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
ATCP 70, Food Processing Plants

3. Date Rule promulgated and/or revised; Date of most recent Evaluation
This emergency rule is concurrent with ongoing permanent rule revisions in 2017

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 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 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 ATCP 70. The lack of equivalence between ATCP 70 and 21 CFR Part 117 also means that DATCP cannot conduct FDA contract inspections under ATCP 70 as in the past. In order to do contract inspections after the start of the Federal fiscal year on October 1, 2017, DATCP would be required to adopt cumbersome credentialing and reporting procedures.

21 CFR Part 117 has already been adopted by reference in chs. ATCP 65 and 71 that apply, respectively, to dairy plants and food warehouses. Since the majority of Wisconsin food facilities subject to this Federal rule are licensed as food processing plants, similar adoption by reference has been proposed for the permanent rule ch. ATCP 70 that is now going through the standard approval process. Concurrent revision under the standard rule writing procedure will also ensure that the requirements for Wisconsin-licensed food processing plants that are not subject to the federal rule, i.e. are not a "facility" or "qualified facility", are modernized. During the period in which this emergency rule is in effect, requirements in the currently existing ch. ATCP 70 will apply to these facilities.

5. Describe the Rule's Enforcement Provisions and Mechanisms

DATCP has broad general authority, under s. 93.07 (1), Stats., to adopt rules to implement programs under its jurisdiction. DATCP 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. DATCP has specific authority, under 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 storage, sanitary production and processing of food, food sources and labels.

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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, i.e., 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 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 only be able to do FDA contract inspections 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 1st. 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 only generate a written summary of objectionable conditions if significant violations are noted. State inspection reports indicate significant violations, along with less significant violations that might develop into significant problems if not corrected. By only following FDA procedures, these latter types of violations would not be documented

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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 they do not violate state rules. Thus, the report would be incomplete. To put it succinctly, a business could receive different sets of information from DATCP and, if there were serious violations, the FDA. This is an unacceptably confusing situation and an ineffective use of resources.

- This 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 the Department now has with industry would be eliminated and a separate inspection and / or report would be necessary in order to share any but the most critical violations with the plants inspected.
- Without the emergency rule, the Department would also not be able to share the 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. Without the emergency rule it would seriously impact both the Department's ability to do inspections and would also be detrimental to industry partners if they found that they were no longer playing on a level playing field and were not given the opportunity to interact with trained regulators who could discuss their findings and concerns.

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 ATCP 70 with the incorporation by reference of 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 entirely 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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