

# 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):

In its rules implementing the Food Safety Modernization Act (“FSMA”), the United States Food and Drug Administration (“FDA”) recently replaced 21 CFR 110 (“Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food”) with 21 CFR 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 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 no longer the functional equivalent of 21 CFR 117. For that reason, Wisconsin now lacks the regulatory authority to enforce all of the requirements of 21 CFR 117, provisions which include: (1) training; (2) implementation of modernized Good Manufacturing Practices, the hazard analysis, and risk-based preventive controls system for ensuring safety of human food; and (3) 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.

Therefore, 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 2018, applicable provisions of 21 CFR 117 must be referenced in Wis. Admin. Code Ch. ATCP 70.

Revising Wis. Admin. Code Ch. ATCP 70 in order to reference 21 CFR 117 (as an emergency rule) is in the best interests of Wisconsin’s food processing plants as well as the Department. In fact, should this emergency rule revision not occur, many licensed food processing plants would be inspected under two sets of rules (Wisconsin’s ATCP 70 in its present form, as well as 21 CFR 117).

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.

If the emergency rule revision fails to proceed, inspections performed pursuant to the FDA contract could only be performed under FDA regulatory authority. That means that Department inspection staff would need to obtain FDA credentials, and submit themselves to a credentialing process which involves

intrusive measures and lengthy background checks. Upon completion of the credentialing process, all inspection reports conducted in Wisconsin would necessarily become the property of federal authorities at the FDA. All these Wisconsin reports would be subject to federal document-control rules and timelines. Reports would be filed into a federal electronic data management system. Besides being bound to the federal rules and regulations, our State of Wisconsin Department staff would be required to expend additional work time in order to be trained to learn and manage the data in the federal databank systems. The Department position is that these additional requirements and duties are 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 heretofore mentioned, the food processing industry is likely to experience confusion. Mandating State of Wisconsin DATCP employees to become federally-credentialed before conducting contract inspections could create serve to further this confusion on a number of fronts.

Currently, under the FDA 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. In such a situation, a sub-standard food processing operator could conceivably receive two different inspection reports. The first report from the State would not reflect all the federal rule violations, even though the food processing firm was inspected by the Department under the authority of the FDA. The firm, with presumably sub-standard business practices, would only learn of its federal rule violations were these violations to rise to the level of necessitating an FDA 483 form. Upon later learning that their business practices also violated federal law, business firms could understandably become quite confused as to which set of standards applied to them and under what circumstances. Business operators would be challenged to assimilate potentially inconsistent inspection and enforcement practices.

Neither would such a result be advantageous to Department staff who would be charged with conducting inspections under circumstances where investigation and enforcement standards between the Department and FDA appear to be seemingly inconsistent. Overall, obtaining credentials for Department staff decreases the efficiency and effectiveness of conducting regulatory inspections on behalf of the FDA. Neither does the imposition of the federal credentialing process upon state employees impart any additional value to industry or the Department.

Pursuant to a Scope Statement approved by the Governor on March 3, 2017, the Department has already begun the process of revising Wis. Admin. Code Ch. ATCP 70 to reference 21 CFR 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. In short, it will prevent a "gap" from forming due to functional inequalities and inconsistencies between the Department's framework and the FDA's regulatory alternative. The permanent revision of Wis. Admin. Code Ch. ATCP 70 is not likely to reach the Legislature until at least December of 2017. By October of 2017, many 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 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. Industry is 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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