



State of Wisconsin
Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection

Ben Brancel, Secretary

DATE: October 25, 2015

TO: Board of Agriculture, Trade and Consumer Protection

FROM: Ben Brancel, Secretary *Ben Brancel*
Steve Ingham, Division of Food Safety Administrator *Steve Ingham*

SUBJECT: ATCP 70 and 71, as they relate to Food Warehouses; Hearing Draft Rule

PRESENTED BY: Steve Ingham

REQUESTED ACTION:

At the November 18, 2015, Board meeting, the department will ask the Board to authorize public hearings on a proposed rule to modify chs. ATCP 70, (Food Processing Plants), and ATCP 71, (Food Warehouses), as these rules relate to food warehouses. This proposed rule will ensure Wisconsin's requirements are consistent with federal regulations and expectations for minimizing food safety hazards, while reducing the regulatory burden on some food warehouse operations. The proposed rule modifies current food warehouse rules to clarify which types of food processing activities in a food warehouse obligate a licensed food warehouse operator to obtain a separate food processing plant license. The proposed rule clarifies requirements for food warehouses that hold fish, fishery products, or molluscan shellfish. The proposed rule harmonizes the food warehouse refrigeration temperature requirement for eggs with the requirement found in ch. ATCP 88, (Eggs). To reduce confusion about which new 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.

SUMMARY:

Background

Under state law, food warehouses (ch. ATCP 71) and food processing facilities (ch. ATCP 70) are distinct entities that require separate licensing. Under current rules, a food warehouse that engages in food processing activities, even low-risk repacking of already-packaged foods, must hold separate food warehouse and food processing plant licenses. The proposed rule change exempts the following from food warehouse activities that must be done under a food processing plant license: 1) re-packing foods that are already packaged and labeled for retail sale into containers for further distribution, 2) combining two or more individually packaged and labeled food items into a combination package for retail sale, and 3) manufacturing ice that is used for temperature control of food during shipment or storage.

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This rule also modifies food warehouse regulations to achieve consistency with federal and state regulations related to the storage of fish, fishery products, and molluscan shellfish. These products pose unique threats to human health, including histamine production in temperature-abused fish species such as tuna, and transmission of *Vibrio vulnificus* via improperly harvested or handled molluscan shellfish. As part of the existing federal-state cooperative program for shellfish safety, state regulations require that Wisconsin firms, including food warehouses, that ship, shuck and pack, re-pack, or re-ship molluscan shellfish for interstate commerce must hold a no-fee licensee-dealer certification. The proposed rule clarifies this requirement in ch. ATCP 71 (Food Warehouses).

Federal regulations include the storage of fish, fishery products, and molluscan shellfish in the definition of processing of these products, and therefore firms performing these activities are subject to Hazard Analysis and Critical Control Point (HACCP) regulations. Wisconsin food processing plant regulations (ch. ATCP 70) adopt, by reference, the federal HACCP regulations for processing of fish and fishery products done in a food processing plant (21 CFR 123, cited in s. ATCP 70.18). Most Wisconsin food warehouse operators are aware of, and follow the HACCP regulations without being explicitly required to do so in Wisconsin rules. The proposed rule clarifies that the federal HACCP requirements also apply to operators of warehouses handling fish, fishery products, and molluscan shellfish, and will be enforced by the department.

This proposed rule harmonizes the food warehouse refrigeration temperature requirement for eggs with the requirement found in ch. ATCP 88 (Eggs). This harmonization will remove confusion over the maximum refrigeration temperature for egg producers or egg handlers who receive eggs from another egg producer or egg handler and store the eggs for more than 24 hours before selling them.

Finally, this proposed rule clarifies which portions of new federal regulations implementing the FDA Food Safety Modernization Act (FSMA) must be followed by Wisconsin-licensed food warehouse operators.

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 already defined in ATCP 70.21(1)(s), and “package” to 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 in 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 conduct a hazard analysis and, if indicated, develop and follow a HACCP plan, and to meet all other applicable requirements in Subchapter IV, ATCP 70.
- Clarifies that eggs stored in a food warehouse must be kept at an ambient temperature of not more than 45 degrees Fahrenheit (7 degrees Celsius).
- Clarifies which portions of new federal regulations implementing the FDA Food Safety Modernization Act (FSMA) must be followed by Wisconsin-licensed food warehouse operators. These requirements are shown schematically in Figure 1.

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. 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 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, which creates 21 CFR 117 and is 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 system for controlling, monitoring, and documenting temperature 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 Preventive Controls – Human Food rule so that Wisconsin-licensed food warehouse operators know the 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 food storage facility/warehouse subcategories 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 will hold one license that covers 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 recently published FDA 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.

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 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.

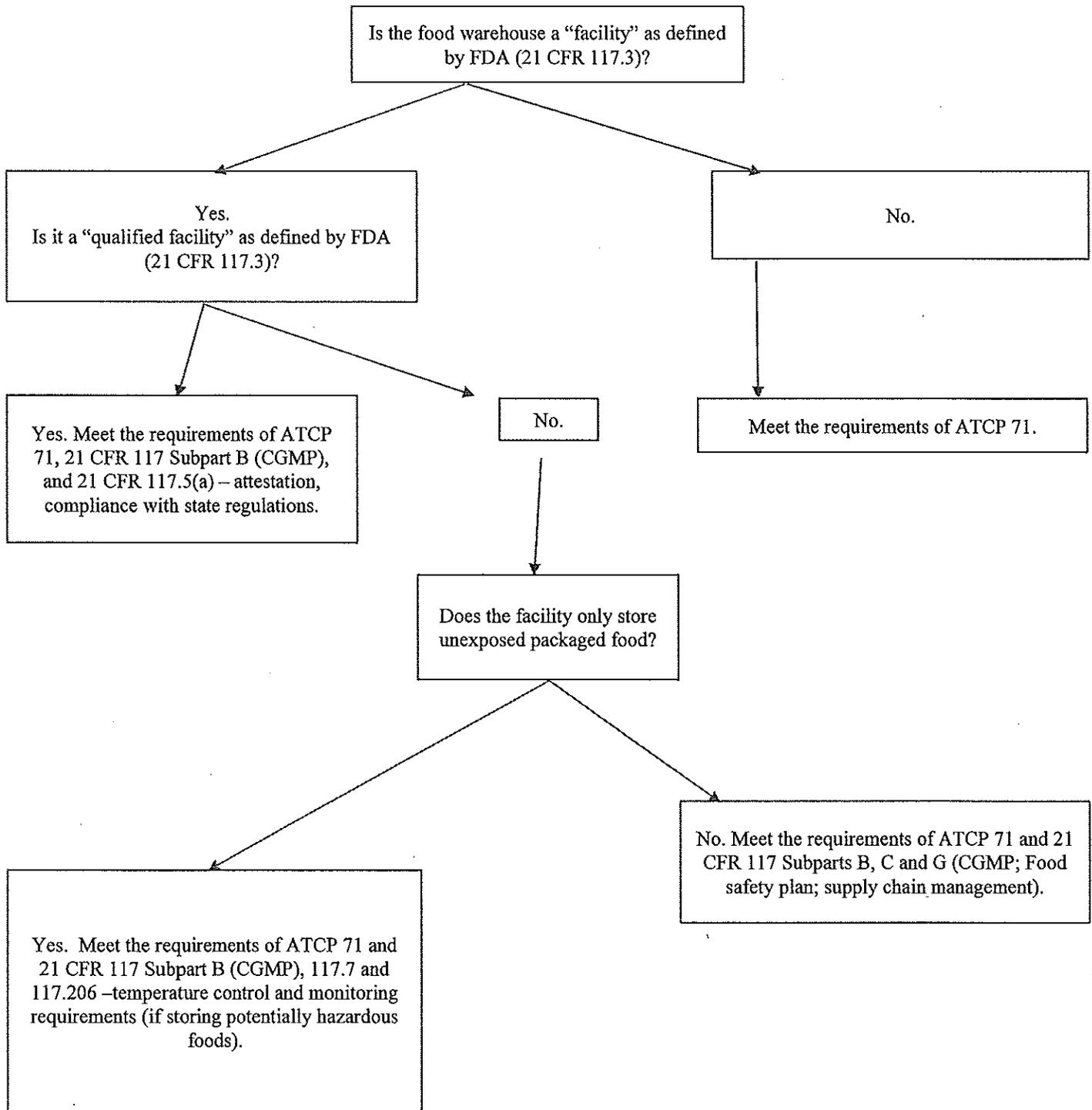
Next Steps

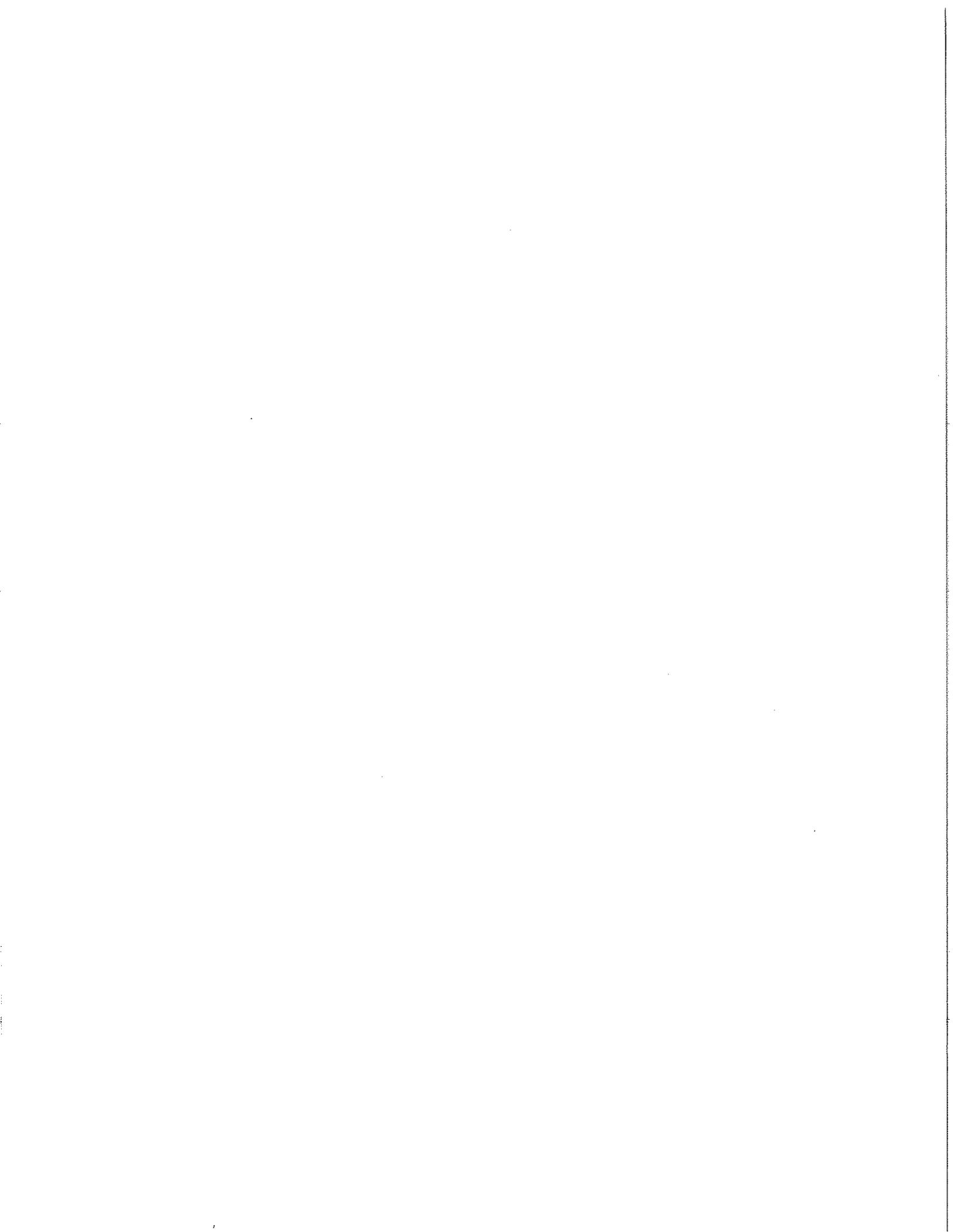
If the Board authorizes public hearings on this rule, the department will refer a copy of the rule to the Legislative Council Rules Clearinghouse and publish a hearing notice in the Wisconsin Administrative Register.

Following the public hearings, the department will evaluate all comments received at the hearings and prepare a final draft rule for the Board's consideration. If the Board approves a final draft rule, the department will transmit the final draft rule for the Governor's approval. After the Governor's approval, the final draft will be submitted for legislative committee review. If the Legislature has no objections to the rule, the Secretary will

sign the final rulemaking order and transmit it for publication. The rule will take effect upon publication in the Wisconsin Administrative Register.

Figure 1. State and federal food safety regulatory requirements applicable to food warehouse businesses.





**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 renumber* ATCP 71.01 (6m), *to amend* ATCP 71.05 (7) (a); and *to create*
3 ATCP 70.03 (7) (f), 71.01 (2m), 71.01 (6d), (6p), and (6t), 71.02 (11), 71.025, and 71.05 (8);
4 *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 obligate a licensed food warehouse operator to obtain a separate food processing plant license. The proposed rule harmonizes the food warehouse refrigeration temperature requirement for eggs with the requirement found in ch. ATCP 88, (Eggs). To reduce confusion about which new 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

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:

- Adds definitions for “licensee dealer”, a term applicable to the regulation of molluscan shellfish and already defined in ATCP 70.21 (1) (s), 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 in 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 conduct a hazard analysis and, if indicated, develop and follow a Hazard Analysis Critical Control Point (HACCP) plan, and to meet all other applicable requirements in Subchapter IV, ATCP 70.
- Harmonizes the food warehouse refrigeration temperature requirement for eggs with the requirement found in ch. ATCP 88.18 (2). This harmonization will remove confusion over the maximum refrigeration temperature for egg producers or egg handlers who receive eggs from another egg producer or egg handler and store the eggs for more than 24 hours before selling them.
- Clarifies which portions of new federal Preventive Controls – Human Food regulations implementing the FDA 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 Hazard Analysis Critical Control Point (HACCP) plan. 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 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 federal Current Good Manufacturing Practice regulations and 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 system for controlling, monitoring, and documenting temperature 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 Preventive Controls – Human Food rule so that Wisconsin-licensed food warehouse operators know what federal requirements they must meet.

Comparison with Rules in Adjacent States

Iowa and Minnesota

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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 food storage facility / warehouse subcategories 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 will hold one license that covers both warehouse and processing activities. The license fees in both states are determined based on the overall value of the food processed and stored.

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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 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.

DATCP Contact

Peter Haase, Director
Bureau of Food Safety and Inspection
Department of Agriculture, Trade and Consumer Protection
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Madison, WI 53708-8911
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E-Mail: Peter.Haase@Wisconsin.gov

Where and When Comments May Be Submitted

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

Peter Haase, Director
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Department of Agriculture, Trade and Consumer Protection
P.O. Box 8911
Madison, WI 53708-8911
Telephone: (608) 224-4711
E-Mail: Peter.Haase@Wisconsin.gov

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

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

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

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

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

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

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

21 ATCP 71.01 (2m) “facility” has the meaning given in 21 CFR 117.3.

22 **SECTION 3.** ATCP 71.01 (6d), (6p) and (6t) are created to read:

1 ATCP 71.01 (6d) "Licensee dealer" means the operator of a food processing plant or food
2 warehouse licensed in Wisconsin for the activities of shellstock shipper, shucker-packer,
3 repacker, or reshipper.

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

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

6 **SECTION 3. ATCP 71.01 (6m) is renumbered as ATCP 71.01 (6h)**

7 **SECTION 4. ATCP 71.025 is created to read:**

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

11 **SECTION 5. ATCP 71.02 (11) is created to read:**

12 ATCP 71.02 (11) **FEDERAL REQUIREMENTS.** (a) A food warehouse which is also a qualified
13 facility shall be comply with the requirements of this chapter and 21 CFR 117, Subpart B and
14 117.5(a).

15 (b) A food warehouse that is a facility, but is not a qualified facility, and only stores
16 unexposed packaged food shall comply with the requirements of this chapter, and 21 CFR 117,
17 Subpart B and 117.7 and 117.206.

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

20 **SECTION 6. ATCP 71.05 (7) (a) is amended to read:**

21 ATCP 71.05 (7) **REFRIGERATED AND FROZEN FOOD.** (a) Potentially hazardous refrigerated
22 food stored at a food warehouse shall at all times be kept refrigerated at a temperature of
23 40°F. (4°C.) or below, except eggs shall be kept refrigerated at an ambient temperature of

1 45°F. (7°C.) or below. Potentially hazardous frozen food shall at all times be kept frozen at a
2 temperature of 5°F. (-15°C.) or below.

3 **SECTION 7.** ATCP 71.05 (8) is created to read:

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

9
10 **SECTION 8. EFFECTIVE DATE AND INITIAL APPLICABILITY.** This rule takes effect on the
11 first day of the month following publication in the Wisconsin administrative register, as provided
12 under s. 227.22(2) (intro.).

Dated this _____ day of _____, 2015.

WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By _____
Ben Brancel, Secretary

Wisconsin Department of Agriculture, Trade and Consumer Protection

Initial Regulatory Flexibility Analysis

Rule Subject: Food Warehouses
Adm. Code Reference: ATCP 70 and 71
Rules Clearinghouse #: Not assigned
DATCP Docket #: 14-R-11

Rule Summary

This proposed rule revision will ensure Wisconsin's requirements are consistent with federal regulations and expectations for minimizing food safety hazards, while reducing the regulatory burden on some food warehouse operations. The proposed rule modifies current food warehouse rules to clarify which types of food processing activities in a food warehouse must be done under a separate food processing plant license. The rule clarifies requirements for food warehouses that hold fish, fishery products, and molluscan shellfish. The proposed rule harmonizes the food warehouse refrigeration temperature requirement for eggs with the requirement found in ch. ATCP 88 (Eggs). Finally, the proposed rule reduces confusion about which new 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.

Small Businesses Affected

The rule will impact food warehouses of all sizes, including many small ones. Of the 860 active food warehouse licenses, 609 (over 70%) are "small" food warehouses, defined by the department as having less than 50,000 square feet of storage area.

The rule will benefit operators of small food warehouse businesses who wish to do minimal repacking of already-packaged products in a licensed food warehouse by exempting the operators from acquiring a separate food processing plant license.

Operators of some small food warehouses may be unaware that they are subject to federal Hazard Analysis and Critical Control Point (HACCP) requirements for ensuring food safety. Storage of fish, fishery products, and molluscan shellfish is defined in federal regulations as a type of processing of these products. Small businesses processing in this way are thereby subject to federal HACCP requirements. These federal HACCP requirements are already adopted and applied to Wisconsin-licensed food processing plant operators who process fish and fishery products in ways more commonly recognized as processing, e.g. smoking, filleting. The proposed rule will clarify that warehouse operators who are storing fish, fishery products, or molluscan shellfish must meet the existing federal HACCP requirements, which will be enforced during

department inspections. The majority of food warehouse operators that currently store fish, fishery products, or molluscan shellfish have already implemented HACCP systems. In addition to the federal HACCP requirements, warehouse-based shippers, shucker-packers, repackers, or reshippers of molluscan shellfish for interstate commerce must hold a no-fee licensee dealer certification and meet existing state regulatory requirements under the federal-state Interstate Shellfish Sanitation Conference program. The proposed rule will clarify this requirement.

Many small food warehouse businesses may be classified as a “qualified facility” under the Preventive Controls – Human Food rule which was recently published by the US Food and Drug Administration (FDA) under the mandate of the FDA Food Safety Modernization Act (FSMA). Under FSMA and the new rule, a qualified facility is exempt from requirements to write and implement a food safety plan and supply chain management controls. The proposed rule refers to this exemption.

Reporting, Bookkeeping and other Procedures

Food warehouses that hold fish, fishery products, and molluscan shellfish will be required to conduct a hazard analysis, if they have not already done so, and if significant hazards are identified, to develop and follow a HACCP plan. Federal HACCP regulations, and thus the proposed rule, require documentation of several tasks conducted under the HACCP plan. Based on our experience with food processing plant operators who process fish, fishery products, and molluscan shellfish; and warehouse operators who are already following a HACCP plan, we believe it is unlikely that the additional time and cost of these efforts will have a significant negative impact on business.

Professional Skills Required

The proposed rule will effectively require operators of food warehouses storing fish, fishery products, or molluscan shellfish to complete HACCP training required in the federal regulations. The two-segment training is presented by internet / learner’s manual (Segment One) and face-to-face (Segment Two) instruction. The Seafood HACCP Alliance, which oversees the training, ensures that training is affordable for small business operators. Many food warehouse operators who currently store fish, fishery products, or molluscan shellfish have already completed the training. The department offers the Segment Two training annually.

Accommodation for Small Business

The HACCP requirements for all food warehouses that hold fish, fishery products, and molluscan shellfish are mandated by federal regulations and therefore an accommodation for small business is not possible. The FSMA Preventive Controls – Human Food rule, cited by the proposed rule contains an exemption which will apply to many small food warehouse businesses.

Conclusion

The provisions in this proposed rule will benefit Wisconsin's food warehouse industry, including small food warehouses, by creating exemptions from food processing plant licensing. The rule will help ensure that small food warehouses storing fish, fishery products, or molluscan shellfish meet federal requirements intended to minimize the unique risks associated with these products.

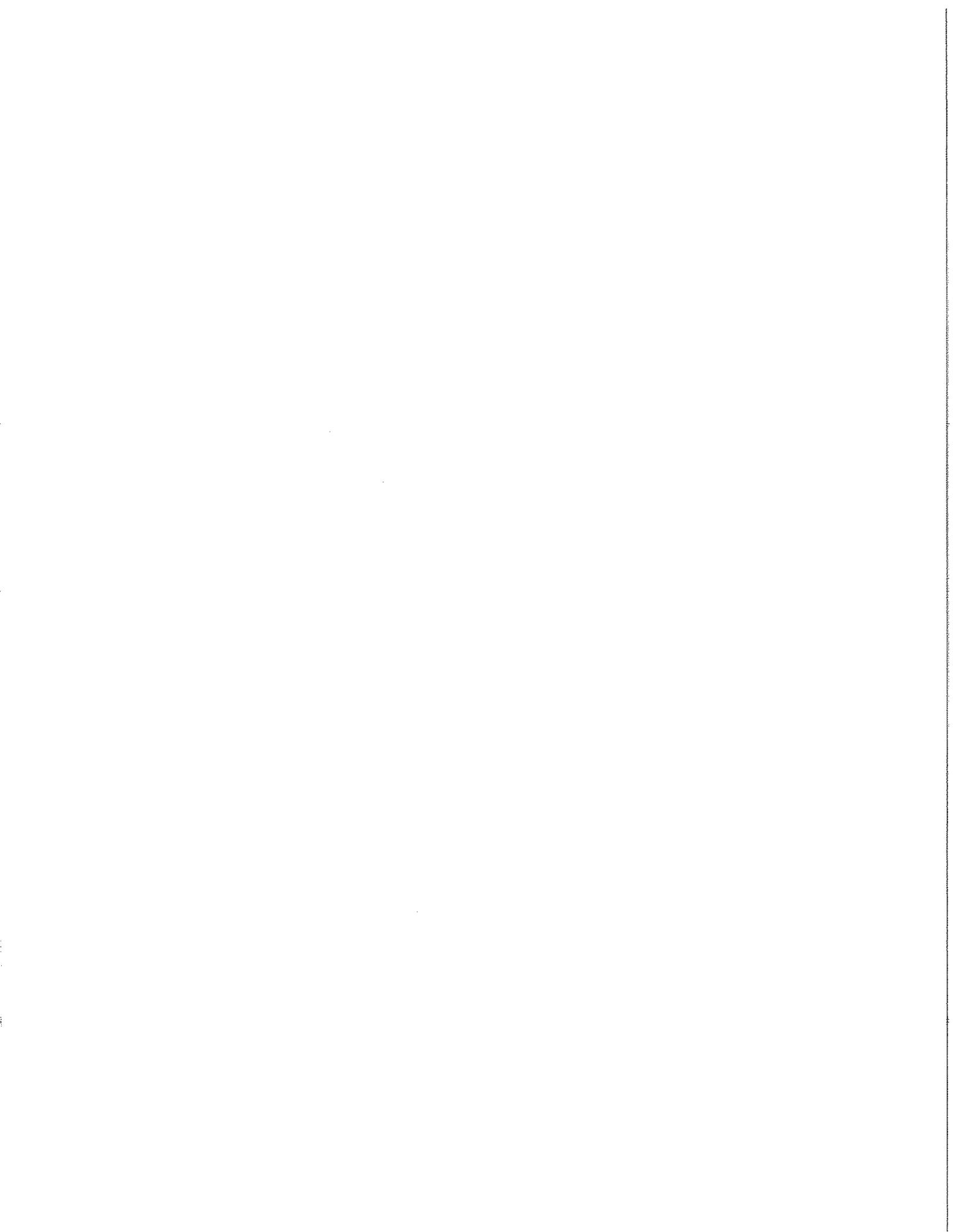
This rule will not have a significant adverse effect on "small business" and is not subject to the delayed "small business" effective date provided in s. 227.22(2)(e), Stats.

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

Dated this 30 day of October, 2015.

STATE OF WISCONSIN
DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By Steve Ingham
Steven C. Ingham, Administrator,
Division of Food Safety



ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

Original Updated Corrected

2. Administrative Rule Chapter, Title and Number

ATCP 70, Food Processing Plants/ATCP 71, Food Warehouses and Milk Distributors

3. Subject

Licensing food processing activities conducted in food warehouses

4. Fund Sources Affected

GPR FED PRO PRS SEG SEG-S

5. Chapter 20, Stats. Appropriations Affected

20.115 (1) (gb)

6. Fiscal Effect of Implementing the Rule

No Fiscal Effect Increase Existing Revenues Increase Costs
 Indeterminate Decrease Existing Revenues Could Absorb Within Agency's Budget
 Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)

State's Economy Specific Businesses/Sectors
 Local Government Units Public Utility Rate Payers
 Small Businesses (if checked, complete Attachment A)

8. Would Implementation and Compliance Costs Be Greater Than \$20 million?

Yes No

9. Policy Problem Addressed by the Rule

Under current Wisconsin rules, a food warehouse that engages in any food processing activities, even low-risk packing 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. The rule revision exempts food warehouse-based repacking of already-packaged foods from the list of activities that must be done under a food processing plant license.

This rule revision clarifies requirements for food warehouse operators who store fish, fishery products, and molluscan shellfish. Some of these 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 fishery products, e.g. histamine formation during temperature-abusive storage of tuna and related fish, and pathogenic *Vibrio* species associated with shellfish. Storage of fish, fishery products, and molluscan shellfish is included in the federal regulatory definition of processing as applied to these products, and businesses processing fish, fishery products, and molluscan shellfish are subject to federal HACCP requirements requiring them to conduct a hazard analysis and, if significant hazards are identified, to develop and follow a HACCP plan. These federal HACCP requirements are already adopted and applied to Wisconsin-licensed food processing plant operators who process fish and fishery products in ways more commonly recognized as processing, e.g. smoking, filleting. The proposed rule will clarify that warehouse operators who are storing fish, fishery products, or molluscan shellfish must meet the existing federal HACCP requirements, which will be enforced during department inspections. In addition to the federal HACCP requirements, warehouse-based shippers, shucker-packers, repackers, or reshippers of molluscan shellfish for interstate commerce must be certified as a licensee dealer (no fee is attached to this certification) and meet existing state regulatory requirements under the federal-state Interstate Shellfish Sanitation Conference program. The proposed rule will clarify this requirement. Most food warehouse operators who hold fish, fishery products, or molluscan shellfish have already met the HACCP requirements.

10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.

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DATCP posted the proposed rule online as required under Wis. Stat. § 227.137 and solicited comments from organizations representing Wisconsin's food warehouse operators, including the Midwest Food Processors Association, Wisconsin Dairy Products Association, Wisconsin Cheesemakers Association, the Wisconsin Warehouse Association, and individual food warehouse operators known by the department to have interest in handling molluscan shellfish for interstate sales. The department did not receive any comments on the economic impact of the rule.

11. Identify the local governmental units that participated in the development of this EIA.

This rule does not impact local governmental units.

12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

Business and Business Sectors

The rule change is expected to create an economic benefit for those food warehouse operators who wish to engage in repacking of already-packaged foods and do not have to obtain a separate food processing plant license in addition to a food warehouse license. Food processing plant license fees range from \$95 to \$835, depending on the annual value of food stored. There are approximately 860 licensed food warehouses in Wisconsin. An unknown number of these may benefit from the food processing plant license exemption. An unknown additional economic benefit might be gained if the repacking activities conducted at the food warehouse lead to increased sales. An unknown economic benefit will also result from following a HACCP plan in facilities storing fish, fishery products, or molluscan shellfish. Following a HACCP plan provides assurance that products are held in a way that maximizes safety, but it is not possible to assign an economic benefit to this assurance.

This rule change is expected to impose a small economic cost on those food warehouse operators handling molluscan shellfish, fish, and fishery products who have not yet obtained HACCP training and have not yet conducted a Hazard Analysis, developed a HACCP plan and followed that plan. However, the majority of food warehouse operators in this situation have already borne these costs and are compliant with the federal requirements. In an effort to reduce costs for business operators, the department offers low-cost HACCP training. In addition to the federal HACCP requirements, some warehouse-based shippers, shucker-packers, repackers, or reshippers of molluscan shellfish for interstate commerce will be required to hold a no-fee licensee dealer certification and meet existing state regulatory requirements under the federal-state Interstate Shellfish Sanitation Conference program. Fewer than five food warehouse operators are expected to want to handle molluscan shellfish for interstate commerce and therefore incur costs associated with meeting these requirements.

State's Economy

The rule will help grow Wisconsin's economy by reducing the regulatory costs for some food warehouse operators, and reducing the likelihood of safety problems associated with handling of molluscan shellfish, fish, and fishery products.

Local Governmental Units and Public Utility Rate Payers

The rule will have no impact on local governmental units or public utility rate payers.

Fiscal Impact

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Since food warehouses and food processing plants are already regulated by DATCP, this rule will not have a significant fiscal impact on state government and DATCP will absorb any costs with current budget and staff.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The rule change will exempt some food warehouses from having to obtain a food processing plant license if they are engaged in re-packing of already-packaged foods. The fee for a food processing plant license ranges from \$95 to \$835. It may allow these food warehouse operators to increase sales by allowing them to conduct minimal repacking and then sell the repacked products.

The rule clarifies requirements for food warehouses that store fish, fishery products, or molluscan shellfish so they are consistent with federal and state regulations. These products pose unique threats to human health. Federal regulations treat storage of fish, fishery products and molluscan shellfish, as processing of these products and therefore subject to regulations mandating the implementation of the 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 federal requirements for HACCP implementation by operators of warehouses which handle fish, fishery products, or molluscan shellfish. The proposed rule eliminates the inconsistency between federal and state regulations without increasing licensing fees for food warehouse operators storing fish, fishery products, or molluscan shellfish.

If this rule is not adopted, some food warehouse operators will continue to have to acquire a second (food processing plant) license to conduct repacking of already packaged foods, an activity that poses little hazard to the public health. Without the rule revision, food warehouses that store fish and fishery products, including molluscan shellfish, may not be aware of practices they must implement to address the unique threats those products pose to human health. As a result, these businesses may not meet federal regulations for fish, fishery products, and molluscan shellfish.

14. Long Range Implications of Implementing the Rule

While there may be some minor costs associated with implementing certain requirements of the rule, there are no negative long range implications of implementing the rule. Increasing the likelihood of safe food handling provides an ongoing, albeit unquantifiable, economic benefit. This rule will help grow Wisconsin's economy by allowing food warehouse operators who wish to create new food product packaging options to engage in limited repacking of already-packaged foods and thereby increase the number of products they sell.

15. Compare With Approaches Being Used by Federal Government

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

Federal fish, fishery products, and molluscan shellfish regulations require processors of these foods to conduct a hazard analysis and, if significant hazards are identified, develop and follow a HACCP plan. HACCP is an approach for preventing food safety hazards that involves a processor conducting an 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 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

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appropriate sanitary controls are not maintained.

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

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 recently published FDA 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

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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.

17. Contact Name	18. Contact Phone Number
Peter Haase, Director Bureau of Food Safety and Inspection	(608) 224-4711

This document can be made available in alternate formats to individuals with disabilities upon request.

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ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

This rule will impact food warehouses of all sizes, including many small ones. Of the 860 active food warehouse licenses, 609 (or about 71%) are "small" warehouses, defined by the department as having less than 50,000 square feet of storage area. The rule will benefit operators of small food warehouse businesses who wish to do minimal repacking of pre-packaged products in a licensed food warehouse by exempting the operators from acquiring a separate food processing plant license. Food processing plant license fees range from \$95 to \$835. A few small food warehouses that store fish, fishery products, or molluscan shellfish may incur costs associated with meeting federal regulations requiring them to conduct a hazard analysis and, if significant hazards are identified, develop and follow a HACCP plan. However, the majority of food warehouse operators who hold fish, fishery products and molluscan shellfish are already following HACCP plans. Although it's not possible to determine the cost of these activities, the impact is expected to be minimal.

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

We reviewed licensing data to determine the total number of food warehouses and the number of small food warehouses, as well as the cost of food processing plant licenses. We solicited input from various individual food warehouse businesses, as well as organizations representing food warehouse operators.

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
- Less Stringent Schedules or Deadlines for Compliance or Reporting
- Consolidation or Simplification of Reporting Requirements
- Establishment of performance standards in lieu of Design or Operational Standards
- Exemption of Small Businesses from some or all requirements
- Other, describe:

Providing sample written recall plans for use by small food warehouses.

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

The rule will eliminate the need for both small and large food warehouses to obtain a separate food processing plant license to do minimal repacking of pre-packaged products in a licensed food warehouse. Federal HACCP regulations apply to all food warehouses that hold fish, fishery products, and molluscan shellfish and no special accommodation can be made for small businesses.

5. Describe the Rule's Enforcement Provisions

The rule does not modify existing enforcement provisions related to food warehouses. All food, dairy, and state-inspected meat businesses are regulated under Chapter 97 of the Wisconsin Statutes. Enforcement provisions for these businesses are outlined in s. 97.72 and 97.73 and apply to both small and large businesses.

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes No
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