



CFSAN Update

Comments by

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**“Who you are is what you
were when...”**

Dr. Morris Massey

What I've Learned

- There is a remarkable depth and breadth of expertise involved in every initiative CFSAN undertakes.
- We stand on two legs: Strong science and our ability to create policy and regulatory solutions to address public health concerns.
- The value of engaging with external stakeholders to learn what expertise they can lend and what constraints they face.

External Engagement

- Consumers (3/26/15)
- Professional/Scientific Organizations (4/09/15)
- Medical/Patient Groups (4/15/15)
- Industry – Growers (4/16/15)
- Industry – Food and Beverage Issues Alliance (4/17/15)
- Industry – Cosmetics (4/24/15)
- Industry – Animal Products (5/21/15)
- Industry – Specialty Foods Association (5/29/15)
- Industry – Biotechnology (6/29/15)



FDA Food Safety Modernization Act (FSMA)

Phase I: FSMA Rulemaking

Regulation	Proposal	Final (consent decree)
Preventive Controls (Human Food)*	Jan 16, 2013	Aug 30, 2015
Preventive Controls (Animal Food)*	Oct 29, 2013	Aug 30, 2015
Produce Safety*	Jan 16, 2013	Oct 31, 2015
Foreign Supplier Verification Program*	Jul 29, 2013	Oct 31, 2015
Third Party Accreditation	Jul 29, 2013	Oct 31, 2015
Sanitary Transport	Feb 5, 2014	Mar 31, 2016
Intentional Adulteration	Dec 24, 2013	May 31, 2016

** Supplemental proposals published September 2014*

FSMA Implementation Topics

- Guiding FSMA Implementation
 - Program Alignment Initiative
 - FSMA Operational Strategy
- FSMA Implementation in Phases
- Focus on FSMA Phase 2

Collaboration within FDA's Food Program

**Office of the Commissioner
Acting Commissioner of Food
and Drugs
Stephen Ostroff, M.D.**

**Directorate of Foods and
Veterinary Medicine
Deputy Commissioner
Michael Taylor, J.D.**

**Directorate of Global
Regulatory Operations and
Policy
Deputy Commissioner
Howard Sklamberg, J.D.**

**Center for Food Safety
and Applied Nutrition**

**Director
Susan Mayne, Ph.D.**

**Center for Veterinary
Medicine**

**Director
Bernadette Dunham,
D.V.M., Ph.D.**

**Office of Regulatory
Affairs**

**Associate
Commissioner
Melinda Plaisier**

**Office of International
Programs**

**Associate
Commissioner
Mary Lou Valdez**

Program Alignment

- **Program Alignment Initiative Announced in February 2014 Memo by Dr. Hamburg, FDA Commissioner**
 - Vertically integrated, commodity-based programs (food and feed)
 - Specialization of inspection/compliance staff, regulatory labs
 - Clear, current, consistently applied policy
 - Roles, responsibilities, streamlined decision-making
 - Risk-based allocation of program resources
 - Agreed-upon performance/public health metrics
- **Result: Successful FSMA Implementation**

FSMA Operational Strategy

- **Made public May 2014**
 - View at fda.gov/fsma (also see Appendix)
- **Foundation for developing and implementing FSMA standards**
 - Regulations, guidance, protocols
- **Captures in broad, high-level terms our current thinking on strategy and guiding principles for implementation**

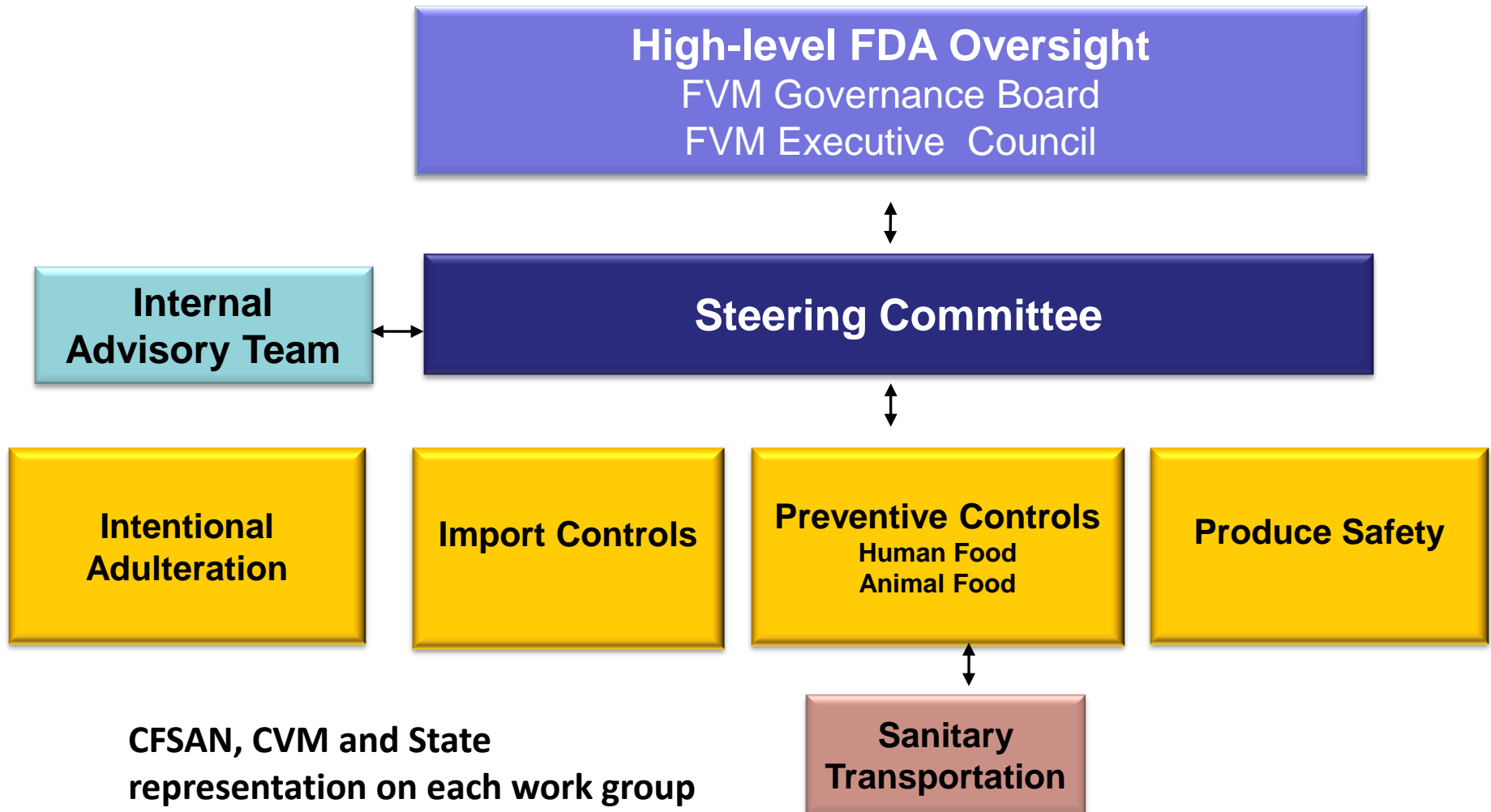
FSMA Implementation as a Continuum

- Phase 1: Set Standards
 - Regulations, guidance, policy
- Phase 2: Planning/Implementation
 - Design strategies and begin implementation to gain/maintain industry compliance with FSMA rules
- Phase 3: Implementation, Monitor, Evaluate, Refresh

Transition to Phase 2: Planning/Implementation

- Phase 1 Teams continue rulemaking, guidance and policy work until completed
- Concurrently, Phase 2 structure established/work initiated
 - Design strategies/frameworks and develop operational plans for gaining and maintaining industry compliance with the foundational FSMA rules

Phase 2: Operations and Policy Working Together



Phase 2: Workgroup Charge

Multi-Year Plan

- Education, outreach and technical assistance for industry
- Training for regulators
- Inspections, compliance and enforcement
- Data collection, analysis and updated Information Technology (IT)
- Performance goals and metrics

How FDA Will Operate Differently

Education Before Regulation

- **Facilitate industry implementation of modern, preventive practices through:**
 - **Commodity and sector-specific guidance**
 - **Education, outreach and technical assistance**
 - **Regulatory incentives for compliance**

President's FY2016 Budget Proposal

- An increase of **109.5 million** requested in the President's budget for FSMA implementation
 - FDA plans to continue to make improvements in the following areas:
 - Inspection Modernization and Training **25 million**
 - National Integrated Food Safety System **32 million**
 - Industry Education and Technical Assistance **11.5 million**
 - Technical Staffing and Guidance Development at FDA **4 million**
 - Modernized Import Safety Programs/System **25.5 million**
 - Risk Analytics and Evaluation **4.5 million**
- And ** 7 million for necessary infrastructure costs*



Food Safety Beyond FSMA

Listeria Monocytogenes

- CDC recently reported several illnesses in an outbreak associated with single serve ice cream manufactured by Blue Bell Creameries
- We don't commonly see *Lm* outbreaks in no growth foods
- The fact that the product is frozen gives us a unique scientific opportunity to enumerate *Lm* in the food and learn about the infectious dose

Chemical Contaminants

- Updating, “Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food” (also known as the “The Redbook”)
- Updating the 2002 Risk Analysis Framework document
- Modernizing the Total Diet Study, including re-evaluating the sampling plan
- Working with EPA to respond to public comments regarding methylmercury in fish advice
- Working with other federal agencies, various stakeholders, and scientists from all sectors to understand and address the risks associated with arsenic in food



Nutrition

(the “N” in CFSAN)

Major 2015 Nutrition Initiatives

- Published final determination that partially hydrogenated oils, the primary source of industrially-produced trans fat in the food supply, are no longer “Generally Recognized as Safe” (GRAS) (6/17/15)
- Published final rule to add the mineral selenium to the list of required nutrients and to establish minimum and maximum levels of selenium in infant formula (6/23/15)

Major 2015 Nutrition Initiatives

- Publish proposed rule on gluten-free labeling of fermented and hydrolyzed foods
- Continue efforts to promote broad, gradual reduction of added sodium in the food supply
- Develop final rules on Nutrition Facts Label and Serving Size
- Publish guidance on Menu Labeling
- Review Scientific Report of the 2015 Dietary Guidelines Advisory Committee and participate in development of the Dietary Guidelines for Americans, 2015 policy document



Internal Initiatives

Internal Initiatives

- Dietary supplements – proposing new office
- Cosmetics - new legislation

International Programs

- Codex Alimentarius
- Public Health and Trade
- Capacity Building
 - APEC Partnership Training Institute Network
 - Global Food Safety Partnership/World Bank
- Systems Recognition
- FSMA International Outreach and Communications

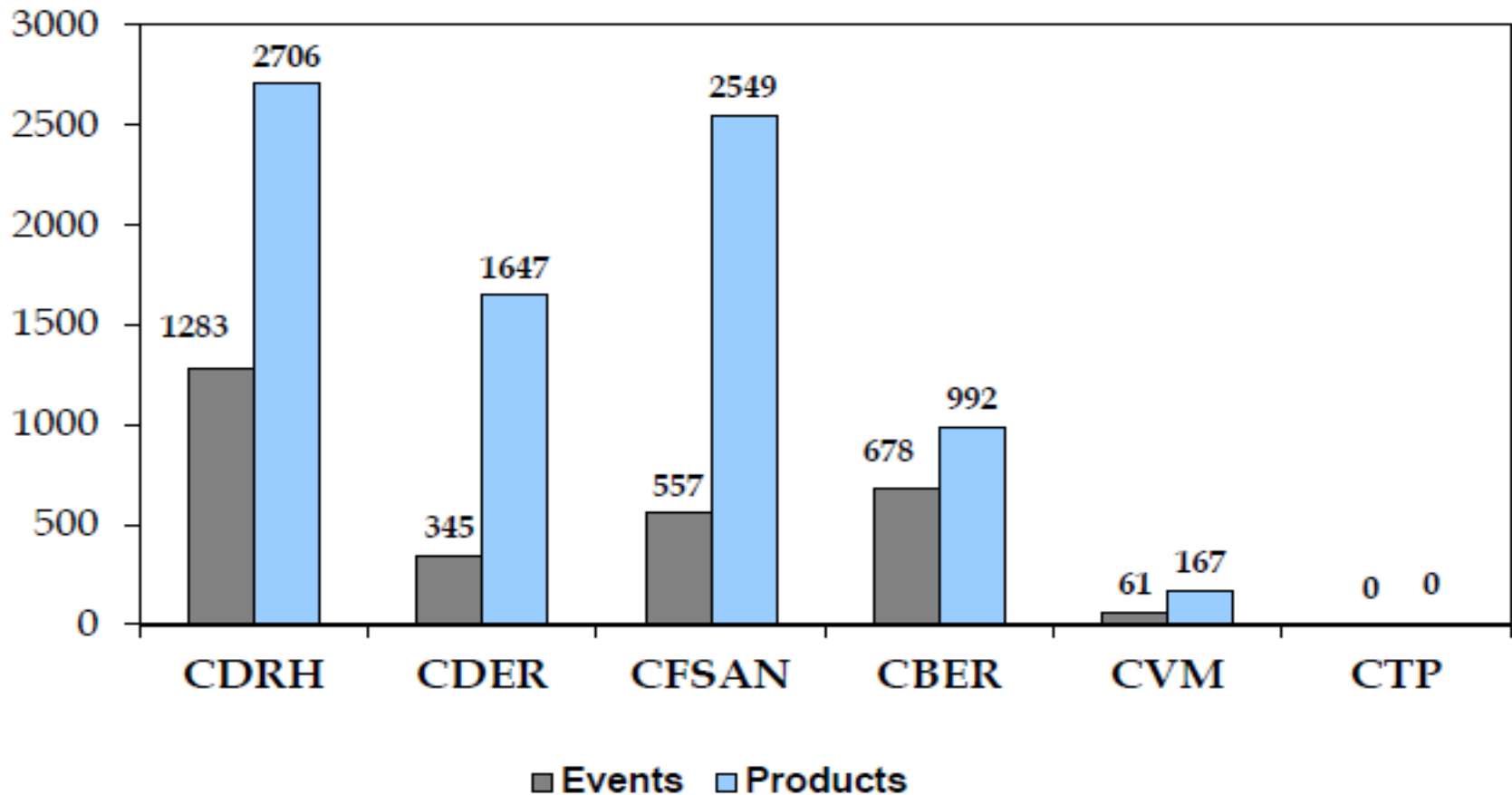




Enforcement

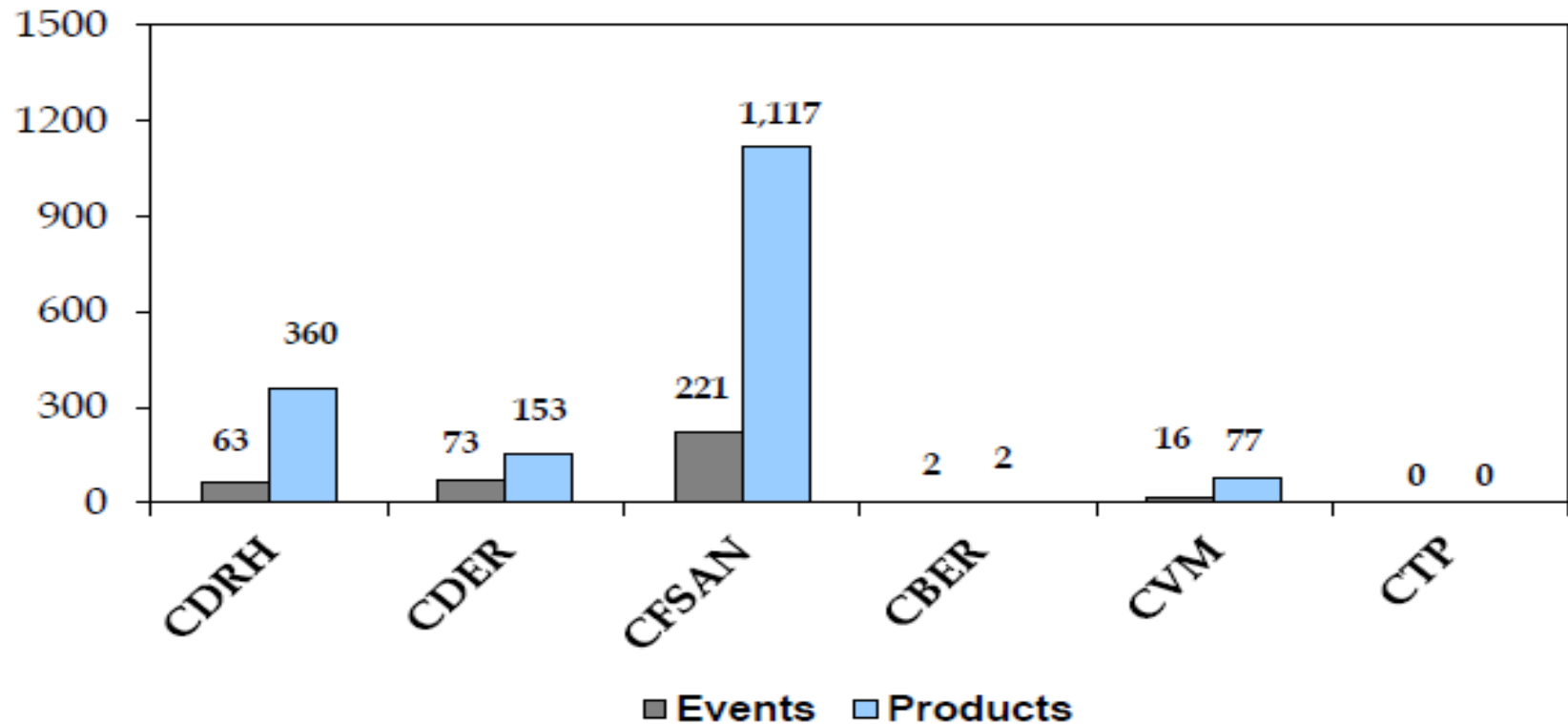


Recalls By FDA Center - All Classes Fiscal Year 2014





Recalls – Class I By FDA Center Fiscal Year 2014



FY2014 Class I Food Recalls: Reasons

- **Microbial Pathogens**
 - *Salmonella, Listeria monocytogenes, E. Coli (STECs)*
- **Undeclared Allergens**
- **Allergen, Cross-Contact**
- **FALCPA Labeling**
- **Undeclared Non-Allergenic Ingredients**
 - *Sulfites, Colors*



Enforcement and Foodborne Outbreaks

- **Use combination of enforcement tools in response to foodborne outbreaks**
- **FDA's Strategy: First prevent further illnesses while responding to outbreaks; then deter recurrence**
- **Do not expect this to change under FSMA**

Enforcement and Outbreaks

Misdemeanor Prosecutions (Park Doctrine)

- **Jensen Farms**
 - 147 ill in 28 States; 33 deaths
 - **Charged September 2013; sentenced January 2014**
 - Plead guilty, in part, to introducing adulterated food into interstate commerce
 - Maximum Penalty: 6 years in prison; \$1.5 million in fines
 - 5 years probation, 6 months home detention, \$150,000 restitution
- **Quality Egg LLC**
 - Over 1,900 illnesses; Recall of 550 million eggs
 - **Charged June 2014; sentenced April 2015**
 - Guilty of bribing USDA inspector, introducing adulterated and misbranded food into interstate commerce
 - \$6.8 million fine; several months in prison



Enforcement and Outbreaks

Misdemeanor Prosecutions - continued

- **ConAgra**
 - 625 illness in 47 states; no deaths reported
 - Plea agreement notes that ConAgra knew peanut butter made in the Georgia facility had twice tested positive for salmonella
 - **In May 2015 ConAgra agreed to plead guilty to one count of introducing adulterated food into interstate commerce and settled agreed to pay \$11million in fines**



Enforcement and Outbreaks

Felony Prosecution

- **Peanut Corporation of America (PCA)**
 - 714 illnesses in 46 States & Canada; 9 deaths
 - Environmental and product sampling performed per client specifications; use of multiple labs/test, released positive product
 - Rolling voluntary recalls – Ingredient based
 - Filed for bankruptcy during investigation – FDA/State of Texas left to carry out recalls related to TX facility



Research Initiatives

Research Initiatives (Office of Regulatory Science)

- Whole genome sequencing/Genome Trakr
- DNA sequencing (aka “DNA barcoding”)
- Improved method for determination of sulfites in food
- Mass-spectrometry based method for detection of gluten

Research Initiatives

(Office of Applied Research and Safety Assessment)

- Cardiotoxicity of dietary supplements
- Rapid molecular methods for improved throughput screening of foodborne pathogens
- Analysis of foods that list live microbes as an ingredient
- Metagenomics

Conclusion

- I feel privileged to be leading CFSAN and championing the very important work that is done by CFSAN employees each and every day.
- I look forward to continuing to meet CFSAN's many stakeholders and working together to address growing challenges and opportunities to protect and promote public health.