



State of Wisconsin  
Governor Scott Walker

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**Department of Agriculture, Trade and Consumer Protection**  
Ben Brancel, Secretary

**DATE:** April 1, 2016

**TO:** The Honorable Mary Lazich  
President, Wisconsin State Senate  
Room 220 South, State Capitol  
Madison, WI 53707-7882

The Honorable Robin Vos  
Speaker, Wisconsin State Assembly  
Room 211 West, State Capitol  
Madison, WI 53708-895

**FROM:** Sandy Chalmers, Assistant Deputy Secretary

**SUBJECT: ATCP 70, Food Processing Plants, and ATCP 71, Food Warehouses and Milk Distributors;  
Final Rule**

### *Introduction*

The Department of Agriculture, Trade and Consumer Protection (“Department”) is transmitting this rule for legislative committee review, as provided in s. 227.19 (2) and (3), Stats. The Department will publish notice of this referral in the Wisconsin Administrative Register, as provided in s. 227.19 (2), Stats.

### *Background*

Under current Wisconsin rules, a food warehouse that engages in any food processing activities, even low-risk packaging of already-packaged foods, must hold separate food warehouse and food processing plant licenses. This requirement may create an unnecessary burden for some warehouse operators.

Some food warehouse operators may be unaware that they are subject to Federal Hazard Analysis and Critical Control Point (HACCP) requirements for ensuring food safety. These requirements are in place to protect the public against health hazards associated specifically with molluscan shellfish, fish, and other fishery products. Storage of fish, fishery products, and molluscan shellfish is defined in federal regulations as processing of these products, and businesses doing this type of processing are subject to HACCP provisions requiring them to conduct a hazard analysis and, if significant hazards are identified, to develop and implement a seafood HACCP plan, *i.e.*, implement a HACCP system. These HACCP requirements are already adopted and applied to commonly recognizable fish processing establishments in Wisconsin, but they have only been officially applied to food warehouse operators by federal regulators.

Under ch. ATCP 70, warehouse-based shippers, shucker-packers, repackers, and reshippers of molluscan shellfish for interstate commerce must be certified as licensee-dealers and meet existing state regulatory

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requirements under the federal-state Interstate Shellfish Sanitation Conference program. This requirement is not clearly spelled out in ch. ATCP 71. Discrepancies exist in refrigerated storage temperature requirements for potentially hazardous foods (ch. ATCP 71), eggs (ch. ATCP 88), dairy products (ch. ATCP 65), fish and fishery products in reduced-oxygen packaging (ch. ATCP 70), and molluscan shellfish (ch. ATCP 70).

Some provisions in the federal Preventive Controls – Human Foods rule, implementing the FDA Food Safety Modernization Act (FSMA) apply to Wisconsin food warehouses although, depending on warehouse scale and scope, many food warehouse are exempt. These requirements are not mentioned in ch. ATCP 71.

### ***Rule Content***

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 ATCP 70.21 (s); “HACCP system,” and “package” to ATCP 71.01.
- Modifies ATCP 70.03 to specify molluscan shellfish-handling activities that may be done in a food warehouse under a no-fee licensee dealer certification (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 s. 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 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 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 products 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 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. By reviewing the licensing data, the Department was able to identify the number of warehouse operators who will be affected by these proposed rule changes and each one's size, based upon the annual license fee paid.

### ***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.

### ***Public Hearing***

DATCP held three public hearings at state office buildings:

February 12, 2016	LaCrosse, Wisconsin
February 17, 2016	Green Bay, Wisconsin
February 19, 2016	Waukesha, Wisconsin

No oral or written comments were submitted at any of the hearings.

### ***Changes from the Hearing Draft:***

In response to comments made during further internal reviews, and in response to comments made by the Wisconsin Legislative Council Rules Clearinghouse, the following changes were made to the Hearing Draft:

- Paragraph ATCP 70.03 (7) (f) was modified to indicate that the exemption from a food processing plant license was for a warehouse operator repacking, not packing, molluscan shellfish.
- Subsections ATCP 70.18 and 70.19 were revised to reflect the latest FDA guidance on safe refrigeration temperatures for raw and processed fish stored in reduced-oxygen packaging.
- A definition for "HACCP system" was added to Section 71.01.
- Different refrigeration storage temperature requirements for dairy products, fish and fishery products under reduced-oxygen packaging, and molluscan shellfish were added to subsection ATCP 71.05 (7).
- Subsection ATCP 71.05 (8) was revised to use the term "operate under a HACCP system" instead of separating out a hazard analysis from the HACCP system.