STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R03/2012)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
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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; storage temperature requirements; federal food safety requirements

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 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.

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

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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.

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.

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 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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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.

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.

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, 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.

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

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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	18. Contact Phone Number
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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 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.

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. HACCP regulations apply to 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