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## A New Mix of Private and Public

*How Well Might the*

*U.S. Food Safety Modernization Act Work?*

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## Global, Local, Private, Public: Rethinking the Categories

- Private Public Partnerships
- The Food Safety Modernization Act as an example

## Food Safety Modernization Act (FSMA)

- 1<sup>st</sup> major update of Food & Drug Administration regulatory system since 1938
  - FDA regulates about 80% of the US food supply
- Gives FDA extensive new powers to
  - Prevent food safety problems
  - Detect and respond to food safety issues
  - Improve the safety of imported foods

## The New Mix of Public and Private Under FSMA

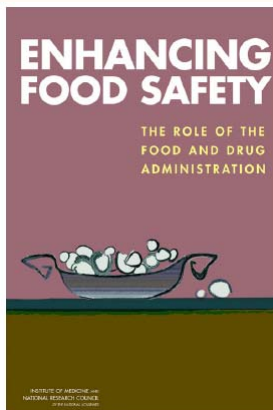
- Preventive Controls for Human Food Rule
- Produce Safety Rule
- Import Rule & Accreditation of Third-Party Auditors

## How Well Might FSMA Work?

- Is it a risk-based food safety system?
- Does it select and set up interventions that effectively reduce risk (& through what mix of private and public effort)?

## How Well Might FSMA Work?

- Is it a risk-based food safety system?
- My standard:



<http://www.iom.edu/Reports/2010/Enhancing-Food-Safety-The-Role-of-the-Food-and-Drug-Administration.aspx>

## The Risk-Based Food Safety System



## How Well Might FSMA Work?

- Is it a risk-based food safety system?
  - Strong move in the right direction, part of a progression
  - Not a transformation
  - Biggest challenge: can incremental change get us to a risk-based system?

## How Well Might FSMA Work?

- Does it select and set up interventions that effectively reduce risk?

## The New Mix of Public and Private Under FSMA

- Preventive Controls for Human Food Rule
  - New requirements for hazard analysis and risk-based preventive controls
  - Extends requirement to entire set of FDA regulated foods for first time
  - Revisions to existing Current Good Manufacturing Practice (GMP) requirements

*Increases and shifts responsibility to industry*

## The New Mix of Public and Private Under FSMA

### ■ Produce Safety Rule

- First extensive on-farm regulation by FDA
  - Examples: water quality and use, use of manure and compost, wildlife control

*Increases and shifts responsibility to industry*

## The New Mix of Public and Private Under FSMA

### ■ Import Rule & Accreditation of Third Party Auditors

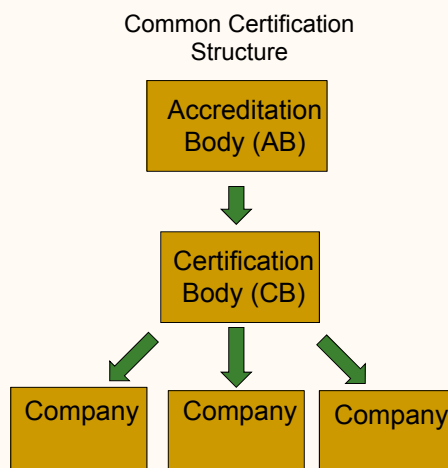
- Lessen reliance on point of entry inspection; change to importer verification of compliance with U.S. standards
- Importer accountability – Foreign Supplier Verification Program
- Use of some Third Party certification (includes foreign governments)
- Authority to deny entry

*Increases and shifts responsibility to industry*

## The Changing Private Public Mix: The Import Rule as an Example

- Importers verify compliance with US standards
- Can use third party certifiers to provide assurance of compliance and in some cases fast track entry to the US
  - Who will be accredited? How will the market develop?

## Structure of Certification Systems ~ The Certification Market~



Commonly:

- AB appointed/approved by standard scheme owner
- AB establishes requirements of CBs
- AB requirements of CBs variable, but often include:
  - Certification to 3<sup>rd</sup> party standard(s)
  - Application, assessment, royalty, and annual accreditation fees



## Structure of Certification Industry

- Extent of competitiveness varies
  - Across sub-national and international regions
  - Across certifications
  - In practice, many local, regional monopolies, oligopolies – especially in foodservice certification

## Knowledge Gaps

- What is the structure of the certification industry?
- Do these certification systems work reliably?
- Are they efficient?
  - Lowest cost for outcomes
- Are they equitable?
  - Costs and benefits fairly shared along the supply chain

## How Well Might FSMA Work?

- Does it select and set up interventions that effectively reduce risk?
  - Strong move in the right direction
  - But did go directly to an intervention answer
  - Many regulatory details still under development

## The Risk-Based Food Safety System



## Post-FSMA Food Safety Certification Industry

- FSMA has important implications for imports and global standards
- Market environment changed; governments are permitted to become accreditors

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