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## **I. Food Safety Modernization Act (FSMA)**

Signed into Law January 4, 2011

- Sign up for FSMA updates:
  - <http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>

### **Recent FSMA Milestones**

- Joint Anti-Smuggling Strategy
- Draft Guidance for Dietary Supplement Industry
- Authority to Suspend Registrations
- Docket on development of Guidance on Preventive Controls

## **Fish & Fishery Products Hazards and Controls Guidance**

- **4<sup>th</sup> Edition:** FR Notice of availability – April 28, 2011
  - represents the agency's current thinking on the hazards associated with fish and fishery products and appropriate controls for those hazards.
- Food Safety Modernization Act - requirement met
- New invertebrate and vertebrate species
- Introductory video now available and several informational videos being prepared to supplement the 4<sup>th</sup> Edition

## **Administrative Detention of Food for Human and Animal Consumption**

- New rule under the Food Safety Modernization Act (FSMA)
  - FR Notice of Interim Final Rule – May 5, 2011
  - Became effective July 3, 2011
- FDA will be able to detain food products believed to be adulterated or misbranded for up to 30 days.

## **On-going FSMA Activities**

- Preventive Controls Rule and Guidance
- Produce Safety Rule and Guidance
- Imports: Third-party certification; Import Certificates; Qualified Importer Program
- Rules for Safe Transport of Foods
- Integration and Infrastructure Development : Fed-State-Local

## **II. Coordinated Outbreak Response & Evaluation (CORE)**

- July 2011 FDA launched CORE
- CORE will manage
  - Incidents involving illness with human and animal foods
  - Significant food contamination events
  - Post-response efforts related to incidents
- 5 Functional Areas
- August 1, 2011 CORE Response Teams began managing new incidents
- To be led by new Chief Medical Officer -Dr. Kathleen Gensheimer

### III. Retail Food Safety Initiative

- Announced in conjunction with October 2010 release of Risk Factor Study Reports
- Recognition that food safety at point of sale and service is important part of FDA's farm-to-table strategy
- Acknowledge key partnerships as part of an integrated food safety system
- Retail Initiative Task Force established
- Action Plan to be announced soon

### FDA's Strategic Direction for Retail

- Increase the presence of certified food protection managers
- Strengthen active managerial control at the retail level and ensure better compliance
  
- Improve the quality of, and access to, training of retail food personnel by the industry
- Promote more widespread, uniform, and complete adoption & implementation of the FDA Food Code
- Ensure prevention-oriented, science-based food safety principles are utilized at the retail level
- Create an enhanced local regulatory environment for retail food operations by:
  - Wider implementation of the *Voluntary National Retail Food Regulatory Program Standards*
  - Seeking increased multi-year funding for state/local/tribal programs
  - Developing programs to ensure universal participation by state/local/tribal regulators in consistent, high-quality training

### IV. Considerations for Next FDA Retail Risk Factor Study

- Streamlined data collection - fewer data items, more easily communicated
- Establish national performance metric
  - % of establishments at some level of compliance
- Examine other correlations based on demographics
  - Establishment characteristics
- Examine impact of different interventions and regulatory strategies on specific risk factor occurrence
- More in-depth assessment of management practices in place
- Assess degree of non-compliance for select items
- Focus on One Facility Category at a Time
  - Larger Sample Size, Smaller Error, Firmer Conclusions
- More Efficient Data Collection Techniques
  - Electronic Capture; Real-Time Database

**V. Supplement to 2009 Food Code**

- Modifies 2009 Food Code
- Due To Post in September 2011
- 13 of 16 Food Code recommendations made at 2010 Meeting of the Conference for Food Protection addressed
- Codified Text and Public Health Reasons (Annex 3)

**Certified Food Protection Manager**

- At least one employee be a Certified Food Protection Manager (new 2-102.12)
  - Management & supervisory role
  - Acknowledge exceptions are appropriate for types of establishment, but does not specify which ones
  - Retain existing requirements for PIC
  - Recognize (not mandate) ANSI-Accredited Certification Programs

- Related to CFP 2010-II-021

**Revised Duties of Person in Charge (2-103.11)**

- Development & implementation of required procedures
  - Reinforce that management needs to ensure procedures are in place, as required
  - Related to CFP 2010-I-024
- Ensuring safety of foods delivered after hours of operation
  - Related to CFP 2010-I-022
- Employees informed of illness reporting requirements in “verifiable” manner
  - Related to CFP 2010-I-011

**Other Select Supplement Items**

- Procedures need for response to vomiting and diarrheal events (new 2-501.11)
  - Purpose specified in codified; areas to consider highlighted in Annex 3
  - Related to CFP-III-023
- Bare Hand Contact with Ready-To-Eat Foods (3-301.11)
  - Prohibition does not apply when adding RTE ingredients to food to be fully cooked to specified minimum temperature
  - Related to CFP 2010-III-013
- Safe Storage/Display of Ground Meats near Intact Whole Muscle Meats (3.302.11)
  - Related to CFP 2010-III-020
- On-Site Generation of Hard Surface Sanitizers (4-501.114 and 7-204.11) and Chemicals Used for Washing Produce (7-204.12)
  - Ensure devices and agents comply with law
  - Related to CFP 2010-III-005
- Revise criteria for Drying Agents used in conjunction with Sanitization (7-204.14)
  - Related to CFP 2010-III-024
- Timely Correction of Violations (8-405.11)
  - Tighter timeframes based on new priority/priority foundation/core designations
  - Related to CFP 2010-I-017

**2010 CFP Issues not addressed in Supplement to 2009 Food Code**

- III- 006; III-007; III-015

## **VI. Voluntary National Retail Food Regulatory Program Standards**

- 2011 Edition Posted in March
- Updates and Revisions based on Eight Recommendations from 2010 CFP
- Limited Revisions to Stds 2, 5, 6 and 9
- Number of enrollments increasing: 400+
- Significant progress made by enrollees
- \$1.3 M made available by FDA to Programs committed to progress this FY

## **VII. New Cooperative Agreement**

- FDA Collaboration with National Association of County and City Health Officials
- Develop and share strategies for Implementing Program Standards
- Pairing-up new enrollees with experienced enrollees
- Explore benefits of using Program Standards as component of Public Health Agency Accreditation
- Gather information on other food safety programs/interventions outside of Program Standards example: Inspection Scoring/Grading Systems

## **VIII. New Educational Materials available on FDA.Gov**

FDA Oral Culture Learner Project – Educational Materials

Employee Health and Personal Hygiene Interactive Tool

Compliments Employee Health and Personal Hygiene Handbook

Commercial Deli Slicers

- Many Current Slicer Designs are
  - Difficult to properly clean and sanitize
  - Have adjoining parts and components with sealants and gaskets that need routine maintenance and inspection
- NSF/ANSI Standard 8, *Commercial Powered Food Preparation Equipment* REVISED in October 2010
- Educational Campaign
  - Target audience specific to:
    - Food Safety Professionals (FLYER)
    - Food Establishment Personnel (POSTER)

New FDA Materials on Sanitation Concerns with Commercial Deli Slicers

- Keep Commercial Deli Slicers Safe – Poster targeted to food establishment personnel
- Commercial Deli Slicer Inspection Tips for Food Safety Professionals – Flyer targeted to food regulatory professionals
- The new poster and flyer are available in both English and Spanish at no charge and can be ordered at:  
<http://www.fda.gov/downloads/Food/ResourcesForYou/UCM222258.pdf>.
- For orders greater than 500, contact Shirley Turpin at shirley.turpin@fda.hhs.gov.

## IX. Restaurant Menu Label Rule

- Established under the Patient Protection Affordable Care Act (PPACA or Affordable Care Act) of 2010
- Requires restaurants or similar retail food establishments with 20 or more locations to:
  - Display on menus and menu boards (including drive-thru) the number of calories in the item for each “standard menu item as usually prepared and offered for sale.”
  - A written statement on the premises that provides other nutrition information (similar to nutrition facts) available upon request.
  - A conspicuous statement on the menu or menu board stating the availability of additional nutrition information
- Does not cover
  - Items not listed on a menu or menu board (such as condiments or items placed on the table or counter for general use);
  - Daily specials, temporary menu items appearing on the menu for fewer than 60 days per calendar year or custom orders;
  - Food that is part of a market test and appears on the menu for fewer than 90 days.
- FDA Published Proposed Rule in April 2011

## X. Retail Food Allergen Manual

- Provide information for regulators to advise the PIC
- Raise food allergy awareness of food employees
- Spell out best practices and strategies for active managerial control of allergens
- Provide direction for establishments that want to prepare “allergen-free” food

### Retail Food Allergen Manual - Components

- Food Allergy Awareness
- Food Allergen Control
- Receiving and Storage
- Cleaning and Sanitizing
- Food Preparation
- Packaging and Labeling
- Food Allergen Management Plan

### Retail Food Allergen Manual-Next Steps

- Under review by CFSAN management
- To be sent to CFP Food Allergen Committee this fall for comment / input
- Review by other external stakeholders prior to availability as FDA Document

## XI. Interagency *Listeria monocytogenes* Studies & Retail Risk Assessments

- FSIS released the comparative LM risk assessment
- New Studies – New Approach: retail cross-contamination model
  - Determine how contamination of deli meat, cheese, and salad occurs
  - Observational study of deli workers completed for real world data
  - Evaluate the impact of various mitigations