U.S. Food and Drug Administration UPDATE

American Society for Quality
Food, Drug, and Cosmetic Division
Fall Midwest Conference

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Food and Drug Administration

FDA Strategic Plan

Efficient Risk Management -- Searching for new and better ways to reduce risks to public health

Better Informed Consumers -- Helping consumers get truthful information about products they use so they can make informed decisions

Patient and Consumer Safety -- Preventing adverse events involving FDA-regulated products

Counterterrorism -- Responding quickly to terrorist acts and enhancing food security

A Strong FDA -- Maintaining a strong science base to support FDA's risk management responsibilities.
Laws Enforced by FDA


(1906 - MEAT INSPECTION ACT enforced by USDA, passed the same day)

Celebrating 100 Years of Public Service

Additional Laws:

- 1997 Modernization Act
- Administrative Procedures Act
- Animal Drug User Fee Act of 2003
- Best Pharmaceuticals for Children Act
- Bioterrorism Act of 2002
Laws Enforced by FDA

- Congressional Reports Elimination Act of 1982
- Controlled Substances Act
- Controlled Substances Import and Export Act
- Delegation of Authority to the Commissioner of Food and Drugs
- Department of Education Organization Act
- Dietary Supplement Health and Education Act of 1994
- Egg Products Inspection Act
- Fair Packaging and Labeling Act
- Federal Advisory Committee Act
- Federal Advisory Committee Amendments
- Federal Anti-Tampering Act
- Federal Fines and Sentencing Laws
- Federal Import Milk Act
- Federal Meat Inspections Act
- Federal Trade Commission Act
- Filled Milk Act
- Food Quality Protection Act of 1996
- Foreign Trade Act

Laws Enforced by FDA

- Federal Anti-Tampering Act
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Laws Enforced by FDA

- Generic Animal Drug and Patent Term Restoration Act of 1988 (Summary)
- Government in the Sunshine Act
- Laws Delegation Authority - Patents
- Lead Based Paint Poisoning Prevention Act
- Mammography Quality Standards Act (MQSA)
- Medical Device User Fee and Modernization Act (MDUFMA) of 2002
- Miscellaneous Provisions Relating to Orphan Drugs
- National Environmental Policy Act of 1969
- Pediatric Research Equity Act of 2003
- Poultry Products Inspection Act
Laws Enforced by FDA

- Prescription Drug User Fee Act
- Project BioShield Act of 2004
- Public Health Service Act
- Reorganization Plan 1
- Sanitary Food Transportation Act
- Sentencing Guidelines
- Tea Importation Act: The Tea Importation Act was repealed in 1996 by Public Law 104-128
- Trademark Act of 1946

Broad Responsibilities

Varied Products
$1 Trillion A Year
Varied Approaches

FDA Centers & FDA Field

Commissioner

FOODS  DRUGS  DEVICE  VET  BIOLISTIC

ORA (FIELD)
Central Region’s District Offices

- Baltimore District (MD, VA, WV, DC)
- Chicago District (IL)
- Cincinnati District (OH, KY)
- Detroit District (MI, IN)
- Minneapolis District (MN, WI, ND, SD)
- New Jersey District (NJ)
- Philadelphia District (PA, DE)
Responsibilities of Regional Office

- Manage the Region
- Cooperative Programs
  - Milk
  - Retail Food
  - Shellfish
  - Radiological Health

Responsibilities of District Office

Regulatory Activities:

- Inspections – Domestic and Foreign
- Investigations
- Sample collections – Domestic and Import
- Sample analysis
- Field Exams – Domestic and Import
- Consumer Complaints
- Recall
- Compliance activities (seizure, injunction, prosecution)
- Public Affairs
Food Safety is a Compelling and Real Public Health Problem

EACH YEAR in the US:
- 76 Million Foodborne Illnesses
- 325,000 Hospitalizations
- 5,000 Deaths

Allotment of FTEs in all Regions - FY05
FDA History of Food Safety and Nutritional Quality

- Early 1900’s – Food Sanitation/Consumer Deception
- 1950’s – Pesticides and food additives
- 1970’s – Botulism in canned food
- 1980’s – Food tampering
- 1990’s – Nutrition Labeling

Food Safety Today

Food Safety and Security

Sound Science

Food Safety Programs

Food Security Enhancements
Partnerships

- Build on a solid foundation of a national partnership with other entities involved in food safety and security.

FDA Strategic Action Plan

Five Strategies

- Enabling Technology Development and Innovation
- Improving Patient and Consumer Protection
- Protecting the Homeland - Counterterrorism
- Improving Manufacturing Practices
- Improving FDA’s Business Practices

FDA Strategic Action Plan

Protecting the Homeland - Counterterrorism

We have developed crisis management plans and have strengthened our readiness by partnering with state and federal agencies in conducting emergency response exercises that simulate chemical, biological, and radiological events.
FDA Strategic Plan and HSPD-9

Go Hand and Hand

HSPD-9

- Establishes national policy to defend the agriculture and food system against terrorist attacks, major disasters and other emergencies.

Bioterrorism Act 2002

- Directed FDA to take aggressive steps to protect the public health from deliberate and accidental contamination of our food supply.
Final Rules

1. Registration of Food Facilities
   - Requires all foreign and domestic facilities that manufacture, process, pack or hold food for human or animal consumption in the United States to register with FDA.

Interim Final Rules

2. Prior Notice of Imported Foods
   - Requires food importers to provide FDA with prior notice of human or animal food shipments imported or offered for import.

New Final Rule

3. Administrative Detention
   - FDA may detain an article of food on the strength of credible evidence or information resulting from an inspection, examination, or investigation.
New Final Rule

4. Establishment and Maintenance of Records

- Identify immediate previous source and immediate subsequent recipients of food

Monitoring and Surveillance

- Methods – developing and validating methods that can be used to detect, enumerate and identify potential non-traditional agents that may threaten the food supply.

FOOD/AGENT SCENARIOS

- Assess risk for specific product-agent-activity combinations covering harvest, production and delivery - farm to table:
  - Farm/dairy farm/orchard/apiary/fishing vessel
  - Bulk transportation
  - Manufacturing (including packing houses)
  - Finished product transportation
  - Warehousing
  - Retail/food service
Vulnerability Assessment

- Evaluating the public health consequences of a range of product-agent scenarios associated with potential tampering, criminal, malicious, or terrorist activity.
- Implement "shields" for protecting those identified food/agent combinations.

Research

- Assessing the abilities of non-traditional microbial pathogens to survive and grow in foods during processing and storage, or the stability and activity of chemical agents while present in foods, and the potential for their inactivation during food processing.

FY 05 Food Security Assignment

- Exercise the planning and implementation for responding to a period of increased food security risk and identify gaps in the system.
- Deter intentional contamination of food through heightened and targeted preventative activities.
FY 05 Food Security Assignment
- Identify foods of concern using ORM
  - Raw milk
  - Fruit and vegetable juice
  - Spring and mineral water
  - Liquid and powdered infant formula
  - Fresh leaf and stem vegetables
- Inspect firms processing that food
- Take samples

FY 05 Food Security Assignment
- Ship and test samples
  - Chemical CT agents (e.g. CN)
  - Microbiological CT agents (e.g. Bot toxin)
- Test infrastructure for handling presumptive and confirmed positives.

FY 06 Strategic Partnership Program
Agroterrorism (SPPA) Initiative
- Joint effort to assess and identify vulnerabilities in the agricultural and food sectors
- FDA, FBI, USDA and DHS will collaborate with states and private industry to protect the nation’s food supply from terrorist threats
- Focus from farm-to-table
- Goal - SPPA intends to provide government and private industry the tools to refine its efforts and to seek better technology or steps to protect the food and agriculture infrastructure with research and development
CT Guidance for Industry

1. RETAIL FOOD STORES AND FOOD SERVICE ESTABLISHMENTS
2. FOOD PRODUCERS, PROCESSORS, AND TRANSPORTERS
3. IMPORTERS AND FILERS
4. COSMETICS PROCESSORS AND TRANSPORTERS
5. MILK PROGRAM

“Firewalls” Against BSE Transmission

- Joint USDA FSIS, USDA APHIS, FDA notice asks for public comment on additional preventive actions being considered on BSE
- An interim final FDA rule prohibits use of certain cattle-derived materials in human food, dietary supplements, and cosmetics
- Proposed FDA rule on recordkeeping for the interim final rule relating to this ban

IMPORTS
Growth of Imported FDA Regulated Entries

What types of goods are imported?

Size of International Market

- 224 countries exporting FDA regulated goods
- 221,100 foreign manufacturers
- 196,224 Shippers
- 127,696 importers of record
- 3,720 active OASIS filers
- 134,433 consignees (includes overlap)

What is PREDICT?

An automated screening system that:

- Associates disparate data to reveal "risk statements" about specific imports
- Is self-learning — "rules evolve with experience"
- Augments FDA science-based risk decisions
FERN

- Food Emergency Response Network – nationwide network of Federal and State laboratories capable of testing the safety of thousands of food samples and enabling us to respond to a terrorist attack.

eLEXNET: What is it?

- An integrated, secure system designed for multiple government agencies involved in food safety activities.
- The necessary infrastructure for an early warning system that identifies potentially hazardous foods and enables health officials to assess risks and analyze trends.

eLEXNET’s GIS Reporting Functions

Report Parameters:
- Salmonella
- Cheese/Cheese Products
- All Laboratories
- All States
- August 2002 to present
FDA Retail Food Program

- Federal, State, Local Gov’t and Industry
- One of several Cooperative Programs
- Program is in FDA Regional Offices
- Field Retail Food Specialists

"Measuring the Effectiveness of the Nation’s Food Service and Retail Food Protection System"

Randomly Selected:
- Delis
- Full service restaurants
- Fast food restaurants
- Schools
- Nursing homes
- Hospitals

"Measuring the Effectiveness of the Nation’s Food Service and Retail Food Protection System"

Risk Factors
- Food from unsafe sources
- Inadequate cooking
- Improper holding temperatures
- Contaminated equipment and
- Poor personal hygiene
"Measuring the Effectiveness of the Nation’s Food Service and Retail Food Protection System"

- Food Code public health interventions:
  - Demonstration of Knowledge
  - Employee health controls
  - Controlling hands as a vehicle of contamination
    - (No bare hand contact with ready to eat food)
  - Time and temperature parameters for controlling pathogens and
  - Consumer advisories

Voluntary National Retail Food Regulatory Program Standards

1. Regulatory Foundation
2. Trained Regulatory Staff
3. Inspection Program Based on HACCP Principles
4. Uniform Inspection Program
5. Food borne Illness Investigation and Response
6. Compliance and Enforcement
7. Industry and Community Relations
8. Program Support and Resources
9. Program Assessment

CURRENT ENROLLMENT

- Nationally – >118 State, local and tribal jurisdictions are enrolled

WE WANT YOU!
RETAIL FOOD PROGRAM RESOURCE DISK

- PROGRAM STANDARDS
- FOOD CODE & supplement
- HACCP GUIDES
- BASELINE DATABASE
- STANDARDIZATION
- MANY OTHERS

IT’S HERE!!!

1 COPY FOR EVERY RETAIL FOOD PROGRAM

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Eureka! Disk

- Free Subscription
- Over 700 Subscribers!
- ORA’s Eureka Database
- Over 12,000 Documents
- 1,800 Graphics
- A Great Resource!
- Use on a Stand Alone or LAN Server

New Format (Web-CD) Technology!

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Eureka! Disk

- FDA regulatory references in electronic format:
  - Federal Food Drug and Cosmetic Act
  - TITLE 21 CFR
  - Compliance Policy Guides
  - Enforcement Reports
  - Talk Papers
  - Import Alerts
  - Food Code
  - Compliance Programs
Eureka! Disk

- Not available to the public
- Available to state and local agencies
- Disk is not releasable under FOI

Disks available from:
FDA Division of Federal-State Relations
Call: 301-827-6906
Email: DFSR@ORA.FDA.GOV

Revitalizing the Nutrition Program

Improving Nutrition

- Better Information
  - Consumer Health Information for Better Nutrition Initiative
- Supporting Consumers
  - Obesity Working Group
Closing

Working together we will rise to the challenge of making sure Americans continue to enjoy a safe food supply and medical products.

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