

Wisconsin Department of Agriculture, Trade and Consumer Protection

Final Regulatory Flexibility Analysis

Rule Subject: **Retail Food Establishments and
the Wisconsin Food Code**
Adm. Code Reference: **ATCP 75, and ATCP 75 Appendix,
The Wisconsin Food Code**
Rules Clearinghouse #: **17-074**
DATCP Docket #: **15-R-16**

Rule Summary

The rule updates Wis. Admin. Code ch. ATCP 75 by incorporating significant rule provisions in the now-repealed Wis. Admin. Code ch. DHS 196 (Restaurants) and by repealing rules in Wis. Admin. Code ch. ATCP 75 concerning agent programs. Agent program rules are currently found in Wis. Admin. Code ch. ATCP 74 (Local Agents and Regulation), which also incorporates provisions from the repealed Wis. Admin. Code ch. DHS 192.

The transfer of DHS' FSRLS 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 could not wholesale food under the DHS rules, while retail food establishment ("RFE") operators under DATCP's authority could engage in a limited amount of wholesaling without holding a food processing plant license. By statute, the Department now licenses restaurants as RFEs, and therefore, restaurants enjoy the same limited ability to wholesale food. The Department undertook the present rule-making process and by January of 2018 had developed a draft rule that for the first time included definitions of "wholesale" and "retail". The Department initially proposed to retain certain limitations and requirements derived from Wis. Admin. Code ch. ATCP 70 (Food Processing Plants) addressed to food processing activities for wholesale conducted by an RFE. The Department presented a final draft reflecting that framework to the Board of Agriculture, Trade and Consumer Protection ("Board") in January 2018. Although the Board approved the draft, it became apparent in the aftermath of the Board meeting that industry participants felt that less restrictive limits and definitions would still adequately protect public health.

In light of this feedback, the Department opted to form a work group comprised of industry and local health department agent program representatives to further revise the rule. During deliberations, the work group determined that the safety of many food processing activities for wholesale, when done by RFEs, could be ensured by compliance with ATCP 75 and the ATCP 75 Appendix, and thus, no additional application of ATCP 70 requirements was necessary. The work group recognized that additional training would be necessary for local health department agent personnel, along with Department sanitarians, assigned to inspect RFEs performing these food processing activities for wholesale. The Department, as part of its ongoing work to train thoroughly food safety personnel at the state and local level, is committed to providing the necessary training.

The work group extensively discussed whether an RFE conducting food processing activities for wholesale, yet exempt from having to hold a food processing plant license, should be required to develop a written recall plan (as required in ATCP 70). Dairy plants and food processing plants must develop a written recall plan, but the work group reached consensus that this requirement was poorly suited and likely ineffective for businesses predominantly engaged in retail activities. As a result, the revised rule states that RFEs are responsible for notifying their wholesale customers of any adulterated or misbranded products that the RFE may have sold to them, as deemed appropriate for the protection of public health. The RFE operator will choose the notification mechanism.

The work group's efforts culminated in the newly revised final draft of ATCP 75, which does all of the following: a) re-defines "wholesale" and "retail", b) clarifies the exemption for RFEs 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 c) re-draws boundaries on what types of food processing activities for wholesale are allowed. Perhaps the most important change in the wholesale and retail definitions is that the Department will no longer regard the transfer of food between two RFEs or food processing plants as wholesaling, so long as the same license holder operates the two businesses involved and the licensee transferring the food does not relinquish control of the food. This change reflects current guidance by the FDA and follows the United States Department of Agriculture (USDA) interpretations related to differentiating "retail" from "wholesale" transactions involving meat and poultry products.

The revised definitions for "wholesale" and "retail" reflect industry practice and the de facto usage of these terms in the marketplace, as well as the FDA's interpretation and sanction of current industry practice. The new definitions also appear in the pending revision to Wis. Admin. Code ch. ATCP 70 (Food Processing Plants). The revised rule does continue to prohibit RFEs from processing canned low-acid or acidified foods for wholesale without holding a food processing plant license and complying with the requirements stated in Wis. Admin. Code ch. ATCP 70. The aim of the update definitions is to promote clarity and uniformity and ideally to facilitate enhanced business opportunities for industry participants.

RFEs operate under a wide range of business models, ranging from traditional restaurants, bakeries, and markets where all sales are made directly to consumers, on the one hand, to larger operations performing varying degrees of processing and wholesaling, on the other hand. The revisions to the rule take cognizance of a recently introduced business model in which a licensed RFE transports prepared food and conducts sales of individual meals directly to a workplace's employees or guests of employees, for a limited number of days each week. Within boundaries delineated in the rule, an additional RFE license is not required for the workplace meal sales. The work group reviewed and approved this revision.

Some RFEs perform food processing for wholesale activities, which are regulated at the federal level by the FDA. This rule revision is calculated to ensure that these businesses do not fall outside the sweep of appropriate regulation. Wis. Admin. Code ch. ATCP 75 and its Appendix specifically govern retail sales and the internal transfer of food between businesses operated by the same license-holding entity. As revised, the rule, with the addition of federal requirements

for juice and seafood processing, will apply to RFEs that conduct wholesaling only to a limited extent ($\leq 25\%$ of gross annual food sales). Businesses that predominantly wholesale the food they process must effectuate enhanced food safety systems, as required by provisions in Wis. Admin. Code ch. ATPC 70.

With this rule revision, the Department has sought to eliminate duplication, clarify expectations, and, to the extent possible, avoid the need to procure multiple licenses for the same business. However, the Department justifiably weighed these objectives in the balance with safety concerns arising from gaps in regulation. Accordingly, this rule proposes that any business holding either a meat establishment license issued by the Department, or a grant of meat / poultry inspection from the federal government, must also obtain an RFE license if the business manufactures for retail sale any meat or poultry products that are never produced under meat inspection and never bear an inspection legend. Prior to this rule revision, meat establishments were allowed to retail up to 25% of *total* meat sales without holding an RFE license because of the frequent state or federal inspection of meat processing overall.

However, it was adjudged during recent discussions that the available meat inspection resources are insufficient to adequately oversee meat and poultry products sold at retail without the state or federal mark of inspection and other safeguards attendant upon RFE status. Federal meat inspection staff are explicitly directed not to inspect retail meat and food operations. The rule revision eliminates the above-described exemption from the requirement to hold an RFE license. Expectations will thus be identical to those for businesses already licensed as RFEs to produce meat and poultry products only for retail sale.

The rule also defines and clarifies the rules for micro-markets, vending machines, and the vending machine commissaries defined in statute as serving both of those business types. The Department will license vending machine commissaries as food processing plants, which reflects the operations of these commissaries. In addition, the Department defines micro-markets so as to acknowledge that the latter typically operate without a human on the premises at all times to oversee operations, which is a requirement for other types of RFEs.

The revised Wis. Admin. Code ch. ATPC 75 Appendix, *Wisconsin Food Code*, provides greater clarification regarding variances and Hazard Analysis Critical Control Point (“HACCP”) plans, including the procedure for variance applications. New language also simplifies the protocols that establishments must follow when performing vacuum packing and sous-vide processing.

A significant change in the *Wisconsin Food Code* pertains to cheese curds. The Department based the revised language on a recent study of the likelihood of pathogenic bacterial growth on cheese curds. The study validates the current 24-hour-at-room-temperature limit for display of cheese curds processed under Cheddar cheese-making conditions. This scientific support of storage requirements for cheese curds allows the Department to meet Standard 1 of the FDA’s Voluntary National Retail Food Regulatory Standards Program by providing validation for any protocols that differ substantively from the *FDA Model Food Code*.

In response to industry comments, the Department added requirements for rendering recent inspection results available to the public, along with a prohibition against any grading or scoring

of RFEs based on inspection reports or other criteria. The intent of these provisions is to avoid problems arising in the event that different jurisdictions utilize discrepant grading or scoring systems or some jurisdictions employed a grading system while others did not. The Department believes that actual inspection reports will tend to be more informative than grades or scores and will allow consumers to draw their own conclusions about the merits of a given RFE. However, after adding this provision, the Department was informed that the City of Milwaukee, which is an agent of the Department, had received a grant from the FDA contingent upon it implementing a grading program. The Department opted to hold discussions with stakeholders including the City of Milwaukee Health Department and retail food establishment associations. All agreed that the Department could oversee a trial program for an agreed-upon duration in Milwaukee to evaluate the efficacy of such a grading program and identify the best practices to be utilized in such a program. The trial program will allow the Department to compare the use of the program in one of its agent jurisdictions against all the other agent jurisdictions that will not have the grading program in place during the trial period. The comparison will be made in terms of public health outcomes agreed upon by stakeholders and approved by the Department. At the conclusion of the trial program, the Department can decide whether grading may be used, and under what circumstances, by any of its agent programs. The proposed rule was amended to include language that implements this trial program.

This revised rule also harmonizes the different requirements that previously existed across DHS and DFS rules as to mobile RFE bases. The enforcement of divergent sets of rules had created a licensing inequity as between various individual operations, depending on the agency conducting oversight. The proposed rule eliminates these inconsistencies and standardizes the requirements for those bases.

Finally, the rule renumbers and consolidates many provisions in the *Wisconsin Food Code* so as to enable greater ease of use and to allow for the intercalation of provisions pertaining to micro-markets and vending machines. The Department has also revised the criteria for setting licensing fees, shifting from basing fees on income and sales volume to a model based primarily on risk and complexity.

Small Businesses Affected

The rule is not anticipated to have a major economic effect on small RFEs since it mainly replaces and updates current rules. No comments were received during the economic impact comment period held August 8, 2017 - September 7, 2017. However, feedback on the rule was solicited from members of the Food Safety Advisory Council (FSAC), a group comprised of business and local health department agent representatives.

For those small RFEs requiring a licensed base, already-licensed mobile retail food establishments serving meals will see no change in requirements because their bases were licensed under the DHS rules that were transferred to the Department. Mobile RFEs that operate at special events or at temporary events will not need a licensed base, just as mobile RFEs serving meals operating at temporary events (such as farmers' markets) currently do not need a licensed base.

For those operators with a base serving mobile RFEs that only sell non-perishable packaged foods, the effect will also be minimal. The only small-scale operators who may face increased regulatory requirements, and the associated expenses to meet them, are those operators who are also doing complex processing and preparation of potentially hazardous food for wholesale. Some activities performed in those settings must also be done under the HACCP system, such as fish processing that would require implementation of a Seafood HACCP system (as required in 21 CFR 123, as cited in Wis. Admin Code s. ATCP 70.44), and juice processing that would require implementation of a Juice HACCP system (as required in 21 CFR 120, as cited in Wis. Admin. Code s. ATCP 70.60).

The proposed rule modifies the criteria for assigning license fees. For purposes of pragmatism, the rule tethers the cost of a given license to the complexity and risk of the food safety hazards associated with the particular activity, and not solely to the size of the RFE and the dollar volume of sales. In many cases, larger establishments that may have been paying a higher license fee because of the sales volume will now pay a lower fee if their processing is not complex or hazardous. A low number of small businesses may face an increased license fee if they are conducting complex or hazardous activities that require increased attention during inspections. However, the Department's analyses suggest that the overall change in total license fees charged will be negligible. The proposed licensing fee criteria more fairly reflect the time and personnel costs to the Department for the inspection.

The requirement to obtain an RFE license in order to conduct retail sales of meat or poultry products that do not bear an inspection legend should not pose a major regulatory burden on small meat establishments operating under state or federal meat inspection programs. Both meat inspection programs require all inspected products to be produced under HACCP. The retail program accepts state or federal HACCP plans for cured or shelf-stable products, and already requires HACCP plans for such products made only under an RFE license.

Reporting, Bookkeeping and other Procedures

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

Professional Skills Required

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

Accommodation for Small Business

The FDA does not make accommodations for food safety practices based on size, so Wisconsin does not do so either. Instead, the rule is cued to the *complexity* of the business. The rule ties the cost of an RFE license to the complexity of the processing activities going on and the food safety risk of those activities. In some cases, larger establishments that may have been paying a higher license fee because of the sales volume will now have that fee reduced if their processing is not complex. The proposed licensing fee criteria more fairly reflects the time and personnel costs to the Department for the inspection.

As noted, feedback on the rule was solicited from members of FSAC, and consensus about final revisions was obtained in an industry-local agent working group. The proposed changes in criteria for license fees were tested by hypothetically applying the criteria to businesses familiar to FSAC members and by evaluating the license fee change to each RFE in a representative county.

Conclusion

The provisions in the rule will benefit Wisconsin's retail food industry and are expected to impose very limited additional costs. It is quite possible that many large, non-complex establishments will actually see a reduction in cost since they are no longer charged for a license based solely on size and dollar volume of sales.

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 Wis. Stat. § 227.22(2)(e).

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

Dated this _____ day of _____, 2019.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE, TRADE AND
CONSUMER PROTECTION

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