
Overview

FDA Food Safety Modernization Act & Product Tracing

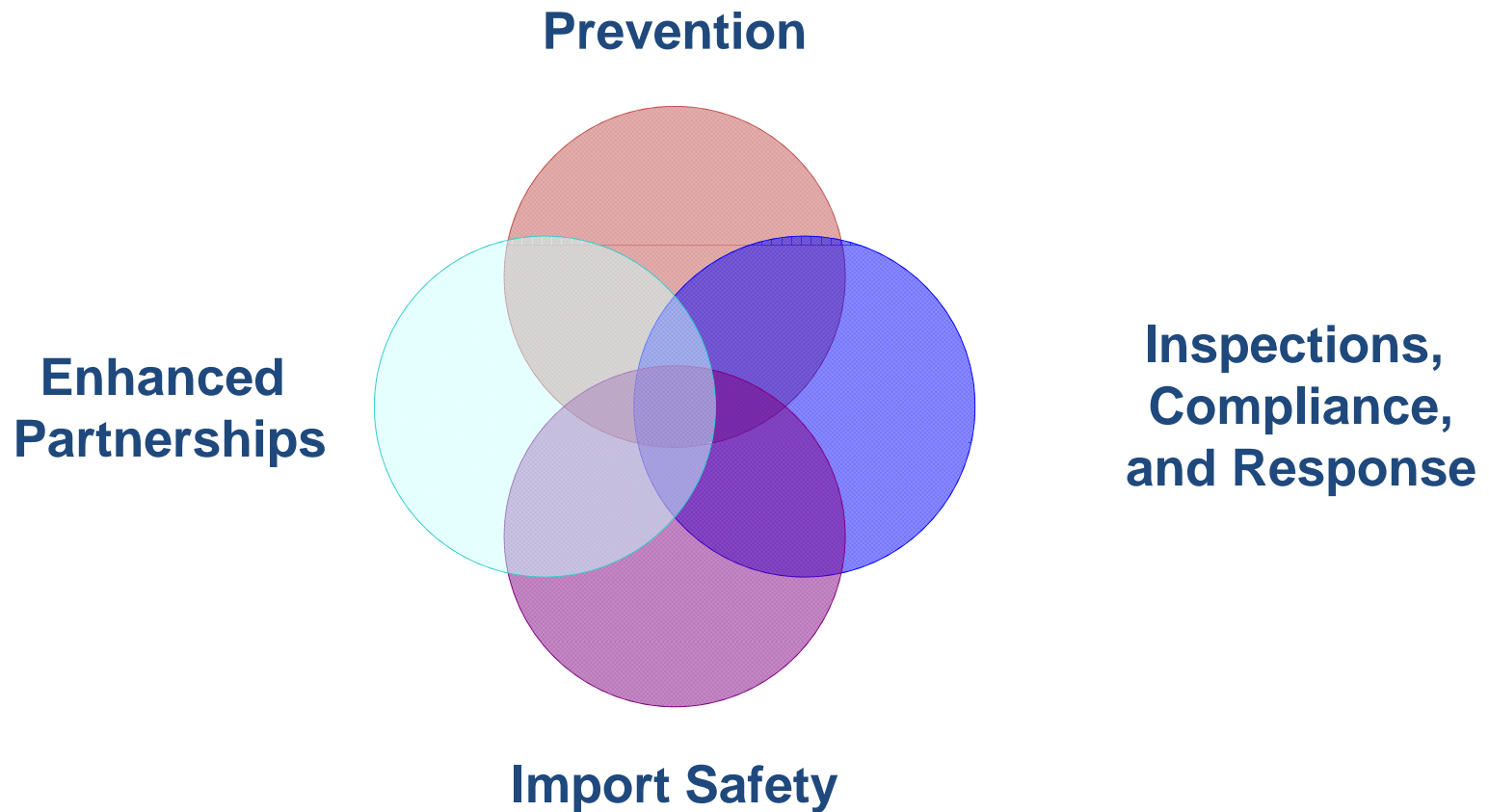


Outline

- Implementation Approach
- Product Tracing Requirements
- High Risk Foods Designation
- Rule making
- Summary



Main Themes of the Legislation



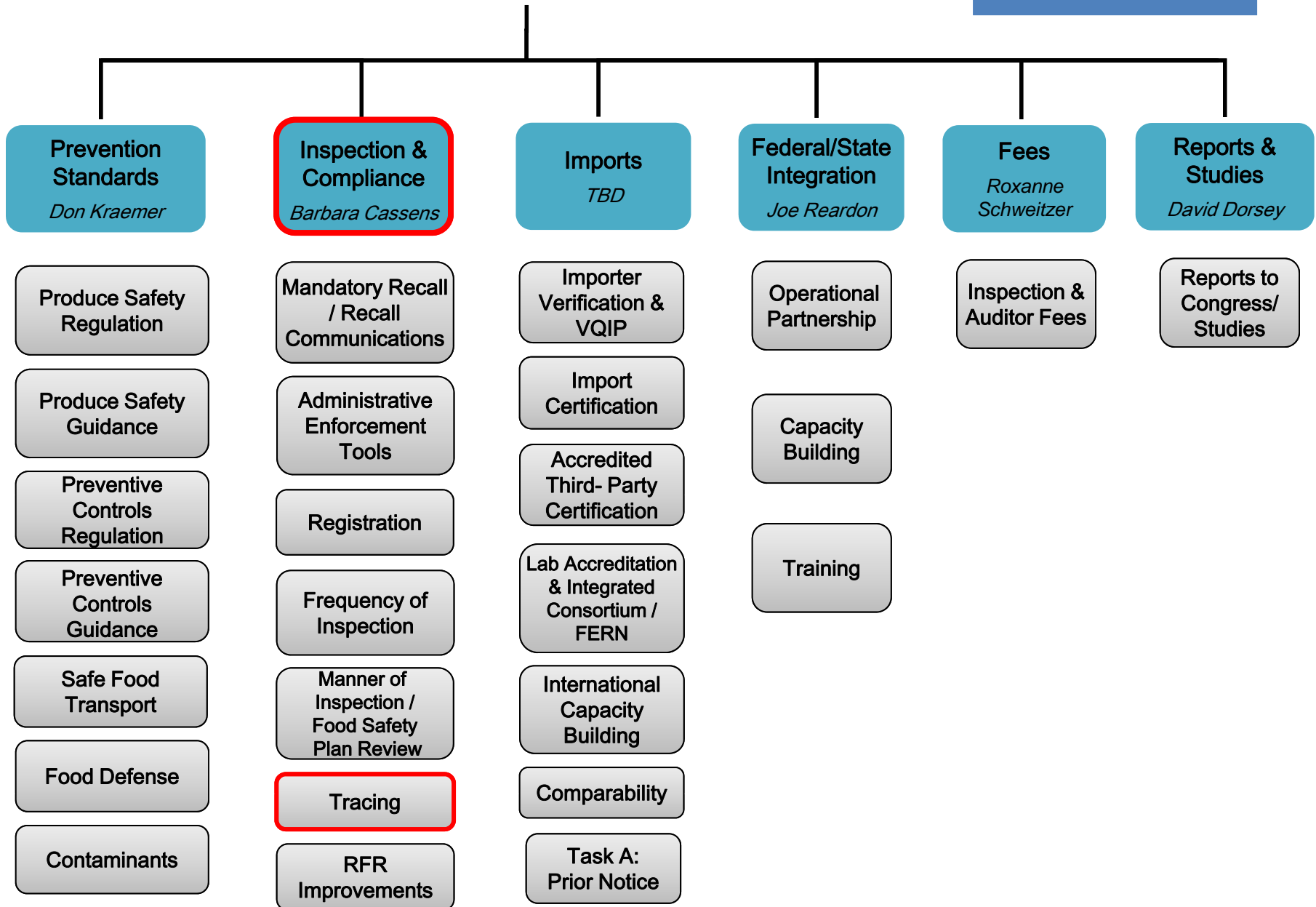
Implementation Approach

- Implementation already underway
- Coalition needed
- 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 –
Sharon Natanblut



Inspection, Compliance, and Response

- Mandated inspection frequency
 - More inspections, but with preventive controls in place, we can consider new ways to inspect
- New tools
 - Mandatory recall
 - Expanded records access
 - Expanded administrative detention
 - Suspension of registration
 - **Enhanced product tracing**
 - Third party laboratory testing



Product Tracing



FDA FOOD SAFETY
MODERNIZATION ACT

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Before FSMA:

- Priority for the Administration
 - President’s FSWG
- Reportable Food Registry – Sept, 2009
- 2 IFT Reports released in Dec, 2009. Industry “best practices” and tomato traceback exercise



Before FSMA:

- 2008 - Two Public Meetings
 - PRODUCE
- 2009 – joint Public Meeting by FDA and USDA
ALL FOODS
 - Purpose to stimulate and focus efforts on mechanisms to enhance product tracing
 - Substantive comments from speaker panels and public comment



FSMA

- FSMA signed into law January 4, 2011
- Title II. Section 204. Enhancing tracking and tracing of food and record keeping



Sec. 204. Key Requirements

- Pilot Projects
- Report to Congress
- Designation of High Risk Foods
- Proposed Rule
- Public meetings
- Final Rule
- Guidance



Pilot Projects

- Collaboration with IFT
- At least 2 pilots required:
 - Produce
 - Processed food
- Stakeholder input critical
- Findings to be included in report to Congress
- Findings to be considered in rulemaking



High Risk Foods List

HRFL designation shall be based on--

(i) the known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food;

(ii) the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce such food;



High Risk Foods List

(iii) the point in the manufacturing process of the food where contamination is most likely to occur;

(iv) the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;



High Risk Foods List

(v) the likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and

(vi) the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.



Determining High Risk Foods

- Many models, publications exists
 - Discussion
- FDA will look for input publicly
- Goal is rapid targeted response as well as prevention w/respect to product tracing
 - Data dependent...HRF..FSMA criteria...rule making...
- High Risk Foods List not static



Proposed Rule

- Product tracing requirement by January 4, 2013
 - FDA prioritizing the many rules required
- Record keeping requirements for high risk foods
 - Info gathering:
 - 3 Public Meetings
- Challenges
 - Many exemptions



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.



But, many challenges

- Enormous workload
 - 50 new rules, guidance documents, reports in 3 years
- Tight deadlines
- Changes won't appear overnight
 - Building new system will be a long-range process
- Resources



Summary

- Pilot projects underway
- Approach to High Risk Foods being formulated
 - Obtain stakeholder input and data
- Report to Congress - 2012
- Begin drafting proposed rule



For more information

FDA Customer Health Information
www.fda.gov/ohrtips

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



- Check <http://www.fda.gov/fsma> to find out what is open for comment
- Send questions to FSMA@fda.hhs.gov