

## Wisconsin Department of Agriculture, Trade and Consumer Protection

### Regulatory Flexibility Analysis

**Rule Subject:** Food Processing Plants

**Adm. Code Reference:** ATCP 70

**Rules Clearinghouse #:** Not assigned

**DATCP Docket #:** 17 – R - 05

#### *Rule Summary*

The Department has revised ch. ATCP 70 to incorporate by reference provisions of an important federal (US 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 110, *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food*). Specifically the 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 business categories.

21 CFR Part 117 deals with preventive food safety systems and has already been incorporated by reference in chs. ATCP 65 (Milk and Milk Products) and ATCP 71 (Food Warehouses and Milk Distributors). Since the majority of Wisconsin food facilities subject to this federal rule are licensed as food processing plants, similar referencing has now been done in ch. ATCP 70. This revision harmonizes state and federal regulations such that state inspection personnel will be able to continue to do FDA contract inspections under state authority in the new federal fiscal year that starts on October 1, 2017. Harmonizing regulatory requirements decreases confusion for food processing plant operators and improves the efficiency and educational value of inspections.

#### *Small Businesses Affected*

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. Under this rule, small businesses will continue to be subject to FDA contract inspections conducted by state personnel and under state regulatory authority.

DATCP solicited comments from representatives of industry that the department licenses and inspects, including Seneca Foods; Kwik Trip, Inc.; and the Midwest Food Products Association. All representatives were supportive of the emergency rule implementation in order to continue working directly with state personnel and regulatory authority.

#### *Reporting, Bookkeeping and other Procedures*

The proposed rule will not require any additional reporting, bookkeeping or other procedures beyond what are already required of food processing plant operators subject to 21 CFR Part 117.

### ***Professional Skills Required***

The proposed rule does not require any new professional skills by small businesses. It does, in fact, eliminate the need for state inspection personnel to obtain FDA credentials and to be trained in federal forms and inspectional protocols.

### ***Accommodation for Small Business***

The requirements for food processing are not size-dependent. There is very little room in the regulations for accommodation due to size since the size-related aspects of the definitions of facility and qualified facility are already set by FDA in 21 CFR Part 117.

### ***Conclusion***

The provisions in this proposed rule will benefit many of Wisconsin's food processing plants by ensuring that they are regulated under harmonized state and federal regulatory requirements. As a result of the rule revisions, state inspection personnel will be able to continue to do FDA contract inspections under state authority in the new federal fiscal year that starts on October 1, 2017. Harmonizing regulatory requirements decreases confusion for food processing plant operators and improves the efficiency and educational value of inspections.

This rule will have little if any effect on "small business" and is not subject to the delayed "small business" effective date provided in s. 227.22 (2) (e), Stats.

DATCP will, to the maximum extent feasible, seek voluntary compliance with this rule.