

The statement of scope for this rule, SS 076-17, was approved by the Governor on August 4, 2017, published in Register 740A3, on August 21, 2017, and approved by Wisconsin Department of Agriculture, Trade and Consumer Protection Board, on September 21, 2017.

This emergency rule was approved by the Governor on September 28, 2017.

DATCP Docket No. 17 – R - 05
September 28, 2017

WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

EMERGENCY RULE

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 ATCP 70, "Food Processing Plants" to incorporate by reference 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 in 21 CFR Part 117, *Current Good Manufacturing Practice, Hazard Analysis and Risk based Preventive Controls for Human Food* (that 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, 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.

Presently Wis. Admin. Code ATCP 70 is not deemed equivalent to 21 CFR Part 117 so 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 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 chs. ATCP 65 and 71 that apply, respectively, to dairy plants and food warehouses. Although DATCP, as part of a current ATCP 70 permanent rule process, is planning on adopting this language by reference, this permanent rule will not be adopted

before the beginning of Federal fiscal year 2018, October 1, 2017. For the purposes of maintaining consistent standards for food processing plants subject to both FDA and state inspection, and performing FDA contract inspections using well-established procedures in Federal fiscal year 2018, applicable provisions of 21 CFR Part 117 must be adopted by reference in ATCP 70.

Statutes Interpreted

Statutes Interpreted: 97.29, Stats., “Food processing plants;”

Statutory Authority

Statutory Authority: ss. 93.07 (1), 97.09 (4), 97.29 (5), Stats.

Explanation of Statutory Authority

DATCP has broad general authority, under s. 93.07 (1), Stats., to adopt rules to implement programs under its jurisdiction. DATCP also has general authority under s. 97.09 (4), Stats., to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. DATCP has specific authority, under 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, 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 s. 97, Stats., and several administrative rule chapters, many of which mirror or reference federal statutes and regulations. Related administrative rules cover retail food establishments, dairy plants and farms, and food warehouses, as well as meat and poultry establishments.

Plain Language Analysis

DATCP has revised ATCP 70 by incorporating by reference 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, *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food*. 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 ATCP 70 is not currently equivalent to 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 ATCP 70. The lack of equivalence between ATCP 70 and 21 CFR Part 117 also means that DATCP cannot conduct FDA contract inspections under ATCP 70 as in the past. In order to do contract inspections after the start of the Federal fiscal year on October 1, 2017, DATCP would be required to adopt cumbersome credentialing and reporting procedures.

21 CFR Part 117 has already been adopted by reference in chs. ATCP 65 and 71 that apply, respectively, to dairy plants and food warehouses. Since the majority of Wisconsin food facilities subject to this Federal rule are licensed as food processing plants, similar adoption by reference has been proposed for the permanent rule ch. ATCP 70 that is now going through the standard approval process. Concurrent revision 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, i.e. are not a “facility” or “qualified facility”, are modernized. During the period in which this emergency rule is in effect, requirements in the currently existing ch. ATCP 70 will apply to these facilities.

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, and 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 similar 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.

Material Incorporated by Reference

21 CFR 117, Current Good Manufacturing Practice, Hazard Analysis and Risk based Preventive Controls for Human Food,

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 level playing field 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 have already been required by the new federal regulations.

DATCP Contact

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

Peter Haase, Director
Bureau of Food and Recreational Businesses
Department of Agriculture, Trade and Consumer Protection
P.O. Box 8911
Madison, WI 53708-8911
Telephone: (608) 224-4711
E-Mail: Peter.Haase@Wisconsin.gov

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 presented to the Board of Agriculture, Trade and Consumer Protection.

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 food processing plants for the FDA each year. The contract requires that states inspect under federal authority or equivalent state authority. Currently contract inspections of food processing plants are done 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, 2017, unless ATCP 70 is revised to become equivalent in effect to 21 CFR Part 117.

(2) In order to continue to perform inspections under contract with the FDA and 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 must obtain FDA credentials, a lengthy and intrusive process, and follow FDA procedures for reporting and data management. Any reports generated under FDA's authority would become the property of the FDA. Only firms with significant violations would receive a summary of objectionable conditions (FDA form 483). Any state report that could be shared with the firm would have to be composed separately and would not include any violations or findings which are outside of the current regulatory scope. Thus, a firm inspected by DATCP under contract and having violative conditions related to 21 CFR Part 117 requirements, would only receive a state report that doesn't reflect all federal rule violations. The firm would merely be informed of having violated federal law via an FDA 483 form and teachable moments where DATCP can work with Industry toward a common food safety goal would be lost. Industry confusion would likely increase in this situation, and the educational value of inspections done by DATCP under FDA contract would likely decrease.

(3) If DATCP cannot adopt this emergency rule revision of ch. ATCP 70, many Wisconsin food processing plants would face inconsistent state and federal regulatory requirements.

(4) This emergency rule is necessary to:

- Harmonize Wisconsin regulations with those used by the Federal government and many of the 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.
- Eliminate the time and expense of DATCP inspection staff completing the FDA credentialing process.

EMERGENCY RULE

SECTION 1. Chapter ATCP 70.02 (15m) is created to read:

(15m) "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 (22m) is created to read:

(35m) "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 which 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 on October 1, 2017, and remains in effect for 150 days. The department may seek to extend this emergency rule as provided in s. 227.24, Stats.