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# Regulatory Alert: FDA Releases Final FSMA Preventive Controls Rules

***Historic Changes Impact Food Manufacturers and Retailers, Compliance Required in 2016***

September 11, 2015

On September 10, 2015, the U.S. Food and Drug Administration (FDA) released the Final Preventive Controls Rules for Human Food and Animal Food. The Preventive Controls for Human Food Rule has very significant impacts on food manufacturers and retailers and imposes major new liabilities on food industry executives. Please contact Erik Lieberman at erl1@liebermanpllc.com or 202.830.0300 if you have questions or would like additional information. Lieberman PLLC assists firms in FSMA compliance and managing regulatory risks.

## Background

Section 103[1] of FSMA required FDA to issue the Preventive Controls Rules for Human and Animal Food. In 2013 FDA published proposed rules in to implement Section 103 (January 2013: Human Food, October 2013: Animal Food). In September 2014 FDA published supplements to the proposed rules. On September 10, 2015, FDA issued the final rules. The final rules also update FDA's Current Good Manufacturing Practice Regulations.

## Key Questions-Preventive Controls for Human Food Rule

**What is in the regulation?**

The regulation changes definitions in FDA's general enforcement regulations, updates FDA's Current Good Manufacturing Practice Regulations (CGMP) for manufacturing, packing or holding human food, and establishes requirements for facilities to establish and implement hazard analysis and risk-based preventive controls and supplier verification.

**What types of facilities are covered by the regulation?**

Facilities that process, pack and hold food. Facilities such as manufacturing plants, central kitchens/delis, distribution centers and packing facilities are all covered.

**What types of establishments are exempt from the regulation?**

Retail store locations, restaurants, farms (generally, farms engaging in certain activities will be covered).

[1] 21 USC 350g

**Are some businesses subject to the CGMP regulations (Subpart B), but exempt from the preventive controls (Subpart C) and supplier verification requirements (Subpart G)?**
Yes. For example, certain small businesses, and facilities solely engaged in the storage of unexposed packaged food are exempt from Subparts C and G, but subject to Subpart B.

**What types of activities are exempt from the preventive controls and supplier verification requirements of the regulation?**

- Activities that are subject to the seafood, juice or low-acid canned food HACCP regulations
- Manufacturing, processing, packaging, or holding of dietary supplements subject to part 111 CGMP requirements
- Activities subject to the Produce Safety Rule
- Certain on-farm activities by small businesses

**When do I have to comply with the requirements of the rule (not including the supplier verification requirements)?**

September 19, 2016, unless your business is a small business or the facility is subject to the Pasteurized Milk Ordinance.

- September 19, 2016 (generally)
- Facilities subject to the Pasteurized Milk Ordinance: September 17, 2018
- Small businesses: September 18, 2017
- "Qualified facilities"*: September 17, 2018, (must retain records to support qualified status beginning in January 1, 2016)

*Small businesses that sell mostly in local markets, and very small businesses

**When do I have to comply with the supplier verification requirements (Subpart G)?**

- Generally 6 months after the date your supplier is required to comply with the Human Preventive Controls or Produce Safety Rules.
- March 17, 2017 generally if your suppliers are not subject to the Human Preventive Controls or Produce Safety Rules
- If you are a small business--the later of September 18, 2017, or 6 months after the supplier is required to comply with the Human Preventive Controls or Produce Safety Rules.
- If you are a small business--September 18, 2017, for suppliers that are not subject to the Human Preventive Controls or Produce Safety Rules.

**How do I comply with the preventive controls requirements?**

You are required to prepare and implement a written food safety plan which includes:

- Hazard analysis
- Preventive controls
- Supply chain program (for manufacturing/processing facilities)
- Recall plan
- Monitoring procedures
- Corrective action procedures
- Verification procedures

FDA outlines specific requirements for each component of the food safety plan in the regulation.

**How long do I have to keep records under this regulation?**

The regulation imposes complex and detailed recordkeeping requirements. Records must be kept generally for at least two (2) years after the date they were prepared. Records that relate to the general adequacy of equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least two (2) years after their use is discontinued.

**Do I have to establish and implement a supplier verification program?**

If your facilities process/manufacture raw material or ingredients you are responsible for approving suppliers and ensuring supplier verification occurs. However, you are not required to conduct supplier verification activities yourself. **Other entities may determine, conduct and document supplier verification activities that you may rely on.** In addition, suppliers may conduct sampling and testing of the raw materials and ingredients they supply to you for purposes of complying with the sampling and testing requirements of the rule.

**What suppler verification activities must occur?**

For hazards for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death an annual onsite audit is required unless there is a determination that other verification activities and less frequent auditing are adequate. For other hazards, onsite auditing, sampling and testing, review of food safety records and other appropriate activities based on supplier performance and risk are permitted.

**How will FDA enforce the rule?**

FDA states that they are working through the Partnership for Food Protection to develop and implement a national Integrated Food Safety System consistent with FSMA's emphasis on establishing partnerships for achieving compliance. FDA will be partnering with State regulators and other governmental agencies in enforcing the regulations.

**Are supermarket distribution centers subject to the preventive controls requirements?**

Generally, yes. A supermarket distribution center is subject to the preventive controls requirements if it handles unpackaged food that is exposed to the environment (e.g. produce in vented boxes, crates or bins).

**Are central kitchens or bakery facilities subject to the supplier verification requirements?**

Yes, because they will be processing raw materials and ingredients. However, other entities may determine, conduct and document supplier verification activities that you may rely on.

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