

EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

Repeal Modification

2. Administrative Rule Chapter, Title and Number

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

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

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

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

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

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

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

Other clarifications, changes, and additions are as follows:

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

5. Describe the Rule's Enforcement Provisions and Mechanisms

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

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

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

- State's Economy
 Local Government Units

- Specific Businesses/Sectors
 Public Utility Rate Payers
 Small Businesses
-

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

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

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

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

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

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

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

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

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

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

10. Fund Sources Affected

- GPR FED PRO PRS SEG SEG-S

11. Chapter 20, Stats. Appropriations Affected

12. Fiscal Effect of Repealing or Modifying the Rule

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

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

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

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

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

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

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

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

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

- Yes No

15. Long Range Implications of Repealing or Modifying the Rule

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

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

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grow and that ensure food safety guidelines are met.

16. Compare With Approaches Being Used by Federal Government

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

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

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

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

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