
Focus on Imports FDA Food Safety Modernization Act

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Food Safety Modernization Act

“I thank the President and members of Congress for recognizing that the burden that foodborne illness places on the American people is too great, and for taking this action.”

*Margaret A. Hamburg, M.D.,
Commissioner of Food and Drugs*



Agenda

- The public health imperative
- Why is the law needed?
- Provisions of the law; focus on imports
- Implementation

The Public Health Imperative

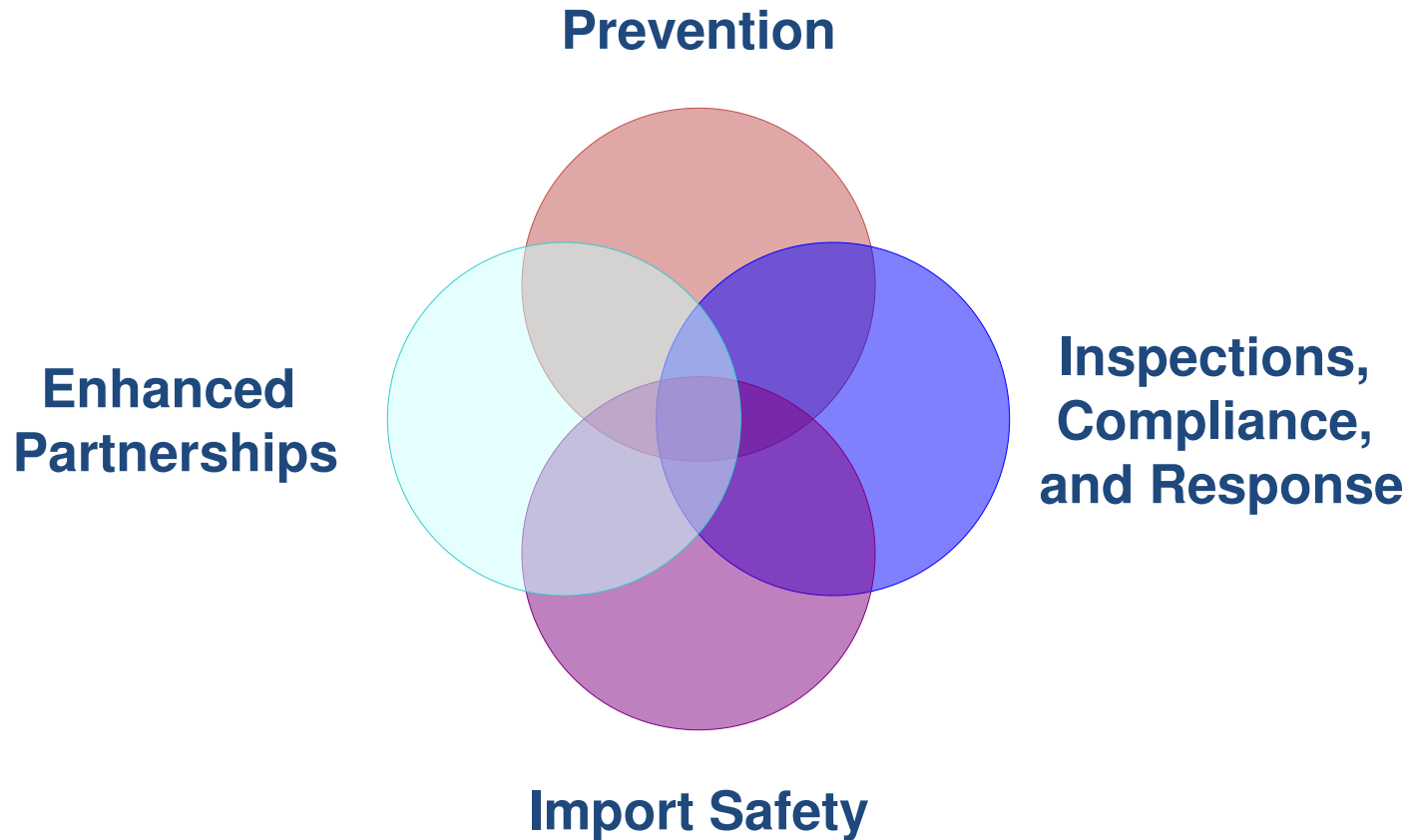
- Foodborne illness is a significant burden
 - About 48 million (1 in 6 Americans) get sick each year
 - 128,000 are hospitalized
 - 3,000 die
- Immune-compromised individuals more susceptible
 - Infants and children, pregnant women, older individuals, those on chemotherapy
- Foodborne illness is not just a stomach ache—it can cause life-long chronic disease
 - Arthritis, kidney failure



Why is the law needed?

- Globalization
 - 15 percent of U.S. food supply is imported
- Food supply more high-tech and complex
 - More foods in the marketplace
 - New hazards in foods not previously seen
- Shifting demographics
 - Growing population (about 30%) of individuals are especially “at risk” for foodborne illness

Main Themes of the Legislation



Import Safety:

Most Groundbreaking Shift

- Current reliance on port-of-entry inspection cannot handle increase in imported food.
- Importers now responsible for ensuring that their foreign suppliers have adequate preventive controls in place
- Requires food from abroad to be as safe as domestic

Import Safety Mandates

Sec. 301. Foreign supplier verification program

- Requires importers to verify their suppliers use risk-based preventive controls that provide same level of protection as U.S. requirements.

Sec. 302. Voluntary qualified importer program

- Allows for expedited review and entry; facility certification required

Sec. 303. Certification for high-risk food imports

- FDA has discretionary authority to require assurances of compliance for high-risk foods



Import Safety Mandates

Sec. 304. Prior notice of imported food shipments

- Requires information on prior refusals to be added to prior notice submission

Sec. 305. Capacity building

- FDA mandate to work with foreign governments to build food safety capacity

Sec. 306. Inspection of foreign food facilities

- Can deny entry if FDA access for inspection is denied

Sec. 201. Targeting of inspection resources

- Increased inspection of foreign as well as domestic facilities



Import Safety Mandates

Sec. 307. Accreditation of third-party auditors

- FDA can rely on accredited third parties to certify that foreign food facilities meet U.S. requirements

Sec. 308. Foreign Offices of the Food and Drug Administration.

- Establish offices in foreign countries to provide assistance on food safety measures for food exported to the U.S.

Sec. 309. Smuggled Food

- In coordination with DHS, better identify and prevent entry of smuggled food



Role of Third-Party Certification Programs

- Tool for importers to obtain needed assurances to meet their obligations for the foreign supplier verification program (sec. 301)
- A way for importers to participate in the voluntary qualified importer program to expedite movement of food through the import process (sec. 302)
- Can be required by FDA to accompany high-risk foods (sec. 303)

Import Provisions Work as a Whole

Accreditation Body
Accredits 3rd parties
Sec. 307

3rd Party Certification
Certify high-risk
food imports
Sec. 303

**Foreign supplier
verification program**
Foreign firms obtain 3rd party
certification as needed
Sec. 301

**Voluntary Qualified
Importer Program**
Importer inspection and
product certification enable
expedited product entry
Sec. 302

Enhanced Partnerships: Vital to Success

International capacity building

- FDA has mandate to work with foreign governments to build their food safety capacity
- Allows FDA to rely more heavily on foreign government oversight
- Capacity building helps to prevent problems before products reach the U.S. port of entry



Trade Agreements

- Section 404, Compliance with International Agreements, explicitly notes that FSMA must be consistent with our agreement with the World Trade Organization (WTO) and any other treaty or international agreement.
- At each stage of the implementation process, we will make every effort to ensure that our proposed activities, policies, and measures are consistent with the WTO.



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

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

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

Import Projects Completed (as of July 2011)

- Updated list and more information can be found at <http://www.fda.gov/fsma>

Sec. 304. Prior notice of imported food shipments

- Requires information on prior refusals to be added to prior notice submission
- Effective July 3, 2011

Sec. 309. Anti-Smuggling Strategy

- Issued July 3, 2011

Outreach

- Public Meeting on Imports
(March 29, 2011)
- Public Hearing on Comparability and Import Practices
(March 30-31, 2011)
- 40 listening sessions, meetings to date
- Foreign government outreach through embassy briefings

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

Snapshots of sections of the FSMA homepage found at <http://www.fda.gov/fsma>

What's New
How to Participate
Main Topics

- Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues
July 2011
- FDA Meeting FSMA Food Safety Goals
A Consumer Update on the implementation of FSMA in the first six months.
July 5, 2011
- FDA Progress Report on Implementing the Food Safety Modernization Act: May – July 2011
July 5, 2011
- Anti-Smuggled Food Strategy Fact Sheet
July 3, 2011

More on What's New...

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Food
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Home - Food - Food Safety - Food Safety Modernization Act (FSMA)

Food Safety

- ▶ **Food Safety Modernization Act (FSMA)**
- About FSMA
- Full Text of the Law
- Implementation and Progress
- Debate Open for Comment
- Meetings, Hearings, and Hearings
- Press Releases
- Speeches and Statements
- Video, Webinars, and Interviews
- Recently Asked Questions
- Translations of Key FSMA Resources

Resources for You

- DA Implementation Timeline
- Recalls, Market Withdrawals, Safety Alerts

The New FDA Food Safety Modernization Act (FSMA)

The FDA Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4th, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it.

▶ Get FSMA Updates by E-mail

FDA Meeting National Food Safety Goals

View the **Progress Report on Implementing the FDA Food Safety Modernization Act** for more details on actions taken in the six months since President Obama signed the FSMA into law.

Anti-Smuggling Strategy

A joint anti-smuggling strategy developed with the Department of Health and Human Services and the Department of Homeland Security is released. [More >](#)



FSMA Blog Posts

The US and Mexico Share Approaches on Food Safety
by Michael R. Taylor
Deputy Commissioner for Foods



In June, I had the opportunity to lead a delegation of food safety officials from the Food and Drug Administration to meet with our Mexican counterparts. The trip was part of a larger, proactive strategy to reach out to stakeholders, both domestic and foreign, to explain the background and implementation strategies for the new Food Safety Modernization Act (FSMA) and importantly, to listen to issues raised by stakeholders. [MORE >](#)

For more blog postings, visit the [FSMA Blog page](#).

Consumer Corner

Featured Item
Safer Fruits and Vegetables: FDA Aims to Set Production Standards



Recently Posted Consumer Updates
FDA Meeting FSMA Food Safety Goals
Fish Hazards and Controls
Food Bill Aims to Improve Safety

More Consumer Updates related to FSMA...

For more information

FDA Consumer Health Information
www.fda.gov/consumer


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 in 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 those produced in the U.S.

FDA Commissioner Margaret A. Hamburg, M.D., says the bill—which President Barack Obama is expected



- Web site is at:
<http://www.fda.gov/fsma>
- Subscription feature available
- Send questions to
FSMA@fda.hhs.gov

THANK YOU!

We look forward to
working together toward
a brighter future in
providing a
safe
food supply
world-wide



Bruce Ross MPH,

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U.S. Embassy - New Delhi, INDIA



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