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
Strategic Communications & Outreach Team –

Implementation Executive Committee

Prevention Standards
- Produce Safety Regulation
- Produce Safety Guidance
- Preventive Controls Regulation
- Preventive Controls Guidance
- Safe Food Transport
- Food Defense
- Contaminants

Inspection & Compliance
- Mandatory Recall / Recall Communications
- Administrative Enforcement Tools
- Registration
- Frequency of Inspection
- Manner of Inspection / Food Safety Plan Review
- Tracing
- RFR Improvements

Imports
- Importer Verification & VQIP
- Import Certification
- Accredited Third-Party Certification
- Lab Accreditation & Integrated Consortium / FERN
- International Capacity Building
- Comparability
- Task A: Prior Notice

Federal/State Integration
- Operational Partnership
- Capacity Building
- Training

Fees
- Inspection & Auditor Fees

Reports & Studies
- Reports to Congress/Studies

Sec 204. Includes: High risk foods to inform record keeping for tracking and tracing

Sec 104a. Most significant foodborne contaminants guidance document
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.
(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

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