



**U.S. FOOD & DRUG
ADMINISTRATION**

Food Defense and Intentional Adulteration from a US/Global Perspective

FSMA Intentional Adulteration Rule

Food Defense Terminology Overview

- Food Defense
 - Efforts to prevent intentional adulteration of food products (*human intervention as the source of contamination*)
- Economically Motivated Adulteration
 - Fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, i.e., for economic gain
- Food Safety
 - Efforts to prevent accidental (unintentional) contamination of food products
- Food Security
 - Access (or lack thereof) to sufficient, safe, nutritious food to maintain a healthy and active life (WHO, 1996)

The combined effort of food defense and food safety is commonly referred to as “Food Protection”

Economically Motivated Adulteration

– Melamine

- March 2007
- Large numbers of dogs and cats (estimated in thousands) in North America developed acute renal failure associated with ingestion of certain brands of pet food.
- Shortly thereafter, a pet food company observed acute renal failure in cats engaged in a routine palatability study.
- Melamine was identified in wheat gluten, a thickening agent.
- Melamine – cyanuric acid

The Washington Post
Democracy Dies in Darkness

FDA Identifies Chemical in Poisoned Pet Food

By William Branigin

March 30, 2007 at 1:00 a.m. EDT

The Food and Drug Administration has identified contaminated wheat gluten from China as the likely cause of poisoned pet food that has sickened a number of dogs and cats, and the agency is investigating to determine whether dry pet foods have also been affected, officials said today.

In a news conference, Stephen F. Sundlof, director of the FDA's Center for Veterinary Medicine, said FDA and independent laboratories have found a chemical called melamine in pet food samples, imported wheat gluten and urine and tissue from diseased pets. He said melamine is used in fertilizer in Asia and in plastic products but is not registered as a fertilizer in the United States.

Economically Motivated Adulteration (EMA)

- Someone intentionally leaves out, takes out, or substitutes a valuable ingredient or part of a food.
- Someone adds a substance to a food to make it appear better or of greater value.
- Regulatory framework:
 - FSMA: Companies required to put preventive controls in place to guard against hazards intentionally introduced for the purpose of economic gain in both human and animal food
 - FDCA: Adulteration and misbranding
 - Labelling and standard of identity regulations

FDA Food Defense Background

- Food Defense - protect food from intentional acts of adulteration where the intent is to cause wide scale public health harm
- In FSMA, Congress directed FDA to regulate to protect food from intentional adulteration (Sec. 103 and 106)
- The Intentional Adulteration (IA) rule requires facilities to take appropriate action to prevent intentional adulteration

Food Defense and Food Safety

- Food Safety Plans focus on known or reasonably-foreseeable hazards
 - Management and verification of relevant controls.
- Food Defense Plans focus on human behavior
 - Insider with intent to do harm



Inside Attacker Case Study

– Japan Malathion

- December 2013
- A contract food worker at a frozen food facility in Japan was arrested for intentionally contaminating food with malathion, resulting in
 - 2,843 reports of foodborne illness, and
 - 6.4 million packages of food recalled



Japan food pesticide scare: Factory worker arrested

🕒 26 January 2014



The company issued public apologies, as shown here, as people complained of illness

Japanese police have arrested a factory worker at a plant that produced food laced with pesticide, which led to hundreds of people being poisoned.

More than six million packages of frozen food were recalled.

Inside Attacker Case Study

– UK Derby Terror Plot

- January 2018
- An individual used counterfeit identification to gain employment at a major manufacturer of ready-meals in the U.K. His girlfriend, a pharmacist, helped him to devise a plan to poison the food using ricin.



What Does the Food Defense Team Do?

- Food Defense Team (formerly Food Defense and Emergency Coordination Staff)
- Division of Preparedness & Emergency Programs (DPEP)
- Office of Coordinated Outbreak Response, Evaluation & Emergency Preparedness (CORE+EP)
- Human Foods Program (HFP)
- FDA's principal advisors and the primary subject matter experts in food defense
- Lead the regulation, guidance, implementation, and training development to support the Food Safety Modernization Act (FSMA) Intentional Adulteration Rule
- Co-chair (with USDA) the Food and Agriculture Government Coordinating Council (GCC) and represent FDA in interagency critical infrastructure activities
- HFP's Emergency Coordinator for natural and man-made disasters affecting foods and cosmetics

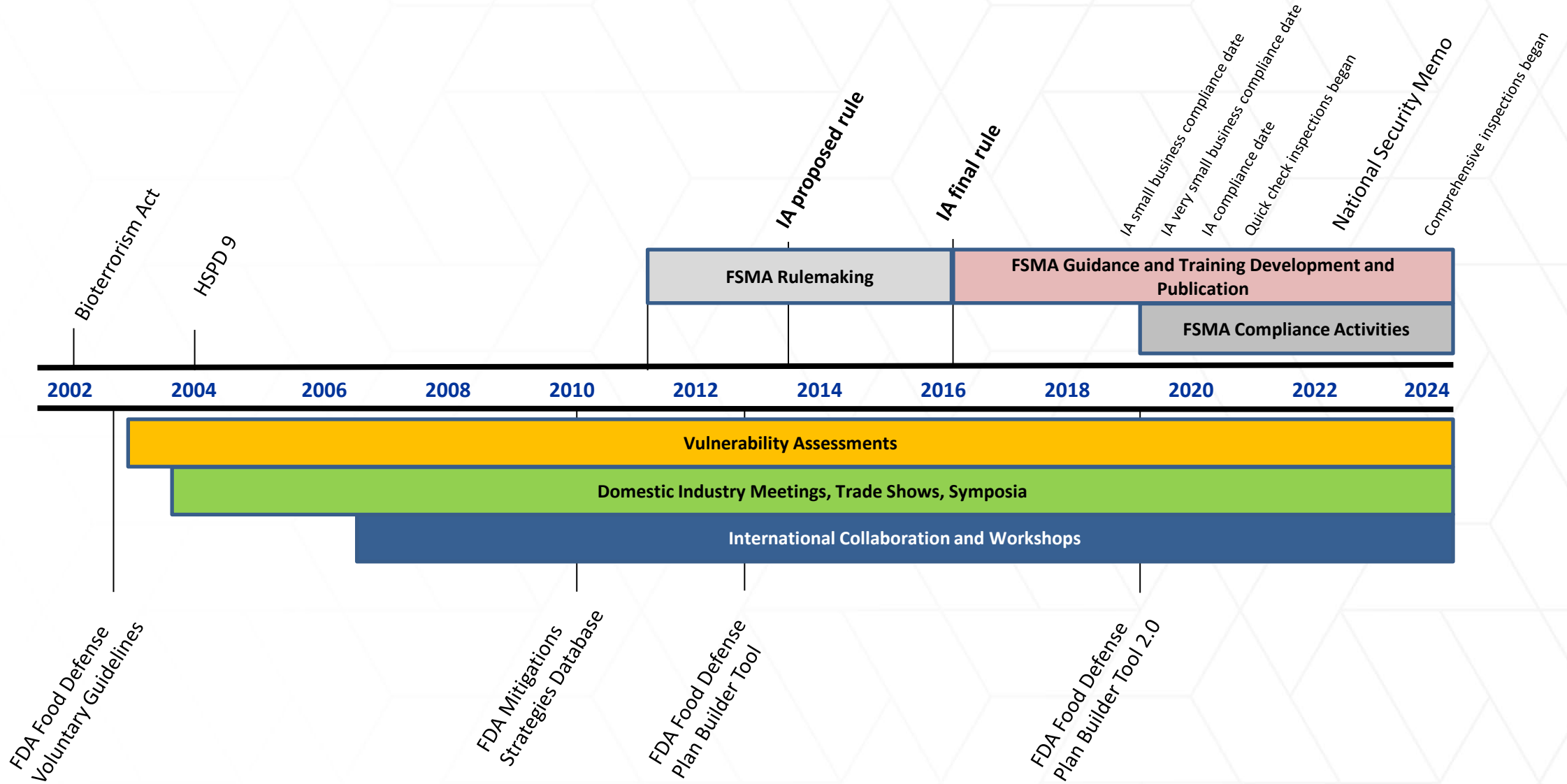
What Does the Food Defense Team Do?

Major Programs & Initiatives

- FSMA IA rule (rule writing and implementation)
- Homeland Security Presidential Directive 9
 - Food Defense Vulnerability Assessments
 - Work with Interagency partners on food defense research
- Report to Congress on National Agriculture and Food Defense Strategy (FSMA Sec. 108)
- Food Defense Plan Builder
- Food-Related Emergency Exercise Bundle (FREE-B)
- Outreach and engagement

www.fda.gov/food/food-defense

Evolution of FDA Food Defense Policy



Requirements of the IA Rule

- **Food Defense Plan**
 - **Vulnerability assessment** to identify significant vulnerabilities and actionable process steps
 - **Mitigation strategies** to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented
 - **Food defense monitoring procedures**
 - **Food defense corrective action procedures**
 - **Food defense verification procedures**
- **Training**- food defense awareness and additional training for food defense qualified individuals
- **Reanalysis**
- **Records**

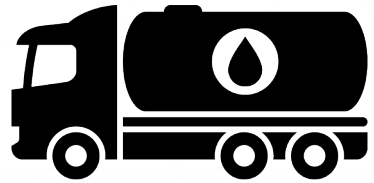
Vulnerability Assessment – Three Fundamental Elements

- **For each point, step, or procedure in the facility's process, three fundamental elements must be evaluated:**
- The severity and scale of the potential impact on public health.
 - Considerations: The volume of product, the number of servings, the number of exposures, how fast the food moves through the distribution system, potential agents of concern and the infectious/lethal dose of each; and the possible number of illnesses and deaths.
- The degree of physical access to the product.
 - Considerations: the presence of such physical barriers as gates, railings, doors, lids, seals and shields.
- The ability to successfully contaminate the product.

Mitigation Strategies

- Identified and implemented at each actionable process step to provide assurances that vulnerabilities will be minimized or prevented. The mitigation strategies must be tailored to the facility and its procedures
- Management components:
 - **Monitoring:** Establishing and implementing procedures, including the frequency with which they are to be performed, for monitoring the mitigation strategies.
 - **Corrective actions:** The response if mitigation strategies are not properly implemented.
 - **Verification:** Verification activities would ensure that monitoring is being conducted and appropriate decisions about corrective actions are being made.
- Training and record-keeping.

Examples of Common Vulnerabilities



- **Bulk Liquid Receiving and Loading**

- Includes all inbound bulk liquid receiving and bulk liquid loading into an outbound conveyance



- **Liquid Storage and Handling**

- Includes storage tanks and intermediate processing tanks
- Open drums/totes or other holding vessels

Examples of Common Vulnerabilities



- **Secondary Ingredient Handling**
 - Includes ingredient staging, preparation, addition, and rework
 - Includes both dry and liquid ingredients
- **Mixing and Similar Activities**
 - Includes steps such as mixing, homogenizing, grinding, coating, and enrobing

Intentional Adulteration Rule Rollout

- New regulatory territory with no precedent
- FDA guidance and tools
 - Two guidance documents, published March 2019 and February 2020
 - Food Defense Plan Builder
 - Mitigations Strategies Database
- Program has rolled out in two phases
 - Quick Checks: a small checklist of yes/no questions to build data on industry, started March 2020 and is ongoing
 - Comprehensive Inspections: in-depth food defense inspections, started August 2024

Comprehensive Food Defense Inspections

- Detailed review of food defense plan and inspection to determine status of plan implementation in the facility
 - Determine adequacy of plan components
 - Assess implementation status
- Conducted by Food Defense Inspection Team (FDIT) members
 - Specialized food defense training
 - Food Defense Team SMEs available for real-time consultation & technical support



Thank you!

- Additional information on the Intentional Adulteration Rule can be found at: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-mitigation-strategies-protect-food-against-intentional-adulteration>
- FDA's website has additional information that is available for review at your convenience
- www.fda.gov/food/food-defense
 - Full text of the IA rule
 - Guidance
 - Food Defense Initiatives
 - Food Defense Tools
 - Food Defense Training and Education

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