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
**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
### Criteria in FSMA for “high risk”

<table>
<thead>
<tr>
<th>Term</th>
<th>Inspection Resources (Domestic)</th>
<th>Inspection Resources (Imports)</th>
<th>Tracking &amp; Tracing</th>
<th>Voluntary Qualified Importer Program</th>
<th>Import Certification</th>
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<tbody>
<tr>
<td>Known safety risks</td>
<td>High risk</td>
<td>High risk</td>
<td>High risk foods</td>
<td>Risk of the food</td>
<td>Risk of the food</td>
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<tr>
<td>Term</td>
<td>The known safety risks of the food manufactured, processed, packed, or held at the facility</td>
<td>The known safety risks of the food imported</td>
<td>The known safety risks of a particular food*</td>
<td>The known safety risks of the food to be imported</td>
<td>The known safety risks associated with the food</td>
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<td>Known safety risks II</td>
<td></td>
<td>The known safety risks of the countries or regions of origin and countries through which such article of food is transported</td>
<td></td>
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<td>known food safety risks associated with the country, territory, or region of origin of the food</td>
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<td>Compliance history</td>
<td>The compliance history of a facility, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards</td>
<td>The compliance history of the importer, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards</td>
<td></td>
<td>The compliance history of foreign suppliers used by the importer, as appropriate</td>
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<td>Rigor and effectiveness of preventive controls</td>
<td>The rigor and effectiveness of the facility’s hazard analysis and risk-based preventive controls</td>
<td>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</td>
<td></td>
<td>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,</td>
<td>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</td>
</tr>
</tbody>
</table>
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