STATEMENT OF SCOPE

Department of Agriculture, Trade and Consumer Protection (DATCP)

Rule No.: Chs. ATCP 71 and ATCP 70, Wis. Adm. Code

Relating to: Food warehouses.

1. Description of the objective of the rule:

This proposed rule will modify current food warehouse rules to align with federal regulations, state statutory requirements, and existing state regulations. The proposed rule may also exempt food warehouse operators from obtaining an additional food processing plant license for certain food processing activities conducted within a food warehouse. These changes may include, but are not limited to, the following:

- Stating that a food warehouse operator must have a written recall plan and/or keep specified records that ensure adequate trace-back and trace-forward capabilities in response to an emergency such as an outbreak of foodborne illness.

- Clarifying that warehouse operators who, handle, receive, store, sort, shuck, repack, or otherwise process molluscan shellfish for interstate commerce must be licensed for these activities as a food processing plant under ch. ATCP 70, Wis. Adm. Code.

- Clarifying that food warehouse operators storing fish or fishery products, including molluscan shellfish, must comply with the provisions of 21 CFR part 23 (Fish and Fishery Products). These federal regulations require implementation of the Hazard Analysis and Critical Control Point (HACCP) system by seafood processors. Federal regulations state that an establishment storing fish or fishery products is considered to be a processor subject to 21 CFR, part 123. Existing state regulations for food processing plants already require the implementation of HACCP, either by directly citing the federal regulations (s. ATCP 70.18 (1), Wis. Adm. Code; for businesses processing fish for wholesale) or by explicitly stating the HACCP requirements (s. ATCP 70.21 (18), Wis. Adm. Code; molluscan shellfish for interstate commerce).

- Stating that food warehouse operators licensed under ch. ATCP 71, Wis. Adm. Code, may engage in limited packaging or repackaging of foods, other than molluscan shellfish, without obtaining a food processing plant license under ch. ATCP 70, Wis. Adm. Code.

2. Description of existing policies relevant to the rule and of new policies proposed to be included in the rule and an analysis of policy alternatives; the history, background and justification for the proposed rule:

Under state regulations, facilities engaged in food processing must create and maintain food recall plans. In order to facilitate trace-back and trace-forward activities during the response to a recall or foodborne illness outbreak, it may be advantageous to require warehouse operators to likewise have written recall plans or other documentation.

Under state law, food warehouses and food processing facilities are distinct entities that require separate licensing, regulations (ch. ATCP 71 and 70, Wis. Adm. Code, respectively), and oversight. Wisconsin regulations do not generally consider food storage to be food processing. However, the storage of fish and fishery products, including molluscan shellfish, can pose unique threats to human health. Federal regulations treat storage of fish and fishery products, destined for wholesale, as processing and therefore subject to regulations mandating the implementation of the Hazard Analysis and Critical Control Point (HACCP) system. Wisconsin food processing plant regulations (ch. ATCP 70, Wis. Adm. Code) adopt, by reference, the federal HACCP regulations for fish processing done in a food processing plant, but are silent on the federal requirement for HACCP implementation by operators of warehouses which handle fish and fishery products. Wisconsin regulations also explicitly require implementation of HACCP for handling of molluscan shellfish which are involved in interstate commerce. These regulations (which are adapted from model federal guidance) also require the handling, receiving, storing sorting, shucking, repacking or other processing of molluscan shellfish for interstate commerce to be done in a licensed food processing plant. This existing requirement means that some Wisconsin food warehouses, specifically those handling molluscan shellfish for interstate commerce, must hold a second (food processing plant) licenses. The existing regulations for food warehouse operators are silent on this topic. Therefore, Wisconsin's regulations governing food warehouses must be revised to achieve clarity and consistency with the aforementioned existing federal and state regulations.

Under current rules, the minimal packaging and re-packaging of foods in an establishment, where the primary function is the storage of foods processed elsewhere, would also require a second (food processing plant) license. This additional license requirement may place an undue burden on businesses and the department should evaluate an exemption.

Confusion about regulatory and licensing requirements can impede the development of new food businesses. The department will evaluate the clarification of licensing requirements for firms storing fish and fishery products, including molluscan shellfish.

Policy Alternatives. Currently, ch. ATCP 71, Wis. Adm. Code, does not require food warehouse operators to create food recall plans. The existing regulations do, however, require food warehouse operators to keep records of each lot of food received and shipped from the warehouse. If the department does not alter the current rules, the lack of a recall plan, or more comprehensive records, at food warehouses could hinder food emergency response efforts by industry and regulators, thus increasing the risk of a public health hazard.

Without rule revision, there could still be confusion about whether federal seafood HACCP requirements are in effect. Fish and fishery product warehouses operating without HACCP plans would be in violation of federal law and could be increasing the risk of a food safety hazard if certain products are incorrectly stored.

If the department does not alter the current rules, state regulations would continue to require two licenses for food warehouse establishments performing only minimal packaging and re-packaging activities. The additional licensing cost may pose a sufficient economic burden to operators to discourage them from market participation. At the very least, additional licensing cost could be passed on to product consumers, making food products more expensive.

3. Statutory authority for the rule (including the statutory citation and language):

Statutory Authority: ss. 93.07 (1), 97.09 (4), 97.27 (5), and 97.29 (5) Stats.

93.07 Department duties. It shall be the duty of the department:

(1) REGULATIONS. To make and enforce such regulations, not inconsistent with law, as it may deem necessary for the exercise and discharge of all the powers and duties of the department, and to adopt such measures and make such regulations as are necessary and proper for the enforcement by the state of chs. 93 to 100, Stats., which regulations shall have the force of law.

97.09 Rules.

(4) The department may, by rule, establish and enforce standards governing the production, processing, packaging, labeling, transportation, storage, handling, display, sale, including retail sale, and distribution of foods that are needed to protect the public from the sale of adulterated or misbranded foods.

97.27 Food warehouses.

(5) RULE MAKING. The department may promulgate rules to establish the fees, required under sub. (3), or to govern the sanitary operation of food warehouses. Rules may include any of the following:

(a) Standards for the construction and maintenance of food storage facilities.

(b) Standards for the storage, identification and handling of food.

(c) Record-keeping requirements to show the length of time that food is kept in storage.

(d) Freezing and temperature requirements applicable to frozen-food warehouses, frozen-food locker plants and cold-storage warehouses.

97.29 Food processing plants.

(5) RULE MAKING. The department may promulgate rules to establish the fees, required under sub. (3) (a) or (c), or to govern the operation of food processing plants. Rules may include standards for the construction and maintenance of facilities; the design, installation, cleaning and maintenance of equipment and utensils; personnel sanitation; food handling and storage; sanitary production and processing; and food sources and food labeling.

4. Estimate of the amount of time that state employees will spend to develop the rule and of other resources necessary to develop the rule:

DATCP estimates that it will use approximately 0.05 FTE staff to develop this rule. That includes time required for investigation and analysis, rule drafting, preparing related documents, coordinating stakeholder meetings, holding public hearings and otherwise communicating with affected persons and groups. DATCP will use existing staff to develop this rule.

5. Description of all entities that may be impacted by the rule:

Warehouse operators who store fish and fishery products, but have not already implemented a HACCP system, would be most directly impacted because they would be required to develop and operate a HACCP system. Warehouse operators engaged in minimal food packaging or repackaging would be exempted from a requirement to purchase a second (food processing plant) license, unless they were engaging in storage or other specified activities with molluscan shellfish destined for interstate commerce. Warehouse operators would be required to create recall plans or keep specified records needed to facilitate trace-back and trace-forward activities during a food emergency. Consumers would benefit from more comprehensive HACCP requirements related to fish and fishery products, and improved effectiveness of food emergency response efforts.

6. Summary and preliminary comparison of any existing or proposed federal regulation that is intended to address the activities to be regulated by the rule:

Federal fish and fishery products regulations require processors of these foods to adopt HACCP systems. HACCP is an approach for preventing food safety hazards that involves identifying key food processing steps essential for ensuring safety. Processors must develop a plan to monitor and document that each of these key steps is functioning properly and minimizing food safety risks. As part of their HACCP plans, federally-inspected processors are required by 21 CFR 123 (c) (1) (ii) to identify preventive measures for food safety hazards that could arise from microbiological contamination. Microbiological contamination of stored product may occur if appropriate sanitary controls are not maintained.

Federal food inspection is divided between the USDA Food Safety Inspection Service (FSIS) and the Food and Drug Administration (FDA). The FSIS regulates meat and poultry production while the FDA regulates almost all other foods. Under 9 CFR 418, enforced by USDA, and a proposed rule by FDA, pursuant to the Food Safety Modernization Act (FSMA), regulated food facilities are required to create and maintain written food recall plans. Our proposed revisions are consistent with the federal rules and will help integrate federal and state food emergency response efforts.

The department's proposed rule revision will ensure Wisconsin's requirements are consistent with federal regulations and expectations for minimizing food safety hazards and food emergency response capability, while reducing the regulatory burden on some food warehouse operators.

7. Anticipated economic impact

This rule change will have a small economic impact on fish and fishery products warehouse operators and all other warehouse operators engaged in food processing as they will have to devote time and resources to developing HACCP systems, and food recall plans or related documentation. It is unlikely, however, that the additional cost will have a significant negative impact on business. Exemption from obtaining a separate food processing plant license in addition to a food warehouse license will help alleviate the economic burden.

Contact Person: Steve Ingham, Division of Food Safety Administrator, DATCP; Phone (608) 224-4701

Ben Brancel

Ben Brancel
Secretary
Department of Agriculture, Trade and Consumer Protection

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Date Signed