

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 proposed 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 _____ day of _____, 2018.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

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