



FSMA Prevention Standards Provisions

*Prevention: The Cornerstone of
the New Food Safety Law*



Prevention Standards Provisions

- Produce Safety Regulation
- Produce Safety Guidance
- Preventive Controls Regulation
- Guidance on Hazard Analysis and Preventive Controls
- Sanitary Food Transportation
- Preventing Intentional Contamination



The new law applies to:

- Businesses required to register under the Bioterrorism Act of 2002
- Human food and animal feed
 - Separate preventive control regulations and guidance for human food and animal feed
 - Produce regulations and guidance apply only to human food
 - Other regulations envisioned to be joint for human food and animal feed



There are some exemptions

- Small and very small businesses*
- Businesses with sales less than \$500,000, where the majority of product is distributed directly to consumers or farmers' markets and restaurants either intrastate or within a 275-mile radius
- Under FSMA, FDA also has authority to modify or exempt certain other facilities, including certain warehouses and other storage facilities.

(*FDA must define, by regulation, "small business" and "very small business," following a study).



Produce Safety

Under FSMA, FDA is to:

- Publish guidance updating good agricultural practices within one year. FDA to hold at least 3 public meetings on the guidance during that time.
- Establish science-based minimum safety standards for higher risk raw agricultural commodities; proposed rule with one year; final rule in two years. FDA to hold at least 3 public meetings during the comment periods.
- Within 180 days of a final rule on raw agricultural commodities, issue a small entity compliance guide.



Preventive Controls

Under FSMA, FDA is to:

- In 18 months, have a final rule in place on mandatory preventive controls, including definitions
- In one year, issue guidance on model assessments and mitigation strategies to protect against intentional adulteration of food; issue regulations within 18 months.



Other Prevention Mandates

- **Facility registration**

- Will improve the accuracy of data by requiring biennial registration
- Allows suspension of facility registration by FDA if “reasonable probability of causing serious adverse health consequences or death to humans or animals” has been determined.



Hazard Analysis and Preventive Controls/Food Safety Plans

Each registered facility would be required to:

- Conduct a hazard evaluation to identify known or reasonably foreseeable hazards
- Put in place controls to significantly reduce or prevent hazards
- Monitor the controls, establish corrective actions, and verify that the plan is working
 - verification to include environmental and finished product testing
- Undergo a hazard re-evaluation every three years
- Provide FDA with a written food safety plan and related records during an inspection

Compliance with prevention standards can be demonstrated in a variety of ways, including:

- Sanitation (including food contact surfaces, utensils and equipment surfaces)
- Training for supervisors and employees
- Environmental controls and monitoring
- Food allergen controls (only applies to human foods)
- Recall contingency plan
- Good Manufacturing Practices (GMPs)
- Supplier verification activities



Other Prevention Mandates (cont'd)

- **Sanitary Transportation of Food**
 - FDA to conduct a food transportation study
 - FDA to issue regulations under existing Section 416(b) of Food, Drug and Cosmetics Act, within 18 months



Other Prevention Mandates (cont'd)

- **Performance standards**
 - Requires FDA, in consultation with U.S. Department of Agriculture, to review, *at least every two years*, relevant data and information to determine the most significant hazards

Note: the law does not specify what form these standards must take (guidance, regulations, other)



Preventing Intentional Contamination

- FDA to issue final rule regarding Intentional Contamination within 18 months
- Requires FDA to issue guidance for Intentional Contamination
- Requires FDA to conduct vulnerability assessments of the food supply and determine mitigation strategies
- FDA, USDA, and DHS are to prepare a National Agriculture and Food Defense Strategy