





State of Wisconsin
Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection

DATE: September 5, 2017

TO: Board of Agriculture, Trade and Consumer Protection

FROM: Jeff Lyon, Interim Secretary 
Steve Ingham, Administrator, Division of Food and Recreational Safety 

SUBJECT: Emergency Rule, ATCP 70 (Food Processing Plants)

PRESENTED BY: Steve Ingham, Division of Food and Recreational Safety

REQUESTED ACTION: Scope Statement Approval

At the September 21, 2017, Agriculture, Trade and Consumer Protection Board (“Board”) meeting, the Department of Agriculture, Trade and Consumer Protection (“Department”) will ask the Board to approve a scope statement for an emergency rule which revises Wis. Admin. Code ch. ATCP 70. The Governor approved this scope statement on August 4, 2017.

This revision ensures that Wisconsin food processing plants are subject to consistent state and federal (US Food and Drug Administration (FDA)) requirements and that the Department can most efficiently and effectively conduct FDA contract inspections of these plants. A repeal and recreation of the existing ch. ATCP 70 is already underway and will include the emergency rule revision. However, the regular administrative rule writing process will not be completed by the start of the federal fiscal year on October 1, 2017.

BACKGROUND

In its proposed permanent revision of ch. ATCP 70, the Department incorporates by reference provisions of federal regulations that implement the 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 will add the federal definitions of “facility” and “qualified facility” and will specify 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 equivalent, in effect, to 21 CFR Part 110, and this equivalency enabled the Department to conduct contract inspections on behalf of the FDA under state authority. Contract inspections conducted in this way reinforce consistency in state and federal regulatory processes and expectations for food processing plant operators.

However, without the proposed revision, Wis. Admin. Code ATCP 70 is no longer equivalent, in effect, to 21 CFR Part 117, and Wisconsin 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

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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. A lack of functional equivalence between ATCP 70 and 21 CFR Part 117 means that the Department may not conduct FDA contract inspections as in the past. Without this proposed emergency rule revision, the Department may not conduct upcoming contract inspections without adopting required cumbersome credentialing and reporting procedures until the permanent ch. ATCP 70 is adopted.

In order to continue to perform inspections under contract with the FDA and meet contractual requirements – without the emergency rule – inspections will be performed under the FDA’s regulatory authority. This will require the Department’s inspection staff to obtain the aforementioned FDA credentials, submit DATCP state employees to a lengthy and intrusive credentialing process, and follow FDA procedures for reporting and data management. Any reports generated solely under the FDA’s authority will become the property of the FDA. Only firms with significant violations will receive a written summary of objectionable conditions (FDA form 483). Any state report that could be shared with the firm will need to be composed separately and will not include any violations or findings outside of the existing regulatory scope. Thus, a firm inspected by the Department under contract, and having violations related to 21 CFR Part 117 requirements, may only receive a state report that does not reflect all federal rule violations. The firm will merely be informed of having violated federal regulations via an FDA 483 form. Any teachable moments whereby the Department could otherwise work with business operators towards the achievement of a common food safety goal will be lost. Moreover, industry confusion will likely increase under these circumstances, and the educational value of inspections performed by the Department pursuant to the FDA contract will likely decrease.

21 CFR Part 117 has already been adopted by reference in chs. ATCP 65 and 71 which apply, respectively, to dairy plants and food warehouses. Since the majority of Wisconsin food facilities subject to 21 CFR Part 117 are licensed as food processing plants, similar adoption by reference will be done in ch. ATCP 70. Concurrent revisions 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 (e.g., do not qualify as a “facility” or “qualified facility”) are modernized. During the period in which this emergency rule is in effect, existing requirements in ATCP 70 will still apply to these facilities.

If the Department does not adopt the ATCP 70 emergency rule, food processing plant operators will be subject to inconsistent requirements resulting from the uneven regulatory foundation on which Department inspectional staff will have to operate. The Department’s FDA contract inspections will become significantly different from the normal state inspections and less efficient.

NEXT STEPS

If the Board approves the ATCP 70 Emergency Rule Scope Statement, the Department will move quickly to draft the emergency rule, which will only include those provisions in the ATCP 70 Permanent Rule hearing draft (also before the Board for approval) that are needed for FDA contract inspection purposes, and then request approval by the Governor for publishing before October 1, 2017. If the Board approves the ATCP 70 Permanent Rule Hearing Draft, the Department expects to hold hearings on both the permanent and emergency rules in December, which falls within the 90-day timeframe during which one or more hearings must be held on an adopted emergency rule when paired with a permanent rule. If needed, the Department will ask for an extension of this emergency rule so that it remains in force until the permanent rule process can be completed.

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.

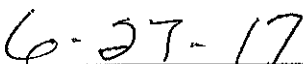
8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

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.

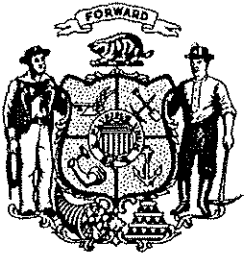
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Department Head or Authorized Signature



Date Submitted



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OFFICE OF THE GOVERNOR
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P.O. Box 7863
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August 4, 2017

Ben Brancel
Secretary
Wisconsin Department of Agriculture, Trade, and Consumer Protection
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RE: Scope Statement for Emergency Rule modifying Ch. ATCP 70 relating to food processing plants and food processing provisions in related administrative rules

Dear Secretary Brancel,

I hereby approve the statement of scope submitted on June 30, 2017 to SBO, pursuant to Wisconsin Statutes § 227.135, in regards to an emergency rule modifying Chapter ATCP 70 of the Wisconsin Administrative Code. You may send the scope statement to the Legislative Reference Bureau for publication pursuant to Wisconsin Statutes § 227.24(1)(e)1d.

Sincerely,

A handwritten signature in black ink, appearing to be "Scott Walker".

Scott Walker
Governor