



State of Wisconsin  
Governor Scott Walker

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

**DATE:** March 8, 2016

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

**PRESENTED BY:** Peter Haase

**REQUESTED ACTION:**

At the March 22, 2016, Board meeting, the Department of Agriculture, Trade and Consumer Protection (“Department”) will ask the Board of Agriculture, Trade and Consumer Protection (“Board”) to approve Final Draft Rules (copy attached), chs. ATCP 70, Food Processing Plants; and ATCP 71, Food Warehouses and Milk Distributors.

**SUMMARY:** 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.

***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 Federal 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

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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 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 in ch. ATCP 71, eggs in ch. ATCP 88, dairy products in ch. ATCP 65, fish and fishery products in reduced-oxygen packaging in ch. ATCP 70, and molluscan shellfish in ch. ATCP 70.

Some provisions in the Federal Preventive Controls–Human Foods rule, implementing the Food and Drug Administration (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 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 aforementioned 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 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.

### ***Public Hearing***

The Department 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:

- 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.
- ATCP 70.18 and 71.19 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 ATCP 71.01.
- Different refrigeration storage temperature requirements for dairy products, fish and fishery products under reduced-oxygen packaging, and molluscan shellfish were added to ATCP 71.05 (7).
- 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.

*Next Steps*

If the Board approves this Final Draft Rule, the Department will transmit the final rule to the Governor for his written approval. After the Department receives written approval from the Governor, the Department will submit the rule to the Legislature for review by appropriate legislative committees. If the Legislature has no objections to the rule, the Secretary will sign the final rulemaking order and transmit it for publication.

**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), 70.18 (2) and 70.19  
3 (1) (d); and *to create* ATCP 70.03 (7) (f), 71.01 (2m), 71.01 (6c), (6d), (6p), and (6t), 71.025, 71.02  
4 (11), and 71.05 (8); *relating to* food warehouse and food processing plant licensing and operation,  
5 and affecting small business.

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**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 (HAACP) 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*

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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.

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### **Illinois**

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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.

### *DATCP Contact*

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- 1       SECTION 1. ATCP 70.03 (7) (f) is created to read:
- 2       (f) A licensed food warehouse under s. 97.27, Stats., at which one or more of the following
- 3       activities are the only food processing activities performed:

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

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

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

12       4. Manufacturing ice for use in the shipment of foods, or to cool or keep foods cold while in  
13 transit or stored in the warehouse. Ice used for this purpose must meet the standards in ATCP  
14 70.07 (8). Ice must be made on site in a commercial ice machine and may not be bagged,  
15 distributed or sold separately from food items that it is used to cool.

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

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

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

22       (d) If hot-smoked fish contained in ~~the package~~ reduced-oxygen packaging as defined in sub.  
23 ATCP70.02 (22n) are sold or distributed in an unfrozen state, the words “PERISHABLE – KEEP

1 REFRIGERATED AT OR BELOW 38° F.” in conspicuous letters at least the size of those used  
2 in the food name.

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

4 **(2m)** “Facility” has the meaning given in 21 CFR 117.3.

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

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

9 **(6d)** “Licensee dealer” means the operator of a food processing plant or food warehouse  
10 licensed in Wisconsin for the activities of shellstock shipper, shucker-packer, repacker, or  
11 reshipper.

12 **(6p)** “Package” has the meaning given in ATCP 90.01(16).

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

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

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

16 **71.025 Shellfish licensee dealer certification.** No person may operate as a shellfish licensee  
17 dealer without a valid annual certificate issued by the department under ATCP 70.21. A certificate  
18 is issued annually by the department under ATCP 70.21 (3).

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

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

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

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

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

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

9 1. Eggs shall be kept refrigerated at an ambient temperature of 45°F. (7°C.) or below.

10 2. Dairy products as defined in s. 97.20 (1) (b) 1. through 5., Stats., shall be kept at 45 ° F.  
11 (7° C.) or below.

12 3. Fish and fishery products in reduced-oxygen packaging as defined in sub. ATCP 70.02  
13 (22n) shall be kept at or below 38° F (3° C.), in accordance with s. ATCP 70.18 and s. 70.19.

14 4. Molluscan shellfish shall be iced or refrigerated to the extent necessary to maintain internal  
15 shellstock temperature as required in s. ATCP 70.21, and

16 5. Potentially hazardous frozen food shall at all times be kept frozen at a temperature of 5°F.  
17 (-15°C.) or below.

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

19 **(8) FISH OR FISHERY PRODUCTS HACCP SYSTEM REQUIRED.** A licensed food warehouse that  
20 engages in the storage of fish as defined in 21 CFR 123 (d), fishery products as defined in 21  
21 CFR 123.3 (e), or molluscan shellfish as defined in 21 CFR 123.3 (h) shall operate under a  
22 seafood HACCP system in accordance with the applicable requirements in Subch. IV, ATCP 70.  
23

1       **SECTION 11. 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.).  
4

Dated this \_\_\_\_\_ day of \_\_\_\_\_, 2016.

WISCONSIN DEPARTMENT OF AGRICULTURE,  
TRADE AND CONSUMER PROTECTION

By \_\_\_\_\_  
Ben Brancel, Secretary

**Wisconsin Department of Agriculture, Trade and Consumer Protection**

**Final Regulatory Flexibility Analysis**

***Rule Subject:*** Food Warehouses  
***Adm. Code Reference:*** ATCP 70 and 71  
***Rules Clearinghouse #:*** 15-093  
***DATCP Docket #:*** 14-R-11

***Rule Summary***

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.

***Small Businesses Affected***

The rule will impact food warehouses of all sizes, including many small ones. Of the more than 800 active food warehouse licenses, about 600 are “small” food warehouses, defined by the Department of Agriculture, Trade and Consumer Protection (“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 the requirement to acquire 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 form of processing of these products. Small businesses processing these items are thereby subject to HACCP requirements. These 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 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 rule will clarify this requirement.

Federal requirements in the Preventive Controls–Human Food rule, which are adopted in the proposed rule, will vary with the size and customers of the food warehouse operation.

### ***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 implement a HACCP plan, i.e. implement a HACCP system. HACCP regulations, and thus the proposed rule, require documentation of several tasks conducted under the HACCP system. Based on our experience with food processing plant operators who process fish, fishery products, and molluscan shellfish, and warehouse operators who have already implemented the HACCP system, 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. The Department offers the Segment Two training to industry at a low cost. Many food warehouse operators who currently store fish, fishery products, or molluscan shellfish have already completed the training.

### ***Accommodation for Small Business***

The HACCP system requirements for food warehouses that hold fish, fishery products, and molluscan shellfish are mandated by federal regulations. No accommodation for small business is possible, other than the HACCP training offered by the Department.

### ***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 to ensure they have minimized 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.

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

Dated this 14th day of March, 2016.

STATE OF WISCONSIN  
DEPARTMENT OF AGRICULTURE,  
TRADE AND CONSUMER PROTECTION

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

## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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1. Type of Estimate and Analysis

Original    Updated    Corrected

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2. Administrative Rule Chapter, Title and Number

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

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3. Subject

Licensing food processing activities conducted in food warehouses; storage temperature requirements; federal food safety requirements

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4. Fund Sources Affected

GPR    FED    PRO    PRS    SEG    SEG-S

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5. Chapter 20, Stats. Appropriations Affected

20.115 (1) (gb)

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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

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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)

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

Yes    No

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9. Policy Problem Addressed by the Rule

Under current Wisconsin rules, a licensed 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 seafood 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 defined in federal regulations as processing of these products, and businesses doing this type of processing are subject to HACCP requirements 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 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 HACCP requirements, which will be enforced during Department inspections. In addition to the HACCP requirements, warehouse-based shippers, shucker-packers, repackers, or reshippers of molluscan shellfish for interstate commerce must be certified as a licensee dealer and meet existing state regulatory requirements under the federal-state Interstate Shellfish Sanitation Conference program. The rule will clarify this requirement. Most food warehouse operators who hold fish, fishery products, or molluscan shellfish already meet these requirements.

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The proposed rule harmonizes the food warehouse refrigeration temperature requirements for eggs, dairy products, fish,

## **ADMINISTRATIVE RULES**

### **Fiscal Estimate & Economic Impact Analysis**

and fishery products in reduced-oxygen packaging, and molluscan shellfish with the requirements found in other rules, thereby reducing potential confusion for 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.

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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.

The Department 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.

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

This rule does not impact local governmental units.

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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 value of annual production. There are over 800 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 implementing a HACCP system in facilities storing fish, fishery products, or molluscan shellfish. The HACCP system 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 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, if necessary, and thereby implemented a HACCP system. However, the majority of food warehouse operators in this situation have already borne these costs and are compliant with the federal requirements. In addition to the 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.

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## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

### 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

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

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

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. They may not meet federal regulations for fish, fishery products, and molluscan shellfish.

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 Hazard Analysis and Critical Control Point (HACCP) system. Wisconsin food processing plant regulations, in ch. ATCP 70, Wis. Adm. Code, adopt, by reference, the 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.

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### 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.

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### 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.

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Federal fish, fishery products, and molluscan shellfish regulations require processors of these foods to conduct a hazard

## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

analysis and, if significant hazards are identified, adopt the HACCP system. 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 appropriate sanitary controls are not maintained.

The proposed rule revision indicates which parts of the federal Preventive Controls – Human Foods rule must be met by food warehouse operators. Product refrigerated storage temperature requirements in the revised rule are consistent with federal requirements.

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### 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. 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

## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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.

17. Contact Name Peter Haase, Director Bureau of Food Safety and Inspection	18. Contact Phone Number (608) 224-4711
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## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

### ATTACHMENT A

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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 more than 800 active food warehouse licenses, about 600 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 implement the HACCP system. However, the majority of food warehouse operators who hold fish, fishery products, and molluscan shellfish have already implemented HACCP systems.

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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.

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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.

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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. HACCP regulations apply to food warehouses that hold fish, fishery products, and molluscan shellfish and no special accommodation can be made for small businesses.

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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.

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

- Yes  No
-