federal rule, are clearly articulated.

The transfer of DHS' FSRL to DATCP's Division of Food Safety necessitated the merger of two food safety regulatory systems. One regulatory paradox was particularly in need of resolution: 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 without holding a food processing plant license. By statute, restaurants are now licensed as retail food establishments, and therefore, also enjoy the same limited ability to wholesale food. In the current rule-making process, DATCP initially proposed to retain certain existing limits and requirements from its prior rule concerning food processing activities for wholesale conducted by a retail food establishment. The Board of Agriculture, Trade and Consumer Protection ("Board") approved a draft rule reflecting this philosophy at its January 2018 meeting. This final draft also for the first time included definitions of "wholesale" and "retail". However, after the Board meeting, it became apparent that industry participants felt that less restrictive limits and definitions would still adequately protect public health.

As a result of this feedback, DATCP opted to form a work group comprised of industry personnel and local health department agent program representatives. They were tasked with further revision of the rule. During deliberations, the work group concluded that the safety of many food processing activities for wholesale, when performed by retail food establishments, could be ensured by compliance with Wis. Admin. Code ch. ATCP 75 and the appendix thereto, *Wisconsin Food Code*. Thus, recourse to the requirements of Wis. Admin. Code ch. ATCP 70 was unnecessary. The work group recognized that additional training would be needed for local health department agent personnel, as well as DATCP sanitarians, who were assigned to retail food establishments performing these food processing activities for wholesale. DATCP, as part of its ongoing mission to thoroughly train food safety personnel at the state and local level, is committed to providing both the necessary initial training and ongoing technical support.

The work group's efforts culminated in this newly revised final draft of Wis. Admin. Code ch. ATCP 70 that redefines "wholesale" and "retail", clarifies the exemption for retail food establishments from the requirement to hold a food processing plant license when conducting limited (not more than 25% of gross annual food sales) food processing activities for wholesale, and redraws the boundaries delimiting the permissible types of food processing activities for wholesale. Perhaps the most salient change to the regulatory territory is that a transfer of food between two food processing plants or retail food establishments will not be regarded as wholesaling, so long as the two businesses involved are operated by the same licensed entity and the firm transferring the food does not relinquish control of the food. This change reflects current guidance by the United States Food and Drug Administration ("FDA") and the United States Department of Agriculture, Food Safety and Inspection Service.

The revised definitions of "wholesale" and "retail" reflect industry practice and the current interpretation of these terms in the marketplace, as well as FDA's recent guidance and its sanction of industry praxis. The revised definitions also appear in the pending revision to Wis.

Admin. Code ch. ATCP 75 (Retail Food Establishments). The revised rule continues to prohibit retail food establishments from processing canned low-acid or acidified foods for wholesale without holding a food processing plant license and complying with Wis. Admin. Code ch. ATCP 70 requirements. DATCP expects these updates to promote clarity and uniformity and to facilitate enhanced business opportunities for retail food establishments in Wisconsin.

Another theme of early discussions of the rule revision was the question of whether additional regulations were necessary to ensure sanitary conditions in food processing plants sharing a building with a residence. The initial draft of the revised rule forbade the licensing of any new or remodeled food processing plant in this context. However, feedback from the working group militated against the need for an outright ban or other additional regulation to ensure adequate separation between residential and processing activities or access for DATCP inspections. Accordingly, the proposed revision was deleted.

In addition to threading a path through these complex issues, the revised rule propounds several other changes. The rule adopts the Model Ordinance for molluscan shellfish, now *marine shellfish*, with the Ordinance replacing all of Wis. Admin. Code s. ATCP 70.21 except for the existing subsection addressed to illnesses and outbreaks associated with shellfish. This modification will keep Wisconsin's regulations current with national standards for shellfish processing and marketing.

This revised rule also:

- Updates the definition of "food processing plant" to render it consistent with the statutory definition.
- Addresses requirements for vending machine commissaries, including those that support micro markets, just as the revised Wis. Admin. Code ch. ATCP 75 and the Appendix thereto (*Wisconsin Food Code*) specify requirements for vending machines and micro markets. These revisions incorporate recently enacted statutory language and ensure consistency and clarity in requirements for both the food processing plant portion of these operations and the retail food establishment business.
- Clarifies the definition of extended runs and the scope of waivers allowing those runs, while clarifying and expanding the list of food processing activities during which daily cleaning and sanitizing are not required.
- Updates certain outdated restrictions on hot-smoked, vacuum-packed fish. The archaic rules were unique to Wisconsin whereas the updates mirror requirements in other states and are based on current, science-based FDA guidance.
- Mandates filing and obtaining process-authority approval for processes used in the preparation of acidified or low acid canned foods.
- Enables food processing plants to obtain waivers or variances from DATCP for non-standardized and innovative processing and procedural activities. Prior to this revision,

waivers and variances could only be obtained by food processing plants for structural and equipment issues.

- Updates and clarifies language pertaining to the standards for 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.
- Expands the scope of bottling rules to encompass more than bottled water and soda, thereby keeping pace with the expansion of this rapidly changing and innovative segment of the bottling industry.
- Removes the regulatory floor of \$25,000 in sales for food processing plants that are required to pay the canning license fee surcharge, in order to reflect the considerable time that has proven to be necessary for DATCP staff to provide information, consultation, and service to persons manufacturing small amounts of canned foods.
- Protects the consistent quality of the Wisconsin “brand” by eliminating many long-expired “grandfather clause” dates in the existing rule and replacing them with language relating to achieving compliance with structural standards in existing buildings.

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 concerning 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. As described above, a work group convened by DATCP made a number of recommendations that were incorporated into the rule.

If the proposed rule is adopted, some small food processing plants may face immediate costs to meet requirements that will be in effect after the elimination of various “grandfather clauses” dating from over thirty years ago. Certain 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. Businesses 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. DATCP’s Manufactured Food Specialists spend a considerable amount of time working with very small canning businesses, and this surcharge recoups a portion of these costs. The service provided by DATCP is comparable to that provided by consultants, but at a significantly lower cost for operations in the sub-\$25,000/year category.

Much of the focus of the proposed rule revision is on the clarification and updating of existing regulations, such as the various exemptions from a food processing plant license and the clarification of various record-keeping requirements. Many of these changes are not anticipated to have a financial or other impact.

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 § 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.

Next Steps

If the Board approves this final draft rule, the Department will submit the final draft rule to the Governor for his written approval. If the Governor approves the final rule, the Department will then submit the rule to the Legislature for legislative committee review. If the Legislature has no objection to the rule, the Department Secretary will sign the final rulemaking order and transmit it for publication. The rule will take effect on the first day of the month following 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 th 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 Representing the Food Industry Council, LLC. 11414 West Park Place, Suite 202 Milwaukee, WI 53224 (920) 698-2561 stevens@foodindustry council.com	Suggested revisions based on the 4 th 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.	Provided Written Comments – 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 th 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.

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3. 12/1/17	Chelsea A. Peabody 100 Colenan St. W Rice Lake, WI 54868 McCain Foods USA, Inc.	None – Present at December 1, 2017 Hearing	Did not wish to testify. Looking for information.
4. 12/1/17	Stephen Bant 2699 23 rd Street, Rice Lake, WI 54868 McCain Foods USA, Inc.	Did not wish to speak – Registered as taking no position at December 1 st Hearing.	Did not wish to testify. Looking for information.
5. 12/1/17	Corey P. Sukalich 723 Creekwood Lane West Bend, WI 53095 Herbal Symphony (a business) and himself listed as the owner/operator	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">1.) Upgrade the facilities to require separation.2.) Not allow currently home-based facilities to expand in the homes.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. 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.	Provided Oral Testimony – 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">1) Statewide consistency: Under the former administrative system, different regional districts and Inspectors interpreted and enforced licensing rules inconsistently.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.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.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. No action taken by the Department.
6. 12/1/17	Joy Durbin 723 Crestwood Drive West Bend, WI 53095 Herbal Symphony (a business) and herself	Spoke – Opposed the proposal Ms. Durbin spoke in favor of allowing small businesses to	Provided Oral Testimony and Brief Written Comment – 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"> 1) Small businesses operating from the home are a necessary starting point for entrepreneurs in the State of Wisconsin. 2) Small businesses are vital to the State's economic growth. 3) "Many" of her colleagues started as small businesses from homes. 4) Products produced by small, home-based businesses are important to local retailers, co-ops, and local communities in general. 5) She fears that eliminating the option of operating from the home will eliminate "mom and pop" stores. 6) She cited enthusiastic support from the City of West Bend. 7) Suggest she may move out of state if she can no longer expand or license a new business at home. 	<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. Midwest Food Products Association, Inc. 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"> 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. 2) ATCP 70.14 - Cleaning frequencies should not be dictated by regulation. He suggests that because of 	<p>Provided Written Comments –</p> <ol style="list-style-type: none"> 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. 2) ATCP 70.14 – Cleaning Frequencies:

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		<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"> • Strike the references to "alternative cleaning and sanitizing." Sanitization should be determined by the processor with input from the 3rd party sanitation provider. • 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." <p>5) 70.08 (3) MWFP 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.</p> <p>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>

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		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"	Provided Written Comments 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.	Provided Written Comments 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.	E-Mail on Alcohol as a food Ingredient 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)	Oral Comments – 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>

**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.

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

This rule repeals and recreates Wis. Admin Code ch. ATCP 70 (Food Processing Plants.) The rule is necessary to update Wisconsin’s food processing plant standards, to incorporate new federal requirements designed to improve the nation’s food safety system, and to clarify requirements for two specific types of food processing plants, vending machines, and micro-market commissaries.

Statutes Interpreted

Statutes Interpreted:

- Wis. Stat. § 97.29, “Food processing plants.”
- Wis. Stat. § 97.30, “Retail food establishments.”
- Wis. Stat. § 97.34, “Bottled drinking water and soda water beverage; standards; sampling and analysis.”
- Wis. Stat. § 97.42, “Compulsory inspection of livestock or poultry, and meat or poultry products.”
- Wis. Stat. § 97.605, “Lodging and vending licenses.”
- Wis. Stat. § 97.61, “Vending machine commissary outside the state.”

Statutory Authority

Statutory Authority: Wis. Stat. §§ 93.07 (1), 97.09 (4), and 97.29 (5).

Explanation of Statutory Authority

The Wisconsin Department of Agriculture, Trade and Consumer Protection (“DATCP”) has broad general authority, under Wis. Stat. § 93.07 (1), to adopt rules to implement programs under its jurisdiction. DATCP also has general authority under Wis. Stat. § 97.09 (4) to adopt rules

specifying standards to protect the public from the sale of adulterated or misbranded foods. DATCP has specific authority, under Wis. Stat. § 97.29 (5), to adopt rules establishing fees; setting facility construction and maintenance standards; and 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

21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, is a critical substrate of the current rule. Related Wisconsin administrative rules include rules pertaining to retail food establishments (Wis. Admin. Code ch. ATCP 75 and the Appendix to that rule); dairy plants (Wis. Admin. Code ch. ATCP 65), food warehouses (Wis. Admin. Code ch. ATCP 71), and meat and poultry establishments (Wis. Admin. Code ch. ATCP 55).

Plain Language Analysis

The proposed rule updates Wis. Admin. Code ch. ATCP 70 by adopting certain federal regulations that implement the requirements of the federal Food Safety Modernization Act (“FSMA”). Specifically, the revised rule incorporates multiple subparts of the recently issued 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, that has superseded 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 federally-registered food facilities are already subject to this federal rule and licensed as food processing plants, this rule features similar referencing for the sake of consistency. This revision also ensures that the requirements for Wisconsin-licensed food processing plants, which are not subject to the federal rule, are clearly articulated.

The transfer of DHS’ FSRL to DATCP’s Division of Food Safety necessitated the merger of two food safety regulatory systems. One regulatory paradox was particularly in need of resolution: 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 without holding a food processing plant license. By statute, restaurants are now licensed as retail food establishments and therefore also enjoy the same limited ability to wholesale food. In the current rule-making process, DATCP initially proposed to retain certain existing limits and requirements from its prior rule concerning food processing activities for wholesale conducted by a retail food establishment. The Board of Agriculture, Trade and Consumer Protection (“Board”) approved a draft rule reflecting this philosophy at its January 2018 meeting. This final draft also for the first time included definitions of “wholesale” and “retail”. However, after the Board meeting, it became apparent that industry participants felt that less restrictive limits and definitions would still adequately protect public health.

As a result of this feedback, DATCP opted to form a work group comprised of industry personnel and local health department agent program representatives. They were tasked with further revision

of the rule. During deliberations, the work group concluded that the safety of many food processing activities for wholesale, when performed by retail food establishments, could be ensured by compliance with Wis. Admin. Code ch. ATCP 75 and the appendix thereto, *Wisconsin Food Code*. Thus, recourse to the requirements Wis. Admin. Code ch. ATCP 70 was unnecessary. The work group recognized that additional training would be needed for local health department agent personnel, as well as DATCP sanitarians, who were assigned to retail food establishments performing these food processing activities for wholesale. DATCP, as part of its ongoing mission to thoroughly train food safety personnel at the state and local level, is committed to providing both the necessary initial training and ongoing technical support.

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The revised definitions of "wholesale" and "retail" reflect industry practice and the current interpretation of these terms in the marketplace, as well as FDA's recent guidance and its sanction of industry praxis. The revised definitions also appear in the pending revision to Wis. Admin. Code ch. ATCP 75 (Retail Food Establishments). The revised rule continues to prohibit retail food establishments from processing canned low-acid or acidified foods for wholesale without holding a food processing plant license and complying with Wis. Admin. Code ch. ATCP 70 requirements. DATCP expects these updates to promote clarity and uniformity and to facilitate enhanced business opportunities for retail food establishments in Wisconsin.

Another theme of early discussions of the proposed rule revision was the question of whether additional regulations were necessary to ensure sanitary conditions in food processing plants sharing a building with a residence. The initial draft of the revised rule forbade the licensing of any new or remodeled food processing plant in this context. However, feedback from the working group militated against the need for an outright ban or other additional regulation to ensure adequate separation between residential and processing activities or access for DATCP inspections. Accordingly, the proposed revision was deleted.

In addition to threading a path through these complex issues, the revised rule propounds several other changes. The rule adopts the Model Ordinance for molluscan shellfish, now *marine shellfish*, with the Ordinance replacing all of Wis. Admin. Code s. ATCP 70.21 except for the existing subsection addressed to illnesses and outbreaks associated with shellfish. This modification will keep Wisconsin's regulations current with national standards for shellfish processing and marketing.

This revised rule also:

- Updates the definition of “food processing plant” to conform to the statutory definition.
- Addresses requirements for vending machine commissaries, including those that support micro markets, just as the revised Wis. Admin. Code ch. ATCP 75 and the Appendix thereto (*Wisconsin Food Code*) specify requirements for vending machines and micro markets. These revisions incorporate recently enacted statutory language and ensure consistency and clarity in requirements for both the food processing plant portion of these operations and the retail food establishment business.
- Clarifies the definition of extended runs and the scope of waivers allowing those runs, while clarifying and expanding the list of food processing activities during which daily cleaning and sanitizing are not required.
- Updates certain outdated restrictions on hot-smoked, vacuum-packed fish. The archaic rules were unique to Wisconsin whereas the updates mirror requirements in other states and are based on current, science-based FDA guidance.
- Mandates filing and obtaining process-authority approval for processes used in the preparation of acidified or low acid canned foods.
- Enables food processing plants to obtain waivers or variances from DATCP for non-standardized and innovative processing and procedural activities. Prior to this revision, waivers and variances could only be obtained by food processing plants for structural and equipment issues.
- Updates and clarifies language pertaining to the standards for 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.
- Expands the scope of bottling rules to encompass more than bottled water and soda, thereby keeping pace with the expansion of this rapidly changing and innovative segment of the bottling industry.
- Removes the regulatory floor of \$25,000 in sales for food processing plants that are required to pay the canning license fee surcharge, in order to reflect the considerable time that has proved to be necessary for DATCP staff to provide information, consultation, and service to persons manufacturing small amounts of canned foods.
- Protects the consistent quality of the Wisconsin “brand” by eliminating many long-expired “grandfather clause” dates in the existing rule and replacing them with language relating to achieving compliance with structural standards in existing buildings.

Federal and Surrounding State Programs

Federal Programs

21 CFR 117 is the cornerstone of the regulations implementing FSMA. The FDA has published a Food Code designed to serve as a model for states. 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 with 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 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 such as those implementing FSMA, FDA guidance on the applicability of Hazard Analysis and Critical Control Point (“HACCP”) requirements for juice and seafood processors; Wisconsin statutes and rules for food processing plants, retail food establishments, meat establishments, and dairy plants; and current industrial practices. Upon learning of industry concerns about proposed licensing and regulatory requirements for retail food establishments conducting food processing for wholesale activities, DATCP delayed further consideration of the rule and convened a collaborative work group comprised of industry and local health department agent personnel to review and revise the requirements. The work group approved requirements in the present revised rule.

Effect on Small Business

If the revised rule is adopted, some small food processing plants may incur immediate costs to meet requirements that will be in effect after the elimination of various “grandfather clauses” dating from over thirty years ago. For example, small plants may now need to upgrade warewashing and handwashing sinks. Another cost that may be incurred by a few very small businesses is the \$320 canning surcharge, which currently is not assessed for food processing plants manufacturing and selling less than \$25,000 of food per year. DATCP’s Manufactured Food Specialists spend a considerable amount of time working with very small canning businesses, and this surcharge recoups a portion of these costs. The service provided by DATCP is comparable to that provided by consultants, but at a significantly lower cost for operations in the sub-\$25,000/year category.

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

clarification of various record-keeping requirements. Many of these changes are not anticipated to have a financial or other impact.

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.

DATCP Contact

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

Steve Ingham, Administrator
Division of Food and Recreational Safety
Department of Agriculture, Trade and Consumer Protection
P.O. Box 8911
Madison, WI 53708-8911
Telephone: (608) 224-4701
E-Mail: Steve.Ingham@Wisconsin.gov

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	Subchapter III. Canning Operations; Supplementary Requirements	
24	ATCP 70.34	General.
25	ATCP 70.36	Low-acid foods packaged in hermetically sealed containers.
26	ATCP 70.38	Acidified foods.
27	ATCP 70.40	Facilities and equipment; cleaning.
28	ATCP 70.42	Handling raw agricultural commodities and by-products.
29	Subchapter IV. Fish Processing Plants; Marine Shellfish Plants; Supplementary	
30	Requirements	
31	ATCP 70.44	Fish processing.
32	ATCP 70.46	Labeling and sale of smoked fish.

33 ATCP 70.48 Fish roe.

34 ATCP 70.50 Marine molluscan shellfish processing.

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

36 ATCP 70.52 Bottling establishments; general.

37 ATCP 70.54 Returnable and single-service bottles.

38 ATCP 70.56 Bottled water product sampling; recordkeeping; reports.

39 ATCP 70.58 Labeling bottled products.

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

41 ATCP 70.60 Juice 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.
51 ATCP 70.02 (23), regardless of whether the food processing plant is subject to licensing under s.
52 97.29 (2), Stats., or this chapter, and all retail food establishments, as defined in s. 97.30 (1) (c),
53 Stats., 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 either engaged in the preparation and sale of beverages, under a license issued
70 under s. 125.26 or 125.51, Stats., or 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 retail food establishment
127 license issued under s. 97.30, Stats., or other 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 used primarily for food processing, where the
146 processed food is not intended to be sold or distributed directly to a consumer. "Food processing
147 plant" does not include any mobile establishment, retail food establishment subject to the
148 requirements of s. 97.30, Stats., or any restaurant or other establishment holding a license under s.
149 97.605, Stats., to the extent that the activities of that establishment are covered by s. 97.30, Stats.,
150 or the license under s. 97.605, Stats.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

190 (35) "Qualified facility" as used in s. ATCP 70.04 has the meaning given in 21 CFR 117.3.

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

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

195 (38) "Retail" means selling food or food products directly to any consumer only for
196 consumption by the consumer or the consumer's immediate family or non-paying guests.

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

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

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

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

203 (c).

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

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

207 (41) "Salt content" means the percent salt (sodium chloride) as determined by the method
208 described in sections 18.034 and 18.035 of the *Official Methods of Analysis*, multiplied by 100 and

209 divided by the sum of the percent salt (sodium chloride) and the percent moisture in the finished
210 product as determined by the method described in section 24.002 of the *Official Methods of*
211 *Analysis*.

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

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

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

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

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

230 **(47)** “Wholesale” means the sale of any food to a person or commercial entity who will either
231 re-sell it, distribute it for re-sale, or use it as an ingredient in a product that will be then offered for
232 sale. Wholesale includes those activities in which the processor relinquishes control of the food.
233 Wholesale does not include the movement of food between two food processing plants or retail
234 food establishments licensed to the same licensee, except for the movement of dairy products as
235 specified in ATCP 65.04.

236 **ATCP 70.04 Federal requirements.** A food processing plant that is also a facility or a
237 qualified facility shall comply with the requirements of this chapter and applicable requirements of
238 21 CFR 117.

239 **Subchapter II. General Requirements**

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

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

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

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

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

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

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

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

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

267 **(5) SURCHARGE FOR OPERATING WITHOUT A LICENSE.** An applicant for a license under sub. (1)
268 shall pay a license fee surcharge of \$100 if the department determines that, within one year prior to
269 submitting the license application, the applicant operated the food processing plant without a
270 license in violation of sub. (1). Payment of this license fee surcharge does not relieve the applicant

271 of any other civil or criminal liability which results from the unlicensed operation of the food
272 processing plant, but does not constitute evidence of a violation of any law.

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

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

280 1. For a license holder of a food processing plant that has an annual production of less than
281 \$250,000, and the license holder is engaged in processing potentially hazardous food or in
282 canning, the reinspection fee is \$255.

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

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

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

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

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

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

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

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

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

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

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

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

324 (a) An operator of a retail food establishment engaged in food processing if all of the
325 following apply:

326 1. The operator is licensed by the department under s. 97.30, Stats., or by an agent as defined
327 in s. ATP 74, under ss. 97.30 and 97.41, Stats.

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

334 3. The operator is not engaged in canning of food products at the retail food establishment.

335 4. The operator may move food between retail food establishments licensed to the same
336 operator.

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

339 1. The operator does not process food for wholesale distribution in excess of 25% of total food
340 sales and is not engaged in canning of food products. The operator may brew beer at the retail
341 food establishment serving meals under the provisions in s. 125.295, Stats.

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

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

346 1. Receipts from non-dairy food processing operations at that location comprise no more than
347 25% of gross annual dairy and non-dairy food sales from that location.

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

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

352 1. The operator of the meat establishment is licensed under s. 97.42, Stats., or inspected under
353 21 USC 601 et seq. or 21 USC 451 et seq.

354 2. The operator is also licensed at the meat establishment to operator a retail food
355 establishment under s. 97.30, Stats., and not engaged in the canning of food products other than

356 meat or poultry products canned under s. 97.42, Stats., or the production of cold-smoked fish or
357 fishery products.

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

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

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

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

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

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

378 Department of Agriculture, Trade and Consumer Protection
379 Division of Food and Recreational Safety

380 P.O. Box 8911
381 Madison, WI 53708

382 (f) The operator of a licensed food warehouse under s. 97.27, Stats., at which one or more of
383 the following activities are the only food processing activities performed:

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

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

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

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

400 **(12) RECORD REQUIREMENTS AND RETENTION.** (a) If a food processing plant is deemed a
401 facility, under 21 CFR 117, the operator shall create all records to meet the requirements for

402 records in 21 CFR 117.305, unless otherwise specified in this chapter or in 21 CFR 120 or 21 CFR
403 123.

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

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

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

412 **ATCP 70.08 Construction and maintenance. (1) CONSTRUCTION AND MAINTENANCE;**
413 **GENERAL.** The operator shall soundly construct and maintain in a clean and sanitary condition all
414 buildings, facilities, and equipment used in food processing operations. The interior and exterior
415 portions of a food processing plant, and the premises on which the food processing plant is located,
416 shall be maintained in a sanitary condition in compliance with this chapter.

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

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

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

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

424 2. All floors, walls, and ceilings shall be kept clean and in good repair.
425 (d) The junctions of walls and floors in processing areas shall be covered to facilitate cleaning.

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

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

431 **(3) APPLICABILITY OF REQUIREMENTS.** A license holder shall be subject to food processing
432 plant requirements in this section if the plant ceases to operate continuously for more than 30 days
433 at any time after the effective date of this section ... [LRB inserts date], has been structurally
434 remodeled or altered in a manner which results in structural changes to a processing area, or has
435 added product lines or processes after the effective date of this section ... [LRB inserts date]. This
436 section does not apply to a food processing plant that closes because of seasonal natural food
437 production cycles of the food processed by that plant, such as an orchard or a maple sap processing
438 facility.

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

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

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

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

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

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

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

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

464 (7) VENTILATION. There shall be adequate ventilation in all areas where food is processed,
465 handled, or stored; in all areas where equipment or utensils are cleaned or sanitized, and in all
466 dressing rooms, locker rooms, toilet rooms, employee break rooms, and garbage or rubbish storage

467 areas. Ventilation shall be adequate to remove excessive heat, steam, condensation, vapors,
468 obnoxious odors, smoke, and fumes. Ventilation systems shall be positioned so that exhaust air is
469 not vented onto exposed food, or onto clean food packages, equipment, or utensils. Intake fans
470 shall be equipped with filters that are readily removable for cleaning and replacement. Intake
471 filters shall be capable of removing at least 85% of particulate matter that is 5 microns or larger in
472 size, or greater than 6 MERV (maximum efficiency reporting value) rating. Exhaust fans, intake
473 fans, ventilation ducts, and filters shall be kept clean and in good repair, and shall be screened or
474 louvered to prevent contamination of food by dust, dirt, insects, or other contaminants. Systems
475 used to ventilate any area of a food processing plant where exposed potentially hazardous food is
476 handled shall be capable of maintaining positive pressures in that area.

477 **(8) TOILET FACILITIES.** (a) The operator shall provide sanitary toilets meeting applicable state
478 and local regulations in sufficient number to accommodate employees. The toilets shall be located
479 in toilet rooms meeting the requirements of this section, for any food processing plant constructed
480 or first licensed after the effective date of this section ... [LRB inserts date]. Toilet rooms and
481 fixtures shall be easily cleanable, and shall be kept clean and in good repair. Non-contiguous toilet
482 facilities, serving food processing plants licensed prior to the effective date of this section ... [LRB
483 inserts date], shall be conveniently adjacent and accessible to the facility, and meet all applicable
484 state and local regulations for unattached or portable toilet rooms.

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

486 (c) Handwashing facilities shall be located in or adjacent to every toilet room. Handwashing
487 facilities serving toilet rooms shall include hot and cold running water, soap in a soap dispenser,
488 and a sanitary single-service means of drying the hands. A sign directing employees to wash their

489 hands shall be prominently posted in every toilet room used by employees. Handwashing facilities
490 serving a toilet room shall comply with all of the following requirements if they are installed after
491 the effective date of this section ... [LRB inserts date], or if they are located in a food processing
492 plant that is initially licensed or licensed to a new operator after the effective date of this section ...
493 [LRB inserts date]:

494 1. Handwashing facilities shall be served by hot and cold running water provided through a
495 mixing valve or combination faucet, or by potable tempered water.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

574 **(14) GARBAGE AND REFUSE DISPOSAL.** Garbage and refuse shall not be allowed to accumulate
575 in or around a food processing plant. Garbage and refuse shall be removed as often as necessary to
576 maintain the premises in a clean and sanitary condition. Garbage storage areas shall be

577 constructed and maintained so that they do not attract or harbor insects, rodents, or other animals.
578 Garbage and refuse shall be held in durable, leak-proof, easily cleanable, and pest-resistant
579 containers. Containers shall be kept covered with tight-fitting lids, and shall be cleaned when
580 necessary to prevent insanitary conditions. Garbage and refuse shall not be burned on the
581 premises, except in compliance with state and local laws. Garbage and refuse shall not be burned
582 on the premises if burning may contaminate food.

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

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

590 **(16) CONSTRUCTION; PLAN REVIEW.** Before a food processing plant is constructed,
591 substantially reconstructed, or extensively altered, the operator shall notify the department in
592 writing. Plans and specifications for the construction, reconstruction, or alteration may be
593 submitted to the department for review before the work is begun. Plans and specifications shall be
594 available for review by the department upon request.

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

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

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

606 (b) Par. (a) does not apply to an operator of a maple sap concentration facility licensed to
607 operate a food processing plant that is required to meet the provisions of s. ATCP 87.28.

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

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

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

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

616 3. Properly stored until used.

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

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

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

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

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

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

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

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

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

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

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

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

639 5. Procedures to evaluate training effectiveness.

640 (f) The operator shall review the training program under par. (e) at least annually.

641 (g) The operator shall maintain records to document compliance with this subsection. Records
642 shall be retained for at least one year after they are made, and shall be available to the department
643 for inspection and copying upon request.

644 (3) CLOTHING AND JEWELRY. Persons in food processing areas or handling unpackaged food
645 shall wear clean, washable outer garments and effective hair restraints, including effective hair
646 restraints for beards longer than 1/2 inch. Hair restraints may include hair nets, caps, and snoods,
647 but do not include hairsprays, visors, or headbands. Persons working in food processing areas or
648 handling unpackaged food shall remove all jewelry from their hands, fingers, and arms before
649 having any direct manual contact with food or food contact surfaces. Jewelry shall not be worn in
650 any part of the body in a manner which creates a risk of food contamination. This subsection does
651 not apply to plain band wedding rings.

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

656 (a) One or more reportable symptoms of communicable disease as defined in ch. ATCP
657 75 Appendix, 2-201.11 (A).

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

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

661 (5) FOOD CONTAMINATION. No person who has received a reportable diagnosis of
662 communicable disease, as defined in ch. ATCP 75 Appendix, part 2–201.11 (A) (2), may work in
663 a food processing plant in any capacity that may contaminate food products.

664 (6) CONSUMPTION OF FOOD, BEVERAGES, AND TOBACCO. No person may consume food,
665 beverages, or tobacco in any food processing area, or in any area where food processing equipment
666 or utensils are cleaned or stored. Employees may not consume food, beverages, or tobacco except
667 in designated areas which are separated from food processing areas. This subsection does not
668 prohibit a sanitary water fountain in a processing area, nor does it prohibit on-line quality control
669 sampling in accordance with quality control procedures written and followed by the license holder.

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

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

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

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

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

698 **(5) MEASURING DEVICES AND CONTROLS.** Every freezer and cold storage compartment used to
699 store or hold potentially hazardous food shall be equipped with a thermometer or other device
700 accurately indicating the temperature in the compartment. Instruments and controls used for
701 measuring, regulating, and recording temperatures, pH, acidity, water activity, or other conditions
702 that control or prevent the growth of undesirable microorganisms in food shall be accurate and
703 adequate for their intended use.

704 (6) LUBRICATION. Equipment shall be designed and constructed so ear and bearing lubricants
705 do not come in contact with food or food contact surfaces. Only food grade lubricants may be
706 used in equipment if incidental food contact may occur.

707 **ATCP 70.14 Cleaning and Sanitizing Equipment and Utensils. (1) GENERAL.** Except as
708 provided in ss. ATCP 70.16 and 70.40, the operator shall do all of the following.

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

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

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

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

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

721 (2) CLEANING AND SANITIZING C-I-P SYSTEMS. C-I-P systems shall be cleaned and sanitized
722 in compliance with manufacturer specifications. Cleaning and sanitizing records shall be
723 maintained for all C-I-P systems. The records shall identify every C-I-P system which has been
724 cleaned or sanitized, the date and time when each C-I-P system was cleaned and sanitized, the
725 temperature of the cleaning and sanitizing solutions, and the length of time for which the C-I-P

726 system was exposed to each cleaning and sanitizing solution. Records shall be signed or initialed
727 by a responsible person, maintained on file for at least 90 days, and made available for inspection
728 and copying by the department upon request.

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

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

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

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

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

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

745 APPROVAL REQUIRED FOR AN ALTERNATIVE CLEANING AND SANITIZING FREQUENCY. Except as
746 provided in sub. (2) or s. ATCP 70.40, if an operator seeks to clean and sanitize equipment and
747 utensils at a frequency other than that required in s. ATCP 70.14 (1), because the equipment and

748 utensils are used with food products, processes, or conditions reducing the risk of foodborne illness
749 or presence of major food allergens, then the operator shall submit to the department, for written
750 approval, an alternate cleaning and sanitizing procedure that includes a monitoring and recording
751 requirement in compliance with s. ATCP 70.18.

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

755 (b) After review by the department, the proposed process may be denied and the department
756 shall issue a letter of denial. If the alternate cleaning and sanitizing procedure is approved, the
757 department shall issue a letter of approval, applicable for not more than 5 years, which shall be
758 maintained on file at the food processing plant.

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

762 **(2) NO APPROVAL REQUIRED FOR AN ALTERNATIVE CLEANING AND SANITIZING FREQUENCY.** An
763 operator is not required to obtain written department approval for use of an alternative equipment
764 and utensil cleaning and sanitizing frequency for the following equipment, provided that the
765 operator cleans and sanitizes the equipment according to manufacturer specifications or according
766 to a validated cleaning process filed with the department:

767 (a) Drying equipment.

768 (b) Cloth-collector systems.

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

- 770 (d) Equipment used in brining, aging, curing, and dry product blending processes.
- 771 (e) Food contact surfaces of equipment used solely to process foods or food ingredients with
772 low water activity (≤ 0.85), or foods which are considered non-Potentially Hazardous Food (non-
773 PHF/non-TCS) foods based on (2) (b) Table A or Table B for Potentially Hazardous Food
774 (time/temperature control for safety food) in par. 1-201.10 (B) of ch. ATCP 75 Appendix, such as
775 chocolate, fats and oils, liquid nutritive sweeteners, peanut butter, or similar foods.
- 776 (f) Ice makers maintained in a cold/frozen state, so long as the operator cleans and sanitizes the
777 ice maker in accordance with ice maker manufacturer instructions for cleaning, or shall clean and
778 sanitize using a validated cleaning process.
- 779 (g) Food contact surfaces of equipment used for brewing or fermentation of alcohol-containing
780 beverages, such as beer brewing or wine fermentation, so long as the operator cleans and sanitizes
781 equipment used following each brewing or fermentation batch.
- 782 (h) Surfaces of aseptic processing equipment that contact food after the food has been
783 sterilized, as long as system sterility is maintained. If system sterility is lost, an operator shall
784 clean, sanitize and re-sterilize equipment.
- 785 (i) Equipment used for food fermentations such as the manufacture of sauerkraut or cucumber
786 pickles, development of one or more pure bacterial cultures, or development of starter cultures, so
787 long as the operator cleans and sanitizes all equipment following each fermentation batch.
- 788 (j) Equipment used for processing of products with a natural pH ≤ 4.0 , so long as the operator
789 cleans and sanitizes all equipment at the end of a continuous operation, not to exceed 30 days (720
790 hours).

791 (k) Equipment used for maple syrup processing, so long as the operator cleans and sanitizes all
792 equipment at the end of a continuous operation, not to exceed 40 days (960 hours).

793 (L) Equipment used for bottled water processing, so long as the operator cleans and sanitizes
794 all equipment at the end of a continuous operation, not to exceed 30 days (720 hours).

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

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

797 An operator may submit a written request for the department to approve alternative cleaning and
798 sanitizing procedures. The request shall include all of the following, and any other information
799 required by the department:

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

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

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

810 (d) A written statement, by the operator, that the alternative cleaning and sanitizing procedure
811 has been determined by competent authority, such as evaluated by a process authority or validated

812 by a published or unpublished peer-reviewed article, challenge studies, or regulatory standards, to
813 be effective in preventing food contamination and ensuring the microbiological safety of food.

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

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

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

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

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

835 (5) OPERATION OF AN ALTERNATIVE CLEANING AND SANITIZING FREQUENCY. An operator that
836 implements an alternative cleaning and sanitizing procedure approved under sub. (2) shall do all of
837 the following:

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

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

842 (c) Collect and retain data and records to document, on a continuing basis, the implementation
843 and efficacy of the approved procedure. The operator shall retain the data and records for at least
844 90 days, and shall make them available upon request for inspection and copying by the
845 department.

846 **ATCP 70.20 Water supply. (1) OPERATIONS WATER.** (a) Operations water, other than
847 water reclaimed according to sub. (3), shall be obtained from a source that complies with ch. NR
848 811, for municipal water systems, or ch. NR 812, for private or non-community water systems.

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

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

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

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

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

859 1. Washing subsequent deliveries of raw fruit or vegetables at the food processing plant if the
860 fruit or vegetable will undergo canning.

861 2. Flushing floors and gutters in the receiving areas for raw fruit or vegetables in the food
862 processing plant.

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

868 (b) Ingredient water obtained from either municipal, private, or non-community water systems
869 shall not exceed the maximum contaminant levels set forth in the drinking water standards in s.
870 NR 809.07, the microbiological standards in s. NR 809.30, and the health-related enforcement
871 standards in s. NR 140.10. At the department's request, an operator shall provide documentation
872 to the department that the water complies with the microbiological standards of s. NR 809.30.
873 Documentation may consist of results from tests performed at a laboratory certified under ch.
874 ATCP 77 for the entity providing the water.

875 (c) If ingredient water is obtained from a privately owned water system, the operator shall
876 sample the water at least once every 12 months, and have the sample tested at a laboratory,
877 certified to perform the appropriate tests, under ch. ATCP 77.

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

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

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

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

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

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

896 **Note:** Copies of the *Standard Methods for the Examination of Water and Waste Water*, twenty-first
897 edition (2005), published by the American Public Health Association (APHA), the American Water Works

898 Association and the Water Environment Federation, are on file with the department and the legislative
899 reference bureau. Copies may be obtained by contacting the "APHA Bookstore" at
900 www.apha.org/publications/bookstore/.

901 5. The reclaimed water is of satisfactory organoleptic quality and has no off-odors, off-flavors,
902 or slime. The operator shall sample and organoleptically test reclaimed water at weekly intervals.

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

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

906 8. The operator tests the reclaimed water for compliance with subds. 1. to 4. at least once
907 during any 6 month interval. The operator shall test the reclaimed water daily for 14 working days
908 after the department approves the reclamation system under subd. 1., and for at least 7 working
909 days after any repairs or alterations to the system.

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

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

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

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

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

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

934 4. The reclaimed water is of satisfactory organoleptic quality and has no off-odors, off-flavors,
935 or slime. The operator shall sample and organoleptically test reclaimed water at weekly intervals.

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

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

939 7. There are no cross-connections between reclaimed water lines and any public or private
940 water system, except for lines with backflow preventers that meet the requirements of chs. SPS
941 382 and 384.

942 8. The reclaimed water, if held for more than 24 hours, is at all times held at a temperature of
943 at least 145°F. (63° C.) or is chemically treated under sub. (4) to suppress bacterial growth.

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

946 10. The operator posts clear instructions for the use of the reclaimed water. The operator shall
947 post the instructions so that they will be seen and understood by persons using the reclaimed water.
948 The instructions shall disclose the limited purposes for which the reclaimed water may be used.

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

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

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

961 (b) An operator shall apply chemicals, under par. (a), according to label directions using an
962 automatic proportioning device. Treated water shall be held for the period of time specified on the
963 chemical label before it is used as ingredient water or operations water. An operator shall conduct
964 a daily testing program for any chemical added to water, to ensure that the chemical concentration
965 does not adulterate food.

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

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

- 972 1. Obtained from a source that complies with chs. NR 811 or 812, as applicable.
- 973 2. Bacteriologically safe.
- 974 3. Protected from contamination.
- 975 4. Tested by the operator for compliance with subd. 2. at 6 month intervals.

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

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

981 **(6) WATER AND POTABLE LIQUIDS TRANSPORTED IN BULK.** (a) Water transported to a food
982 processing plant in a bulk tanker or bulk container, for use as an ingredient or in other plant
983 operations, shall be potable and shall be obtained from a source that complies with chs. NR 811 or
984 812.

985 (b) Whenever potable water or another potable liquid is transported to or from a food
986 processing plant in a bulk tanker or bulk container, it shall be loaded, transported, and unloaded in
987 a sanitary manner that prevents contamination. The bulk tanker or bulk container shall be

988 thoroughly cleaned and sanitized before being filled. Suitable pumps, hoses, and fittings shall be
989 used to transfer potable water and potable liquids to and from bulk tankers and bulk containers
990 shall be cleaned and sanitized prior to use.

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

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

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

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

999 4. It shall be effectively sealed to protect the potable water or potable liquid from
1000 contamination during transit.

1001 **Note:** Effective sealing systems include manhole cover gaskets and seals.

1002 5. It shall be properly stored and serviced to prevent contamination. When not in use, pumps,
1003 hoses, and fittings shall be properly maintained, capped, stored, and protected from contamination.

1004 (7) CULINARY STEAM. Water used to produce culinary steam shall be potable. Water
1005 reclaimed from food processing operations may not be used to produce culinary steam unless it
1006 complies with sub. (3) (a) or (b). In boilers used to produce culinary steam, boiler water additives
1007 shall comply with 21 CFR 173.310.

1008 (8) ICE. Ice used to cool or maintain the temperature of foods shall be made from potable
1009 water. Ice used to cool or maintain the temperature of ready-to-eat foods shall not have been

1010 previously used for any other purpose. Ice shall be received, handled, and stored in a manner to
1011 prevent contamination or adulteration. Any ice which is not made on site shall be inspected upon
1012 receipt, and rejected if it is delivered in a way that has not adequately protected the ice from
1013 contamination.

1014 **ATCP 70.22 Food ingredients. (1) GENERAL.** Food ingredients shall be safe, wholesome,
1015 and unadulterated, and shall comply with applicable standards of identity under s. 97.09, Stats.
1016 Raw agricultural commodities and other food ingredients shall be segregated and examined as
1017 necessary to determine whether they are clean and fit for processing. Processed foods and dairy
1018 products which are used as food ingredients shall be obtained from sources which comply with
1019 applicable licensing and inspection requirements.

1020 **(2) EGGS AND EGG PRODUCTS.** Only clean whole eggs, pasteurized eggs in liquid, frozen or
1021 dry form, or pasteurized egg products may be used in food processing. Eggs and egg products
1022 may be pasteurized during processing. Clean whole eggs shall be equivalent to USDA Grade B or
1023 better with shells intact.

1024 **ATCP 70.24 Food handling and storage. (1) GENERAL.** Food shall be protected from
1025 contamination and decomposition while being processed, handled, conveyed, or held at a food
1026 processing plant. Food shall be processed and held in a manner which keeps the food in a safe,
1027 wholesome, and unadulterated condition. Potentially hazardous foods shall be processed and held
1028 at temperatures, or in a manner, which minimizes the potential for growth of undesirable
1029 microorganisms.

1030 **(2) FOOD STORAGE.** Food storage areas shall be maintained in a clean, sanitary, and orderly
1031 condition, free from conditions which may result in the adulteration of food. Potentially hazardous

1032 foods shall be stored at safe temperatures. Storage areas shall be constructed and maintained so
1033 that waste water and other waste liquids do not drain into, or accumulate in, any storage area.
1034 Food shall not be stored in a manner which may attract or harbor pests.

1035 (3) FOOD PROCESSING. (a) Food processing shall be conducted under appropriate conditions
1036 and controls to minimize the potential for growth of undesirable microorganisms, or the
1037 contamination of food.

1038 **Note:** One way to comply with this requirement is to follow a HACCP plan which monitors and
1039 controls food safety variables at critical control points in the manufacturing process. Monitoring and
1040 controlling food safety variables such as time, temperature, humidity, water activity (a_w), pH, pressure, and
1041 flow rate at critical control points can ensure that mechanical breakdowns, time delays, temperature
1042 fluctuations, and other conditions do not contribute to the decomposition or contamination of food.

1043 (b) If potentially hazardous food is heated, refrigerated, or frozen in the course of processing,
1044 the internal temperature of the food shall be accurately monitored, as necessary, to ensure that safe
1045 temperatures are promptly attained and maintained.

1046 (c) Any testing and monitoring done to minimize the potential for growth of undesirable
1047 microorganisms or the contamination of food during processing and storage as required in this
1048 section shall be recorded, the records shall be maintained on site for one year, and shall be made
1049 available to the department or its agents on request for copying or photographing.

1050 (d) Potentially hazardous frozen foods, if thawed for processing, shall be thawed by one of the
1051 following methods:

1052 1. By placing the frozen food in a refrigerated space at a temperature of not more than 41°F.
1053 (5°C.).

1054 2. Placing the frozen food under potable running water, at a temperature of not more than
1055 70°F. (21°C.), for no more time than is needed to thaw the food. Water velocity shall be sufficient
1056 to agitate loose particles and drain or float them away from the food being thawed.

1057 3. By microwave heating, if the food is fully cooked in the microwave oven, or if cooking is
1058 immediately completed in another cooking facility.

1059 4. In any cooking facility, as part of the process by which the food is fully cooked.

1060 **(4) BULK FLOUR HANDLING SYSTEMS.** (a) Food contact surfaces of bulk flour handling
1061 equipment shall comply with the provisions of s. ATCP 70.12 (2). Pneumatic systems using
1062 storage bins constructed of semi-permeable cloth material are exempt from the requirement that
1063 surfaces be smooth and nonabsorbent, provided the surfaces can be effectively cleaned.
1064 Attachment mechanisms for holding inspection port covers, access doors, delivery pipe caps, or
1065 other removable accessories shall have no loose parts. Delivery pipe caps shall be kept in place,
1066 and secured against removal, except when a bulk flour handling system is in use. Outside
1067 installations shall be watertight or suitably covered to prevent entry of water and foreign material.

1068 (b) Intake air used in pneumatic flour handling systems shall be filtered to exclude particles of
1069 50 microns or larger. Air discharged from the system shall be filtered so that no visible dust
1070 escapes. Filters shall be readily removable for cleaning or replacement. Straight runs of
1071 pneumatic conveyors shall comply with the provisions of s. ATCP 70.12 (1), except that piping
1072 which is self-purging is exempt from accessibility requirements.

1073 **(5) RAW INGREDIENTS AND FINISHED PRODUCTS; SEPARATE HANDLING.** Effective measures
1074 shall be taken to prevent cross contamination between raw ingredients and finished food products.
1075 Raw ingredients shall not be handled simultaneously with finished products in any part of a food
1076 processing plant if either the raw materials or the finished products are uncovered or unprotected,
1077 and if the handling may result in contamination.

1078 **(6) SALVAGING DISTRESSED FOOD.** (a) In this subsection:

1079 1. "Distressed food" means processed food exposed to a fire, flood, transportation accident,
1080 refrigeration breakdown, or other unusual condition which may affect its safety or suitability as
1081 human food. "Distressed food" does not include food or food packages damaged during normal
1082 conditions of food and food product handling, transit, or storage.

1083 2. "Reconditioned food" means packaged distressed food distributed or offered for sale as
1084 human food after its package is repaired or relabeled without being opened.

1085 3. "Reprocessed food" means distressed food subsequently processed in accordance with the
1086 requirements under this chapter and distributed or offered for sale as human food.

1087 (b) An operator shall notify the department within 3 days after the operator takes possession of
1088 any distressed food, or within 3 days after food in the operator's custody becomes distressed food.
1089 The operator shall notify the department before the operator reprocesses or reconditions the
1090 distressed food.

1091 (c) An operator shall identify distressed food as such, and shall separate it from other food.
1092 No operator may store distressed food in a processing area, or under conditions which may lead to
1093 the contamination of other food, equipment, utensils, or packaging materials.

1094 (d) No operator may do either of the following:

1095 1. Reprocess for sale, as human food, any distressed food which is unwholesome or
1096 adulterated.

1097 2. Offer for sale, sell, or distribute food in packages that are damaged to such an extent that the
1098 food may have been exposed or subjected to possible contamination, including packages with
1099 bulging ends, ruptures, hairline fractures, breakage along critical seams, or openings which may
1100 have exposed food to contamination.

1101 (e) No operator may sell or distribute reprocessed or reconditioned food at wholesale unless
1102 the operator gives the purchaser or recipient written notice that the food is reprocessed or
1103 reconditioned. The notice shall also include the name and address of the person who reprocessed
1104 or reconditioned the distressed food. The notice may be included on an invoice, bill of lading, or
1105 other documentation of the sale or distribution of the food.

1106 (f) An operator shall keep, for the period of time set forth in 21 CFR 117.315, all of the
1107 following records related to distressed food handled by that operator:

1108 1. A description of the distressed food, including the type of food, the package or container
1109 style, and the amount of the food.

1110 2. The source of the distressed food, or the conditions which caused it to become distressed
1111 food.

1112 3. The date on which the operator received the distressed food.

1113 4. The nature of any reprocessing or reconditioning which the operator performed on the
1114 distressed food.

1115 5. The final disposition of the distressed food if the distressed food was not sold directly at
1116 retail. That record shall include the name and address of the person, such as the food wholesaler,
1117 food distributor, waste disposal firm or waste disposal site operator, to whom the food processing
1118 plant operator delivered the food.

1119 (7) FOOD IRRADIATION. Irradiation in the production, processing, and handling of food shall
1120 comply with applicable federal regulations under 21 CFR 179.

1121 (8) EGG CLEANING AND STORAGE. Cleaning and storage of eggs shall be done in compliance
1122 with the requirements of s. ATCP 88.20.

1123 **ATCP 70.26 Food packaging and labeling. (1) GENERAL.** Food packages shall be of
1124 sanitary design and construction, so as to protect food contents from reasonably foreseeable risks
1125 of contamination. Food packages shall be clean, sanitary, and free of any extraneous or deleterious
1126 substance. Food shall not be sold or distributed in packages which are damaged to the extent that
1127 food contents may be adulterated as a result of the damage. A sealed food package is damaged
1128 within the meaning of this subsection if the package or seal is broken or bulged.

1129 **(2) CLEANING AND SANITIZING RETURNABLE FOOD PACKAGES.** Returnable or multi-use food
1130 packages, including returnable bottles, shall be effectively cleaned and sanitized before being
1131 reused. Cleaning and sanitizing processes shall remove all extraneous matter and potential
1132 adulterants from a food package before the food package is reused. Sanitizing methods shall
1133 comply with s. ATCP 70.28. No food package may be reused unless it is specifically designed and
1134 constructed for that purpose.

1135 **(3) INSPECTION OF RETURNABLE FOOD PACKAGES.** Returnable or multi-use packages, after
1136 being cleaned and sanitized, shall be inspected before being reused. Inspection shall be adequate
1137 to detect extraneous material and visible adulterants, and any damage to product contact surfaces.
1138 Inspection shall be performed on surfaces lighted in compliance with s. ATCP 70.08 (6) (b).

1139 **(4) SINGLE-SERVICE FOOD PACKAGES.** Single-service food packages, including bottle caps and
1140 other single-service articles used to package food, shall be made from clean, sanitary materials.
1141 Single-service food packages shall be clean and sanitary at the time of use. Single service food
1142 packages shall be protected from contamination prior to use, and shall be handled in a sanitary
1143 manner. Single-service food packages, including single-service bottles and bottle caps, shall not
1144 be re-used.

1145 (5) FOOD PACKAGE LABELING. Packaged food shall be packaged and labeled according to all
1146 of the following, as applicable:

1147 (a) 21 CFR 101.

1148 (b) s. 97.09, Stats., and federal regulations incorporated by reference in s. 97.09, Stats.

1149 (c) ch. ATCP 90.

1150 (d) ch. ATCP 75 Appendix, part 3-201.11(C).

1151 (e) If the packaged food contains a major food allergen, the ingredient statement on the
1152 package shall disclose the common name of the major food allergen. The disclosure shall be
1153 equivalent in size and prominence to the rest of the ingredient statement. If an allergen originates
1154 from fish, crustacean shellfish, or tree nuts, the disclosure shall include the common name of the
1155 source species.

1156 **Note:** For example, if a food product includes an allergen that originates from fish, the ingredient
1157 statement must disclose the common name such as bass, flounder, or cod. If the allergen originates from
1158 crustacean shellfish, the ingredient statement must disclose the common name such as crab, lobster, or
1159 shrimp. If the allergen originates from tree nuts, the ingredient statement must disclose the common name
1160 such as almond, pecan, walnut, or coconut.

1161 (6) EGG PACKAGING AND LABELING. The packaging and labeling of eggs shall be done in
1162 compliance with the requirements of ss. ATCP 88.32, 88.34, and 88.38.

1163 (7) ALCOHOL RESTRICTIONS AND LABELING. If a product contains more than 1.0 % but less
1164 than 7.0 % alcohol it is regulated by the labeling provisions of this subsection and the alcohol
1165 would be declared as an ingredient in normal descending order of predominance.

1166 (a) Ice cream containing more than 2.0% alcohol is not regulated by this chapter.

1167 (b) If the alcohol is part of other ingredients such as a flavoring, and it is less than 0.5% of the
1168 finished product by volume, then it is considered an incidental ingredient.

1169 **ATCP 70.28 Sanitizers and sanitizing methods. (1) SANITIZING METHODS.** All returnable
1170 or multi-use food packages, and all food contact surfaces of equipment and utensils used to handle
1171 foods, shall be effectively sanitized prior to each use.

1172 **(1m) CHEMICAL SANITIZERS; REQUIREMENTS.** The operator shall use only chemical sanitizers
1173 that comply with 21 CFR 178.1010, are registered with the U.S. environmental protection agency,
1174 are applied according to manufacturer's instructions, labeled for use in food processing plants on
1175 food contact surfaces, and, do not leave an unacceptable residue on the food contact surface when
1176 used appropriately.

1177 **(2) BAKING AND COOKING CONTAINERS; EXEMPTION.** Sub. (1) does not apply to baking and
1178 cooking containers if heating time and temperature combinations meet industry standards and are
1179 adequate to destroy pathogenic microorganisms, provided that the containers are cleaned, stored,
1180 and used in a manner which prevents contamination of food.

1181 **(3) SANITIZERS; MAXIMUM CONCENTRATIONS.** The operator shall use sanitizers and cleaning
1182 compounds so no toxic or otherwise unacceptable residue is left on any food contact surface.
1183 Sanitizing solutions shall not exceed the maximum concentrations established by the food and
1184 drug administration, United States department of health and human services, under 21 CFR
1185 178.1010. A test kit or other device that measures the concentration of sanitizing solutions in parts
1186 per million shall be used as necessary to ensure compliance with this subsection.

1187 **(4) SANITIZERS; DEPARTMENT APPROVAL. (a)** Sanitizers approved by the U.S. environmental
1188 protection agency and labeled for use on food contact surfaces are also accepted by the department
1189 for use according to their labels. The department may approve other sanitizers and sanitizing
1190 methods that it finds to be safe and effective for the purpose used.

1191 (b) The department may deny or withdraw approval of any sanitizer or sanitizing method if the
1192 department determines that the sanitizer or sanitizing method is not safe or effective for the
1193 purpose or under the conditions used, or that it adversely affects the sanitary characteristics of
1194 equipment, utensils or food packages.

1195 **ATCP 70.30 Ready-to-eat foods; reporting pathogens and toxins. (1) REQUIREMENT.**

1196 Except as provided under sub. (2), an operator shall report to the department the results of any
1197 microbiological test or laboratory analysis which indicates that any ready-to-eat food produced by
1198 that operator contains pathogenic organisms, toxins resulting from the growth of pathogenic
1199 organisms, or any other adulterant capable of causing disease or injury if ingested. The operator
1200 shall report to the department within 24 hours after the operator obtains the test results. The
1201 operator may report orally, electronically, or in writing.

1202 **Note:** The State of Wisconsin's Emergency Management phone number is (800) 943-0003. The general
1203 number of the Division of Food and Recreational Safety is (608) 224-4700, and its FAX number is (608)
1204 224-4710.

1205
1206 **(2) EXEMPTION.** An operator is not required to report test results under sub. (1) if all of the
1207 following apply:

1208 (a) The ready-to eat-food is identified by a product code or production lot number.

1209 (b) The operator has not yet sold or distributed any of the ready-to-eat food represented by the
1210 product code or production lot number under par. (a), but retains direct control over all of that
1211 ready-to-eat food.

1212 **ATCP 70.32 Recall plan. (1) PLAN REQUIRED.** An operator shall have a written plan for
1213 identifying and recalling food produced at that plant, should a food recall become necessary. The
1214 operator shall update the plan as necessary, and shall make it available to the department for
1215 inspection and copying upon request.

1216 **(2) PLAN CONTENTS.** A plan, under sub. (1), shall do all of the following:

1217 (a) Identify key individuals or positions that are responsible for planning, approving, and
1218 implementing recalls on behalf of the operator.

1219 (b) Identify key individuals or entities to be contacted or consulted in connection with a recall.

1220 (c) Include procedures for the routine identification, dating, and tracking of food production
1221 lots, so that affected lots can be identified and distinguished from unaffected lots in the event of a
1222 recall.

1223 (d) Include procedures to enable routine identification, dating, and tracking of food shipments
1224 from the food processing plant. Tracking shall identify shipment recipients and contents, cross-
1225 referenced to production lots, so that recipients of affected lots may be contacted in the event of a
1226 recall.

1227 (e) Include procedures for determining the nature and scope of a recall, including affected
1228 food production lots, shipments, and shipment recipients.

1229 (f) Include procedures for identifying and communicating with affected persons, including
1230 suppliers, food shipment recipients, down-line buyers, consumers, government agencies, and
1231 others.

1232 (g) Identify potential target audiences for recall information, including consumers,
1233 distributors, and government agencies.

1234 (h) Identify potential methods for communicating with target audiences under par. (g).

1235 (i) Identify key information, including the identity of the affected food, the reason for the
1236 recall, and suggested actions to be taken by affected persons, which may need to be communicated
1237 in the event of a recall.

1238 (3) DEVIATIONS FROM PLAN. Actual recall procedures may deviate from the recall plan under
1239 sub. (1), as circumstances warrant.

1240 **Subchapter III. Canning Operations; Supplementary Requirements**

1241 **ATCP 70.34 General. (1) APPLICABLE REQUIREMENTS.** Operators engaged in canning
1242 operations shall comply with applicable provisions of subch. II. Operators engaged in canning
1243 operations shall also comply with this subchapter and shall file processes, as required, with the
1244 U.S. food and drug administration according to the provisions in 21 CFR 108.

1245 (2) RESTRICTIONS ON SALE, DISTRIBUTION, AND DONATION OF HOME-CANNED FOODS. Home-
1246 canned low-acid or acidified foods may not be donated to charitable organizations, food banks,
1247 food pantries, or other non-profit organizations that will distribute or sell the home-canned foods.
1248 The individual canning processor may not sell the home-canned foods at a food bank or food
1249 pantry, or on behalf of a charitable or non-profit organization, unless exempted by statute or rule.

1250 **ATCP 70.36 Low-acid foods packaged in hermetically sealed containers.** The operator
1251 of a food processing plant that processes and packages low-acid foods in hermetically sealed
1252 containers shall comply with applicable federal regulations under 21 CFR 108.35 (c) and 21 CFR
1253 113.

1254 **Note:** Section ATCP 70.36 applies to all low-acid foods processed and packaged in hermetically sealed
1255 containers, including thermally processed and aseptically processed low-acid foods.

1256 **ATCP 70.38 Acidified foods.** Persons who process acidified foods shall comply with
1257 applicable federal regulations under 21 CFR 108.25 (c) and 21 CFR 114.

1258 **ATCP 70.40 Facilities and equipment; cleaning. (1) EQUIPMENT DESIGN, CONSTRUCTION,**
1259 **AND ACCESSIBILITY.** The operator of a food processing plant facility handling raw agricultural
1260 commodities to prepare the commodities for canning, shall use product-handling equipment that is

1261 kept clean and in good repair and is designed and constructed in a way that allows easy
1262 accessibility for maintenance and cleaning.

1263 **(2) EQUIPMENT, WATER, AND SUPPLIES USED FOR CLEANING.** The operator of a food processing
1264 plant conducting canning operations shall use cleaning equipment that is adequate and in good
1265 repair, and shall provide ample supplies of water and steam or other approved cleaning and
1266 sanitizing materials for cleaning purposes at the facility.

1267 **(3) CLEANING REQUIREMENTS FOR EQUIPMENT USED TO PROCESS FOOD BEFORE THERMAL**
1268 **PROCESSING.** The operator at a canning facility shall clean equipment used to process food before
1269 thermal processing, in accordance with a written plan kept at the canning facility and made
1270 available to the department for review upon request. The written plan shall include:

1271 (a) A clear and complete description of the affected food processing equipment and utensils,
1272 including any continuously-operated equipment. The description shall identify sanitary design
1273 features that are relevant to the proposed cleaning and, if deemed appropriate, sanitizing
1274 procedures.

1275 (b) The types of food produced with the affected equipment or utensils, the purposes for which
1276 the food will be used, and the thermal processing conditions to which the food will be subjected.

1277 (c) A clear and complete description of the alternative procedures used to clean and, if deemed
1278 appropriate, sanitize the equipment, including equipment used to conduct these procedures,
1279 frequency, methods, materials, and relevant process parameters such as time and temperature. The
1280 description shall include a flow diagram of the alternative procedures.

1281 (d) A written statement, by the operator, that the alternative cleaning and sanitizing procedures
1282 have been determined by competent authority, such as a process authority or validated by a

1283 published or unpublished, peer-reviewed article, challenge studies, or regulatory standards, to be
1284 effective in preventing finished food product contamination and ensuring the microbiological
1285 safety of food.

1286 (e) Identification of foreseeable hazards, critical control points, critical safety parameters and
1287 limits, and monitoring procedures and controls to ensure that the procedure is effective and
1288 appropriately implemented.

1289 **ATCP 70.42 Handling raw agricultural commodities and by-products. (1) PRE-**
1290 **CANNING OPERATIONS.** Raw agricultural commodities shall be washed, sorted, trimmed as
1291 necessary, and inspected before being canned. This requirement does not apply to the washing of
1292 cabbage being prepared to make sauerkraut.

1293 **(2) WASTE HANDLING.** Waste and by-products from canning operations shall be stored and
1294 handled in a sanitary manner.

1295 **Subchapter IV. Fish Processing Plants; Marine Shellfish Plants; Supplementary**
1296 **Requirements**

1297 **ATCP 70.44 Fish processing. (1) APPLICABLE REGULATIONS.** A fish processing plant
1298 operator shall comply with subch. II and 21 CFR 123. The operator shall have and operate in
1299 accordance with HACCP plans that comply with 21 CFR 123 and address food safety hazards that
1300 may occur in fish processing. If a fish processing plant produces smoked fish products or smoke-
1301 flavored fish products, the HACCP plan for that fish processing plant shall address potential
1302 botulism risks as provided in 21 CFR 123 part B.

1303 **(2) RESTRICTION ON USE OF COLD-PROCESS SMOKED FISH.** Cold-process smoked fish may
1304 not be used as an ingredient in any other ready-to-eat, potentially hazardous food.

1305 **ATCP 70.46 Labeling and sale of smoked fish. (1) MANDATORY LABEL INFORMATION.**

1306 Every package containing smoked fish shall be clearly and conspicuously labeled, on the principal
1307 display panel of that package, with all of the following information:

1308 (a) The name and address, including the zip code, of the smoked fish processor or distributor.

1309 (b) The name of the product, including the common name of the fish from which the product
1310 is derived as found in Table 3-2 of the Fourth Edition of *Fish and Fishery Products Hazards and*
1311 *Controls Guidance*.

1312 **Note:** A copy of the current edition of the *Fish and Fishery Products Hazards and Controls Guidance*,
1313 may be obtained from the University of Florida Bookstore by calling (800) 226-1764, or it may be
1314 downloaded from the U.S. food and drug administration website:
1315 <http://www.fda.gov/Food/GuidanceRegulation/Guidance DocumentsRegulatoryInformation/default.htm/>
1316

1317 (c) The net weight of the package contents.

1318 (d) If cold-smoked fish is contained in reduced-oxygen packaging and sold or distributed in an
1319 unfrozen state, the words “PERISHABLE – KEEP REFRIGERATED AT OR BELOW 38° F” in
1320 conspicuous letters at least the size of those used in the food name.

1321 (e) If smoked fish contained in the package are sold or distributed in a frozen state, the words
1322 “PERISHABLE — KEEP FROZEN PRIOR TO USE” in conspicuous letters at least the size of
1323 those used in the food name.

1324 (f) The processing date or processing date code of the smoked fish.

1325 **(2) PROHIBITION AGAINST COMMINGLING.** Smoked fish processed on different dates or codes
1326 may not be commingled in the same container, either at the processing plant or while the fish are
1327 being stored, distributed, or offered for sale at wholesale or retail.

1328 **(3) MISREPRESENTATION OF PROCESSING DATE OR PROCESSING DATE CODE PROHIBITED.** No
1329 person may misrepresent a smoked fish processing date or processing date code, or sell or

1330 distribute smoked fish labeled with any processing date or processing date code other than the
1331 original date or code affixed by the processor.

1332 **(4) REMOVAL OF MISLABELED OR MISHANDLED SMOKED FISH.** Food consisting of or containing
1333 smoked fish shall be immediately removed from sale, and shall be destroyed or treated to render it
1334 unattractive and unfit for human consumption, if any of the following occurs:

1335 (a) The food package is not labeled with a processing date or processing date code.

1336 (b) Vacuum-packaged, cold-smoked fish is held, other than for brief periods during
1337 distribution, at a temperature above 38° F. (3.4° C.) prior to retail sale. This paragraph does not
1338 apply to a food which the department specifically exempts in writing because it is not subject to
1339 spoilage and does not support pathogen growth.

1340 **(5) APPLICABILITY OF SMOKED FISH REGULATIONS IN WISCONSIN.** No smoked fish may be sold,
1341 distributed, or offered or exposed for sale in this state unless the smoked fish have been processed,
1342 labeled, and handled in compliance with this subchapter. This subsection applies to every person
1343 engaged in the sale or distribution of smoked fish in this state, regardless of whether the person
1344 processes smoked fish in this state.

1345 **ATCP 70.48 Fish roe. (1) REFRIGERATION.** Roe and any attached entrails harvested from
1346 a fish shall be refrigerated at a temperature of not more than 38° F. (3.4° C.). Processing of dry
1347 salted roe or salted roe product shall be done in accordance with 21 CFR 123.

1348 **(2) HARVESTING AND HANDLING.** Roe and attached entrails, if any, shall be harvested, stored,
1349 and transported for processing in covered food grade containers. Each container shall be
1350 conspicuously labeled to indicate when each of the following operations was performed, if that
1351 operation has been performed:

1352 (a) The roe and attached entrails, if any, were harvested from the fish.

1353 (b) The roe sacks were separated from attached entrails, if any. Roe sacks shall be separated
1354 from attached entrails within 48 hours after the roe sacks and entrails are harvested from the fish.

1355 (c) The roe was separated from the roe sacks. Roe shall be separated from roe sacks within 72
1356 hours after the roe sacks are harvested from the fish, unless the roe is processed and packed in roe
1357 sacks. Roe processed and packed without being separated from roe sacks shall be processed and
1358 packed within 72 hours after the roe sacks are harvested from the fish.

1359 **(3) RECEIPT FOR PROCESSING.** A fish processing plant operator may not accept for processing
1360 any roe that has been held, transported, or processed in violation of sub. (1) or (2).

1361 **(4) PROCESSING STANDARDS.** (a) Roe shall be held and processed according to s. ATCP 70.24
1362 (1).

1363 (b) Processed roe shall contain a minimum of 2.5% salt by weight, as determined by
1364 quantitative analysis for total salt content.

1365 (c) No fish processing plant personnel may have direct hand contact with finished, ready-to-
1366 eat roe.

1367 **(5) PRODUCT REPRESENTATION.** (a) No roe product may be labeled or represented as "caviar"
1368 unless one of the following applies:

1369 1. The product consists only of the eggs of sturgeon prepared by a salting and separation
1370 process traditionally associated with the term "caviar."

1371 2. The product consists of roe prepared by a salting and separation process traditionally
1372 associated with the term "caviar," and the name of the fish species is clearly disclosed with the
1373 term "caviar" whenever that term is used.

1374 **Note:** For example, a caviar-type product made from whitefish eggs, using the traditional caviar
1375 process, may not be labeled as “caviar” unless it is labeled as “whitefish caviar.” All packaged food
1376 product labels, including “caviar” labels, must also include a statement of ingredients listed by their
1377 common or usual names in descending order of prominence (see s. ATCP 70.26).

1378 (b) No person may misrepresent the identity or value of any roe product by adding a color
1379 additive to the roe product. This paragraph does not prohibit the use of color additives in roe
1380 products if all of the following apply:

1381 1. The color additive is approved by the United States food and drug administration.

1382 2. The product includes a conspicuous label disclosure, such as “artificially colored” or “color
1383 added,” which clearly indicates that the product includes a color additive. The disclosure shall
1384 appear on the product label directly below the product name in type at least one-third the size of
1385 the type used in the product name.

1386 3. The color additive is included in the ingredient statement on the product label.

1387 **ATCP 70.50 Marine molluscan shellfish processing. (1) APPLICABLE FEDERAL**
1388 **REGULATIONS.** Shellfish processing and shipping operations shall comply with subch. II, the U.S.
1389 food and drug administration’s *Guide for the Control of Marine Shellfish, The Model Ordinance,*
1390 and applicable sections of 21 CFR 123. Shellfish processing plant operators shall have HACCP
1391 plans that comply with 21 CFR 123 and address food safety hazards that may occur in shellfish
1392 processing. If a shellfish processing plant produces smoked shellfish products or smoke-flavored
1393 shellfish products, the HACCP plan for that fish processing plant shall address potential botulism
1394 risks as provided in 21 CFR 123 part B.

1395 **(2) ILLNESS OUTBREAKS ASSOCIATED WITH SHELLFISH.** (a) At any time shellfish are
1396 potentially implicated in an illness outbreak involving at least 2 persons not from the same
1397 household, or at least one person in the case of paralytic shellfish poisoning, the department shall

1398 determine whether an epidemiological association exists between the illness and the shellfish
1399 consumption by reviewing each consumer's food intake history and the shellfish handling
1400 practices of the consumer and retailer.

1401 (b) When the department has determined an epidemiological association exists between an
1402 illness outbreak and shellfish consumption, the department shall conduct an investigation of the
1403 outbreak to determine whether the illness is related to the shellfish growing area or to post-harvest
1404 contamination or mishandling.

1405 (c) Upon completion of the investigation, the department shall notify receiving states and the
1406 United States food and drug administration of the findings, and take appropriate steps in
1407 cooperation with the licensee dealer to recall the affected product and, if necessary, inform
1408 consumers about the outbreak and associated product.

1409 (3) DOCUMENTS ASSOCIATED WITH SHELLFISH PROCESSING. Any documents generated by the
1410 facility in the course of its operation shall be available to the department within 24 hours of request
1411 by the department or its agent.

1412 **Subchapter V. Bottling Establishments; Supplementary Requirements**

1413 **ATCP 70.52 Bottling establishments; general.** Bottling establishments shall comply with
1414 subch. II and this subchapter. Bottling establishments producing bottled water shall comply with
1415 21 CFR 129.

1416 **ATCP 70.54 Returnable and single-service bottles.** Bottles shall comply with food
1417 package requirements under s. ATCP 70.26 (1). Returnable bottles shall be cleaned, sanitized, and
1418 inspected in compliance with ss. ATCP 70.26 (2) and (3). Single service bottles shall comply with
1419 s. ATCP 70.26 (4).

1420 **ATCP 70.56 Bottled water product sampling; record keeping; reports.**

1421 **(1) SAMPLING AND ANALYSIS.** The operator of a bottled water plant shall collect and analyze
1422 samples of bottled product for the following contaminants at the following minimum frequency,
1423 and more frequently if necessary, to provide reasonable assurance of compliance with this
1424 subsection:

1425 (a) A weekly total coliform analysis. Pursuant to 21 CFR 129.80 (g) (1), a positive total
1426 coliform analysis requires follow-up testing for *E. coli* and, pursuant to 21 CFR 165.110 (b) (2)
1427 (B), if *E. coli* is present the bottled water will be deemed adulterated.

1428 (b) An annual physical analysis pursuant to 21 CFR 165.110 (b) (3) for turbidity, color and
1429 odor analysis.

1430 (c) An annual chemical analysis pursuant to 21 CFR 165.110 (b) (4).

1431 (d) An annual radiological analysis pursuant to 21 CFR 165.110 (b) (5).

1432 **(2) REPORTING OF ANALYTICAL RESULTS.** A processor of bottled water shall report the results
1433 of all required analyses, under sub. (1), to the department, for each license year upon request. If
1434 the result of any individual analysis exceeds the established enforcement standard, the bottled
1435 water processor shall submit a copy of that analytical report to the department within 7 days of the
1436 completion of the analysis.

1437 **ATCP 70.58 Labeling bottled products.** (1) Bottled products shall be labeled according to
1438 s. ATCP 70.26 (5). Bottled water shall also be labeled according to 21 CFR 165.110. Juice shall
1439 be labeled according to 21 CFR 120, and any applicable regulations found in this chapter.

1440 **Subchapter VI. Juice and Juice HACCP**

1441 **ATCP 70.60 Juice and Juice HACCP. (1)** APPLICABLE REGULATIONS. Food processing
1442 plants producing and packaging or bottling juice shall comply with subch. II and this subchapter.
1443 Food processing plants engaged in juice processing and packaging or bottling shall comply with 21
1444 CFR 120.

1445 **(2) LABELING REQUIREMENTS.** A juice label may not misrepresent that juice has been
1446 pasteurized or has undergone a process equivalent to pasteurization. A juice label may not
1447 represent as “fresh” any juice that has been treated with ultra-violet light.

1448 **Subchapter VII. Effect of Rules on Local Ordinances**

1449 **ATCP 70.62 Effect of rules on local ordinances. (1)** NON-CONFLICTING LOCAL
1450 ORDINANCES PERMITTED. This chapter does not prohibit or nullify any local government ordinance
1451 with which it is not in direct conflict as provided in sub. (2).

1452 **(2) PRE-EMPTION OF CONFLICTING LOCAL ORDINANCES.** If this chapter conflicts directly with
1453 any local government ordinance, so that it is impossible to comply with one except by violating the
1454 other, this chapter controls.

1455 **(3) DUTY TO COMPLY.** Compliance with local government ordinances does not relieve any
1456 person from the duty of complying with this chapter.

1457 **Subchapter VIII. Variances**

1458 **ATCP 70.64 Variances. (1) ISSUANCE.** The department may issue a written waiver granting
1459 a variance from a construction, equipment, or processing standard under this section if the
1460 department finds that the variance is reasonable and necessary under the circumstances, and that it
1461 will not compromise the purpose served by the construction, equipment, or processing standards.
1462 The administrator of the department’s division of food and recreational safety may issue a waiver

1463 on behalf of the department. The department shall keep a copy of the waiver on file for as long as
1464 the waiver remains in effect.

1465 (2) SUBMISSION OF REQUEST FOR A VARIANCE. A variance request shall be submitted to the
1466 department through the sanitarian assigned by the department to inspect the food processing plant,
1467 and shall include all validation documents as well as a HACCP plan required under 21 CFR, parts
1468 120 or 123, if applicable; or food safety preventive controls plan as required under 21 CFR 117,
1469 Subpart C, if it is for a waiver of accepted processing protocols.

1470 (3) DURATION AND EXPIRATION. All waivers granted under this section shall expire 5 years
1471 from the date of issuance or when changes are made that could have an effect on the validity of the
1472 procedures or process.

1473 **SECTION 2. EFFECTIVE DATE.** This rule shall take effect on the first day of the month
1474 following publication in the Wisconsin Administrative Register, as provided under s. 227.22 (2)
1475 (intro.), Stats.

Dated this ____ day of _____, 2018.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE, TRADE
AND CONSUMER PROTECTION

By _____
Sheila Harsdorf, Secretary

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

The Department of Agriculture, Trade and Consumer Protection (“DATCP”) has, on a fairly consistent basis, amended or recreated 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 also 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”) that occurred in July 2016, forming the current Division of Food and Recreational Safety (“DFRS”).

The transfer of DHS’ FSRL to DATCP’s Division of Food Safety necessitated the merger of two food safety regulatory systems. One regulatory paradox was particularly in need of resolution: 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 without holding a food processing plant license. By statute, restaurants are now licensed as retail food establishments and therefore also enjoy the same limited ability to wholesale food. In the current rule-making process, DATCP initially proposed to retain certain existing limits and requirements from its prior rule concerning food processing activities for wholesale conducted by a retail food establishment. The Board of Agriculture, Trade and Consumer Protection (“Board”) approved a draft rule reflecting this philosophy at its January 2018 meeting. This final draft also for the first time included definitions of “wholesale” and “retail”. However, after the Board meeting, it became apparent that industry participants felt that less restrictive limits and definitions would still adequately protect public health.

As a result of this feedback, DATCP opted to form a work group comprised of industry personnel and local health department agent program representatives. They were tasked with further revision of the rule. During deliberations, the work group concluded that the safety of many food processing activities for wholesale, when performed by retail food establishments, could be ensured by compliance with Wis. Admin. Code ch. ATCP 75 and the appendix thereto, Wisconsin Food Code. Thus, recourse to the requirements Wis. Admin. Code ch. ATCP 70 was unnecessary.

Initially, the revised rule forbade the licensing of any new or remodeled food processing plant located in a residential building. Feedback from the working group indicated that this ban was not necessary to ensure adequate separation between residential and processing activities or

access for DATCP inspections. Accordingly, the proposed revision was deleted and no new requirements were added to those previously present in the rule.

Rule Content

The proposed rule updates Wis. Admin. Code ch. ATCP 70 by adopting certain federal regulations that implement the requirements of the federal Food Safety Modernization Act (“FSMA”). Specifically, the revised rule incorporates multiple subparts of the recently issued 21 CFR 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food*, that has superseded 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 federally-registered food facilities are already subject to this federal rule and licensed as food processing plants, this rule features similar referencing for the sake of consistency. This revision also ensures that the requirements for Wisconsin-licensed food processing plants, which are not subject to the federal rule, are clearly articulated.

This final draft of Wis. Admin. Code ch. ATCP 70 that redefines “wholesale” and “retail”, clarifies the exemption for retail food establishments from the requirement to hold a food processing plant license when conducting limited (not more than 25% of gross annual food sales) food processing activities for wholesale, and redraws the boundaries delimiting the permissible types of food processing activities for wholesale. Perhaps the most salient change to the regulatory territory is that a transfer of food between two food processing plants or retail food establishments will not be deemed to be wholesaling, so long as the two businesses involved are operated by the same licensed entity and the firm transferring the food does not relinquish control of the food. This change reflects current guidance by the United States Food and Drug Administration (“FDA”) and the United States Department of Agriculture, Food Safety and Inspection Service.

The revised definitions for “wholesale” and “retail” reflect industry practice and interpretation of these terms as well as FDA’s recent interpretation and sanction of current industry practice, and are concomitantly being incorporated into ATCP 75 (Retail Food Establishments). The revised rule continues to prohibit the processing of canned low-acid or acidified foods for wholesale without holding a food processing plant license and meeting ATCP 70 requirements. DATCP expects these updates to promote clarity, uniformity, and provide enhanced business opportunities for retail food establishments in Wisconsin.

The rule adopts the Model Ordinance for molluscan shellfish, now *marine shellfish*, with the Ordinance replacing all of Wis. Admin. Code s. ATCP 70.21 except for the existing subsection addressed to illnesses and outbreaks associated with shellfish.

The revised rule also:

- Addresses requirements for vending machine commissaries, including those that support micro markets, just as the revised Wis. Admin. Code ch. ATCP 75 and the Appendix thereto (*Wisconsin Food Code*) specify requirements for vending machines and micro markets. These revisions incorporate recently enacted statutory language and ensure consistency and clarity in requirements for both the food processing plant portion of these operations and the retail food establishment business.
- Clarifies the definition of extended runs and the scope of waivers allowing those runs, while clarifying and expanding the list of food processing activities during which daily cleaning and sanitizing are not required.
- Updates certain outdated restrictions on hot-smoked, vacuum-packed fish. The archaic rules were unique to Wisconsin whereas the updates mirror requirements in other states and are based on current, science-based FDA guidance.
- Mandates filing and obtaining process-authority approval for processes used in the preparation of acidified or low acid canned foods.
- Enables food processing plants to obtain waivers or variances from DATCP for non-standardized and innovative processing and procedural activities. Prior to this revision, waivers and variances could only be obtained by food processing plants for structural and equipment issues.
- Updates and clarifies language pertaining to the standards for 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.
- Expands the scope of bottling rules to encompass more than bottled water and soda, thereby keeping pace with the expansion of this rapidly changing and innovative segment of the bottling industry.
- Removes the regulatory floor of \$25,000 in sales for food processing plants that are required to pay the canning license fee surcharge, in order to reflect the considerable time that has proved to be necessary for DATCP staff to provide information, consultation, and service to persons manufacturing small amounts of canned foods.
- Protects the consistent quality of the Wisconsin “brand” by eliminating many long-expired “grandfather clause” dates in the existing rule and replacing them with language relating to achieving compliance with structural standards in existing buildings.

Small Businesses Affected

If the revised rule is adopted, some small food processing plants may incur immediate costs to meet requirements that will be in effect after the elimination of various “grandfather clauses” dating from over thirty years ago. For example, small plants may now need to upgrade warewashing and handwashing sinks. Another cost that may be incurred by a few very small

businesses is the \$320 canning surcharge, which currently is not assessed for food processing plants manufacturing and selling less than \$25,000 of food per year. DATCP's Manufactured Food Specialists spend a considerable amount of time working with very small canning businesses, and this surcharge recoups a portion of these costs. The service provided by DATCP is comparable to that provided by consultants, but at a significantly lower cost for operations in the sub-\$25,000/year category.

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.

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 plants are not size-dependent. Similarly, comparable federal regulations that set sanitation, facility, and general operations standards do not vary with business size. Thus, there is very little flexibility 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 some smaller, traditional processors.

Conclusion

The provisions in this proposed rule will benefit Wisconsin's food processing plants and consumers of their products. The propose rule will impose costs for only a few, older small-scale food processing plants.

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 7th day of November, 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

EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

Repeal Modification

2. Administrative Rule Chapter, Title and Number

Wis. Admin. Code ch. ATCP 70, Food Processing Plants

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

Most recent corrections made in August 2016.

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

DATCP has, 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 also 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") that occurred in July 2016.

The proposed rule updates Wis. Admin. Code ch. ATCP 70 by adopting certain federal regulations that implement the requirements of the federal Food Safety Modernization Act ("FSMA"). Specifically, the revised rule incorporates multiple subparts of the recently issued 21 CFR 117, Current Good Manufacturing Practice, Hazard Analysis, and Risk based Preventive Controls for Human Food, that has superseded 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 federally-registered food facilities are already subject to this federal rule and licensed as food processing plants, this rule features similar referencing for the sake of consistency. This revision also ensures that the requirements for Wisconsin-licensed food processing plants, which are not subject to the federal rule, are clearly articulated.

The transfer of DHS' FSRL to DATCP's Division of Food Safety necessitated the merger of two food safety regulatory systems. One regulatory paradox was particularly in need of resolution: 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 without holding a food processing plant license. By statute, restaurants are now licensed as retail food establishments and therefore also enjoy the same limited ability to wholesale food. In the current rule-making process, DATCP initially proposed to retain certain existing limits and requirements from its prior rule concerning food processing activities for wholesale conducted by a retail food establishment. The Board of Agriculture, Trade and Consumer Protection ("Board") approved a draft rule reflecting this philosophy at its January 2018 meeting. This final draft also for the first time included definitions of "wholesale" and "retail". However, after the Board meeting, it became apparent that industry participants felt that less restrictive limits and definitions would still adequately protect public health.

As a result of this feedback, DATCP opted to form a work group comprised of industry personnel and local health department agent program representatives. They were tasked with further revision of the rule. During deliberations, the work group concluded that the safety of many food processing activities for wholesale, when performed by retail food establishments, could be ensured by compliance with Wis. Admin. Code ch. ATCP 75 and the appendix thereto, Wisconsin Food Code. Thus, recourse to the requirements Wis. Admin. Code ch. ATCP 70 was unnecessary. The work group recognized that additional training would be needful for local health department agent personnel, as well as DATCP sanitarians, who were assigned to retail food establishments performing these food processing activities for wholesale. DATCP, as part of its ongoing mission to thoroughly train food safety personnel at the state and local level,

EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

is committed to providing both the necessary initial training and ongoing technical support.

The work group's efforts culminated in this newly revised final draft of Wis. Admin. Code ch. ATCP 70 that redefines "wholesale" and "retail", clarifies the exemption for retail food establishments from the requirement to hold a food processing plant license when conducting limited (not more than 25% of gross annual food sales) food processing activities for wholesale, and redraws the boundaries delimiting the permissible types of food processing activities for wholesale. Perhaps the most salient change to the regulatory territory is that a transfer of food between two food processing plants or retail food establishments will not be regarded as wholesaling, as long the two businesses involved are operated by the same licensed entity, and the firm transferring the food does not relinquish control of the food. This change reflects current guidance by the United States Food and Drug Administration ("FDA") and the United States Department of Agriculture, Food Safety and Inspection Service.

The revised definitions of "wholesale" and "retail" reflect industry practice and the current interpretation of these terms in the marketplace, as well as FDA's recent guidance and its sanction of industry praxis. The revised definitions also appear in the pending revision to Wis. Admin. Code ch. ATCP 75 (Retail Food Establishments). The revised rule continues to prohibit retail food establishments from processing canned low-acid or acidified foods for wholesale without holding a food processing plant license and complying with Wis. Admin. Code ch. ATCP 70 requirements. DATCP expects these updates to promote clarity and uniformity, and to facilitate enhanced business opportunities for retail food establishments in Wisconsin.

Another theme of early discussions of the rule revision was the question of whether additional regulations were necessary to ensure sanitary conditions in food processing plants sharing a building with a residence. The initial draft of the revised rule forbade the licensing of any new or remodeled food processing plant in this context. However, feedback from the working group militated against the need for an outright ban or other additional regulation to ensure adequate separation between residential and processing activities or access for DATCP inspections. Accordingly, the proposed revision was deleted.

In addition to threading a path through these complex issues, the revised rule propounds several other changes. The rule adopts the Model Ordinance for molluscan shellfish, now marine shellfish, with the Ordinance replacing all of Wis. Admin. Code s. ATCP 70.21 except for the existing subsection addressed to illnesses and outbreaks associated with shellfish. This modification will keep Wisconsin's regulations current with national standards for shellfish processing and marketing.

This revised rule also:

- Updates the definition of "food processing plant" to render it consistent with the statutory definition.
- Addresses requirements for vending machine commissaries, including those that support micro markets, just as the revised Wis. Admin. Code ch. ATCP 75 and the Appendix thereto (Wisconsin Food Code) specify requirements for vending machines and micro markets. These revisions incorporate recently enacted statutory language and ensure consistency and clarity in requirements for both the food processing plant portion of these operations and the retail food establishment business.
- Clarifies the definition of extended runs and the scope of waivers allowing those runs, while clarifying and expanding the list of food processing activities during which daily cleaning and sanitizing are not required.
- Updates certain outdated restrictions on hot-smoked, vacuum-packed fish. The archaic rules were unique to Wisconsin whereas the updates mirror requirements in other states and are based on current, science-based FDA guidance.

EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

- Mandates filing and obtaining process-authority approval for processes used in the preparation of acidified or low acid canned foods.
- Enables food processing plants to obtain waivers or variances from DATCP for non-standardized and innovative processing and procedural activities. Prior to this revision, waivers and variances could only be obtained by food processing plants for structural and equipment issues.
- Updates and clarifies language pertaining to the standards for 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.
- Expands the scope of bottling rules to encompass more than bottled water and soda, thereby keeping pace with the expansion of this rapidly changing and innovative segment of the bottling industry.
- Removes the regulatory floor of \$25,000 in sales for food processing plants that are required to pay the canning license fee surcharge, in order to reflect the considerable time that has proved to be necessary for DATCP staff to provide information, consultation, and service to persons manufacturing small amounts of canned foods.
- Protects the consistent quality of the Wisconsin “brand” by eliminating many long-expired “grandfather clause” dates in the existing rule and replacing them with language relating to achieving compliance with structural standards in existing buildings.

5. Describe the Rule’s Enforcement Provisions and Mechanisms

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

DATCP Environmental Health Sanitarians visit businesses to inspect and license them for safe operation. The Department also conducts follow-up inspections and billable reinspections that are done to determine that violations are effectively corrected. In cases of repeated or egregious non-compliance, DATCP will attach conditions to a license, assess a civil forfeiture, suspend a license, or void a license. However, DATCP uses a progressive compliance philosophy utilizing the least punitive step to effectuate compliance. For example, firms may enter into Voluntary Compliance Agreements with DATCP, stating the timetable of correcting violations.

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

- | | |
|---|---|
| <input type="checkbox"/> State’s Economy | <input checked="" type="checkbox"/> Specific Businesses/Sectors |
| <input type="checkbox"/> Local Government Units | <input type="checkbox"/> Public Utility Rate Payers |
| | <input checked="" type="checkbox"/> 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.

If the revised rule is adopted, some small food processing plants may incur immediate costs to meet requirements that will be in effect after the elimination of various “grandfather clauses” dating from over thirty years ago. For example, small plants may now need to upgrade warewashing and handwashing sinks. Another cost that may be incurred by a few very small businesses is the \$320 canning surcharge, which currently is not assessed for food processing plants manufacturing and selling less than \$25,000 of food per year. DATCP’s Manufactured Food Specialists spend a considerable amount of time working with very small canning businesses, and this surcharge recoups a portion of these costs. The service provided by DATCP is comparable to that provided by consultants, but at a significantly lower cost for operations in the sub-\$25,000/year category.

EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

Much of the focus of the proposed rule revision is on the clarification and updating of existing regulations, such as the various exemptions from a food processing plant license and the clarification of various record-keeping requirements. Many of these changes are not anticipated to have a financial or other impact.

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 dem

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.

Before drafting the rule, 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. DATCP convened a work group to develop policy recommendations on several issues.

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 equivalent in effect to federal regulations implementing the Food Safety Modernization Act (FSMA). Therefore, DATCP staff will not be required to be credentialled by the FDA, saving time and expense, and providing industry with consistent expectations and reporting processes.

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.

EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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

Yes No

15. Long Range Implications of Repealing or Modifying the Rule

DATCP has updated ATCP 70 with the incorporation by reference of provisions of federal regulations that implement the requirements of FSMA so that Wisconsin's food processing industry can produce and sell products on a level playing field with businesses across the country.

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. 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 during interstate commerce.

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.

18. Contact Name

Steve Ingham, Administrator, Division of Food and Recreational Safety

19. Contact Phone Number

(608) 224-4701

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