

STATEMENT OF SCOPE

Department of Agriculture, Trade and Consumer Protection (DATCP)

Rule No.: Chs. ATCP 70 Wis. Adm. Code (Existing)

Relating to: Food Processing Plants

Rule Type: Emergency

1. Finding/nature of emergency (Emergency Rule only):

For the purpose of maintaining a single set of consistent standards for food processing plants, subject to both FDA and state inspection, and to perform the Department's usual number of FDA contract inspections in federal fiscal year 2019, applicable provisions of 21 CFR Part 117 must be referenced in Wis. Admin. Code Ch. ATCP 70. As detailed below, a continuation of the status quo of inconsistent state and federal standards would negatively impinge on the welfare of industry stakeholders.

In its rules implementing the Food Safety Modernization Act ("FSMA"), the United States Food and Drug Administration ("FDA") recently replaced 21 CFR Part 110 ("Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food") with 21 CFR Part 117 ("Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food"). The Department's administrative rule for food processing plants, Wis. Admin. Code Ch. ATCP 70, has been deemed equivalent, in effect, to 21 CFR Part 110, which enabled the Department to conduct contract inspections on behalf of the FDA. This, in turn, has resulted in consistent state and federal regulatory expectations for food processing plant operators.

At this time, however, Wis. Admin. Code Ch. ATCP 70 is not yet the functional equivalent of 21 CFR Part 117. Revising Wis. Admin. Code Ch. ATCP 70 in order to reference 21 CFR Part 117 (as an emergency rule) is in the best interests of Wisconsin's food processing plants as well as the Department. The Department contracts with the FDA to perform well over two hundred contract food processing plant inspections each year. Without the emergency rule change, the Department's ability to efficiently perform inspections under the FDA contract will be impeded. These inspections are an important step towards a nationally integrated food safety regulatory system. Reimbursement for the inspections is also an important Department revenue stream.

In the spring of 2018, as the promulgation of the rule was nearing completion, the Department convened further stakeholder review of the proposed draft to receive additional input from industry partners on specific provisions of the draft, all of which are not related to 21 CFR 117 and the purview of the emergency rule. In response to provisions identified by the workgroup, none of which are related to the scope or content of the emergency rule, the Department convened a working group comprised of key industry stakeholders and local health department agent programs to resolve the issues that had been raised. A final draft of ATCP 70 incorporating the decisions of the industry working group, will be presented to the DATCP Board on September 20, 2018 and will likely be submitted for legislative review

in January 2019. The adoption by reference of pertinent sections of 21 CFR Part 117, as contained in the emergency rule, will be in the final draft of the permanent rule.

If the emergency rule revision fails to proceed, there are three consequences that will occur: inconsistency in communicating results of manufactured food inspections; potential loss of contract dollars that support the Bureau's budget; and the loss of efficiency due to retraining staff to adhere to FDA procedures.

Without the emergency rule, inspections performed pursuant to the FDA contract could only be performed under FDA regulatory authority. That means that Department inspection staff would have to obtain FDA credentials and would be required to expend valuable work time to be trained to work and manage data in the federal electronic information management systems. The Department's position is that these additional requirements and duties would be burdensome, duplicative, and unnecessarily onerous. Department staff time would be better spent conducting inspections and responding to consumer complaints from citizens of the State of Wisconsin.

Besides the inefficiencies just mentioned, food processing industry stakeholders would likely experience confusion. Mandating State of Wisconsin DATCP employees to become federally-credentialed before conducting contract inspections could further this confusion on a number of fronts.

Currently, under the FDA's inspection reporting system, only firms with significant violations receive a summary of objectionable conditions (FDA form 483). A State of Wisconsin food processing plant inspection report (were one to be generated following an inspection conducted under the authority of the FDA) would need to be prepared separately from the Department's current inspection reporting system and could not describe any violations or findings outside of the Department's current regulatory scope. This duplicative and inconsistent process could generate inspection reports that have the potential to create confusion for substandard firms concerning the delineation of inspections and enforcement practices between state and federal rule violations. Overall, obtaining federal credentials for state inspectors decreases the efficiency and effectiveness of conducting regulatory inspections on behalf of the FDA and does not impart any clear additional value to industry or the Department.

Pursuant to a statement of scope approved by the Governor on March 3, 2017, the Department had already begun the process of revising Wis. Admin. Code Ch. ATCP 70 to reference 21 CFR Part 117. Performing this same revision in an emergency rule will harmonize the existing state and federal regulatory investigation and enforcement practices until the permanent rule-making process is completed. The permanent revision of Wis. Admin. Code Ch. ATCP 70 will not reach the Legislature until January 2019. By then, most Wisconsin food processing plants will be subject to the federal rules. In essence, an emergency rule revision will span the gap between the federal compliance date and the completion of the state permanent rule-making process.

2. Detailed description of the objective of the proposed rule:

This emergency rule will add federal definitions of "facility" and "qualified facility" and specify which requirements of 21 CFR Part 117 must be met by licensed food processing plants in these two federally-defined food business categories.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

The Department's regulatory foundation in the past was deemed the equivalent, in effect, to that of the FDA. This equivalency meant that food processing plant operators could come to expect consistent state and federal regulatory requirements, and that Department staff could efficiently perform food processing plant inspections under the FDA contract. A failure to revise Wis. Admin. Code Ch. ATCP 70 (in order to retain regulatory equivalency with the FDA) would lead to confusion for food processing plant operators and reduced efficiency for the Department's food processing plant regulatory oversight.

4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

The Department has specific authority to adopt rules related to food grade standards in Wis. Stat. § 93.09 (1). Additionally, the Department has specific authority to promulgate rules related to food processing plants in Wis. Stat. § 97.29 (5).

The Department has broad general authority, under Wis. Stat. § 93.07 (1), to adopt rules to implement programs under its jurisdiction. The Department also has general authority under Wis. Stat. § 97.09 (4) to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods.

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule :

This emergency rule will take approximately 20 hours of staff time to develop.

6. List with description of all entities that may be affected by the proposed rule :

The rule will affect the majority of the state's approximately 2,100 food processing plants.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule :

The proposed revision in Wis. Admin. Code Ch. ATCP 70 would make this rule equivalent to FDA rules already in effect, or soon to be in effect, for food facilities and qualified facilities.

8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

The Department expects the proposed emergency rule to have no negative economic impact on Wisconsin's food processing industry. Food business operators are accustomed to consistent regulatory inspections conducted by Department staff enforcing state rules, Department staff under FDA contract, and federal staff. For some food processing plants, the complexity of inspections may increase, but this complexity would be consistent across federal and state inspections.

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I, Keeley Moll, Deputy Secretary of the Department of Agriculture, Trade & Consumer Protection, the Department having submitted this statement of scope before the Governor of the state of Wisconsin and now in receipt of his approval dated August 29, 2018, hereby approve this statement of scope as evidenced by my signature below.