

**PROPOSED ORDER
OF THE WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION
ADOPTING RULES**

- 1 The Wisconsin department of agriculture, trade and consumer protection hereby proposes the
2 following rule *to create* ATCP 70.03 (7) (f), 71.07 (6e) and (6s), 71.025, 71.05 (8) and 71.08;
3 *relating to* food warehouses and food processing plant licensing, and affecting small business.

**Analysis Prepared by the Department
of Agriculture, Trade and Consumer Protection**

This proposed rule modifies current food warehouse rules to clarify which types of food processing activities in a food warehouse require a licensed food warehouse operator to obtain a separate food processing plant license. The proposed rule requires food warehouse operators to create a written recall plan, aligning food warehouse requirements with other types of food establishments.

Statutes Interpreted

Statutes Interpreted: ss. 97.27, Stats., (Food warehouses), and 97.29, Stats., (Food processing plants).

Statutory Authority

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

Explanation of Statutory Authority

DATCP has broad general authority, under s. 93.07 (1), Stats., to adopt rules to implement programs under its jurisdiction. DATCP also has general authority under s. 97.09 (4), Stats., to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. The department has specific authority to promulgate rules related to food warehouses under s. 97.27 (5), Stats., which allows the department to establish rules related to licensing fees and sanitary operation of food warehouses, such as standards for construction and maintenance of food storage facilities, record-keeping requirements, and temperature requirements. The department also has specific authority to promulgate rules related to the sanitary operation of food processing plants under s. 97.29 (5), Stats.

Related Statutes and Rules

Wisconsin's food warehouses and food processing plants are governed by ch. 97, Stats. (Food Regulation). Food warehouses are governed by s. 97.27, Stats., and food processing plants are governed by s. 97.29, Stats. Chapter 70, Wis. Adm. Code, interprets ch. 97, Stats., as it relates to food processing plants and Ch. 71, Wis. Adm. Code interprets state statutes relating to food warehouses.

Plain Language Analysis

This proposed rule does all of the following:

- Modifies ATCP 70.03 to clarify activities that may occur in a food warehouse that do not require a separate food processing plant license.
- Creates a new exemption allowing a licensed food warehouse to conduct minimal repacking activities without a food processing plant license as long as applicable packaging and labeling requirements are met.
- Clarifies licensing, certification and sanitation requirements for packing of molluscan shellfish in a food warehouse.
- Adds definitions for “licensee dealer” and “package” to ATCP 71.01.
- Clarifies that a food warehouse operator must hold certification to operate as a shellfish licensee dealer.
- Requires the operator of a licensed food warehouse that stores fish, fishery products, or molluscan shellfish to conduct a hazard analysis and, if required, develop a Hazard Analysis Critical Control Point (HACCP) plan and implement a HACCP system, and to meet all other applicable requirements in Subchapter IV, ATCP 70.
- Requires food warehouse operators to develop a written recall plan, aligning food warehouse regulations with regulations for other food establishments.

Summary of, and Comparison with Existing or Proposed Federal Statutes and Regulations

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

Federal fish and fishery products regulations require processors of these foods to adopt the HACCP system. HACCP is an approach for preventing food safety hazards that involves a processor conducting a hazard analysis to identify hazards that are likely to occur in the production of a particular food. If such hazards are identified, the processor then identifies key food processing steps essential for ensuring safety, and develops a plan to monitor and document

that each of these key steps is functioning properly and minimizing food safety risks. As part of their hazard analysis processors under FDA jurisdiction are required by 21 CFR 123.6 (c) (1) to identify preventive measures for food safety hazards that could arise from contamination with microbiological, chemical, or physical hazards. This contamination of stored product may occur in a food warehouse 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 processing of meat, poultry, and certain egg products 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. The proposed revisions in this rule are consistent with the federal rules and will help integrate federal and state food emergency response efforts.

Comparison with Rules in Adjacent States

Iowa and Minnesota

Iowa and Minnesota license and regulate food warehouses as food processing plants. Minnesota issues many food warehouse operators a Wholesale Food Handler License, while cold storage facilities must hold a Wholesale Food Processor or Manufacturer License. Iowa licenses food warehouses as Food Processing Plants. Dry food storage, refrigerated storage, frozen storage, and repackaging/relabeling are listed as facility subcategories for food warehouses on the Iowa Food Processing Plant License application form. Unlike in Wisconsin, a food warehouse operator who also conducts food processing in either Iowa or Minnesota would hold one license that would cover both warehouse and processing activities. The license fees in both states are determined based on the overall values of the food processed and stored.

Both Iowa and Minnesota adopt 21 CFR 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, and inspect warehouses for compliance with requirements therein related to basic sanitation, facility and equipment, and personnel.

Neither Minnesota nor Iowa have a specific requirement for food warehouse operators to develop a written recall plan. Minnesota has record-keeping requirements specifically pertaining to cold storage facilities. Operators of Minnesota cold storage facilities are required to keep records showing the kind, quantities, date of entry, and date of withdrawal for stored food; names and addresses of parties withdrawing foods; and the sale or transfer of foods during storage, with dates, names, and business addresses.

Illinois

Illinois does not currently require licensing of food warehouses or food processing plants. Illinois has specific statutory requirements for cold storage facilities, but other food storage facilities are treated as food processing plants. While the Illinois Department of Public Health oversees food processing plants, including most food warehouses, the Illinois Department of Agriculture is responsible for regulating refrigerated warehouses. Illinois' food warehouse regulations are

described in “Manufacturing, Processing, Packing or Holding of Food Code”, which is found in Part 730 of Title 77 (1) (m) of their administrative code. Section 730.9010 of the Illinois’ administrative code exempts raw agricultural products that are “ordinarily cleaned, prepared, treated or otherwise processed before being marketed to the consuming public” from Illinois’ food processing regulations. Similarly, Wisconsin law exempts washing and packaging fresh fruits and vegetables from food processing regulations if the fruits and vegetables are not otherwise processed at the packaging establishment. Wisconsin state law also does not require a food warehouse license for a business that is solely storing grain or other raw agricultural commodities.

Although Illinois does not explicitly require a food warehouse operator to prepare a written recall plan, section 730.7090 of the Illinois’ administrative code requires “meaningful coding of products sold or otherwise distributed from a manufacturing, processing, packing, or repacking activity” to “enable positive lot identification to facilitate, where necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use.” Illinois requires these records to be retained for a period of time that exceeds the shelf life of the product, but not more than 2 years.

Illinois has adopted, by reference, federal regulations addressing molluscan shellfish. Wisconsin has equivalent regulations for molluscan shellfish.

Michigan

Michigan defines a food warehouse as a food establishment that “stores or distributes prepackaged food, including a small or large food warehouse, distribution center, transfer station, public cold storage facility, or reclamation center.” Michigan requires food warehouse operators to hold a separate food warehouse license, and regulates food warehouses under adopted federal regulations (21 CFR 110) and the Michigan Food Law. In addition to general sanitation requirements, section 289.4105 (1)(m) of the Michigan Food Law outlines licensing exemptions for food warehouse operators and food processors if the warehouse: contains or the processor handles only uncut fruits or vegetables that are not considered potentially hazardous food (time/temperature control for safety food) as defined in the food code, and is owned and operated by the person producing the fruits or vegetables, and only contains the owner’s/operator’s produce or the same produce items raised by other producers. Activities at exempted warehouses are limited to storing, grading, sorting, packing, washing, trimming, and refrigerating.

Michigan doesn’t explicitly require food warehouses to develop a recall plan but, like Illinois, the Michigan Food Law includes a provision requiring that all products “...sold or otherwise distributed from a manufacturing, processing, packing, or repacking activity shall be marked with a meaningful, visible, and legible code to enable positive lot identification and to facilitate, where necessary, the segregation of specific lots that may have become contaminated or are otherwise unfit for their intended use.” Like Illinois, Michigan has adopted, by reference, federal regulations related to the control of molluscan shellfish.

Summary of Factual Data and Analytical Methodologies

Proposed rule changes were developed after consultation with industry, a review of federal requirements, and a review of practices in neighboring states.

Analysis and Supporting Documents used to Determine Effect on Small Business

Determining the effect on small business was based upon regular contact with industry and reviewing licensing data within the department's records.

Effect on Small Business

This rule change is expected to 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. 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 would be required to create recall plans or keep specified records needed to facilitate trace-back or trace-forward activities during a food emergency. It is unlikely, however, that the additional cost of these efforts 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 any economic burden on small businesses. 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.

DATCP Contact

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Where and When Comments May Be Submitted

Questions and comments related to this rule may be directed to:

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Rule comments will be accepted up to two weeks after the last public hearing is held on this rule. Hearing dates will be scheduled after this rule is approved by the Board of Agriculture, Trade and Consumer Protection.

1 **SECTION 1.** ATCP 70.03 (7) (f) is created to read:

2 ATCP 70.03 (7) (f) A licensed food warehouse under s. 97.27, Stats., at which one or
3 more of the following activities are the only food processing activities performed:

4 1. Packing molluscan shellfish, provided that the licensed warehouse operator holds a
5 licensee dealer certification as required under ATCP 70.21 (2), that annual inventory value of
6 molluscan shellfish packed at the licensed warehouse does not exceed 25% of the gross annual
7 inventory value of the food warehouse, and the licensed food warehouse meets all of the
8 applicable requirements of ATCP 70.21.

9 2. Packing items that are already packaged and labeled for retail sale into containers for
10 further distribution.

11 3. Combining two or more food items that are already individually packaged and labeled for
12 final retail sale into a combination package for retail sale, if the label on each individual item
13 inside the combination package remains visible or if the package of combined items is labeled
14 for retail sale. All packaging and labels shall comply with ATCP 70.10.

15 4. Manufacturing ice for use in the shipment of foods, or to cool or keep foods cold while in
16 transit or stored in the warehouse. Ice used for this purpose must meet the standards in ATCP
17 70.07 (8). Ice must be made on site in a commercial ice machine and may not be bagged,
18 distributed or sold separately from food items that it is used to cool.

1 **SECTION 2.** ATCP 71.01 (6e) and (6s) are created to read:

2 ATCP 71.01 (6e) “Licensee dealer” means the operator of a plant or warehouse licensed in
3 Wisconsin for the activities of shellstock shipper, shucker-packer, repacker, or reshipper.

4 ATCP 71.01 (6s) “Package” has the meaning given in ATCP 90.01(16).

5 **SECTION 3.** ATCP 71.025 is created to read:

6 ATCP 71.025 **Shellfish licensee dealer certification.** No person may operate as a shellfish
7 licensee dealer without a valid annual certificate issued by the department under s. ATCP 70.21.

8 A certificate is issued annually by the department under ATCP 70.21 (3).

9 **SECTION 4.** ATCP 71.05 (8) is created to read:

10 ATCP 71.05 (8) FISH OR FISHERY PRODUCTS HACCP REQUIRED. A licensed food warehouse
11 that engages in the storage of fish as defined in 21 CFR 123 (d), fishery products as defined in 21
12 CFR 123.3 (e), or molluscan shellfish as defined in 21 CFR 123.3 (h) shall conduct a hazard
13 analysis and implement a seafood HACCP system in accordance with the applicable
14 requirements in Subchapter IV, ATCP 70.

15 **SECTION 5.** ATCP 71.08 is created to read:

16 ATCP 71.08 **Recall plan required. (1) PLAN REQUIRED.** A food warehouse operator shall
17 have a written plan for identifying and recalling food stored at or distributed from that
18 warehouse, should a food recall become necessary. The operator shall update the plan as
19 necessary, and shall make it available to the department for inspection and copying upon request.

20 **(2) PLAN CONTENTS.** A plan under sub. (1) shall do all of the following:

21 (a) Identify key individuals or positions that are responsible for planning, approving, and
22 implementing recalls on behalf of the food warehouse operator.

1 (b) Identify key individuals or entities to be contacted or consulted in connection with a
2 recall.

3 (c) Include procedures for the routine identification, dating, and tracking of food production
4 lots, so that that affected lots can be identified and distinguished from unaffected lots in the event
5 of a recall.

6 (d) Include procedures to enable routine identification, dating, and tracking of food
7 shipments from the food warehouse. Tracking shall identify shipment recipients and contents,
8 cross-referenced to production lots, so that recipients of affected lots can be contacted in the
9 event of a recall.

10 (e) Include procedures for determining the nature and scope of a recall, including affected
11 food production lots, shipments, and shipment recipients.

12 (f) Include procedures for identifying and communicating with affected persons, including
13 suppliers, food shipment recipients, down-line buyers, consumers, government agencies, and
14 others.

15 (g) Identify potential target audiences for recall information, including consumers,
16 distributors, and government agencies.

17 (h) Identify potential methods for communicating with target audiences under par. (g).

18 (i) Identify key information, including the identity of the affected food, the reason for the
19 recall, and suggested actions to be taken by affected persons, which may need to be
20 communicated in the event of a recall.

21 **(3) DEVIATIONS FROM PLAN.** Actual recall procedures may deviate from the recall plan under
22 sub. (1), as circumstances warrant.

1 **SECTION 6. EFFECTIVE DATE AND INITIAL APPLICABILITY.** This rule takes effect on the
2 first day of the month following publication in the Wisconsin administrative register, as provided
3 under s. 227.22(2)(intro.).

Dated this _____ day of _____, 2015.

WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By _____
Ben Brancel, Secretary