

DATCP Docket No. 14-R-11
Rules Clearinghouse No. 15-093

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

The Wisconsin department of agriculture, trade and consumer protection hereby adopts the following rule *to renumber* ATCP 71.01 (6m), *to amend* ATCP 71.05 (7) (a), 70.18 (2) and 70.19 (1) (d); and *to create* ATCP 70.03 (7) (f), 71.01 (2m), 71.01 (6c), (6d), (6p), and (6t), 71.025, 71.02 (11), and 71.05 (8); *relating to* food warehouse and food processing plant licensing and operation, 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 do not obligate a licensed food warehouse operator to obtain a separate food processing plant license. The proposed rule harmonizes the food warehouse refrigeration temperature requirements for eggs, dairy products, fish, and fishery products in reduced-oxygen packaging, and molluscan shellfish with the requirements found in other rules. To reduce confusion about which federal food safety regulations must be followed by food warehouse operators, the proposed rule adopts federal regulations by reference for certain types of food warehouses, and indicates that other food warehouses can qualify for an exemption from most requirements of the new Federal Preventive Controls–Human Food rule.

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

The Department of Agriculture, Trade and Consumer Protection (“Department”) has broad general authority, under s. 93.07 (1), Stats., to adopt rules to implement programs under its jurisdiction. The Department 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 ATCP 70, Wis. Adm. Code, interprets ch. 97, Stats., as it relates to food processing plants and Ch. ATCP 71, Wis. Adm. Code, interprets state statutes relating to food warehouses.

Plain Language Analysis

This proposed rule does all of the following:

- Adds definitions for “licensee dealer,” a term applicable to the regulation of molluscan shellfish, and defined already in s. ATCP 70.21 (s); “Hazard Analysis Critical Control Point (HACCP) system” and “package” to s. ATCP 71.01.
- Modifies s. ATCP 70.03 to specify molluscan shellfish-handling activities that may be done in a food warehouse, under a no-fee licensee dealer certification issued under s. ATCP 70.21 (2), and for which a separate food processing plant license is not required.
- Creates new exemptions allowing a licensed food warehouse to do the following without a food processing plant license: 1) re-pack foods that are already packaged and labeled for retail sale into containers for further distribution, 2) combine two or more individually packaged and labeled food items into a combination package for retail sale, and 3) manufacture ice that is used for temperature control of food during shipment or storage.
- Requires the operator of a licensed food warehouse that stores fish, fishery products, or molluscan shellfish to operate under a HACCP system.
- Harmonizes the food warehouse refrigeration temperature requirements for eggs, dairy products, fish, and fishery products stored in reduced-oxygen packaging, and molluscan shellfish with the requirements found in ch. ATCP 88 (Eggs), ch. ATCP 65 (Milk and Milk Products), and ch. ATCP 70 (Food Processing Plants). This harmonization will reduce confusion for some food warehouse operators who store only the afore-mentioned products.
- Modifies ss. ATCP 70.18 (2) and ATCP 70.19 (1) (d) to reflect current science on safe refrigeration temperatures for raw and processed fish and hot-smoked fish, in reduced-oxygen packaging.
- Clarifies which portions of federal regulations implementing the Federal Food Safety Modernization Act (FSMA) must be followed by Wisconsin-licensed food warehouse operators.

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

This proposed rule revision will ensure Wisconsin's requirements are consistent with U.S. Food and Drug Administration (FDA) regulations and expectations for minimizing food safety hazards, while reducing the state regulatory burden on some food warehouse operations.

Fish and fishery products regulations enforced by FDA require processors of these foods to conduct a hazard analysis and, if indicated, develop and follow a HACCP plan, i.e., implement a HACCP system. In developing a seafood HACCP plan, a processor identifies key food processing steps essential for ensuring safety and spells out how 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 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. Contamination of stored product may occur in a food warehouse if appropriate sanitary controls are not maintained, so a food warehouse holding fish and fishery products generally must operate in accordance with a HACCP plan.

The FDA recently published a final rule revising the agency's definitions of current good manufacturing practice and requiring "food facilities" to implement Hazard Analysis and Risk-Based Preventive Controls. This rule, known as the Preventive Controls–Human Foods rule, implements provisions of the FSMA. Food warehouses generally are food facilities as defined under FSMA and the Preventive Controls–Human Foods rule. However, several exemptions and modified requirements may apply. A food warehouse that meets the FDA definition of a "qualified facility," generally one that sells a small volume of food predominantly to consumers or retail food establishments, must only submit an attestation of its status to FDA and then comply with state regulations. A food warehouse that is subject to the FDA seafood HACCP regulations need not meet requirements to implement a food safety plan and supply chain management practices. A warehouse that is not subject to the FDA seafood HACCP regulations, and sells only unexposed packaged foods, also does not have to implement a food safety plan and supply chain management practices. However, if a food warehouse in this category is storing packaged foods for which time and temperature control are required to ensure product safety and wholesomeness, the food warehouse operator must develop and implement a temperature control and documentation system as defined in the rules. A food warehouse storing exposed food is required to implement a food safety plan and supply chain management practices. The proposed rule cites the pertinent sections of the FSMA rule so that Wisconsin-licensed food warehouse operators know what federal requirements they must meet.

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 (Chapter 28A, Minnesota Statutes). Iowa licenses food warehouses as Food Processing Plants under Chapter 137F, Iowa Code. 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 value 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. The Preventive Controls–Human Food rule implementing FSMA will replace 21 CFR 110 with Subpart B (Current Good Manufacturing Practice) of 21 CFR 117.

Neither Iowa or Minnesota participate in the Interstate Shellfish Sanitation Conference (ISSC) and therefore businesses in these states cannot store, sort, shuck, repack, or otherwise process molluscan shellfish for interstate commerce. Wisconsin is a member of ISSC and has regulations for processing of shellfish for interstate commerce.

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.

Illinois is a participant in the ISSC and regulates the processing of molluscan shellfish for interstate commerce.

Michigan

Under the Michigan Food Law, 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, like Iowa and Minnesota, regulates food warehouses under adopted federal regulations (21 CFR 110).

Like Illinois, Michigan is an ISSC member and has promulgated regulations related to molluscan shellfish processing for interstate commerce.

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

We determined the effect on small business after contacting 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 warehouse operators storing fish, fishery products, or molluscan shellfish, as some will have to devote time and resources to obtain HACCP training, conduct a hazard analysis, and, if indicated, develop and follow a HACCP plan. Some warehouse operators will have to obtain no-fee licensee dealer certification if they engage in specified activities with molluscan shellfish destined for interstate commerce. The exemption from obtaining a separate food processing plant license, in addition to a food warehouse license, for repacking of already-packaged foods, may reduce the economic burden on small businesses.

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

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

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

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

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

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

SECTION 2. ATCP 70.18 (2) is amended to read:

(2) Raw or processed fish that is packaged in reduced-oxygen packaging, as defined in sub. ATCP 70.02 (22n), shall immediately be refrigerated to a temperature of 38° F. (3° C.) or below, and shall be kept at or below that temperature until sold to consumers at retail, unless one of the following applies:

SECTION 3. ATCP 70.19 (1) (d) is amended to read:

(d) If hot-smoked fish contained in ~~the package~~ reduced-oxygen packaging as defined in sub. ATCP 70.02 (22n) are sold or distributed in an unfrozen state, the words “PERISHABLE – KEEP REFRIGERATED AT OR BELOW 38° F.” in conspicuous letters at least the size of those used in the food name.

SECTION 4. ATCP 71.01 (2m) is created to read:

(2m) “Facility” has the meaning given in 21 CFR 117.3.

SECTION 5. ATCP 71.01 (6c), (6d), (6p) and (6t) are created to read:

(6c) “HACCP system” means the process of analyzing food manufacturing or storage for food safety hazards, and developing and implementing a written hazard analysis and critical control points plan in accordance with 21 CFR, part 123.6 – 123.9.

(6d) “Licensee dealer” means the operator of a food processing plant or food warehouse licensed in Wisconsin for the activities of shellstock shipper, shucker-packer, repacker, or reshipper.

(6p) “Package” has the meaning given in ATCP 90.01(16).

ATCP 71.01 (6t) “Qualified facility” has the meaning given in 21 CFR 117.3.

SECTION 6. ATCP 71.01 (6m) is renumbered as ATCP 71.01(6h).

SECTION 7. ATCP 71.025 is created to read:

71.025 Shellfish licensee dealer certification. No person may operate as a shellfish licensee dealer without a valid annual certificate issued by the department under ATCP 70.21. A certificate is issued annually by the department under ATCP 70.21 (3).

SECTION 8. ATCP 71.02 (11) is created to read:

(11) FEDERAL REQUIREMENTS. (a) A food warehouse which is also a qualified facility shall comply with the requirements of this chapter and 21 CFR 117.5(a).

(b) A food warehouse that is a facility, but is not a qualified facility, and only stores unexposed packaged potentially hazardous food shall comply with the requirements of this chapter, and 21 CFR 117.7 and 117.206.

(c) A food warehouse that is a facility, but is not a qualified facility, and stores exposed food shall comply with the requirements of this chapter and 21 CFR 117, Subparts C and G.

SECTION 9. ATCP 71.05 (7) (a) is amended to read:

(a) Potentially hazardous refrigerated food stored at a food warehouse shall at all times be kept refrigerated at a temperature of 40°F. (4°C.) or below, except:

1. Eggs shall be kept refrigerated at an ambient temperature of 45°F. (7°C.) or below.
2. Dairy products as defined in s. 97.20 (1) (b) 1. through 5., Stats., shall be kept at 45 ° F. (7° C.) or below.
3. Fish and fishery products in reduced-oxygen packaging as defined in sub. ATCP 70.02 (22n) shall be kept at or below 38° F (3° C.), in accordance with s. ATCP 70.18 and s. 70.19.
4. Molluscan shellfish shall be iced or refrigerated to the extent necessary to maintain internal shellstock temperature as required in s. ATCP 70.21, and
5. Potentially hazardous frozen food shall at all times be kept frozen at a temperature of 5°F. (-15°C.) or below.

SECTION 10. ATCP 71.05 (8) is created to read:

(8) FISH OR FISHERY PRODUCTS HACCP SYSTEM REQUIRED. A licensed food warehouse that engages in the storage of fish as defined in 21 CFR 123 (d), fishery products as defined in 21 CFR 123.3 (e), or molluscan shellfish as defined in 21 CFR 123.3 (h) shall operate under a seafood HACCP system in accordance with the applicable requirements in Subch. IV, ATCP 70.

SECTION 11. EFFECTIVE DATE AND INITIAL APPLICABILITY. This rule takes effect on the first day of the month following publication in the Wisconsin administrative register, as provided under s. 227.22(2)(intro.).