



FDA Food Safety Modernization Act & Implications for International Trade

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Specialty Crop Council



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 and their significance
- Implementation timeline and plans



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

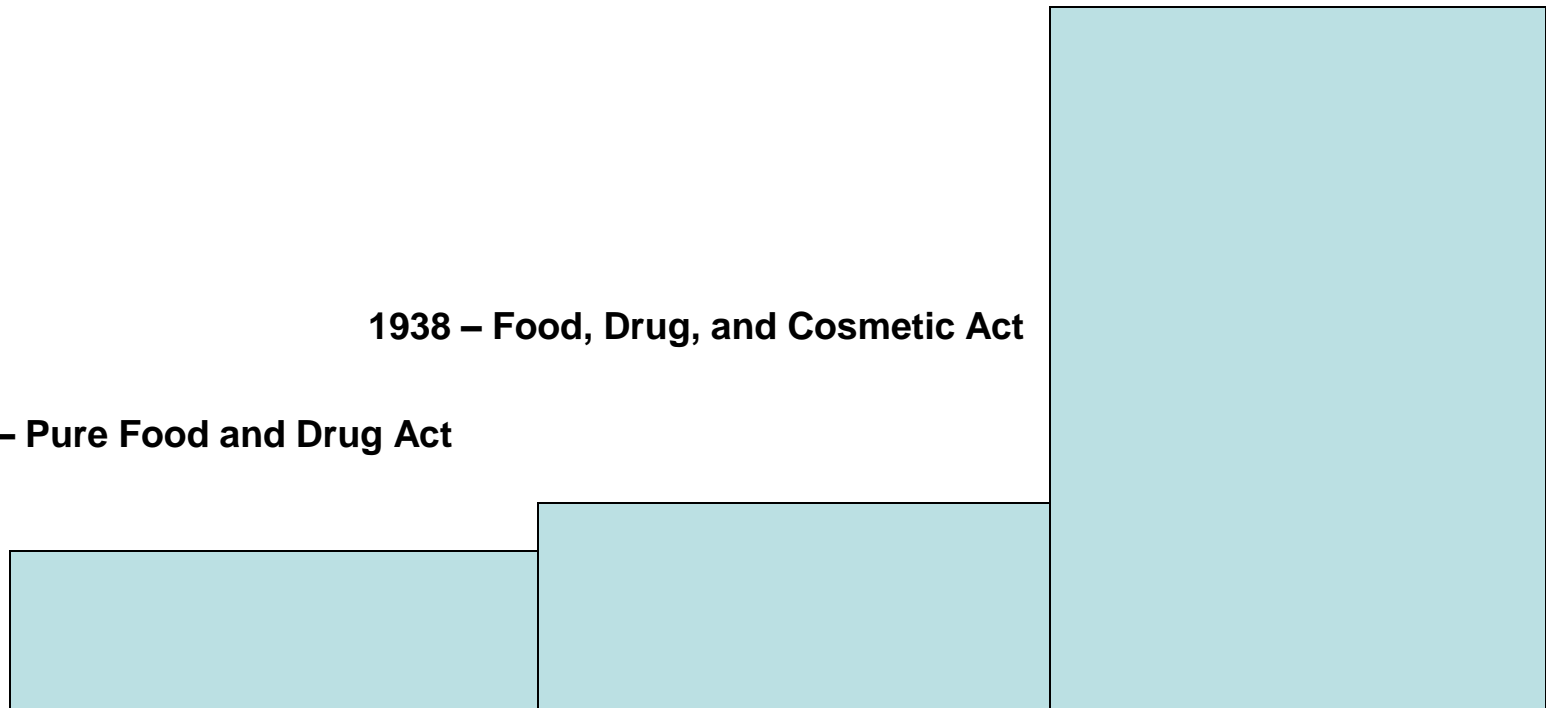


New law updates authority and tools

2011 – Food Safety Modernization Act

1938 – Food, Drug, and Cosmetic Act

1906 – Pure Food and Drug Act





What's so historic about the law?

- Involves creation of a new food safety system
- Broad prevention mandate and accountability
- New system of import oversight
- Emphasizes partnerships
- Emphasizes farm-to-table responsibility
- Developed through broad coalition



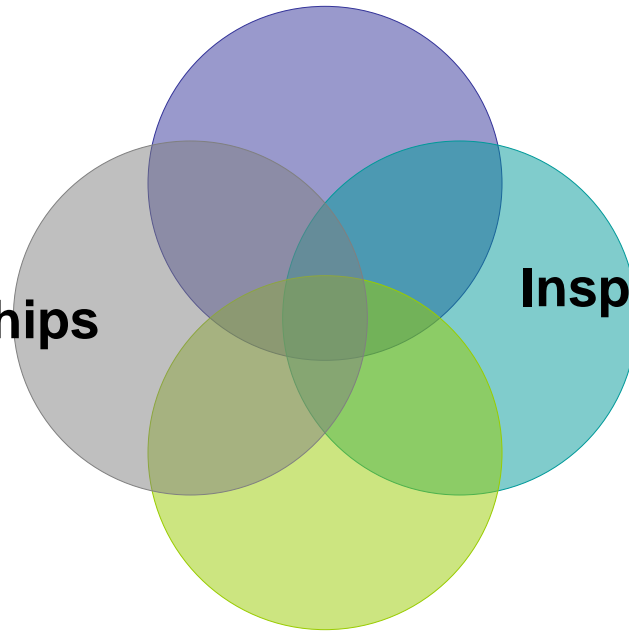
Main Themes of the Legislation

Prevention

Enhanced Partnerships

**Inspections, Compliance,
and Response**

Import Safety





Prevention:

The cornerstone of the legislation

- Comprehensive preventive controls for food facilities
 - Prevention is not new, but Congress has given FDA explicit authority to use the tool more broadly
 - Strengthens accountability for prevention
- Produce safety standards
- Intentional adulteration standards



Inspection, Compliance, and Response

- Mandated inspection frequency
 - Considering new ways to inspect
- New tools
 - Mandatory recall
 - Expanded records access
 - Expanded administrative detention
 - Suspension of registration
 - Enhanced product tracing
 - Third party laboratory testing



Import Safety: Most groundbreaking shift

- Importers now responsible for ensuring that their foreign suppliers have adequate preventive controls in place
- FDA can rely on third parties to certify that foreign food facilities meet U.S. requirements
- Can require mandatory certification for high-risk foods
- Voluntary qualified importer program--expedited review
- Can deny entry if FDA access for inspection is denied
- Requires food from abroad to be as safe as domestic



Import Provisions Work as a Whole

Accreditation Body
Accredit 3rd parties

FDA sets standards for accreditation bodies and recognizes those that meet standards. FDA may serve as an accreditation body and perform direct accreditation

Third Party
Certification
Entity

FDA audits accredited 3rd parties and relies on their certifications.

Importer
Verification
Certification
VQIP

Foreign Manufacturer
Mfr under preventive controls
Obtain 3rd party certification
as needed

FDA inspects importers, holds them accountable, requires certification as needed, and expedites entry of products for firms under VQIP.

FDA inspects foreign manufacturers and may rely on 3rd parties to inspect. FDA also works internationally to develop foreign capacity.



Enhanced Partnerships: Vital to Success

- Reliance on inspections by other agencies that meet standards
- State/local and international capacity building
- Improve foodborne illness surveillance
- National agriculture and food defense strategy
- Consortium of laboratory networks
- Easier to find recall information



Implementation: FDA is prepared

- Experience in preventive controls
- Implementation process in place
- Much work already underway



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



Implementation Approach

- Coalition needed
- Transparency a priority
- Focus on public health protection
- Engage with stakeholders to help determine reasonable and practical ways to do so



Priorities

- **Prevention**
 - Mandatory preventive controls for facilities (FR 18 months)
 - Produce safety standards (FR 2 years)
 - Intentional contamination (FR 18 months)
- **Inspection, Compliance, and Response**
 - Administrative detention (IFR 120 days)
 - Recall (Upon enactment)
 - Suspension of registration (180 days)
- **Imports**
 - Foreign supplier verification program (Guidance and FR 1 year)
 - Accredited third-party certification program (FR 2 years)
 - Mandatory certification for high risk foods (Upon enactment)



The Food and Drug Administration is seeking public comment on preventive control measures for food facilities through a public docket opened this week as part of the FDA Food Safety Modernization Act (FSMA), signed into law by President Obama in January.

The FSMA requires registered food and feed facilities to evaluate the food safety hazards that could affect food and feed they manufacture, process, pack, or hold and to identify and implement preventive controls to address those hazards. The agency opened the docket to solicit specific recommendations from stakeholders on what preventive control measures are

Comments may be submitted either electronically or in writing until August 22, 2011. Submit electronic comments at

<http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0238-0001>.

Submit written comments to:

The Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852



For more information



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 message 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



- www.fda.gov
- www.foodsafety.gov