

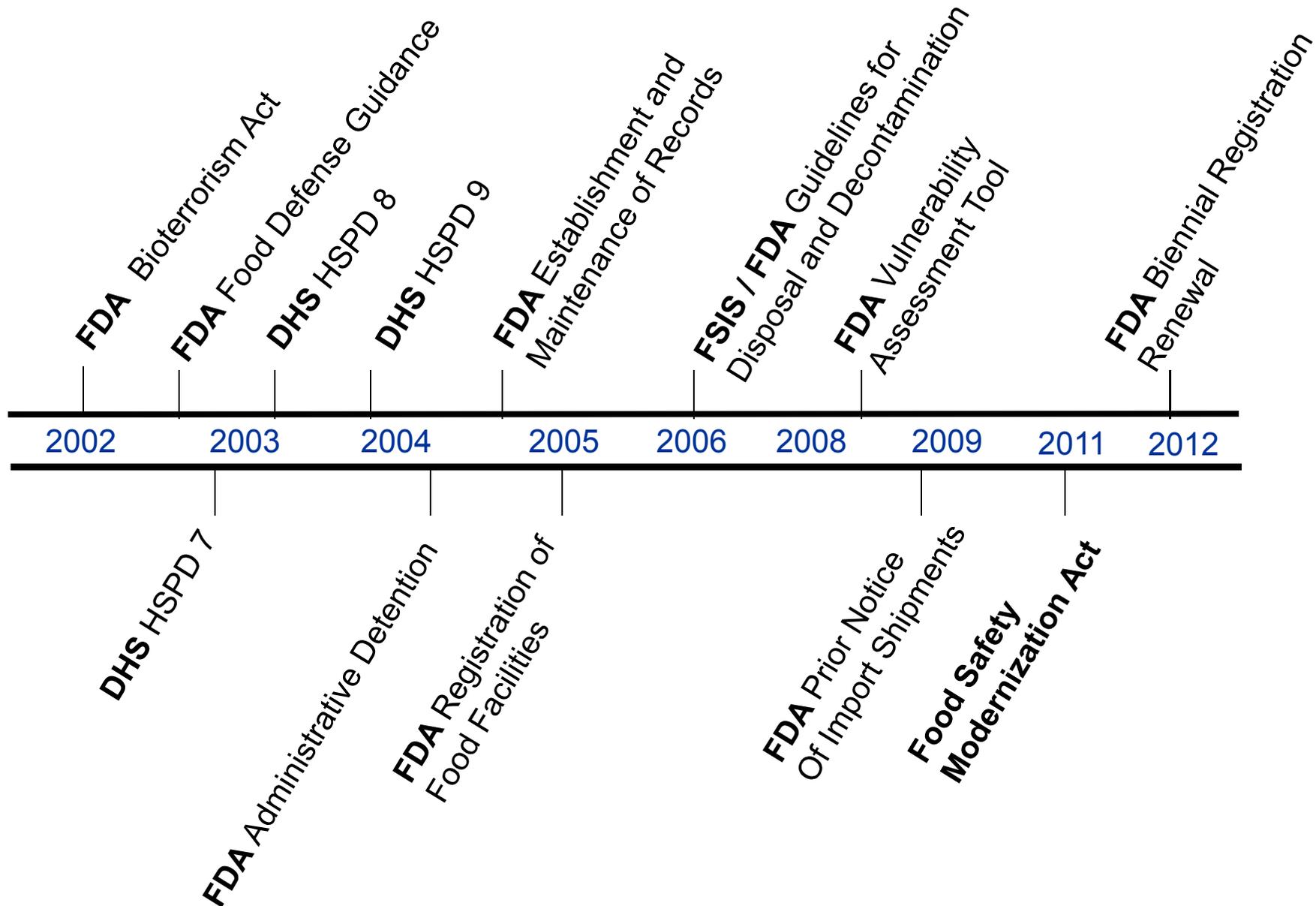


U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov

Food Defense: U.S. Regulations and Policies

Evolution of U.S. Food Defense Policy





Bioterrorism Act of 2002

Goal: to improve capacity to prevent, detect, and respond to terrorist acts

- Administrative detention
- Registration of food facilities
- Maintenance and inspection of records
- Prior notice of import shipments

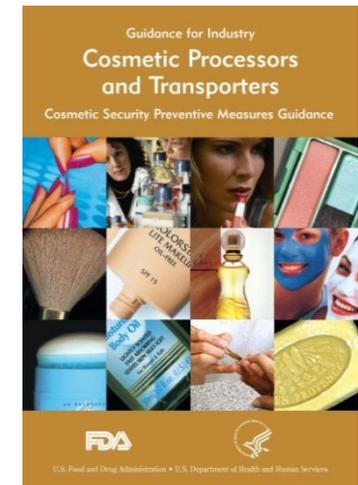
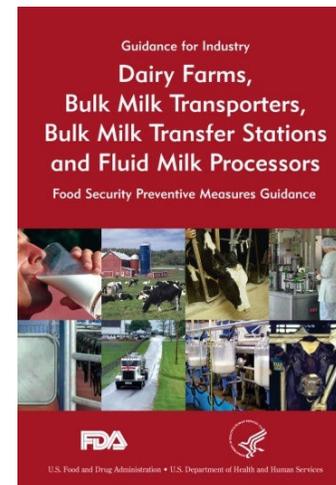
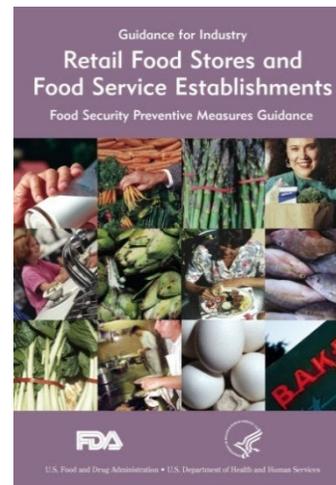
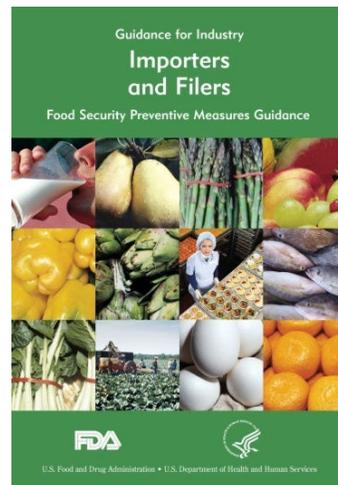
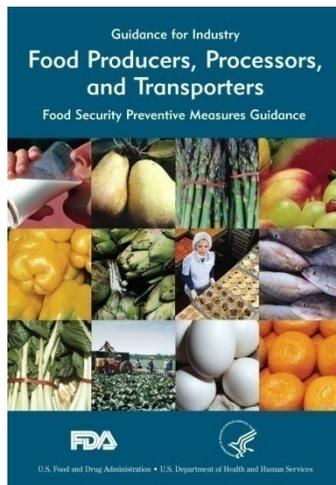


<http://www.fda.gov/oc/bioterrorism/bioact.html>



FDA Food Defense Guidance

1. Food producers, processors and transporters
2. Importers and filers
3. Retail food stores and food service establishments
4. Dairy farms, transporters, processors
5. Cosmetic processors and transporters





Cross-Government Initiatives

Homeland Security Presidential Directives

- HSPD 7: Identified Food & Ag Sector as a critical infrastructure to be protected
- HSPD 8: Preparedness
- HSPD 9: National policy to defend the agriculture and food system from terrorist attack, major disasters and other emergencies





Cross-Government Initiatives

- HSPD-9 requires FDA and USDA to conduct assessments of the food system
- Update biannually
- Both agencies have completed many assessments including transportation, distribution and production:
 - Meat and poultry
 - Seafood
 - Packaged food products
 - Raw commodities
- Outcomes used to guide development of countermeasures and research needs
 - Effort includes other agencies and industry



Cross-Government Initiatives

Strategic Partnership Program Agroterrorism

- 2005 – 2007
- FDA, USDA, FBI and DHS
- Partnered with industry, academic, State and local stakeholders to conduct vulnerability assessments of over 30 different food systems
 - Identified vulnerabilities
 - Discussed preventions and research



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*

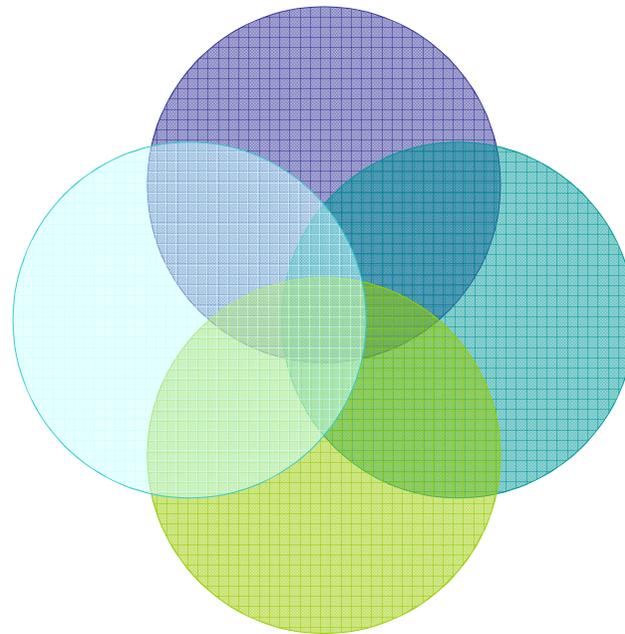




Main Themes of the Legislation

Prevention

**Enhanced
Partnerships**



**Inspections,
Compliance,
and Response**

Import Safety



Prevention: The cornerstone

- Comprehensive preventive controls for food and feed 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
- Transportation



Food Safety Modernization Act

Sec. 103 Hazard analysis and risk-based preventive controls

- Identify and evaluate hazards that *may be intentionally introduced, including by acts of terrorism*
- Implement preventive controls to prevent hazards;
- Monitor controls and maintain monitoring records; and
- Conduct verification activities.



Food Safety Modernization Act

Sec. 105. Standards for Produce Safety

- Establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables
- Consider hazards that occur naturally, may be unintentionally introduced, *or may be intentionally introduced, including by acts of terrorism.*



Food Safety Modernization Act

Sec. 106. Protection against Intentional Adulteration

- Issue regulations and guidance to protect against the intentional adulteration of food
- Conduct vulnerability assessments of the food supply and determine mitigation strategies

Sec. 108. Prepare a National Agriculture and Food Defense Strategy with USDA, and DHS



For More Information

The screenshot shows the FDA website's navigation and content for the Food Safety Modernization Act (FSMA). The top navigation bar includes links for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The main content area is titled "The New FDA Food Safety Modernization Act (FSMA)" and features a "NOTE" box with a red border stating: "Biennial Registration Renewal for Food Facilities began at 12:01 AM on October 22, 2012. The updated food facility registration system is accepting food facility registration renewals." Below this, there is a section titled "Updated Guidance Improves Food Facility Registration" with a photograph of a food processing facility. A "Resources for You" section is also visible, listing "FDA Implementation Timeline" and "Recalls, Market Withdrawals, & Safety Alerts".

- FDA's FSMA Website: <http://www.fda.gov/fsma>
- Email subscription feature available
- Send questions to FSMA@fda.hhs.gov



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FDA Food Defense Oversight Team

www.fda.gov/fooddefense

FoodDefense@fda.hhs.gov