

## Wisconsin Department of Agriculture, Trade and Consumer Protection

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

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

### *Rule Summary*

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

- **Definitions.** This rule harmonizes current definitions with federal rules and Wisconsin retail food rules under ch. ATCP 75 (Model Food Code).
- **Handwashing facilities.** This rule updates current standards related to handwashing facilities serving toilet rooms and food processing areas. New requirements apply only to facilities installed after the effective date of this rule, to food processing plants initially licensed after the effective date of this rule, or to food processing plants licensed to a new operator after the effective date of this rule.
- **Hand contact with ready-to-eat food.** This rule prohibits bare hand contact with ready-to-eat food, unless bare hand contact is reasonably necessary and does not contaminate food. If a food processing plant operator allows bare-hand contact with ready-to-eat food, the operator must establish written policies and procedures, and an employee training program, to prevent food contamination from bare-hand contact. Requirements are consistent with current retail food rules under ATCP 75 (Model Food Code).
- **Cleaning and sanitizing procedures.** This rule updates and clarifies current requirements for cleaning and sanitizing food processing equipment and utensils, and it creates procedures by which DATCP may authorize alternative procedures and sanitizing materials.
- **Reclaimed water.** This rule updates and clarifies current standards related to use of reclaimed water in food processing plants.
- **Re-circulated water systems.** This rule regulates the use of re-circulated water in coolers and heat exchangers (if there is any possibility that the re-circulated water may come in contact with any food product or food contact surface).

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

- ***Water and potable liquids transported in bulk.*** This rule regulates the transportation and handling of water and other potable liquids transported to or from a food processing plant. Transported water must be obtained from a potable source that complies with DNR rules. Bulk tankers must be constructed, maintained, cleaned and sanitized for sanitary operation, and bulk liquids must be loaded and unloaded in a sanitary manner.
- ***Labeling packaged food.*** This rule incorporates, by reference, current federal and state food packaging and labeling requirements. Among other things, this rule incorporates current federal rules related to disclosure of major food allergens.
- ***Recall plan.*** Consistent with current federal rules, this rule requires a food processing plant operator to have a written plan for identifying and recalling food produced at the plant, should a food recall become necessary. This rule establishes general content standards, but allows operators to determine plan specifics. Actual recall procedures may deviate from advance plans, as circumstances warrant.
- ***Low-acid food packaged in hermetically sealed containers.*** This rule clarifies that low-acid food packaged in hermetically sealed containers (including aseptically processed food as well as thermally processed food) must be processed according to federal rules under 21 CFR 113.
- ***Fish processing; general.*** This rule repeals and recreates current rules related to fish processing, in order to make the rules consistent with federal rules under 21 CFR 123.
  - Under federal rules and this rule, fish processors must have a HACCP plan to identify and control food safety hazards associated with fish processing. Plans must meet federal standards.
  - This rule repeals current required procedures related to smoked-fish processing, in favor of the more flexible HACCP plan approach. However, this rule encourages smoked fish processors to incorporate and adapt the repealed procedures, as appropriate, in their HACCP plans (this rule includes the repealed procedures in an appendix, which processors may consult for guidance).
  - This rule updates and clarifies current rules related to the labeling and sale of smoked fish. Among other things, this rule repeals the current 21-day shelf-life limit on sales of smoked fish (this rule requires a stated shelf-life expiration date, but shelf-life will be based on the HACCP plan per federal rules).
  - This rule updates and clarifies current rules related to processing, labeling and sale of fish eggs (roe). This rule applies to all fish roe, not just “caviar.” This rule clarifies current labeling requirements related to processed fish roe. A fish roe product, other than a sturgeon roe product, may not be labeled as “caviar” unless the name of the fish species is also disclosed (e.g., “whitefish caviar”).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

***Conclusion***

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

Dated this \_\_\_\_\_ day of \_\_\_\_\_, 2009

STATE OF WISCONSIN  
DEPARTMENT OF AGRICULTURE,  
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