MEHA Fall Seminar

November 2021
FDA’s Regulatory Responsibility

FDA has authority over the following products in interstate commerce:

- Food and Feed
- Human and Animal Drugs
- Cosmetics
- Medical Devices
- Biologics (Tissues, Blood, etc.)
- Tobacco Products
FDA web site

- Main page:
  - www.fda.gov

- Retail Food Protection Page:
  - https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ucm2006807.htm
Overview of FDA’s Retail Food Program
FEDERAL-STATE COOPERATIVE PROGRAMS

- MILK
- RETAIL FOOD
- SHELLFISH
FDA Retail Food Program

- A Cooperative Program
  - U.S. Food and Drug Administration
  - > 3000 federal, state, local and tribal agencies
  - 1.5 million restaurants, retail food stores, vending commissaries, hospitals, institutions
State and local regulatory jurisdictions have the authority to directly regulate shellfish, grade “A” milk, and retail establishments through their statutes and local ordinances.
FDA’s Role

with respect to retail food establishments is to:

http://www.fda.gov/RetailFoodProtection

- Provide uniformity by issuing model codes/guidance documents
- Work with the respective conferences on food safety issues and recommendations
- Provide technical support to FDA field staff and state/local regulatory authorities
- Standardize state and agriculture officials
- Initiate and oversee research on food safety issues affecting the retail and foodservice sector
Title III of the U.S. Public Health Service Act [42 USC 243] states:

“...The Secretary shall...assist states and their political subdivisions in the prevention and suppression of communicable diseases, and with respect to other public health matters, shall cooperate with and aid state and local authorities in the enforcement of their...health regulations and shall advise the several states on matters relating to the preservation and improvement of public health.”
**FDA’s Retail Food Support Team**

**Center for Food Safety & Applied Nutrition**
(Policy, National Meetings, Federal Standardizations)

<table>
<thead>
<tr>
<th>Retail Food Specialists</th>
<th>Division of Human Resource Development (DHRD)</th>
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<td>(Regional Field Support, Risk Factor Study, State Standardizations, Program Standards)</td>
<td>(Training)</td>
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**Office of Partnerships**
(Grants/Cooperative Agreements)
FDA’s Retail Food Program

- FDA works in cooperation with
  - Sister agencies – CDC, USDA, EPA, etc.
  - State/local Health and Agriculture Departments
  - Professional and Trade Organizations
  - National Advisory Committee on Microbiological Criteria for Foods (NACMCF)
  - National Sanitation Foundation (NSF) and Underwriter Laboratories (UL)
FDA RETAIL FOOD PROGRAM

- **STANDARDIZE REGULATORY OFFICIALS**
  - Conducted to promote uniformity in inspection methodology and in Food Code interpretation

- **Voluntary National Retail Food Regulatory Program Standards**
FDA RETAIL FOOD PROGRAM

- TECHNICAL ASSISTANCE and TRAINING
  - Food Code Interpretations
  - Retail HACCP
  - Special Processes
  - Retail Food Protection
  - Risk Factor Study
FDA RETAIL FOOD PROGRAM

SPECIAL PROJECTS

- NATIONAL SECURITY EVENTS
  - OLYMPICS
  - INAUGURATION
  - NATO

- DISASTER RECOVERY

- PILOT PROJECTS
FDA FOOD CODE

Promote Adoption of the FDA Food Code
Changes to the 2013 Food Code go into its Supplement and eventually incorporated into the 2017 “Full Edition”
FDA Food Code

- Uses sound science and HACCP Principles
- Addresses risk factors that contribute to foodborne illness
- Contains 5 key public health interventions
- Identifies Good Retail Practices (GRP’s) as foundation of food safety – safe water, sewage disposal, pest control, plumbing, etc.
- Promotes uniformity across the country
- Receives input from industry, states, local agencies, academia and the public through the Conference for Food Protection (CFP) every 2 years
Purpose & Authority of the Food Code

**Purpose**
- to assist food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail segment of the food industry.

**Authority**
- PHS authority is derived from the Public Health Service Act [42 USC 243], Section 311(a).
- Responsibility for carrying out the provisions of the Act delegated within the PHS to the Commissioner of Food and Drugs in 1968 [21 CFR 5.10(a)(2) and (4)].
- Assistance provided to local, state, and federal governmental bodies is also based on FDA's authorities and responsibilities under the Federal Food, Drug, and Cosmetic Act [21 USC 301].
Intent of the Food Code

- Promotes Uniformity
  - 49/50 States adopted codes patterned after any version of the Food Code. This represents 96% of the US population.
  - Implementation supported by other program elements

- Designed to minimize foodborne illness by focusing on the CDC-identified risk factors

- Provides jurisdictions with a scientifically sound technical and legal basis for regulating the retail food store and foodservice segment of the food industry

- Codes are written to be consistent with federal food laws and regulations and for ease of legal adoption at all levels of government
FDA Food Code

- Ch. 1 – Definitions
- Ch. 2 – Management & Personnel
- Ch. 3 – Food
- Ch. 4 – Equipment, Utensils, Linens
- Ch. 5 – Water, Plumbing, Waste
- Ch. 6 – Physical Facilities
- Ch. 7 – Poisonous or Toxic Materials
- Ch. 8 – Compliance & Enforcement
FDA Food Code

- Annex 1 – Compliance & Enforcement
- Annex 2 – References, Supporting Documents
- Annex 3 – Public Health Reasons, Guides
- Annex 4 – Management of Food Practices
- Annex 5 – Risk-Based Inspections
- Annex 6 – Food Processing Criteria
- Annex 7 – Forms, Guides, Aids
Conference for Food Protection

http://www.foodprotect.org

- Regulatory/Industry/Academia/Consumer Partnership
- 3 Councils debate submitted issues and voting delegates make recommendations to FDA
  - Council I – Laws & Regulations
  - Council II – Administration, Education & Certification
  - Council III – Science & Technology
- Committees of regulators, industry & academia are also created to address issues for Council consideration
- Guidelines and training materials
  - See “Conference-Developed Guides and Documents at http://www.foodprotect.org/guides/"
New Era of Food Safety: E-commerce Summit

- If you missed the summit you can view recordings:
  - New Era of Smarter Food Safety Summit on E-Commerce: Ensuring the Safety of Foods Ordered Online and Delivered Directly to Consumers - 10/19/2021 - 10/21/2021 | FDA

- Public Docket for Comments (closes Nov 20th):
  - Docket FDA-2021-N-0929
  - www.regulations.gov
Questions