Wisconsin Department of Agriculture, Trade and Consumer Protection

Initial Regulatory Flexibility Analysis

Rule Subject: **Food Processing Plants**
Adm. Code Reference: **ATCP 70**
Rules Clearinghouse #: **Not assigned**
DATCP Docket #: **17 – R - 05**

Rule Background

DATCP has, on a fairly regular basis, amended or re-created this rule in order to keep pace with changes in industry as well as the FDA's regulatory philosophy. In this rule revision, DATCP has been especially cognizant of clarifications necessitated by the merger between the DATCP's Division of Food Safety and the Department of Health Services' ("DHS") Food Safety and Recreational Licensing Section ("FSRL") which occurred in July of 2016. In the wake of this merger, as DATCP continues to seek better ways to serve our stakeholders in particular and Wisconsin residents generally, DATCP will continue to advance improvements to Wisconsin's administrative rules and statutory framework.

One major change in implementing this merger involved evaluating the food processing and wholesaling (activities regulated by ATCP 70) operations of persons holding retail food establishment licenses. It should be noted that provisions of ATCP 70 related to these activities will impact restaurants, now licensed as retail food establishments. This rule, for the first time, spells out definitions for "wholesale" and "retail." This rule also requires retail food establishment license holders exempted from the requirement of holding an additional food processing plant license to still meet safe food manufacturing requirements in ATCP 70.

Rule Content

DATCP has updated ATCP 70 with the incorporation by reference of provisions of Federal regulations that implement the requirements of 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 ATCP 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 DHS' FSRL to form the new Division of Food and Recreational Safety ("DFRS"), a merger of the two food safety regulatory systems became necessary. For example, 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 now 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. The new ATCP 70 also incorporates, for the first time, specific definitions for wholesaling and retailing concomitantly being incorporated into ATCP 75 (Retail Food Establishments) and ATCP 55 (Meat and Meat Food Products). DATCP expects these updates to promote clarity, uniformity, and improved guidance to food businesses in Wisconsin.

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

In revising this rule, DATCP sought to eliminate duplication, improve regulatory transparency, and, to the extent possible, ensure that food businesses are not required to hold multiple licenses, except when completely necessary. In doing so, DATCP never relinquishes its public health mission or compromises its directive to ensure that food is produced safely and pursuant to some responsible form of inspection. In some cases, such as meat establishments that produce some products under a state license or a federal grant of inspection and other products separate from that inspection, businesses will be allowed to obtain a retail food establishment license from the state or local agency with jurisdiction in that area, in addition to the state meat establishment license or federal grant of meat inspection. This ensures that those business 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, 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 exempt 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 real need of 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 replacing them with language about gaining compliance for structural standards in existing buildings and updating the expectations for structural standards in new plants. Most significantly, the proposed rule promotes

consistent food safety by not allowing a food processing plant in a residence to be licensed after the effective date of this rule.

Small Businesses Affected

The businesses affected by this rule run the gamut from very small to very large operations. The businesses range from one- and two-person popcorn wholesalers to multi-national corporations that are on the cutting edge of food science. 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. They will 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 disproportionate amount of time working with very small canning businesses, and this surcharge recoups these costs. The service provided by DATCP 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, as well as the clarification of various record-keeping requirements.

A positive impact of this rule revision on all classes of business is the expanded ability of food processing plants to apply for processing or procedural waivers. This 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.

Reporting, Bookkeeping and other Procedures

The proposed rule will not require any additional reporting, bookkeeping, or other procedures.

Professional Skills Required

The proposed rule does not require any new professional skills by small businesses.

Accommodation for Small Business

The requirements for food processing are not size-dependent. There is very little room in the regulations for accommodations due to size, but the department has rewritten the language on waivers to allow processors using alternative methods of processing or

cleaning to apply for waivers if they can show equivalent food safety. This may be of use to smaller, traditional processors.

Conclusion

The provisions in this proposed rule will benefit Wisconsin's food processing plants and are expected to impose costs for only a few, older small-scale food processing plants, particularly those located in residences.

This rule will not have a significant adverse effect on "small business" and is not subject to the delayed "small business" effective date provided in s. 227.22(2)(e), Stats.

DATCP will, to the maximum extent feasible, seek voluntary compliance with this rule.

Dated this _____ day of _____, 2017.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

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