STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2050 (C04/2012)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
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EXISTING ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☐ Repeal ☒ Modification

2. Administrative Rule Chapter, Title and Number
Wis. Admin. Code ch. ATCP 70, Food Processing Plants

3. Date Rule promulgated and/or revised; Date of most recent Evaluation
This emergency rule is consistent and concurrent with ongoing permanent rule revisions in 2018.

4. Plain Language Analysis of the Rule, its Impact on the Policy Problem that Justified its Creation and Changes in Technology, Economic Conditions or Other Factors Since Promulgation that alter the need for or effectiveness of the Rule.

DATCP has revised Wis. Admin. Code ch. ATCP 70 by incorporating by reference provisions of federal regulations that implement the requirements of the federal Food Safety Modernization Act (FSMA) and are found in 21 CFR Part 117, Current Good Manufacturing Practice, Hazard Analysis and Risk based Preventive Controls for Human Food. Specifically, the emergency rule revision adds federal definitions of "facility" and "qualified facility" and specifies which requirements of 21 CFR Part 117 must be met by licensed food processing plants that are in these two federally-defined food business categories.

21 CFR Part 117 supersedes 21 CFR Part 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. For the past several years, Wis. Admin. Code Ch. ATCP 70 was deemed to be equivalent in effect to 21 CFR Part 110. This equivalency enabled the Department to conduct contract inspections on behalf of the FDA under state authority. Given the equivalent regulatory foundation, contract inspections have always reinforced consistency in state and federal regulatory expectations for food processing plant operators.

Because Wis. Admin. Code ch. ATCP 70 is not currently equivalent to 21 CFR Part 117, Wisconsin now specifically lacks the regulatory authority to enforce federal requirements related to: 1) training, 2) modernized Good Manufacturing Practices, 3) the hazard analysis and risk-based preventive controls system for ensuring food safety, and 4) implementation of a supply-chain program. These FDA regulatory requirements apply to many, but not all, licensed Wisconsin food processing plants that are under the jurisdiction of Wis. Admin. Code ch. ATCP 70. The lack of equivalence between Wis. Admin. Code ch. ATCP 70 and 21 CFR Part 117 also means that DATCP cannot conduct FDA contract inspections under Wis. Admin. Code ch. ATCP 70 as in the past. In order to do contract inspections after the start of the federal fiscal year on October 1, 2018, DATCP would be compelled to pursue cumbersome credentialing and reporting procedures.

21 CFR Part 117 has already been adopted by reference in Wis. Admin Code chs. ATCP 65 and 71 that apply, respectively, to dairy plants and food warehouses. The permanent rule-making for Wis. Admin Code ch. ATCP 70 that is now in process contemplates that 21 CFR Part 117 will be also be incorporated by reference into ATCP 70. The effect of this incorporation will be to extend the provisions of 21 CFR Part 117 to all Wisconsin-licensed food processing plants, including those that are not specifically subject to the federal rule, that is, the processing plants that are not technically a "facility" or "qualified facility." During the period until the permanent rule is adopted (including the time during which this emergency rule, if adopted, is in effect), the requirements in the currently existing Wis. Admin. Code ch. ATCP 70 will continue to apply to these processing plants.

5. Describe the Rule's Enforcement Provisions and Mechanisms

DATCP has broad general authority, under Wis. Stat. s. 93.07 (1), to adopt rules to implement programs under its jurisdiction. DATCP also has general authority under Wis. Stat. s. 97.09 (4) to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. DATCP has specific authority, under Wis. Stat. s. 97.29 (5) to adopt rules establishing fees; setting facility construction and maintenance standards; setting standards for the design, installation, maintenance, and cleaning of equipment and utensils; personnel sanitation; food handling and

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storage; sanitary production and processing of food; food sources; and labels.

DATCP Environmental Health Sanitarians visit businesses to inspect and license them for safe operation.

6. Repealing or Modifying the Rule Will Impact the Following (Check All That Apply)

- ☐ State's Economy
- ☐ Local Government Units
- ☒ Specific Businesses/Sectors
- ☐ Public Utility Rate Payers
- ☒ Small Businesses

7. Summary of the Impacts, including Compliance Costs, identifying any Unnecessary Burdens the Rule places on the ability of Small Business to conduct their Affairs.

No economic impact to small businesses is expected. The businesses affected by this rule run the gamut from one- and two-person popped popcorn wholesalers to multi-national corporations that are on the cutting edge of food science. DATCP's challenge is to provide a level playing field without penalizing either end of this range of business types. Because only small businesses already subject to FDA inspection will be affected (e.g., facilities and qualified facilities), this emergency rule will have no additional effect on them. Any provisions in the emergency rule resulting in additional costs have already been required by the new federal regulations. Under this rule, small businesses will continue to be subject to FDA contract inspections conducted by state personnel and under state regulatory authority.

8. List of Small Businesses, Organizations and Members of the Public that commented on the Rule and its Enforcement and a Summary of their Comments.

DATCP solicited comments from representatives of industry that the department licenses and inspects, including Seneca Foods; Kwik Trip, Inc.; and the Midwest Food Products Association. All representatives were supportive of the emergency rule implementation in order to continue working directly with state personnel and regulatory authority.

9. Did the Agency consider any of the following Rule Modifications to reduce the Impact of the Rule on Small Businesses in lieu of repeal?

- ☐ 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:

10. Fund Sources Affected

☐ GPR ☐ FED ☐ PRO ☐ PRS ☐ SEG ☐ SEG-S

11. Chapter 20, Stats. Appropriations Affected

12. Fiscal Effect of Repealing or Modifying the Rule

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

13. Summary of Costs and Benefits of Repealing or Modifying the Rule

If Wis. Admin. Code ch. ATCP 70 is not revised to define "facility" and "qualified facility", and to indicate that businesses falling into these FDA-defined categories must meet specific requirements of 21 CFR Part 117, the Department will be able to do FDA contract inspections only if state sanitarians obtain FDA credentials. This is a costly and inefficient process. "Credentialing" involves an intrusive and time-consuming background check that would not be completed by October 1, 2018. More importantly, there would be an issue for industry partners becasue all inspections done by credentialed DATCP personnel would be documented only according to FDA protocols and could only be shared with our industry partners in a very limited way.

FDA procedures generate a written summary of objectionable conditions only if significant violations are noted. State inspection reports indicate significant violations, along with less significant violations that might develop into significant

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problems if not corrected. By following only FDA procedures, these latter types of violations would not be documented and valuable education opportunities would be lost. If the Department attempted to also write a state inspection report of a contract inspection that indicated the less significant violations, that report could not indicate violations of the new components of 21 CFR Part 117 because those latter violations do not violate state rules as currently written. Thus, the report would be incomplete. In a nutshell, a business could receive different sets of information from DATCP and, if there were serious violations, the FDA. This would result in confusion and inefficiencies.

- The proposed emergency rule allows the Department to operate under state rules without going through the lengthy, expensive, and intrusive process of being "credentialed" by the FDA.
- Without the emergency rule, the educational, interactive relationship that the Department now has with industry would be undermined and a separate inspection and/or report would be necessary in order to communicate all but the most critical violations with the plants inspected.
- Without the emergency rule, the Department would also not be able to share critical violations in a timely fashion but would only be able to do so after the reports had made its way through the FDA process.
- The FDA contract is an important part of the Department's program funding. A gap in that revenue would seriously impact the Department's ability to conduct inspections.

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

☐ Yes ☒ No

15. Long Range Implications of Repealing or Modifying the Rule

DATCP has updated Wis. Admin. Code ch. ATCP 70 by incorporating by reference the provisions of federal regulations that implement the requirements of FSMA so that Wisconsin's food processing industry can produce and sell products on a level playing field with businesses across the country. DATCP will continue to inspect and enforce standards that meet FDA's Manufactured Foods Regulatory Program Standards for facilities and equipment.

Long range implications include the ability of DATCP to continue vigilantly promoting healthy food business practices that help businesses to grow while protecting public health.

16. Compare With Approaches Being Used by Federal Government

By harmonizing state and federal regulatory requirements for certain federally defined categories of food processing plants, the emergency rule is consistent with the federal government's regulatory approach.

17. 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 as does Wisconsin. Illinois food processors are regulated only by the FDA.

18. Contact Name	19. Contact Phone Number
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