

The statement of scope for this emergency rule, SS 105-18, was approved by the Governor on August 29, 2018, was published in Register No. 753A2 on September 10, 2018, and was approved by the Board of Agriculture, Trade and Consumer Protection on September 20, 2018.

This emergency rule was approved by the Governor on October 11, 2018.

DATCP Docket No. 18-R-06
October 22, 2018

**WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION**

**EMERGENCY RULE
CHAPTER ATCP 70**

The Wisconsin department of agriculture, trade and consumer protection hereby proposes the following emergency rule *to create* ATCP 70.02 (15m) and (22m) and ATCP 70.035, *relating to* food processing plants and affecting small business.

**Analysis Prepared by the Department
of Agriculture, Trade and Consumer Protection**

This emergency rule revises Wis. Admin. Code ch. ATCP 70, “Food Processing Plants”, so as to adopt certain provisions of an important Federal Food and Drug Administration (“FDA”) regulation that implements the requirements of the Food Safety Modernization Act (“FSMA”). This regulation is primarily located in 21 CFR Part 117, *Current Good Manufacturing Practice, Hazard Analysis and Risk based Preventive Controls for Human Food*. 21 CFR Part 117 superseded 21 CFR Part 110, *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food*.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, which enabled the Department of Agriculture, Trade and Consumer Protection (“DATCP”) to conduct contract inspections on behalf of the FDA. Because of this regulatory equivalence, there have been consistent state and federal regulatory expectations for food processing plant operators.

At the present time, however, Wis. Admin. Code ch. ATCP 70 has not yet been deemed equivalent to the new federal regulation that is 21 CFR Part 117. Accordingly, Wisconsin now lacks the regulatory authority to enforce 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 Wis. Admin. Code ch. ATCP 70. Furthermore, the lack of regulatory equivalence means that DATCP will not be allowed to conduct FDA contract inspections in the coming federal fiscal year and thereafter; instead, DATCP would be required to adopt cumbersome credentialing and reporting procedures in order to conduct the 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. Although DATCP is planning to adopt this language by reference as part of a current Wis. Admin. Code ch. ATCP 70 permanent rule process, that permanent rule will not be adopted before the beginning of the 2019 federal fiscal year on October 1, 2018. For the purposes of maintaining consistent standards for food processing plants subject to both FDA and state inspection, as well as performing FDA contract inspections using well-established

procedures in the 2019 federal fiscal, applicable provisions of 21 CFR Part 117 must be adopted by reference in Wis. Admin. Code ch. ATCP 70.

Statutes Interpreted

Statutes Interpreted: Wis. Stat. § 97.29, “Food processing plants.”

Statutory Authority

Statutory Authority: Wis. Stat. §§ 93.07 (1), 97.09 (4), 97.29 (5).

Explanation of Statutory Authority

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

Related Statutes and Rules

Since the transfer of the Department of Health Service’s (DHS) Food Safety and Recreational Licensing unit in July 2016 to DATCP, the latter agency has regulated food from farm to table. Once it leaves the farm, food is almost entirely the responsibility of DATCP’s Division of Food and Recreational Safety (DFRS). Food is specifically regulated under subchapter II of Wis. Stat. § 97 and several administrative rule chapters, many of which mirror or reference federal statutes and regulations. Related administrative rules cover retail food establishments, dairy plants, farms, food warehouses, as well as meat and poultry establishments.

Plain Language Analysis

DATCP seeks to revise Wis. Admin. Code ch. ATCP 70 by adopting certain provisions of federal regulations that implement the requirements of 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. 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 ch. ATCP 70 is not currently the equivalent of 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 Wis. Admin. Code ch. ATCP 70. The lack of equivalence between Wis. Admin. Code ch. ATCP 70 and 21 CFR Part 117 also means that DATCP cannot conduct FDA contract inspections under Wis. Admin. Code ch. ATCP 70, as in the past. In order to do contract inspections after the start of the 2019 federal fiscal year (which begins on October 1, 2018), DATCP would be required to adopt cumbersome credentialing and reporting procedures.

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-making for Wis. Admin Code ch. ATCP 70 that is now in process contemplates that 21 CFR Part 117 will also be adopted into ATCP 70. The effect of this adoption will be to extend the provisions of 21 CFR Part 117 to all Wisconsin-licensed food processing plants, including those that are not specifically subject to the federal rule, that is, the processing plants that are not technically a “facility” or a “qualified facility.” During the period until the permanent rule is adopted (including the time in which this emergency rule, if adopted, is in effect), the requirements in the currently existing Wis. Admin. Code ch. ATCP 70 will continue to apply to these processing plants.

Federal and Surrounding State Programs

Federal Programs

Food processing plants in Wisconsin that participate in interstate commerce are subject to the requirements of the Food, Drug and Cosmetic Act, as well as the federal regulations written to enforce these statutory requirements. The adoption of FSMA into law in 2011 was followed by the mandated development of several new federal regulations. The major part of federal regulations affecting Wisconsin food processing plants is 21 CFR Part 117 (*Current Good Manufacturing Practice, Hazard Analysis and Risk based Preventive Controls for Human Food*).

Surrounding State Programs

Food processing facilities in Michigan, Iowa, and Minnesota are licensed and regulated similarly to those in Wisconsin. Illinois food processors are regulated only by the FDA.

Data and Analytical Methodologies

DATCP reviewed recent changes in FDA regulations such as the rules implementing FSMA and federal requirements for conducting FDA contract inspections.

Effect on Small Business

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 consistent and fair regulatory environment 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 are already required by the new federal regulations.

DATCP Contact

Questions and comments (including hearing comments) related to this rule may be directed to:

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Rule comments will be accepted up to two weeks after the last public hearing is held on this rule. Hearing date(s) will be scheduled after this rule is promulgated.

FINDING OF EMERGENCY

(1) The FDA recently replaced 21 CFR Part 110 with 21 CFR Part 117. DATCP's administrative rule for food processing plants (ATCP 70) is equivalent in effect to 21 CFR Part 110, but not to 21 CFR Part 117. Wisconsin performs over two hundred contract inspections of processing plants on behalf of the FDA each year. The contract requires that states inspect under federal authority or equivalent state authority. Until the most recent federal fiscal year, contract inspections of food processing plants were conducted under equivalent Wisconsin authority, but this will no longer be possible under the new FDA contract with Wisconsin that goes into effect on October 1, 2018, unless ATCP 70 is revised to become equivalent in effect to the federal rule.

(2) In order to continue to perform inspections for the FDA and to meet contractual requirements – without the emergency rule – inspections would have to be performed under the FDA's regulatory authority. This would mean that DATCP's inspection staff would have to obtain FDA credentials. Only those firms that are found to have significant violations would 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 could create confusion for firms.

(3) This emergency rule is necessary to:

- Harmonize Wisconsin regulations with those used by the federal government and by many other states.
- Maintain State of Wisconsin control over inspection reports written in Wisconsin's food processing plants when doing FDA contract inspections.
- Allow DATCP to more fully and transparently communicate all regulatory findings with industry, specifically, to eliminate the risk of the food processing plant operator not being informed in writing of violations of 21 CFR Part 117 requirements that cannot be cited on a state report and are not serious enough to warrant a written federal report.
- Forestall the need for DATCP inspection staff to obtain FDA credentials.

EMERGENCY RULE

SECTION 1. Chapter ATCP 70.02 (11m) is created to read:

(11m) "Facility" as used in s. 70.035 of this rule has the meaning given in 21 CFR 117.3.

SECTION 2. Chapter ATCP 70.02 (22d) is created to read:

(22d) “Qualified facility” as used in s. 70.035 of this rule has the meaning given in 21 CFR 117.3.

SECTION 3. Chapter ATCP 70.035 is created to read:

ATCP 70.035 Federal requirements. (1) QUALIFIED FACILITIES. A food processing plant that is also a qualified facility shall comply with the requirements of this chapter and applicable requirements of 21 CFR 117.

(2) FACILITIES. A food processing plant that is a facility, but is not a qualified facility, shall meet the requirements of this chapter and applicable requirements of 21 CFR 117.

SECTION 4. EFFECTIVE DATE: This emergency rule takes effect upon publication, and remains in effect for 150 days. The department may seek to extend this emergency rule as provided in s. 227.24, Stats.

Dated this 22nd day of October, 2018.

WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By: Sheila Harsdorf, Secretary