

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.

ADMINISTRATIVE RULES

Fiscal Estimate & Economic Impact Analysis

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

ADMINISTRATIVE RULES

Fiscal Estimate & Economic Impact Analysis

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

ADMINISTRATIVE RULES

Fiscal Estimate & Economic Impact Analysis

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

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

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
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ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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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