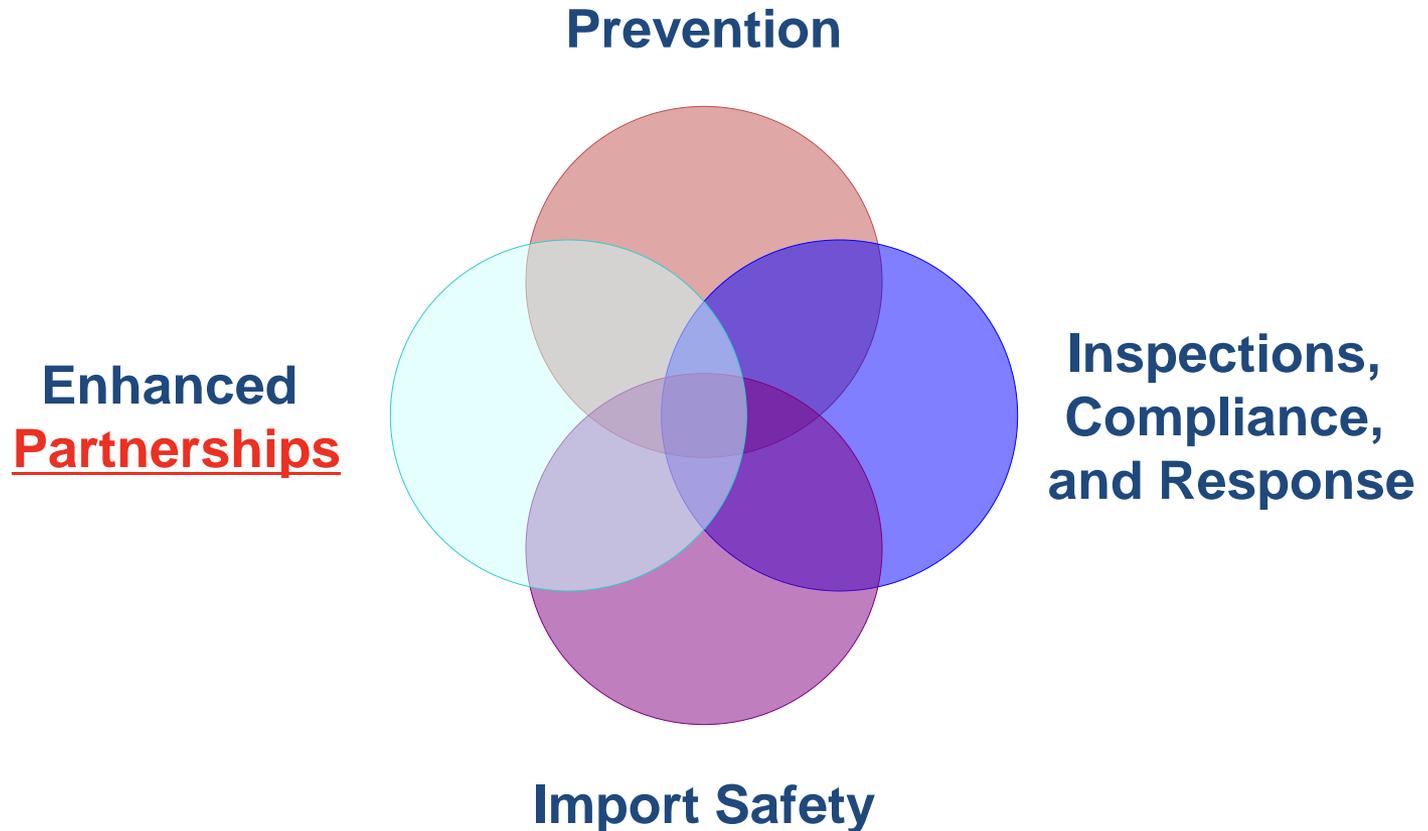

FDA Food Safety Modernization Act Amendments to Food, Drug & Cosmetic Act (Focus on Imports):

<http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>

**John T. Sproul, Ph.D.
Assistant Director (Foods)**



Main Themes of the Legislation



Food, Drug & Cosmetic Act (FD&C)

Leading India Violation in Spices & Botanicals “**Adulteration**” & “**Misbranded**”

FD&C Act: Sec.402 (**Adulteration**)

A food shall be deemed adulterated if:

- contains unsafe, poisonous, deleterious substance;
- consists whole or in part with filthy, putrid, substance;
- prepared, packed, or held under insanitary conditions;

FD&C Act: Sec.403 (**Misbranded**)

A food shall be deemed Misbranded if:

- labeling is false or misleading, etc.

FD&C Act: Sec.801 (Imports)

A food shall be refused admission if appears adulterated or misbranded...



U.S. FOOD AND DRUG ADMINISTRATION WEB PAGE NAVIGATING

Import Alerts: (REGULATION COMPLIANCE ISSUES)

<http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm>

Spices & Botanical Issues: (examples)

- Salmonella (IA 99-19)
- Pesticides (IA 99-08)
- Filth: (IA 21-07 Tamarind; IA 28-02 Pepper),

FDA Homepage: <http://www.fda.gov/food>

“Information for Industry”

GMP Regulations (Spices) & Dietary Supplement (botanicals)

21 CFR 110 (GMP), 101 (labeling), 111 (Dietary Suppl.)

**U.S. FOOD AND DRUG ADMINISTRATION
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NAVIGATING**

FDA Homepage: <http://www.fda.gov/>

Import Refusals:

(REGULATION COMPLIANCE ISSUES)

<http://www.accessdata.fda.gov/scripts/importrefusals/>

Monthly Import Refusal Report

India

Food Safety Modernization Act

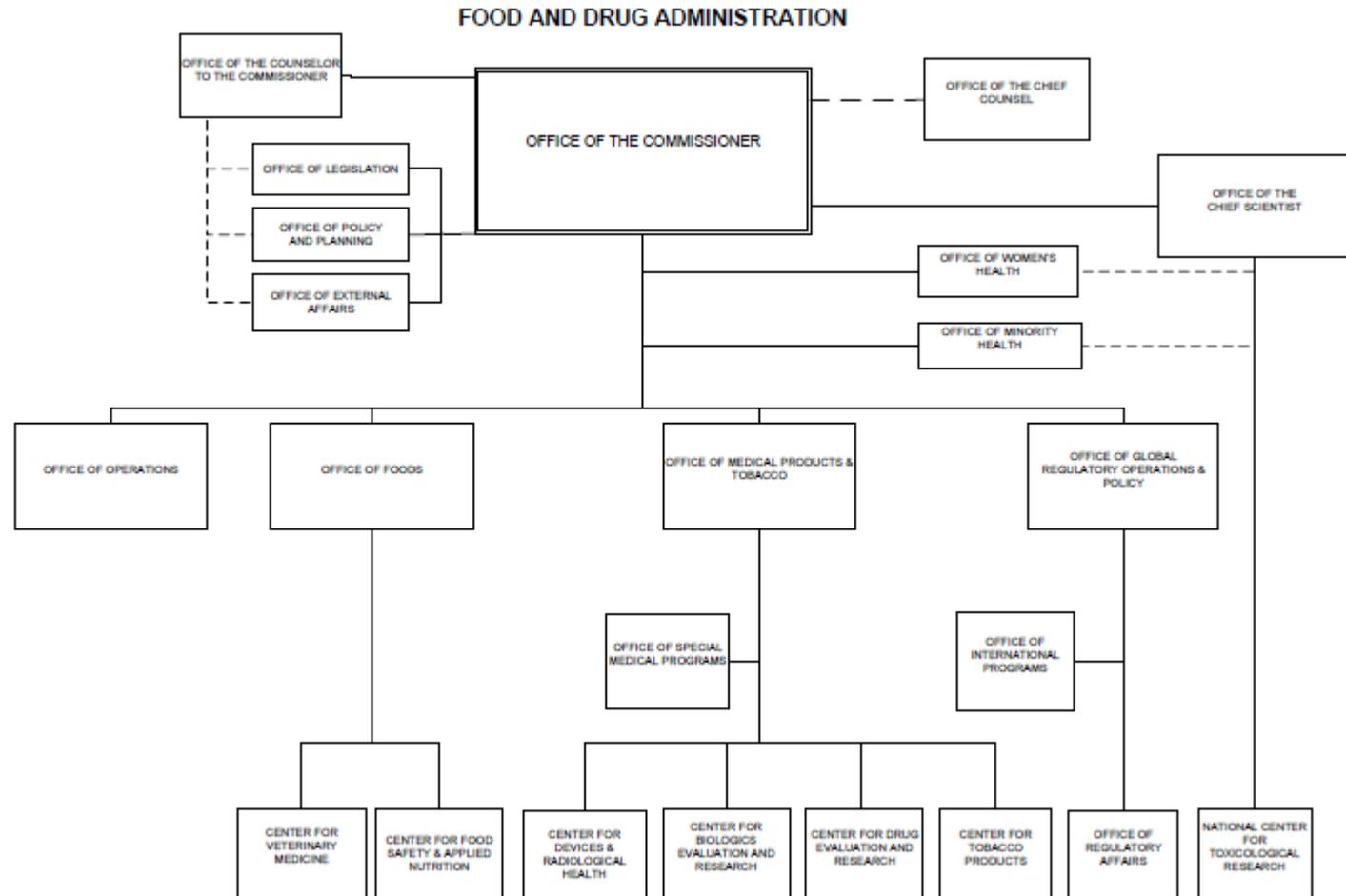
“I thank the President and members of Congress for recognizing that the burden that foodborne illness places on the American people is too great, and for taking this action.”

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



FDA Org. Chart: Implementation

Staff Manual Guide 1110.1
Organizations and Functions
Effective Date: July 26, 2011



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

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. 103. Hazard Analysis & Preventative Controls

- Seafood HACCP compliant firm Exemption (418(j)(1)(A))

Sec. 204. Food Tracking & Tracing Recordkeeping

- FDA “Product Tracing System” after pilot study (traceability)

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.
- Seafood HACCP compliant firm Exemption (805(e)(1))

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

Example Exemptions: If HACCP Compliant

Sec. 103. Hazard Analysis & Preventative Controls

Sec. 301. Foreign supplier verification program

Exemption states:

- “ This section shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, **and is in compliance with** the following standards and regulations ... ”
- **FDA Seafood HACCP Program,**
- FDA Thermally Processed LACF Standard,
- FDA Juice HACCP Program...



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 (1,000's of inspection per year abroad, doubling annually)

Sec. 204. Food Tracking & Tracing Recordkeeping

- FDA “Product Tracing System” after pilot study (**traceability**)



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. (for example **India Office in New Delhi, India**)

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



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...](#)

U.S. Department of Health & Human Services
www.hhs.gov

FDA U.S. Food and Drug Administration
A-Z Index Search

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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
- Dockets Open for Comment
- Meetings, Hearings, and Workshops
- Press Releases
- Speeches and Statements
- Videos, Webinars, and Interviews
- Frequently Asked Questions
- Translations of Key FSMA Resources

Resources for You

- FSMA 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 >](#)



◀ 2 of 3 ▶

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 on science and addresses hazards from farm to table, putting greater emphasis on preventing food-borne illness. The reasoning 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 foods produced in the U.S.

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



1 | FDA Consumer Health Information | U.S. Food and Drug Administration | DECEMBER 2010

- Web site is at:
<http://www.fda.gov/fsma>
- Subscription feature available
- Send questions to
FSMA@fda.hhs.gov
- Sign-up for FSMA e-mail updates on the website

**U.S. FOOD AND DRUG ADMINISTRATION
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**FDA Import Registration Requirement:
“Information for Industry”**

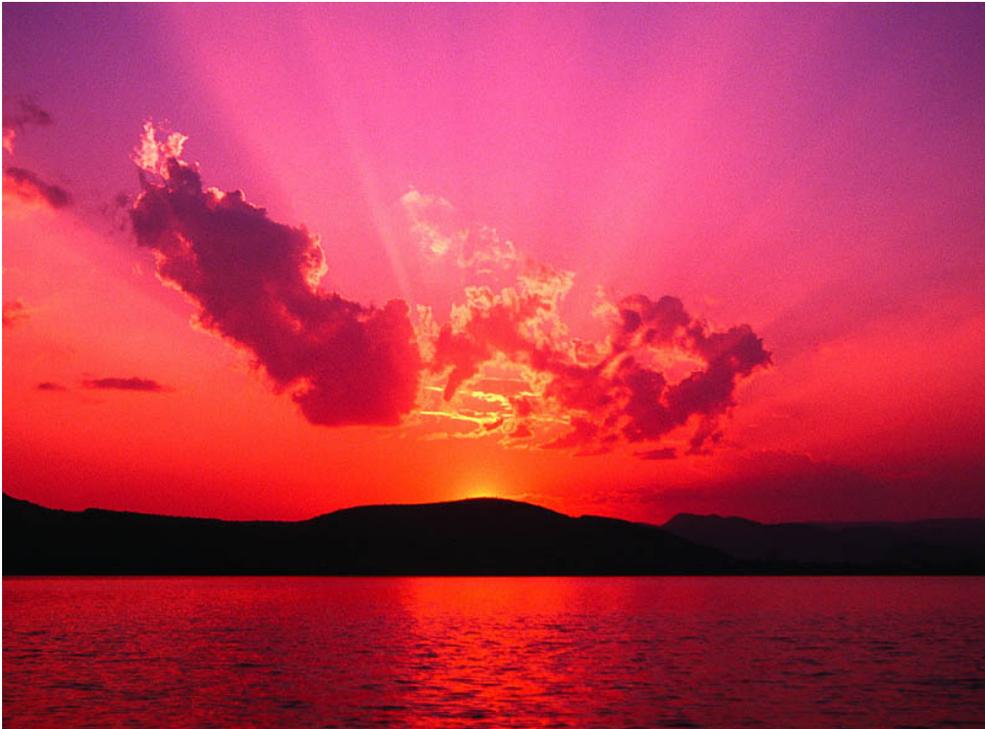
<http://www.fda.gov/Food/default.htm>

- 1) Registration of Food Facilities (online)**
- 2) Prior Notice Requirement**
- 3) Reportable Food Registry**

NOTE: GMP Regulations (Spices) & Dietary Supplement (botanicals)

THANK YOU!

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



John T. Sproul, Ph.D. Assistant Director (Foods)
U.S. Embassy - New Delhi, INDIA



John.Sproul@fda.hhs.gov

FDA FOOD SAFETY
MODERNIZATION ACT
