CFSAN Update

Steven Musser, Ph.D.,
Deputy Director for Scientific Operations
Center for Food Safety and Applied Nutrition

September 24, 2019
Center for Food Safety and Applied Nutrition (CFSAN)

- Susan Mayne, PhD, FACE, Center Director (OCD)
- Douglas Stearn, JD, Deputy Director for Regulatory Affairs (OCD)
- Stic Harris, Director, Coordinated Outbreak Response and Evaluation Network (CORE)
- Conrad Choiniere, PhD, Director, Office of Analytics and Outreach (OAO)
- William Correll, Jr., Director, Office of Compliance (OC)
- Steven Tave, Director, Office of Dietary Supplements (ODSP)
- Mark Moorman, PhD, Director, Office of Food Safety (OFS)
- Jennifer Dooren, Director, Communication and Public Engagement Staff (CPES)
- Laura Pillsbury, Director, Office of Executive Programs (OEP)
- Philip Chao, JD, LLM, Director (Acting), Office of Regulations and Policy (ORP)
- Camille Brewer, Director, International Affairs Staff, Office of the Center Director (OCD/IAS)
- Douglas Balentine, PhD, Director, Office of Nutrition and Food Labeling (ONFL)
- Steven Musser, PhD, Deputy Director for Scientific Operations (OCD)
- Steven Torrence, DVM, PhD, DACVPM, Director, Office of Applied Research and Safety Assessment (OARSA)
- Linda Katz, MD, MPH, Director, Office of Cosmetics and Colors (OCAC)
- Mickey Parish, PhD, Senior Science Advisor, Office of the Center Director (OCD/SSAS)
- V. Kelly Bunning, PhD, Director, Office of Regulatory Science (ORS)
- Linda Kux, Deputy Director for Regulatory Policy, Nutrition, and Engagement (OCD)
- Jennifer Dooren, Director, Communication and Public Engagement Staff (CPES)
- Camille Brewer, Director, International Affairs Staff, Office of the Center Director (OCD/IAS)
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November 21, 2019
FDA Food Safety Modernization Act (FSMA)
FSMA FY 19 Priorities

• Continue inspection activities under preventive controls for human food final rule

• Produce Safety Rule
  – Routine inspections of large farms (other than sprouts) started in Spring 2019
  – Agricultural water standards
  – Re-evaluate farm definition

• Intentional Adulteration Rule (July 26, 2019, compliance date for large businesses)
  – Issue remaining (third) draft guidance
  – Continue work to develop training
  – Public meeting (4/17/19)
  – Routine inspections will start in March 2020

• Issue and collect fees for two new types of food export certificates
Produce Safety Rule
Draft Guidance

• Draft guidance on Produce Safety Rule covers:
  ✓ Personnel requirements and training
  ✓ Health and Hygiene
  ✓ Biological soil amendments of animal origin
  ✓ Domesticated and wild animals
  ✓ Growing, harvesting, packing and holding
  ✓ Equipment, tools and sanitation
  ✓ Records
  ✓ Variances

• “At a Glance” overviews available for each chapter
• FDA hosted 4 regional public meetings to discuss the draft guidance
• Launched web page to support compliance (2/7/19)
Oversight of Imported Foods

- FDA Strategy for the Safety of Imported Food (2/25/19)
- Maintain level playing field
- Foreign Supplier Verification Programs (FSVP)
  - Expand inspections and conduct follow-up
- Accredited Third-Party Certification Program
- Voluntary Qualified Importer Program (VQIP) application portal open through May 31, 2019 for FY 20 benefits
- Overseas inspections and border surveillance
- International food safety agreements (e.g., systems recognition and equivalence determinations)
- Issue draft lab accreditation rule
Food Safety, Nutrition and Health
“Improvements in diet and nutrition offer us one of our greatest opportunities to have a profound and generational impact on human health....The public health gains of such efforts would almost certainly dwarf any single medical innovation or intervention we could discover.”

Scott Gottlieb, M.D.
National Food Policy Conference
March 29, 2018
Modernizing Standards of Identity

- Standards of identity establish requirements related to the content and production of certain food products.
- FDA will take a fresh look at existing standards of identity in light of marketing trends and the latest nutritional science.
- The goal is to maintain the basic nature and nutritional integrity of products while allowing industry flexibility for innovation to produce more healthful foods.
- Public Meeting – 9/27/19
Use of Dairy Names for Plant-Based Substitutes

• Request for information published 9/27/18
  ▪ How do you use plant-based products?
  ▪ What is your understanding of dairy terms like milk, yogurt and cheese when they are used to label plant-based products?
  ▪ Do you understand the nutritional characteristics of products? Do you know how they are different from each other? Do you know how their nutritional qualities compare with dairy products?
• Completing review of 13,000+ comments
Nutrition Initiative Strategy – Other FY 19 Priorities

- Publish a proposed rule on use of the term “healthy” in food labeling.

- Explore ways to help industry use statements or claims that could facilitate innovation to promote healthful eating patterns, for instance by a FDA-sanctioned “healthy” icon.

- Review the National Academy of Science, Engineering and Medicine’s Dietary Reference Intakes for Sodium and Potassium report with regard to FDA’s guidance for voluntary short-term sodium reduction goals.

- Publish remaining guidance for the industry to facilitate implementation of the Nutrition Facts label (NFL).
Other Priority Initiatives
Outbreak Investigations and Recalls

• Improve traceability through the food supply chain
  ➢ Speed traceback
  ➢ Expedite recalls

• Enhance and improve outbreak investigation capacity
  ➢ CORE and field capacity
  ➢ Lab methods and results turnaround time

• Recall guidances
  ➢ Streamlined process
  ➢ Expedited release of recall information
  ➢ Enhanced disclosure of retail distribution
Multi-year Longitudinal Environmental Surveys
Metagenomics
Innovations on FDA’s radar include cell-cultured meat and plant biotechnology.
Reach FDA through fda.gov or by calling 1-888-SAFEFOOD.
Cosmetics

• Industry survey on current manufacturing practices
• Tattoo inks that have microbial contamination
• Talc containing cosmetics
• New legislation??
Dietary Supplements

- Recent announcement to modernize regulations and strengthen oversight of dietary supplements (2/11/19)
  - FDA Dietary Supplement Working Group
- FDA launched Dietary Supplement Ingredient Advisory List (4/16/19)
- Public meeting, “Responsible Innovation in Dietary Supplements,” May 16, 2019, Wiley Auditorium, 8:30 am – 4:00 pm
- President’s FY 2020 budget includes a request for mandatory product listing
Smarter Food Safety

- Publish “Blueprint for a New Era of Smarter Food Safety”
- Evaluate role of new technologies to enhance food traceability
- Conduct a new pilot that will leverage machine learning as added functionality to FDA’s existing import screening tool
- Public meeting – October 21, 2019