

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis <input type="checkbox"/> Original <input checked="" type="checkbox"/> Updated <input type="checkbox"/> Corrected	2. Date 9-5-2019
3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) ATCP 70, Wholesale Food Manufacturing, Clearinghouse Number 17-073	
4. Subject Food Processing Plants, and relating to small business	
5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	6. Chapter 20, Stats. Appropriations Affected
7. Fiscal Effect of Implementing the Rule <input checked="" type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input checked="" type="checkbox"/> Could Absorb Within Agency's Budget	
8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input checked="" type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input checked="" type="checkbox"/> Small Businesses (if checked, complete Attachment A)	
9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$656,000	
10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
11. Policy Problem Addressed by the Rule Updating to: 1) reconcile previously different (DATCP vs. DHS) rules on wholesale food processing activities that may be conducted by retail food establishments, 2) revise definitions of wholesale and retail processing to be consistent with industry practices and federal policies, 3) remain consistent with federal regulations applicable to food processing plants and thereby enable DATCP to conduct contract inspections for the FDA under state authority, 4) provide additional flexibility to wholesale food manufacturers seeking variances from requirements related to equipment, utensils, processes, and procedures; 5) expand the range of food processing activities for which daily cleaning and sanitizing of equipment is not required, 6) clarify the duration and review of waivers granted by the department for variances from construction, equipment, utensil, process and procedure requirements, 7) clarify the duration and review for department approval of alternative cleaning and sanitizing schedules, 8) adopt the federal model ordinance as required for Wisconsin to continue participating in the national shellfish sanitation program, 9) clarify requirements for use of reclaimed water in food processing plants, and 10) continue providing appropriate flexibility in certain construction standards.	
12. 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. Supervisors of DATCP staff who inspect all of licensed food processing plants were surveyed to provide an estimate of the number of license-holders that would be affected by new requirements. DATCP staff knowledgeable in facility construction costs were queried about likely costs of new facility requirements. These staff, in turn, consulted commercial equipment and construction personnel to obtain or verify cost estimates. Finally, all licensed food processing plants were contacted by either e-mail (1,378 businesses) or mail (531 businesses) and asked for their assessment of costs they would have to bear due to new requirements. Over 200 responses (greater than 11%) were received.	
13. Identify the Local Governmental Units that Participated in the Development of this EIA. None. The rule does not affect Local Governmental Units.	
14. 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	

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Incurred)

The estimated economic impact listed in item 9 is \$656,000 across 1900 businesses. Costs have been attributed to possible one-time upgrades in handwashing sinks, toilet rooms, and exit doors that some firms may have to make. The rule requires handwashing sinks in toilet rooms or food processing areas to meet modern requirements for mixing of hot and cold water and hands-free operation in newly licensed facilities or in facilities operated by a license-holder continuing since on or before November 1, 2009 in which the handwashing sinks are substantially reconstructed or extensively altered. The requirement is already in place for new license-holders or installations of handwashing sinks in already-licensed food processing plants. DATCP estimates that not more than 40 businesses would face the costs of new sink installation. DATCP estimates that costs for these businesses would not exceed \$1,000 apiece. The figure in item 9 includes \$40,000 for handwash sink upgrades. Survey response data supports this estimate as approximately 70% of respondents indicated that "none" or "slight" costs would be imposed. Comments indicated a high level of existing compliance with this requirement. Cost estimates listed in the comments ranged from a few hundred dollars to less than \$10,000 per business. Some commenters who provided relatively higher cost estimates were apparently unaware that less-expensive "wrist paddle" or "foot pedal" operation would meet the requirement and described the costs and challenges of installing and using electronic-sensor operated faucets.

The rule requires newly installed toilet rooms to be contiguous to the food processing area. This requirement applies if either the toilet room was constructed after the date of this rule or in food processing plants newly opened or operated by a new license-holder after the date of this rule. Pre-existing non-contiguous toilet rooms in a food processing plant operated by the same license-holder since on or before the date of this rule would be allowed, provided applicable state and local regulations were met. DATCP estimates that, based on history, not more than 40 businesses choose to install a toilet room in a given year. Costs of construction could vary widely depending on the situation, but a worst-case estimate of \$10,400 per business was used in arriving at the figure of \$416,000 included in the item 9 total. Survey responses corroborate DATCP's estimate as more than 80% of respondents indicated none or slight costs for compliance. Most of the written comments indicated that firms were in compliance, either with contiguous toilet rooms or non-contiguous toilet rooms that complied with state and local requirements.

The rule contains a provision that food processing plant exit doors open outwards, consistent with long-standing building code requirements. More than 70% of survey respondents indicated none or slight costs of compliance. Most written comments described compliant exit doors or doors that likely would be approved following the Department's variance process. The costs of door replacements described by a small number of commenters were less than \$10,000. DATCP estimates that not more than 40 businesses would face costs of \$5,000 or less; a figure of \$200,000 is included in the item 9 total.

The rule continues to allow firms operated without changes in processing area dimensions by the same license-holder since on or before June 30, 1989, to be exempt from requirements for coving of floor-wall junctions, floor slope and drains, and provision of service sinks or curbed floor drains for disposal of mop water and similar wastes. Since 1989, these requirements have been enforced on all new license holders pursuant to state statute requiring licenses to be non-transferable. The rule clarifies this interrelationship of statute and administrative rule and thus no "new" costs are added to industry or included in the total amount shown for item 9. The Department has added flexibility to the previous requirement for coving to reduce costs that would be faced by "grandfathered" businesses that choose to alter their processing area dimensions or by new license-holders operating in a previously grandfathered facility.

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

Under the rule, Wisconsin food processing plants will be able to use current industry best practices without running afoul of out-of-date regulatory requirements. DATCP will be able to continue to conduct paid contract inspections for the FDA under state authority, thereby increasing consistency in inspection reports received from DATCP staff and avoiding the costs of credentialing DATCP staff to conduct FDA inspections under federal authority. Multi-state firms will be

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able to operate under Wisconsin rules that are consistent with other state and federal rules. All sizes of food processing plants will be able to apply for variances from a wider range of requirements, thereby having greater opportunities for innovation. Clear limits to the range and amount of wholesale food processing activities done by retail food establishments will be in place, eliminating a possible source of confusion.

The alternative to promulgating this rule, maintaining the current rule, could stifle industry innovation and hinder consistent DATCP conduct of state and FDA-contract inspections.

16. Long Range Implications of Implementing the Rule

Implementation of the rule will ensure that Wisconsin's wholesale food manufacturers can continue to produce and sell products in fair competition with businesses across the country.

17. Compare With Approaches Being Used by Federal Government

The rule, via reference citation, is consistent with federal requirements implemented under the Food Safety Modernization Act (21 CFR Part 117), federal rules for Hazard Analysis Critical Control Point (HACCP) food safety systems for juice and seafood processors (21 CFR Parts 120 and 123), federal canning rules (21 CFR Parts 108, 113, and 114) and the federal model ordinance for harvesting, shucking, packing, shipping and re-packing of marine shellfish.

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

Michigan, Iowa, and Minnesota license and regulate food processing facilities within their borders in a manner similar to Wisconsin. Each of these states is an active participant, as is Wisconsin, in the FDA Manufactured Foods Regulatory Program Standards program which requires a state to have a regulatory foundation equivalent to the FDA's. Illinois food processing plants are not licensed at the state level. Illinois and Michigan have state programs in the national shellfish sanitation program which allows permitted businesses in these states to receive, process, and ship shellfish wholesale across state borders.

19. Contact Name

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20. Contact Phone Number

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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)

Only a very small proportion of food processing plants will face the costs associated with facility updates described in the preceding summary. The Department wasn't able to clearly identify survey responses were from small businesses because small businesses, as defined for the purposes of this analysis, could hold any of the size-defined categories for a food processing plant license (the largest category has annual sales of \$250,000 or more). Thus, no differentiation by size was done in the department's economic analysis. The Department believes that the majority of businesses identified by staff as facing new facility-related costs are relatively small in size. The vast majority of businesses achieving compliance by virtue of various grandfather clauses are also toward the smaller side of the size spectrum.

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

Supervisors of DATCP staff who inspect all of licensed food processing plants were surveyed to provide an estimate of the number of license-holders that would be affected by new requirements. DATCP staff knowledgeable in facility construction costs were queried about likely costs of new facility requirements. These staff, in turn, consulted commercial equipment and construction personnel to obtain or verify cost estimates. Finally, all licensed food processing plants were contacted by either e-mail (1,378 businesses) or mail (531 businesses) and asked for their assessment of costs they would have to bear due to new requirements. Over 200 responses (greater than 11%) were received.

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:

DATCP continued to not charge a canning surcharge on the license of food processing plants with annual food sales of less than \$25,000. Many grandfather exemptions were retained in consideration of small businesses operated continuously by the same license-holder.

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

The broader range of requirements from which a variance may be requested will likely prove to be useful to small business operators seeking less expensive ways to meet the public health objective that a rule requirement is intended to meet. The costs facility upgrades necessitated by the loss of a grandfather exemption may be mitigated if the license-holder requests a variance from a facility requirement, provided the variance meets the public health intent of the requirement.

5. Describe the Rule's Enforcement Provisions

DATCP uses a "progressive compliance" approach in which the least stringent step to encourage compliance is the first step taken. Typical compliance steps include increased inspection frequencies or conditions on the license-holder's license related to specific food safety activities the plant operator must take. Quite often these activities are simply industry best practices.

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

- Yes No
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