

EXISTING ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

Repeal Modification

2. Administrative Rule Chapter, Title and Number

Wis. Admin. Code ch. ATCP 75, Retail Food Establishments, and ATCP 75 Appendix, The Wisconsin Food Code

3. Date Rule promulgated and/or revised; Date of most recent Evaluation

Recent corrections made in 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.

The proposed rule modifies Wis. Admin. Code ch. ATCP 75 by incorporating significant rule provisions of repealed Wis. Admin. Code ch. DHS 196 (Restaurants) and repealing provisions of Wis. Admin. Code ch. ATCP 75 dealing with agent programs. Agent program rules are now 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 ATCP 74 (Local Agents and Regulation), which also incorporates provisions from the repealed Wis.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' Food Safety and Recreational Licensing Section 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 rulemaking 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 convene a work group comprised of industry and local health department agent program representatives to further revise the rule. In the course of its deliberations, the work group concluded that the safety of many food processing activities for wholesale, when performed by RFEs, could be ensured by compliance with Wis. Admin. Code ch. ATCP 75 and the ATCP 75 Appendix, and thus no further recourse to the strictures of Wis. Admin. Code ch. ATCP 70 was needed. The work group recognized that additional training would be necessary for local health department agent personnel, as well as Department sanitarians, who are assigned to inspect RFEs performing these food processing activities for wholesale. The Department, as part of its ongoing mission to train thoroughly food safety personnel at the state and local level, is committed to providing the necessary training.

The work group extensively discussed the question of whether an RFE that conducts food processing activities for wholesale, yet that is exempt from having to hold a food processing plant license, should be required to develop a written recall plan (as required by Wis. Admin. Code ch. ATCP 70). Dairy plants and food processing plants are required to develop written recall plans, but the work group reached a consensus that this requirement was poorly suited to and likely ineffective for businesses predominantly engaged in retail activities. As a result, the revised rule provides that RFEs bear responsibility 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 is to choose the notification mechanism.

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The work group's efforts culminated in the newly revised final draft rule, which does all of the following: a) redefines "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) redraws the boundaries defining permissible types of food processing activities for wholesale. Perhaps the most salient change reflected in the new definitions of "wholesale" and "retail" is that the Department will no longer deem as wholesaling a transfer of food between two RFEs or food processing plants, as 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 United States Food and Drug Administration (FDA) and follows the United States Department of Agriculture (USDA)'s interpretations of "wholesale" and "retail" in connection with the differentiation of retail and 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 readings of the terms and its sanction of current industry practice. The new definitions also appear in the completed and published 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 updated 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, to larger operations performing varying degrees of processing and wholesaling. The revisions to the rule recognize 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 (< 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. ATCP 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 weighed these objectives against 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 USDA, 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

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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. ATCP 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.

After evaluating local public health department agent program and industry comments, the Department originally chose to add requirements for making recent inspection results available to the public, and 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 utilized discrepant grading or scoring systems or some jurisdictions employed a grading system while others did not. The Department believes that actual inspection reports tend to be more informative than grades or scores and allow consumers to draw their own conclusions about the merits of a given RFE. The Department has been aware that the City of Milwaukee, which is an agent of the Department, received a grant from the FDA contingent upon it implementing a grading program. Milwaukee's grading program is now entering its third year. Because there is no clear statutory authorization or prohibition of grading or scoring systems, and because ATCP 75 as currently written is silent on this issue, the Department has removed rule language pertaining to a grading or scoring system.

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.

The Department is statutorily bound to base licensing fees for RFEs not serving meals on "gross receipts from food sales at the retail food establishment during the previous license year." The Department is not statutorily prohibited from considering food safety risks associated with activities at these RFEs, as the original license fees in statute are also based on whether potentially hazardous food is processed. Statute also allows the Department to revise in rule license fees for RFEs not serving meals. In accordance with these statutory boundaries, the Department has added an additional gross food sale receipt volume range and several risk factors to the criteria for setting licensing fees for RFEs not serving meals.

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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.

5. Describe the Rule's Enforcement Provisions and Mechanisms

The Department has broad general authority, pursuant to Wis. Stat. s. 93.07 (1), to adopt rules to implement programs under its jurisdiction. The Department also has general authority, pursuant to Wis. Stat. s. 97.09 (4), to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. The Department has specific authority, pursuant to Wis. Stat. s. 97.30 (5), to adopt rules for RFEs concerning fees; to set facility construction and maintenance standards; to set rules for the design, installation, maintenance, and cleaning of equipment and utensils; personnel sanitation; food handling, display, and storage; food sources and food labeling.

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 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

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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.

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 comments were received during the economic impact comment period held August 8, 2017 - September 7, 2017. However, feedback on the rule was solicited at this stage from members of the Food Safety Advisory Council (FSAC), a group comprised of business and local health department agent representatives. The Department held five public hearings on the proposed rule: (1) November 16, 2017 in Sheboygan; (2) November 22, 2017 in Rhinelander; (3) November 24, 2017 in Madison; (4) December 1, 2017 in Eau Claire; and (5) December 8, 2017, in Shawano, Wisconsin. Public hearing notices were posted at the State Legislature's Active Rules Clearinghouse website and in the Administrative Register. Electronic notices were sent out to all licensed businesses for which the Department had e-mail addresses. Information about the hearings was specifically sent to Susan Quam of the Wisconsin Restaurant Association, Michelle Kussow of the Wisconsin Grocers Association, and Jay Ellingson of Kwik Trip, Inc.

A total of 35 persons/organizations attended the hearings and/or submitted comments. The comments addressed several issues, but many of them were form statements in opposition to the licensing exemptions for non-profits occasionally serving meals or food other than meals.

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: The FDA does not make accommodations for food safety practices based on size, so Wisconsin does not do so either. Instead, this rule makes accommodation for the complexity of the business. The rule more realistically 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.

10. Fund Sources Affected

- GPR FED PRO PRS SEG SEG-S

11. Chapter 20, Stats. Appropriations Affected

20.115 (1)(gb)

12. Fiscal Effect of Repealing or Modifying the Rule

- | | | |
|---|--|---|
| <input type="checkbox"/> No Fiscal Effect | <input type="checkbox"/> Increase Existing Revenues | <input type="checkbox"/> Increase Costs |
| <input checked="" type="checkbox"/> Indeterminate | <input checked="" 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

This rule continues to ensure that Wisconsin's retail food establishments meet federal requirements by incorporating the U.S. Food and Drug Administration (FDA) Model Food Code. In order to have rules relevant to evolving business models, be in compliance with state statutory and federal requirements, and provide RFEs with new business opportunities related to wholesaling, the Department would like to implement the rule as soon as possible.

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

- Yes No

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15. Long Range Implications of Repealing or Modifying the Rule

The rule will continue to facilitate the working relationship between the Department, the FDA, and the retail food industry. If the rule is not revised, outdated and unnecessary regulations will remain in place, requiring both industry and the Department to spend unnecessary time on seeking variance approvals. This will negatively impact micro-markets, patrons with dogs in outdoor eating areas, and meat plants that will no longer be allowed to cure and smoke retail-only products under meat establishment licenses. Revision of the rule moves the licensing categories away from a solely sales-volume-based model, which is specifically not fair to large, non-complex facilities. Finally, revision of the rule lessens inconsistency and improves clarity for regulation of retail operations that serve meals and retail operations that do not serve meals, and the clearly states requirements and boundaries for retail food establishments performing food processing for wholesale activities.

16. Compare With Approaches Being Used by Federal Government

The FDA does not have a retail food inspection or regulation program. The FDA promulgates the Model Food Code, a guide used in formulating state regulations or adopted by state programs to promote a uniform level of food safety throughout the nation.

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

This rule is generally consistent with rules in neighboring states. Surrounding states have all adopted various versions of the FDA's Model Food Code. The criteria for retail food establishment license fees differ somewhat from those in surrounding states, in the emphasis placed on complexity and risk of food safety hazards.

IL: RFEs in Illinois are licensed at the county or municipal level. Cook County does not have a separate category for mobile RFE bases. Licensing fees for RFEs are based on whether the establishment has seats for customers and if not, the total area occupied by the business. Chicago differentiates licenses for mobile food dispensers and mobile food preparers.

MN: Minnesota has different license categories for mobile and stationary retail food businesses, with the fee based on sales volume. There is no separate Minnesota license category for mobile RFE bases. RFEs that are not restaurants in Minnesota are primarily regulated by the Department of Agriculture. Minnesota restaurants are primarily regulated by county or municipal agencies. Hennepin County, for example, sets license fees based on menu breadth, degree of hazard of menu items, and size of operation, with separate categories for mobile and itinerant businesses.

IA: Iowa has a separate license category for a commissary serving a mobile RFE. The RFE category in Iowa includes restaurants.

MI: Michigan includes restaurants as a type of RFE and has separate categories for mobile and mobile commissary operations.

18. Contact Name

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19. Contact Phone Number

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