



State of Wisconsin
Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection
Sheila E. Harsdorf, Secretary

DATE: September 6, 2018

TO: Board of Agriculture, Trade and Consumer Protection

FROM: Sheila Harsdorf, Secretary *Kelley Moll for*
Steve Ingham, Division of Food and Recreational Safety *Steve Ingham*

SUBJECT: Food Processing Plants
Wis. Admin. Code ch. ATCP 70, Emergency rule (Statement of Scope)

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

REQUESTED ACTION: Approval of Statement of Scope

At the September 20, 2018 meeting of the Board of Agriculture, Trade and Consumer Protection, the Department of Agriculture, Trade and Consumer Protection will ask the DATCP Board to approve a statement of scope for an emergency rule that revises Wis. Admin. Code ch. ATCP 70. The Governor approved this statement of scope on August 29, 2018.

SUMMARY

This proposed emergency rule is designed to ensure that Wisconsin food processing plants will be subject to standards that are consistent as between state requirements and federal Food and Drug Administration (FDA) requirements, and that the Department can efficiently and effectively conduct FDA contract inspections of those plants. A repeal and re-creation of the existing Wis. Admin. Code ch. ATCP 70 is underway and will include the content of this emergency rule. However, the rule-writing process for the permanent rule will not be completed by the start of the federal fiscal year on October 1, 2018. The proposed emergency rule is needed to enable the Department to continue to conduct contract inspections in the ordinary course of the new fiscal year.

Proposed Rule

In its pending proposed permanent revision of Wis. Admin. Code ch. ATCP 70, the Department incorporates by reference provisions of federal regulations that implement the Food Safety Modernization Act (FSMA) which are found in 21 CFR Part 117, *Current Good Manufacturing Practice, Hazard Analysis and Risk based Preventive Controls for Human Food*. The revision effectuated by the proposed emergency rule would add the federal definitions of "facility" and "qualified facility" to the rule and would specify which requirements of 21 CFR Part 117 must be met by licensed food processing plants that fall within these two federally-defined food business categories.

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For the past several years, Wis. Admin. Code ch. ATCP 70 was deemed equivalent, in effect, to 21 CFR Part 110, which enabled the Department to conduct contract inspections on behalf of the FDA. It also provided for consistency between state and federal regulatory processes and clarified expectations for food processing plant operators.

The federal regulation, 21 CFR Part 117, now supersedes 21 CFR Part 110, *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food*. This proposed emergency rule will make sure that the Department complies with all of the standards contained in 21 CFR Part 117.

Without passage of this proposed emergency rule, Wisconsin would lack 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.

Without the emergency rule, any inspections performed by the Department under contract with the FDA would be performed under the FDA's regulatory authority rather than state authority. That means that the Department's inspection staff would have to undergo a lengthy and intrusive credentialing process and follow FDA procedures for reporting and data management, even possibly leading to confusion for industry participants. For example, food processing plant operators would be subject to inconsistent requirements resulting from uneven regulations. The Department's FDA contract inspections would become significantly different from, and less efficient than, the normal state inspections.

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 for Wis. Admin. Code ch. ATCP 70 will do the same.

In the fall of 2017, the DATCP Board approved a similar emergency rule that was designed to preserve Department operations until the anticipated completion of the permanent ATCP 70 rule in the next legislative cycle. However, the Department invited further stakeholder review of the proposed draft to receive additional input from industry partners. The Department convened a working group of key industry stakeholders and local health department agent programs to address food safety issues. A final draft of the ATCP 70 permanent rule is expected for the November 20, 2018 DATCP Board meeting.

Next Steps

If the Board approves this statement of scope, the Department will move quickly to draft the emergency rule, which will include only those provisions of the ATCP 70 permanent rule hearing draft that are needed for FDA contract inspection purposes, and then will request approval by the Governor for publishing before October 1, 2018. If the Board subsequently 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):

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.

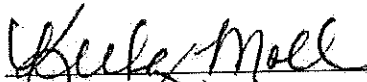
8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):

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.

Contact Person:

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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.



Deputy Secretary

9/4/2018

Date



SCOTT WALKER
OFFICE OF THE GOVERNOR
STATE OF WISCONSIN

P.O. Box 7863
MADISON, WI 53707

August 29, 2018

Sheila Harsdorf
Secretary
Wisconsin Department of Agriculture,
Trade, and Consumer Protection
2811 Agriculture Drive
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RE: Scope Statement for Emergency Rule modifying ATCP 70 relating to food processing plants

Dear Secretary Harsdorf,

I hereby approve the statement of scope submitted on August 24, 2018 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,

Scott Walker
Governor