



U.S. Food and Drug Administration  
Protecting and Promoting Public Health

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# FSMA-Related Needs For A Risk-Based Decision-Making System

***COLLABORATIVE FOOD SAFETY FORUM  
Food Attribution Session***

***February 1, 2012***





# Objectives

 Prepare the playing field



FSMA



Risk-Based Decision Making

 Attribution is key to food safety game plan



PUBLIC LAW 111-353—JAN. 4, 2011      124 STAT. 3885

Public Law 111-353  
111th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

Jan. 4, 2011  
(H.R. 2751)

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

FDA Food Safety  
Modernization  
Act.

**SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.**

21 USC 2201  
note.

(a) **SHORT TITLE.**—This Act may be cited as the “FDA Food Safety Modernization Act”.

(b) **REFERENCES.**—Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) **TABLE OF CONTENTS.**—The table of contents for this Act is as follows:

Sec. 1. Short title; references; table of contents.

**TITLE I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS**

- Sec. 101. Inspections of records.
- Sec. 102. Registration of food facilities.
- Sec. 103. Hazard analysis and risk-based preventive controls.
- Sec. 104. Performance standards.
- Sec. 105. Standards for produce safety.
- Sec. 106. Protection against intentional adulteration.
- Sec. 107. Authority to collect fees.
- Sec. 108. National agriculture and food defense strategy.
- Sec. 109. Food and Agriculture Coordinating Councils.
- Sec. 110. Building domestic capacity.
- Sec. 111. Sanitary transportation of food.
- Sec. 112. Food allergy and anaphylaxis management.
- Sec. 113. New dietary ingredients.
- Sec. 114. Requirement for guidance relating to post harvest processing of raw oysters.

# FDA Food Safety Modernization Act

## Prevent Food Safety Problems

## Detect and Respond to Food Safety Problems

## Safety of Imported Foods

## Miscellaneous Provisions







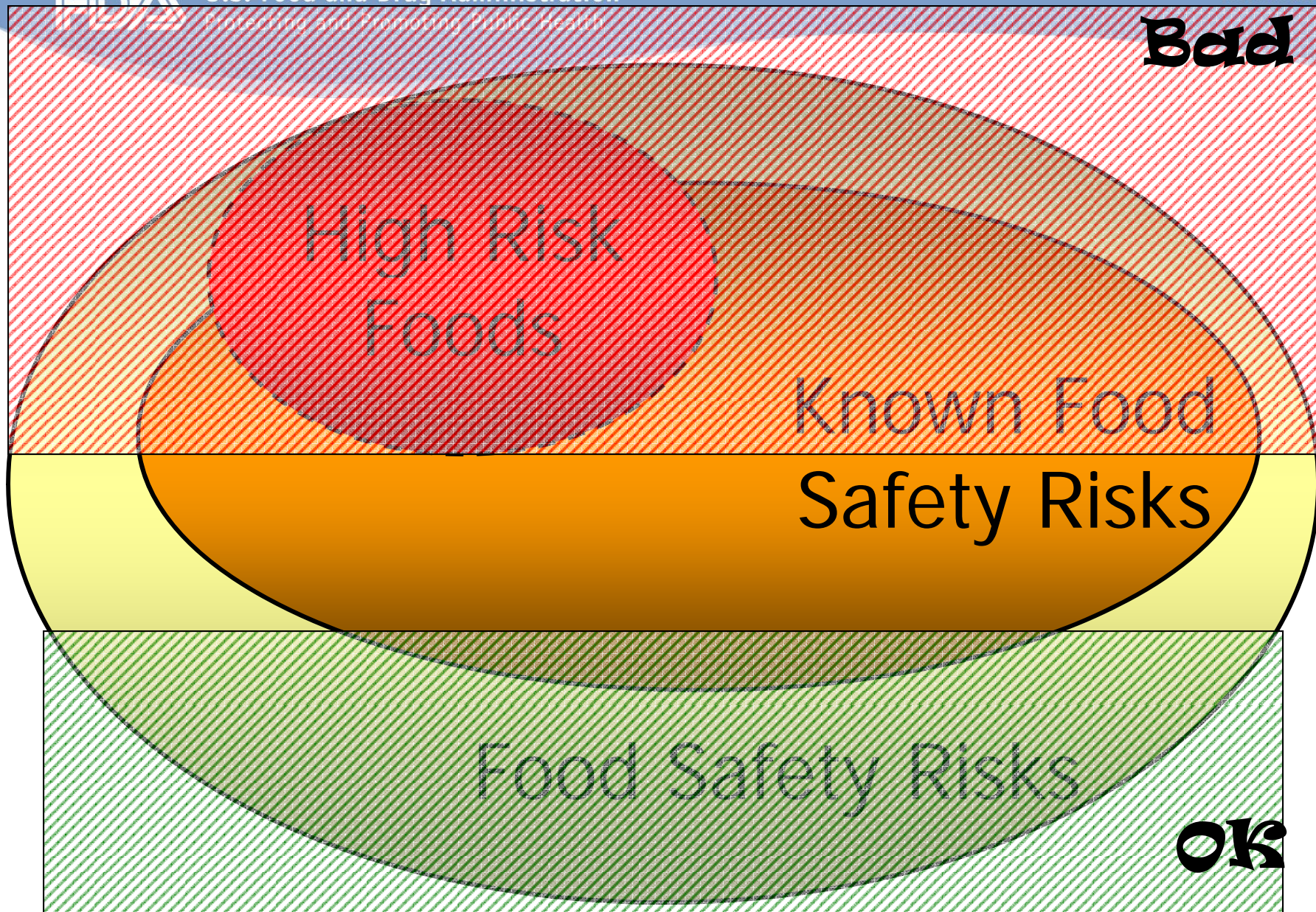
# FSMA Risk Terms

- 🍌 Most significant foodborne contaminants
- 🍌 Known food safety risks
- 🍌 High risk facilities/known safety risks of facilities [*Domestic*]
- 🍌 Known safety risks of the article of food [*Imported*] –
- 🍌 High-risk foods
- 🍌 High risk facilities, suppliers, and food types
- 🍌 Level of risk
- 🍌 Risk of the food



# More FSMA Risk Terms

-  Low risk foods
-  Low risk on-farm manufacturing, processing, packing, or holding activities
-  Low risk fruits and vegetables that are raw agricultural commodities
-  Automated risk assessment system for food safety surveillance and allocation of resources



\*Not Drawn to Scale



# Criteria in FSMA for “high risk”

	Inspection Resources (Domestic)	Inspection Resources (Imports)	Tracking & Tracing	Voluntary Qualified Importer Program	Import Certification
Term	High risk	High risk	High risk foods	Risk of the food	Risk of the food
Known safety risks	The known safety risks of the food manufactured, processed, packed, or held at the facility	The known safety risks of the food imported	The known safety risks of a particular food*	The known safety risks of the food to be imported	The known safety risks associated with the food
Known safety risks II		The known safety risks of the countries or regions of origin and countries through which such article of food is transported			known food safety risks associated with the country, territory, or region of origin of the food
Compliance history	The compliance history of a facility, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards	The compliance history of the importer, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards		The compliance history of foreign suppliers used by the importer, as appropriate	
Rigor and effectiveness of preventive controls	The rigor and effectiveness of the facility’s hazard analysis and risk-based preventive controls	The rigor and effectiveness of the activities conducted by the importer of such article of food to satisfy the requirements of the foreign supplier verification program under section 805		1) The capability of the regulatory system of the country of export to ensure compliance with United States food safety standards for a designated food; 2) The compliance of the importer with the requirements of section 805; 3) The recordkeeping,	a finding by the Secretary, supported by scientific, risk-based evidence, that the food safety programs, systems, and standards in the country, territory, or region of origin of the food are inadequate to ensure that the article of food is as safe as a similar article of food



## **Enhancing Food Safety: The Role of the Food and Drug Administration**

(Institute of Medicine 2010)

### **IOM reports lists 23 recommendations**

Toward a risk-based approach

Sharing the Responsibility

Creating a Data Surveillance Infrastructure

Creating a Research Infrastructure

Integrating Federal, State, and Local Food Safety Programs

Enhancing the Efficiency of Inspections




Improving Food Safety and Risk Communication

Modernizing Legislation




Realizing the Vision of an Efficient Food Safety System





# IOM's Attributes of a Risk-Based Food Safety System

-  A risk-based system is proactive and based on a strategic management plan
-  A risk-based system is data driven
-  A risk-based system is grounded in the principles of risk analysis

# Attributes of a Risk-Based Food Safety System

- 
 A risk-based system employs analytical methods to rank risks based on public health impact
- 
 A risk-based system employs analytical methods to prioritize the allocation of limited resources to manage risk most effectively
- 
 A risk-based system considers other factors in decision making when appropriate

# Attributes of a Risk-Based Food Safety System

-  A risk-based system employs measures to evaluate the efficacy of the risk management program on a continuous basis
-  A risk-based system performs all of these functions in a systematic and transparent manner with the involvement of stakeholders



# Points to Ponder

🏈 “Black Boxes” and “Turn the cranks”

🏈 Risk-Based / Risk-Informed