

## Wisconsin Department of Agriculture, Trade and Consumer Protection

### Initial 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 #:** Not assigned

**DATCP Docket #:** 15 – R - 16

#### *Rule Summary*

The Department is updating ch. ATCP 75 by incorporating large parts of repealed ch. DHS 196 (Restaurants) and repealing rules in ch. ATCP 75 dealing with agent programs. These agent program rules are now found in the new ch. ATCP 74 (Local Agents and Regulation), which also incorporates rules from the repealed ch. DHS 193.

With the merger, changes must be made to merge the different rules used by the two agencies. In addition to new language clarifying the responsibilities of food retailers who take advantage of the exemption from the requirement to hold a food processing plant license under ch. ATCP 70 but wholesale up to 25% of their gross food sales, the proposed ch. ATCP 75 will incorporate, for the first time, specific definitions for “wholesaling” and “retailing” which are now being incorporated into chs. ATCP 70 and ATCP 55 to provide guidance, clarity, and uniformity for food processors and retailers in Wisconsin.

As previously stated, the proposed ATCP 75 contains language that specifically clarifies the responsibilities for retail food establishments exempt from the requirement to hold a food processing plant license but also doing a limited amount of wholesaling, and to follow the ATCP 70 safety, processing, and labeling requirements for the food produced for wholesaling. This not only ensures that all persons doing similar business activities are similarly regulated, but also ensures that all businesses selling at remote locations have the enhanced food safety processes in place, such as a written recall plan and a written food safety production plan as required by rules in ch. ATCP 70.

A major change in this rule is the elimination of the exemption from the requirement to hold a retail food establishment license for persons holding either a meat establishment license issued by the Department or a grant of meat / poultry inspection from the federal government. Prior to the adoption of this rule, those meat establishments were allowed to retail up to 25% of total meat sales without a retail license because of the pervasive state or federal inspection of meat processing. However, recent discussions between the regulators in food and meat inspection have made it clear that meat and poultry products, sold at retail but not imbued with the state or federal mark of inspection, and other aspects of a retail food establishment, were not being inspected by meat inspection staff. The result of this oversight means that those establishments with meat establishment licenses or federal grants of inspection would not be able to retail any product other than meat or poultry products bearing the legend. With the proposed rule, the department would make it possible for them to continue to sell a full line of products while assuring the consuming public that the food products were subject to a proper inspection. It also levels the playing field for businesses already licensed to produce meat and poultry products only for retail sale.

The Department worked to combine the duties, activities, and expectations of both the merged agencies in a way that eliminates duplication, clarifies expectations, and, to the extent possible, ensures that multiple licenses are not needed. The Department has, however, balanced these

objectives with its responsibility to the public and its mission as food safety regulators to ensure that all food is produced according to law and under some form of inspection. For some situations, such as meat establishments that produce some products under state or federal inspection with a mark of inspection and some product without that inspection or mark, the proposed rule will allow an additional retail license from the state or local agency with jurisdiction in that area, as well as the state meat establishment license or federal grant of inspection.

The new rule focuses on defining and clarifying the rules for micro-markets, vending machines, and the commissaries that serve both of those business types. The commissaries for both micro-markets and vending machines are now to be licensed as food processing plants, which reflects the operations of these commissaries. In addition, micro-markets are defined with the recognition that they operate without a person in charge at all times in overseeing their operations, which is a requirement for other types of retail food establishments.

Greater clarification is also given to the Department's rules for Hazard Analysis Critical Control Point ("HACCP") Plans and HACCP variances, including the procedure for variance applications. New language also simplifies the protocols that establishments must follow for doing vacuum packing and sous-vide processing.

A significant change in the *Wisconsin Food Code* deals with cheese curds. The Department proposes to include language that references a process authority study on cheese curds, which validates the 24-hour at-room temperature rule and, moreover, allows the Department to meet Standard 1 of the FDA's Retail Food Regulatory Standards Program.

This proposed rule harmonizes the different licensing rules used by DHS and the Department for mobile retail food establishment bases. The application of the different sets of rules created a licensing inequity between those operations, depending on the overseeing agency. These inconsistencies have now been eliminated, and the proposed rule also clarifies the rules for using those bases.

The Department renumbered and consolidated many provisions in the *Wisconsin Food Code* to achieve greater ease in use and to allow for the incorporation of rules on micro-markets and vending machines. The Department has also revisited the criteria for licensing fees, changing from income-and-sales-volume-based fees to risk-complexity-based fees.

Other clarifications, changes, and additions include the following:

- Language and terminology are standardized and clarified between the two merged programs.
- The definitions section is expanded to facilitate understanding of the merged language and the new programs.
- The *Wisconsin Food Code* is rearranged to help clarify its contents and applications. It is also expanded to stay current with recent federal and state initiatives.

### ***Small Businesses Affected***

The rule should not have a major economic effect on retail food establishments since it mainly replaces and updates current rules.

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

For those operators with a base serving mobile retail food establishments that only sell non-perishable packaged foods, the effect will also be minimal. The only 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. 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 part 123, as cited in s. ATCP 70.18), juice processing that would require implementation of a Juice HACCP system (as required in 21 CFR part 120, as cited in s. ATCP 70.23), or the processing and/or repacking of marine shellfish that would require compliance with the HACCP-based Marine Shellfish Program found in s. ATCP 70.21.

The major change in ch. ATCP 75 is the change in the criteria for assigning license fees. The rule more realistically ties the cost of the license to the complexity and food safety hazards of the processing activities going on and not to the size of the establishment and 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. The Department's analyses suggest that the overall change in total license fees charged will be negligible. The proposed licensing fee criteria more fairly reflects the time and personnel costs to the Department for the inspection.

The additional retail license should not pose a major fiscal impact on plants operating under state or federal meat inspection programs. Both meat inspection programs require all inspected products to be produced under HACCP. The retail program will be willing to accept state or federal HACCP plans for cured or shelf-stable products, and already requires them under the retail program. If the proposed rule is not approved, it may not be possible for establishments operating under USDA or Wisconsin meat inspection programs to continue to operate unlicensed, uninspected retail outlets.

### ***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 by small businesses.

### ***Accommodation for Small Business***

A major change in these rules is the chart that assigns points for risk in processing. This replaces the chart that assigned a license based on the size of the operation and the dollar volume of sales. This rule does not actually make an accommodation for the *size* of the business as much as it makes accommodation for the *complexity* of the business. The FDA does not make accommodations for food safety practices based on size, so Wisconsin does not do so either, but

non-complex operations of any size are now charged less for a license than a complex operation even if the dollar volume of sales is much higher for the non-complex.

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. The proposed changes in criteria for license fees were tested by applying the criteria to businesses familiar to FSAC members and by evaluating the license fee change to each retail food establishment in a representative county.

### ***Conclusion***

The provisions in this proposed rule will benefit Wisconsin's retail food industry and is 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 based 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 s. 227.22(2)(e), Stats.

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