Modernization of Food cGMP Regulations

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Food cGMP Regulations

- Current Good Manufacturing Practice (cGMP) regulations (21 CFR Part 110) last revised in 1986
- Many changes have occurred in the food industry since 1986
  - Increased availability of RTE foods, refrigerated prepared foods, heat-and-serve foods
  - Better understanding of foodborne illness, pathogens, allergens

Food cGMP Modernization Working Group

- In 2002, CFSAN formed a cGMP Modernization working group (WG) to determine if changes to cGMP regulation were needed
- In 2003, the WG initiated research
  - Food recall analysis (1999-2003)
  - Literature review
  - Expert elicitation

Recalls

- 88% occurred because of GMP-related problems
- 34% involved undeclared allergenic ingredients
- 17% microbiological contamination
- Root causes – incorrect packaging/ labeling, ineffective employee training, failure to follow established SOPs for processing

Expert Elicitation

- Top food safety problems faced by manufacturers
  - Deficient employee training
  - Contamination of raw materials
  - Poor plant and equipment sanitation
  - Poor plant design and construction

Expert Elicitation

- Preventive controls identified:
  - Training
  - Audits
  - Documentation
  - Validation/evaluation

Food cGMP Modernization

- Preliminary findings from research: "GMPs for the 21st Century - Food Processing" (2004)
- *Federal Register* notice (69 FR 29220)
  - Requested comments on GMP modernization
  - Announced 3 public meetings (College Park, Chicago, and San Jose)

Food cGMP White Paper

- "Food CGMP Modernization – A focus on Food Safety" (2005)
- Report summarized public comments and detailed the WG's key findings
  - White Paper available at: **http://www.fda.gov/ohrms/dockets/dockets/04n0230/04n-0230-rpt0001-vol4.pdf**

White Paper: Opportunities for Modernization (1)

- Require appropriate training for supervisors and workers (now only recommended)
  - Food hygiene
  - Food protection
  - Employee health and personal hygiene

Easily understood

Maintain record of training

White Paper: Opportunities for Modernization (2)

- Require an allergen control plan for facilities using major food allergens
  - Training of processing and supervisory personnel
  - Segregation of allergens (storage and handling)
  - Validated cleaning procedures
  - Prevention of cross contact during processing
  - Product label review
  - Label usage and control
  - Supplier control program (ingredients and labels)

White Paper: Opportunities for Modernization (3)

- Require written environmental pathogen control program for facilities producing RTE foods that support growth of *Listeria monocytogenes*
  - Microbiological monitoring
  - Records
    - Judge effectiveness of program
    - Identify root cause of sanitation failures
    - Document corrective actions

White Paper: Opportunities for Modernization (4)

- Require that food processors develop and maintain written sanitation procedures, at a minimum, for all food contact equipment and food contact surfaces
  - Scope/objective
  - Management responsibility
  - Monitoring, corrective action, record keeping

White Paper: Opportunities for Modernization (5)

- Obtain further comments on removing the exclusion from cGMP compliance for establishments engaged in harvesting, storage, and distribution of raw agricultural commodities

White Paper: Opportunities for Modernization (6)

- Require that food processors maintain certain critical records and that these be made available for review and evaluation by FDA investigators to confirm compliance with GMPs.

White Paper: Opportunities for Modernization (7)

- Obtain further comments on use of time-temperature relationships for proper refrigerated storage or hot holding.

Additional cGMP Research

- Food cGMP survey – to obtain baseline data on current food safety practices in *domestic* facilities
- Expert elicitation - to obtain baseline data on current food safety practices in *foreign* facilities

Food cGMP Survey

- Purpose: to obtain baseline data on current food safety practices in domestic facilities
- Random sample of registered domestic facilities (FDA Food Facility Registration database) – 2,700 facilities
- Expected response rate – 56% or 1,500 respondents
- Mixed mode approach – survey available by internet or mail

Survey Question Topics

- Establishment characteristics (e.g., number of employees, product type)
- Use of food safety plans (e.g., HACCP)
- Employee training
- Sanitation and personal hygiene practices
- Allergen controls
- Process controls
- Supplier approval practices
- Recordkeeping

Expert Elicitation

- Purpose: to obtain baseline data on current food safety practices in foreign facilities
- 10 individuals with expert knowledge of food manufacturing practices in various countries or regions identified
- Experts asked to estimate the current baseline on food safety practices in foreign facilities
- Instrument used in expert elicitation was modeled after the internet survey

Food Safety Reform

- Has been an issue in Congress for several years
- Major domestic policy issue for the Obama administration

Food Safety Enhancement Act (FSEA) of 2009

- House bill - Would amend the Federal Food, Drug, and Cosmetic Act to set forth provisions related to food safety
- Provisions in FSEA could impact FDA's approach to cGMPs
- Senate bill has many similar provisions

FSEA Food Safety Plan

- Requires each food facility to:
  - (1) conduct a hazard analysis;
  - (2) implement preventive controls; and
  - (3) implement a food safety plan.

FSEA Preventive Controls

- Sanitation procedures and practices
- Training (supervisor, manager and employee hygiene)
- Process controls
- Allergen control program
- GMPs
- Supplier verification activities (on-sight audits, testing of incoming ingredients)

FSEA Plan Validation

- Food Safety Plan must include scientific/technical validation that the system of controls will prevent, eliminate or reduce hazards to an acceptable level.

FSEA Guidance

- Science-based standards for
  - conducting a hazard analysis,
  - documenting hazards,
  - identifying and implementing preventive controls, and
  - documenting the implementation of the preventive controls, including verification and corrective actions
- Guidance to assist small businesses in complying with the requirements

FSEA Finished Product Testing

- Required from facilities producing high risk foods
- Pilot projects (2 or more) to evaluate the feasibility of collecting positive finished product testing results and corrective actions
- Feasibility study: feasibility and benefits of the reporting by facilities subject to GMP regulations of appropriate finished product testing results from category 1 facilities to the Secretary

FSEA Food Defense Plan

- Assessment to identify conditions and practices that may permit a hazard that may be intentionally introduced
  - processing security
  - cybersecurity
  - material security (including ingredients, finished product, and packaging)
  - personnel security
  - storage security
  - shipping and receiving security
  - utility security

FSEA Food Defense Plan

- Preventive measures
- Procedures to check for and identify any circumstances in which the preventive measures are not fully implemented or were ineffective.
- Procedures for taking corrective actions
- Evaluation activities for the preventive measures
- Records

FSEA Performance Standards

- Established for the most significant food-borne contaminants and the most significant resulting hazards
  - Based on epidemiology and research
  - Every two years
- Publish list of food-borne contaminants that have the greatest adverse impact on public health
- May make recommendations to industry for conducting product sampling

FSEA – Raw Agricultural Commodities

- Regulations: scientific and risk-based food safety standards for the growing, harvesting, processing, packing, sorting, transporting, and holding of
  - fruits, vegetables, nuts, or fungi
  - for which such standards are reasonably necessary to minimize the risk of serious adverse health consequences or death to humans or animals.

FSEA Inspections

- CATEGORY 1- a high-risk facility that manufactures or processes food
  - at least every 6 to 12 months.
- CATEGORY 2- a low-risk facility that manufactures or processes food or a facility that packs or labels food
  - at least every 18 months to 3 years.
- CATEGORY 3- a facility that holds food
  - at least every 5 years.

FSEA Records Access

- FDA would have access to all records relating to determining whether a food may be adulterated or misbranded.

FSEA Timeframe

- Food Safety Plan
  - 18 months
  - 2 years, small businesses
  - 3 years, very small businesses
- Finished product testing – 2 years
- Risk-based inspections – 18 months

FDA is Moving Forward

- FDA is Developing Produce Standards
- FDA is revising its GMPs
- Both will be consistent with legislative requirements that are enacted

What's next?

- Regulation Circle Dance
- Propose rule

Timing

- Can’t tell you
- If I could tell you, I would probably be wrong
- Good news – Fast track
- Bad news – it’s the government’s track
- Good news – there’s a new sheriff in town

Questions?