

Practical Aspects of the Food Safety Modernization Act of 2011

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Overview

- About NSF International
- Key Food Safety Issues
- The Impact of Foodborne Illness
- Food Trends in the U.S.
- The Food Safety Modernization Act of 2011
- Focus on Imports
- Private Sector Activity to Support FSMA

About NSF International

Founded as **National Sanitation Foundation** at the University of Michigan, School of Public Health in **1944** as a 501 c 3 non-profit to test for **public health and safety**.



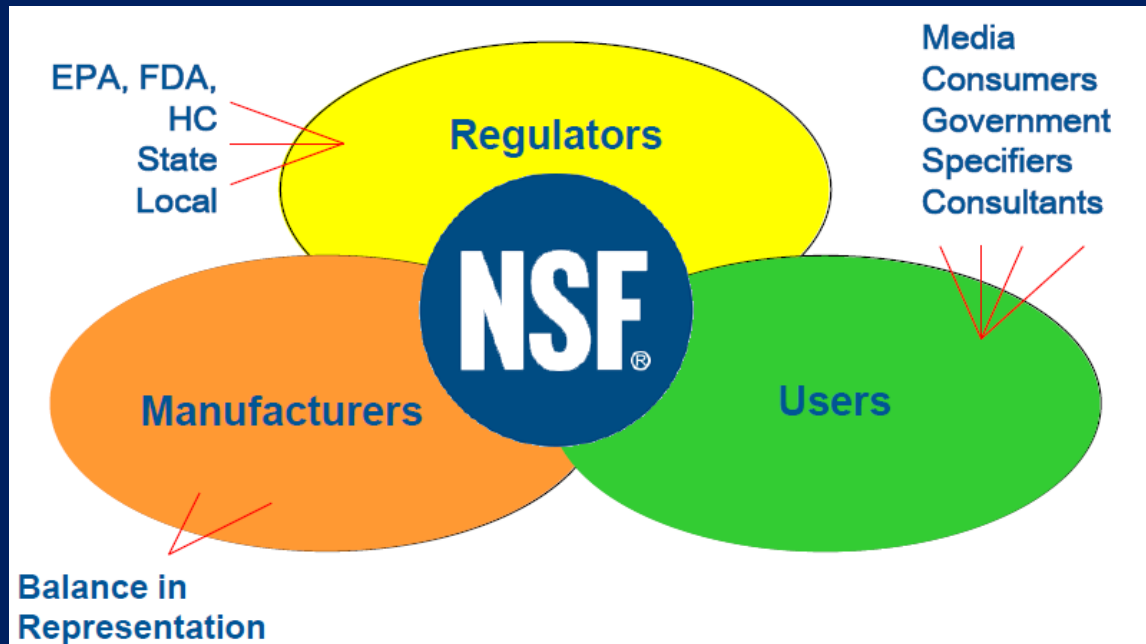
About NSF International

- Develop Voluntary Consensus Standards

- Foodservice equipment
- Water Supply Products
- Biohazard Cabinetry
- Wastewater equipment
- OMB A119
- NTTAA

- Inspect, test and certify

- Health departments
- Food codes
- Plumbing codes



About NSF International

- Product inspections/testing/certifications include:
 - Foodservice Equipment
 - Water Supply Chemicals and Equipment
 - Biohazard Cabinetry
 - Wastewater Equipment
 - Food (farm to fork)
 - Dietary Supplements and GMPs
 - Reference Standards
 - Toys and Children's Products
 - Sustainability
 - Green Chemistry
 - Organic Certification



About NSF International

Key Facts

- >1200 employees (chemists, microbiologists, sanitarians, engineers)
- 20 offices worldwide
- Serve tens of thousands of companies in more than 100 countries
- Perform > 160,000 inspections/audits/year – most in food safety
- World Health Organization Collaborating Centre
 - Food / Water / Indoor Environment
- Laboratories in Michigan, UK, China
- Accredited certification programs
- Largest domestic GFSI certifier in SQF and BRC
- Toxicology department publishes chemical risk assessments
- Hundreds of thousands of formulations on file



Current Partners for Certification

Each Lot is tested for more than 140 banned substances



- Stimulants
- Narcotics
- Steroids
- Diuretics
- Beta-2 Agonists
- β -blockers
- Masking agents

Guided by:



CCES Canadian Centre for Ethics in Sport
Centre canadien pour l'éthique dans le sport

Events Driving Regulatory Change

- **Bioterrorism**
 - 9/11 & Anthrax attacks
 - BT Act of 2002
- **Hazardous Imports**
 - Lead in Toys and Contaminated Toothpaste
 - Action Plan for Import Safety of 2007
 - CPSIA of 2008
- **Foodborne Illnesses & Recalls**
 - Melamine in Pet Foods
 - High Profile Foodborne Illness Outbreaks
 - Food Protection Plan of 2007
 - FSMA of 2011

High Profile Foodborne Illness Outbreaks

- E. coli O157:H7 in CA bagged spinach (2006)
- Salmonella in pot pies
- E. coli O157:H7 in ground beef
- Botulism in chili sauce
- Salmonella in peanut butter
- E. coli O157:H7 in green onions or lettuce
- Salmonella (St. Paul) in salsa ingredient (tomato/pepper/cilantro)
- Salmonella in peanut butter (PCA) + Pistachios
- Listeria in sliced meats (Maple Leaf)
- E. coli O157:H7 in cookie dough (Nestle Toll House)
- Sliced salami for salmonella, imported black pepper suspected
- E. coli in romaine lettuce
- Eggs with high levels of Salmonella (2010)
- Hazelnuts in shells – E. coli O157:H7 (2011)
- Listeria in Cantaloupes (Jensen Farms) (2011)

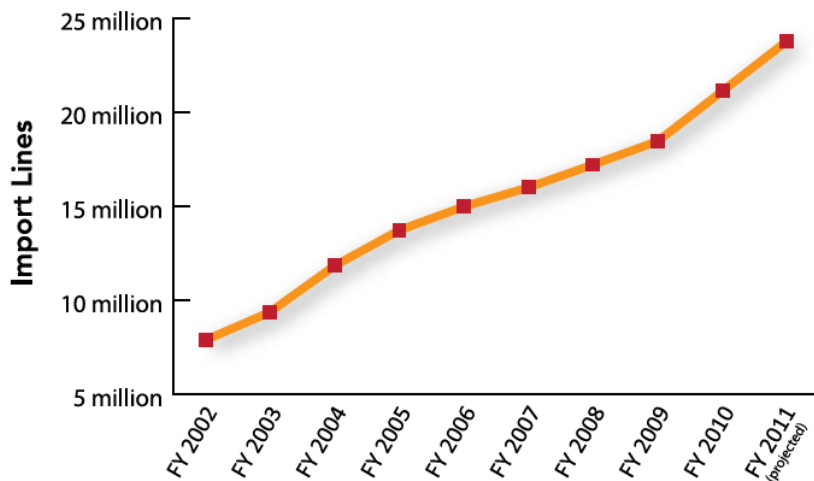
High Cost of Foodborne Illness Outbreaks

- Foodborne illness is a significant burden (CDC 2011)
 - 48 million (1 in 6 Americans) get sick each year
 - 128,000 are hospitalized
 - 3,000 die
- Costs are in the tens of billions of dollars
- Immune-compromised individuals more susceptible
 - Infants and children, pregnant women, seniors, those on chemotherapy, transplant
- Foodborne illness can cause life-long chronic disease
 - Arthritis, kidney failure

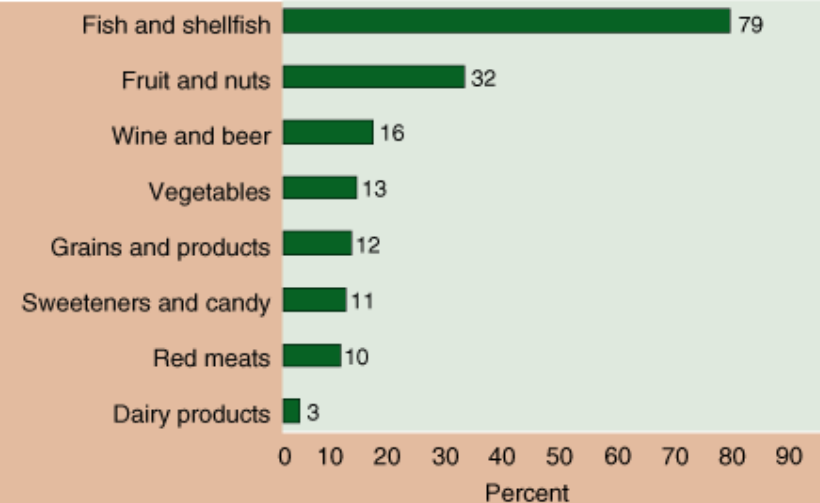
Food and Import Trends

- **Globalization**
 - 15% of U.S. food supply and 80% of seafood is imported
 - 20% of vegetables and 50% of fresh fruit are imported
- **Food supply more high-tech and complex**
 - More foods in the marketplace and emerging hazards
- **Shifting demographics**
 - Growing population (30%) is “at risk” for foodborne illness

Imports of FDA-Regulated Products
Have Grown Dramatically in Recent Years



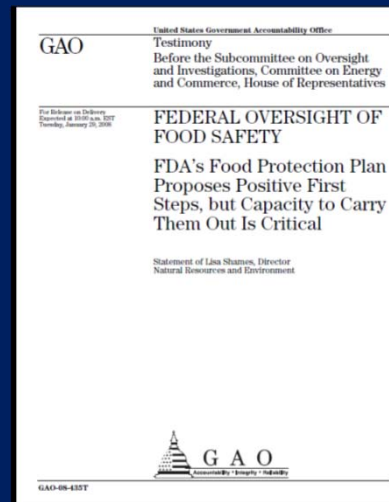
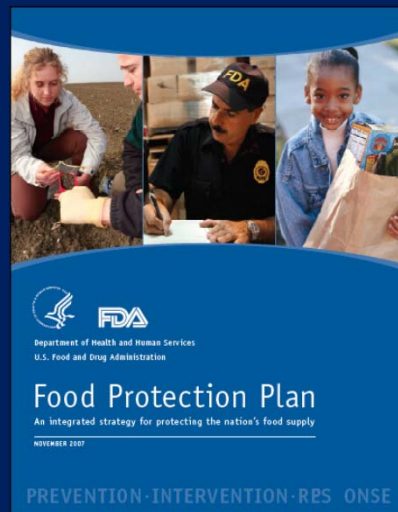
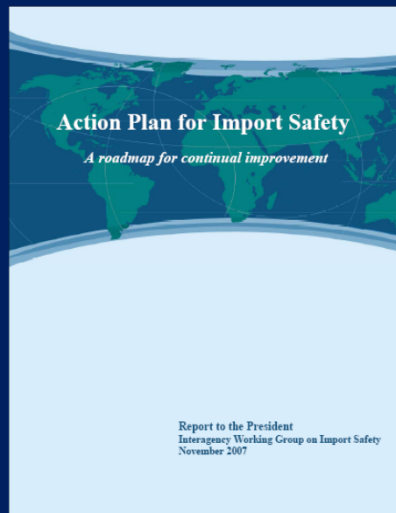
Import shares by volume are highest for fish and shellfish, 2000-05



Source: USDA, Economic Research Service.

Government Attempts to Address Risks

- FDA Food Protection Plan in 2007
 - Prevention, Intervention, Response
- Multiple bills over last 3 Congresses
- HR 2749 passed July 2009
- S 510 passed in December 2010
- President signs HR 2751 (FSMA) Jan 4, 2011



What's in FSMA

- Lots of Detail – 236 pages
- Most changes to FDCA since 1938
- Risk Based and Science Based
- Mandates to FDA and to Industry
- New FDA Enforcement Authorities
- New Import Requirements
- More Inspections Mandated
- Performance Standards
- Consumer Communications
- More Funding*

H. R. 2751

One Hundred Eleventh Congress
of the
United States of America

AT THE SECOND SESSION

Began and held at the City of Washington on Tuesday,
the fifth day of January, two thousand and ten

An Act

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

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

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

(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 oys-
ters.
Sec. 115. Port shopping.
Sec. 116. Alcohol-related facilities.

TITLE II.—IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD
SAFETY PROBLEMS

Sec. 201. Targeting of inspection resources for domestic facilities, foreign facilities,
and ports of entry; annual report.
Sec. 202. Laboratory accreditation for analyses of foods.
Sec. 203. Integrated consortium of laboratory networks.
Sec. 204. Enhancing tracking and tracing of food and recordkeeping.
Sec. 205. Surveillance.
Sec. 206. Mandatory recall authority.
Sec. 207. Administrative detention of food.
Sec. 208. Denaturation and disposal standards and plans.
Sec. 209. Improving the training of State, local, territorial, and tribal food safety
officials.
Sec. 210. Enhancing food safety.

FSMA Highlights

- **Timing of Requirements**
 - Some effective immediately
 - Some to be phased in
 - Some require rulemaking
 - Some require funding
- **Focus Areas**
 - Prevention
 - Detection
 - Response
 - Imported Foods
- **Exemptions**
 - Facilities already subject to HACCP requirements
 - Animal food, grain storage facilities
 - On-Farm Manufacturing, Processing, Packing, Holding Operations
 - Qualified Facilities (Small Farms)
 - Revenue limited businesses



HR2751 – Title 1: Prevention

- 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 for fees (re-inspection, recalls, VQIP)
- 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. Guidance on processing of raw oysters
- Sec. 115. Port shopping
- Sec. 116. Alcohol-related facilities

HR2751- Title 2: Detection / Response

- Sec. 201. Targeted inspection of food facilities & ports (Risk Based)
- Sec. 202. Laboratory accreditation for analyses of foods
- Sec. 203. Integrated consortium of laboratory networks
- Sec. 204. Enhancing tracking/tracing of food and recordkeeping
- Sec. 205. Enhance Surveillance by FDA and CDC
- Sec. 206. Mandatory recall authority
- Sec. 207. Administrative detention of food
- Sec. 208. Decontamination and disposal standards and plans
- Sec. 209. Improving training standards for State and Territory FSOs
- Sec. 210. Enhancing food safety through grants to States etc.
- Sec. 211. Improving the reportable food registry

HR2751 – Title 3: Imports

- Sec. 301. Foreign supplier verification program. FSVP
- Sec. 302. Voluntary qualified importer program. VQIP
- Sec. 303. Authority to require import certifications.
- Sec. 304. Prior notice of imported food shipments.
- Sec. 305. Building capacity of foreign governments.
- Sec. 306. Inspection of foreign food facilities.
- Sec. 307. Accreditation of third-party auditors.
- Sec. 308. Foreign offices of the FDA.
- Sec. 309. Smuggled food.

HR2751 – Title 4: Miscellaneous

Sec. 401. Funding for food safety

Sec. 402. Employee protections (whistle blower protection)

Sec. 403. Jurisdiction; authorities

Sec. 404. Compliance with international agreements

Sec. 405. Determination of budgetary effects

FDA Implementation Executive Committee

Strategic Communications
& Outreach Team –
Sharon Natanblut

Prevention Standards

Don Kraemer

Produce Safety
Regulation

Produce Safety
Guidance

Preventive
Controls
Regulation

Preventive
Controls
Guidance

Safe Food
Transport

Food Defense

Contaminants

Inspection & Compliance

Barbara Cassens

Mandatory Recall
/ Recall
Communications

Administrative
Enforcement
Tools

Registration

Frequency of
Inspection

Manner of
Inspection /
Food Safety
Plan Review

Tracing

RFR
Improvements

Imports

David Elder

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

Joe Reardon

Operational
Partnership

Capacity
Building

Training

Fees

*Roxanne
Schweitzer*

Inspection &
Auditor Fees

Reports & Studies

David Dorsey

Reports to
Congress/
Studies

FSMA Progress in 2011

Jan '11	President Obama signed bill	
April	Consumer-Friendly Web Search for Recalls	(SEC. 205)
April	First HHS Report to Congress	(SEC. 201)8
April	Guidance on Seafood Safety Hazards	(SEC. 103)4
May	Interim Rule on Prior Notice of Imports	(SEC. 304)14
May	Interim Rule on Administrative Detention	(SEC. 207)12
May	Preventive Controls for Registered Facilities Docket Opened	(SEC. 103)10
July	Joint Anti-Smuggling Strategy	(SEC. 309)18
July	Draft Guidance for Dietary Supplement Industry	(SEC. 113)20
July	Authority to Suspend Facility Registration Established	
July	MOU Signed with USDA on training	(SEC. 209)16
July	Anti-smuggling strategy of HHS & DHS	(SEC. 309)19
July	Draft dietary supplement guidance re NDIs	(SEC. 113)20
Aug	2012 fee schedule for facility re-inspections	(SEC. 107)22
Sept	Report on FERN coordination of 172 test labs	(SEC. 202)
Oct	Guidance on Administrative Detention of Food	
Nov	FDA Budget FY12 increased by \$50M to \$2.5B	

FSMA Progress 2012

Jan	One Year Anniversary of FSMA	
Feb	Guidance on FDA Records Access Authority (FFDCA 414 & 704)	FDA-2011-D-0674
Feb	Interim Final Rule on FDA Access to Records	FDA-2002-N-0153
Feb	Report to Congress on FDA Offices Overseas (13 to date)	
Feb	Taylor addresses GFSI in Orlando	
Mar	FDA Announces Foods for Product Tracing Pilots (IFT)	
	Tomatoes, Frozen Kung Pao Entrees, Jarred Peanut Butter	
Mar	Identifying High Risk Facilities	

FSMA Risk Factors

Risk Based Factor	Data Elements
Known Safety Risks of the Food	Class 1 recalls and/or Outbreaks
Facility Compliance History	Significant violations (OAI) or History of non-compliance (VAI>3)
Facility's Hazard Analysis or Risk Based Preventive Controls	Facility has limited data upon which to evaluate
Priority under Section 801(h) (1)	Not applicable to domestic facilities
Certifications for Imported Foods	Programs not yet established
Other relevant criteria	Establishment type, type of activity, and years since last inspection.

Expectations in FSMA

- Domestic High Risk = 5yr/3yr thereafter
- Domestic Non High Risk = 7yr/5yr thereafter
- 600 foreign inspections in year 1, 9600 by year 5
- How will we get there?
 - Recognizing other countries' food safety systems
 - MOUs and USDA model
 - Building capacity of foreign governments
 - Focus resources on risk
 - Recognizing third party audits and certifications
- Building domestic capacity
 - IFPTI to train federal, state and local capacity
 - Auditor competency

Current Regulatory Oversight

- HHS Inspector General Report of 2010
 - FDA inspects < ¼ of facilities
 - >56% are > 5years w/o inspection
 - OAI's have declined over time
 - FDA took regulatory action against 46% of OAI's
 - FDA took no further action against 36% of OAI's
- HHS Inspector General Report of 2011
 - FDA has increasingly relied on States to inspect food facilities
 - In 8 States, FDA failed to ensure that the required number of inspections was completed
 - FDA paid for many inspections that were incomplete
 - FDA did not ensure all State inspections were properly classified and all violations remedied
 - FDA failed to complete the required number of audits for 1/3 of States and did not always follow up on systemic problems identified

	Domestic Facilities	2011 FDA Inspected	2011 State Inspected
Active Registered	167,000		
Food Processing	82,300		
High Risk	22,335	6,500	4,500
Non-High Risk	60,000	3,200	4,800
Other		800	700
Total		10,500	10,000
Budgets	\$172M	\$130M	\$17M
Cost / Facility Inspected		\$12,400	\$1700

estimates	Foreign Facilities	2011 FDA Inspected	Third Party Audits
Active Registered	254,000		
Food Processing	??		
High Risk	34,000 (min)		
Non-High Risk	220,000		
Other			
Total		357	Unlimited
Budget	\$25.7M	\$25.7M	
Cost to Govt / Facility Inspected		\$72000	0

Importing Food



Close Up on Section 307 - Certification

- Accreditation of Third Party Certification Programs
 - Role restricted to certification of imported foods
 - Supports FSVP and VQIP
 - FDA must identify accreditation body in 2 years, or FDA accredits
 - Certifiers will pay fees – TBD
 - Sharing inspection data with FDA upon demand
 - Tight rules around auditor qualifications, training, experience
 - Tightening Conflict of Interest rules
 - Distinction between Consultative and Regulatory Audits
 - Overdue proposed rules

Third Party Certification

- Very well defined system of using accredited third party certification as a compliance tool
 - Electrical, Fire Safety, Plumbing, Medical Devices, Toys
- Definitions
 - 1st Party – Internal
 - 2nd Party – Contractual
 - 3rd Party – Independent Certification to Established Standard
 - Accredited and Unaccredited
 - 4th Party – Government / Regulatory
- Accreditations
 - ISO 17065
- Examples
 - GFSI = SQF, BRC, ISO 22000, etc



Using Third Parties Effectively

- Global environment demands a global solution
- Government cannot and should not, do it all
 - See HHS OIG reports for 2010 and 2011
- OMB A119 and NTTAA
- All national accreditation bodies are not created equal
- All third parties are not created equal
- GFSI benchmarked standards comply with FDA and Codex
- Food Safety Services Providers = 10 Accredited GFSI firms
- Talk to us! We really are here to help.



Questions???



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