
Overview

FDA Food Safety Modernization Act

Section 104. Performance Standards

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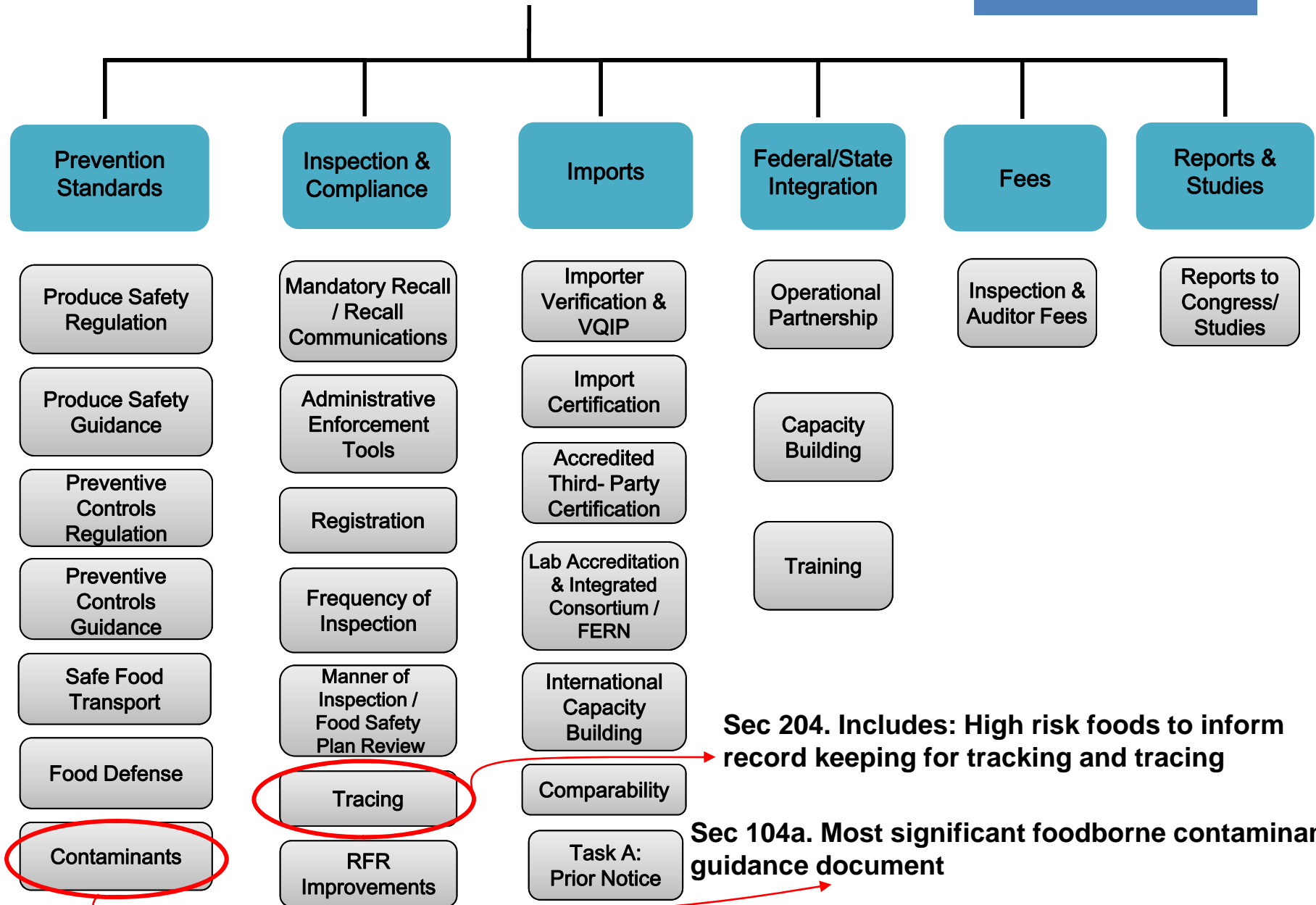
FSMA Implementation Approach

- Implementation is underway
- Transparency a priority
- Focus on public health protection
- Engage with stakeholders to help determine reasonable and practical ways to implement provisions



Implementation Executive Committee

Strategic Communications
& Outreach Team –



Rulemaking Process

- Rulemaking is open and public.
- Draft rules are published on <http://www.regulations.gov>.
- Time is allowed for public comment, and FDA is required to consider significant comments during the rulemaking process.
- Check <http://www.fda.gov/fsma> to find out what is open for comment.



FSMA Section 104

Performance Standards



FSMA Section 104. Performance Standards

(a) IN GENERAL.—The **Secretary shall**, in coordination with the Secretary of Agriculture, not less frequently than every 2 years, review and evaluate relevant health data and other relevant information, including from toxicological and epidemiological studies and analyses, current Good Manufacturing Practices issued by the Secretary relating to food, and relevant recommendations of relevant advisory committees, including the Food Advisory Committee, to **determine the most significant foodborne contaminants.**



FSMA Section 104. Performance Standards

(b) GUIDANCE DOCUMENTS AND REGULATIONS.—Based on the review and evaluation conducted under subsection (a), and when appropriate to reduce the **risk** of serious illness or death to humans or animals or to prevent adulteration of the food under section 402 of the Federal Food, Drug, or Cosmetic Act (21 U.S.C. 342) or to prevent the spread by food of communicable disease under section 361 of the Public Health Service Act (42 U.S.C. 264), the **Secretary shall issue** contaminant-specific and science-based **guidance documents**, including guidance documents regarding action levels, **or regulations**. Such guidance, including guidance regarding action levels, or regulations—

(1) shall apply to products or product classes;

(2) shall, where appropriate, differentiate between food for human consumption and food intended for consumption by animals other than humans; and

(3) shall not be written to be facility-specific.



FSMA Section 104. Performance Standards

(c) NO DUPLICATION OF EFFORTS.—The **Secretary shall coordinate with the Secretary of Agriculture** to avoid issuing duplicative guidance on the same contaminants.

Key role for IFSAC to provide forum for discussions with FSIS on Most Significant Foodborne Contaminant attribution and to provide database for FSMA Contaminant Working Group analysis.



FSMA Section 104. Performance Standards

(d) REVIEW.—The **Secretary shall periodically review and revise**, as appropriate, the **guidance documents**, including guidance documents regarding action levels, **or regulations** promulgated under this section.

The effort to determine Most Significant Foodborne Contaminants (104a) will be revisited every two years. Other guidance and regulations under 104b will be periodically reviewed and revised.



Current Thinking in FDA regarding 104(a)



Current Thinking in FDA

Guiding Principals for Determining MSFC:

1. Utilize objective public health data when available
2. Science-based
3. Seek public input
4. Transparent process



Current Thinking in FDA

1. Three-Track Approach

1. Pathogen – Food category pairing

Based on CDC database and food categories

IFSAC involvement and cooperation

Rank pathogens within food categories by cost and QALYs

2. Chemical contaminants

Less public health data available

Supplement data with qualitative analysis

Allergens, elementals, mycotoxins, seafood toxins, pesticide residues, other chemicals

3. Animal food/feed

Based on CVM data and expertise



Current Thinking in FDA

2. **Emphasis on contaminants with robust public health data (illnesses, hospitalizations and deaths)**
3. **Considerations related to contaminants having effective regulatory controls in place (e.g., pesticides, mycotoxins)**
4. **Considerations of contaminants with acute reactions versus those with chronic long-term exposure issues**
5. **Considerations for determining “most significant” versus “significant” status**



For more information

FDA Customer Health Information
www.fda.gov/ohrt

Food Bill Aims to Improve Safety

Recent data from the Centers for Disease Control and Prevention show that one in six people in the United States suffers from food-borne illness each year. Over the past few years, high-profile outbreaks related to various foods, from spinach and peanut products to eggs, have underscored the need to make continuous improvements in food safety.

The Food Safety Modernization Act (FSMA) gives FDA a mandate to pursue a system that is based on science and addresses hazards from farm to table, putting greater emphasis on preventing food-borne illness. The accounting is simple: The better the system handles producing, processing, transporting, and preparing foods, the safer our food supply will be.

Under the provisions of FSMA, companies will be required to develop and implement written food safety plans. FDA will have the authority to better respond and require recalls when food safety problems occur, and FDA will be able to better ensure that imported foods are as safe for consumers as foods produced in the U.S.

FDA Commissioner Margaret A. Hamburg, M.D., says the bill—which President Barack Obama is expected



1 | FDA Consumer Health Information | U.S. Food and Drug Administration | DECEMBER 2010

- Web site is at <http://www.fda.gov/fsma>
- *Watch for FSMA MSFC 104 open docket announcement*
- Subscription feature available
- Send questions to FSMA@fda.hhs.gov