FSMA: Key Provisions

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http://www.fda.gov/food/guidanceregulation/cgmp/default.htm

CGMP History

Food GMP Development Timeline	
Date	**Milestone**
1906	The Bureau of Chemistry passes the 1906 Pure Food and Drugs Act, prohibiting interstate commerce in misbranded and adulterated foods, drinks, and drugs
1933	FDA recommends revising the 1906 Pure Food and Drugs Act
1938	FDA passes the 1938 Federal Food, Drugs, and Cosmetics Act, which provides identity and quality standards for food
Mid 1960s	FDA decides to clarify the FDCA through GMP regulations
1968	FDA proposes food GMP regulations
1969	FDA finalizes food GMP regulations
Early 1970s	FDA considers promulgating industry-specific regulations
Late-1970s	FDA decides to revise the general GMPs rather than adopting industry-specific GMPs
1986	FDA publishes revised food GMPs
2002	FDA forms Food GMP Modernization Working Group
2004	FDA announces effort to modernize food GMPs
Source: Dunkelberger, 1995; FDA, 1981b.	

CGMP Modernization Discussions

- CGMP Modernization Working Group formed (July 2002)
- To examine
  - Which CGMPs have the greatest impact on food safety
  - Economic impact of CGMPs
  - Which CGMPs to keep
  - Which CGMPs to improve or revise

FDA's Approach

- CGMP notice of public meeting, May 21, 2004
- FDA's intent to modernize CGMPs
- Holding of 3 public meetings
  - Review data
  - Solicit comments
  - Industry practices vs scientific data

- FDA provided data that examined process-specific recalls
- Scientific data on applications of CGMPs to food safety (literature)
- Elicitation from industry experts (Delphi technique; 3 rounds plus 2 additional sessions)
  - What hazards should be addressed
  - How best to address the hazards

Top 10 Food Safety Problems and Preventive Controls/Corrective Actions

Food safety problem	Preventive controls
Contamination during processing	Separate production lines and staging areas
Contamination of raw materials	Supplier audits, raw material testing and verification, supplier certifications, pre-processing treatments
Deficient employee training	Specific, bilingual, printed, videos, evaluation of training
Difficult-to-clean equipment	Environmental sampling, identify niche areas, SSOPs, ability to disassemble equipment, add a kill step
Incorrect labeling or packaging	Label review policies, remove old labels from inventory, verify labels by barcode scanning, label audits, training of employees
No preventive maintenance	Document repairs/servicing
Poor employee hygiene	Sensor equipped towel/sanitizer dispensers, keypad controls for hand washing
Poor plant and equipment sanitation	Keypad control to track hand washing, pay incentives to employees, beeping dispenser at end of hand washing, hygiene documentation

Food safety problem	Preventive controls
Poor plant design and construction	Properly conducted third party audit
Post processing contamination at manufacturing facility	Environmental sampling, inclusion of a kill step at end of processing, use of preservatives, and SSOPs

All 10 problems require input of an unbiased third party auditor!

7 Key Areas for CGMP Modernization (Nov. 2, 2005)

- (1) Training of employees and supervisors
  - Knowledge and expertise in food hygiene and protection
  - Documentation of training
- (2) Allergen control plan
  - Training of processing/supervisory personnel
  - Segregation of allergen vs non-allergen materials
  - Validate cleaning procedures
  - Prevent cross contamination
  - Product label/review/usage
  - Supplier allergen control program/labels

- (4) Written environmental pathogen control program
  - For RTE foods, especially with special reference to *L. monocytogenes*
  - Identify potential risks of processing and packaging environments
  - Microbial monitoring
  - Validation of SSOPs
  - Maintenance of records

- (5) Written SSOPs
  - Define scope, objectives, purpose and effectiveness of SSOPs
  - Management's responsibility
  - Record keeping
  - Written SSOPs

- (6) Maintain critical records for review by FDA
  - Accessibility
- (7) Obtain further comments on temperature-time relationships and inactivation of pathogens at refrigerated or hot food products
  - Avoid discrepancy between FDCA and Food Code

FSMA: KEY PROVISIONS

1. New responsibilities on food manufacturers and food producers

Hazard analysis and identification of preventive controls

- ✓ Each registered facility will be required to conduct a hazard analysis of reasonably foreseeable hazards and put into place preventive controls designed to significantly minimize or prevent those hazards.
- ✓ Each registered facility will be required to implement its preventive controls through a system that includes monitoring , corrective actions, and verification that the system is working properly.
- ✓ Finished product and environmental testing is considered part of the facility's verification process.

Supply chain management

- ✓ Supplier verification activities are expressly listed as one of the preventive controls to be implemented.

- ✓ (See also foreign supplier verification program below under Import Controls.)

Records maintenance and access

- ✓ Each registered facility will be required to document its hazard analysis and preventive controls system including corrective actions and product/environmental testing and to make those records available to FDA upon request.

Intentionally introduced hazards

- ✓ Each registered facility will also be required to conduct a hazards analysis of those hazards that may be intentionally introduced including those introduced by acts of terrorism and to implement appropriate mitigation steps as deemed necessary by the FDA.

Traceability

- ✓ FDA will be required to conduct pilot tests and issue regulations for “high risk” products.

Very small business exemption

- ✓ The bill contains a limited exemption from the both the preventive controls provision and from any mandatory produce standards for very small businesses and very small farms, based on limited sales and area of distribution.

2. Tighter controls over imports

Foreign supplier verification program

- ✓ Importers will be required to verify that imported food and food ingredients are produced in accordance with U.S. requirements.
- ✓ Records must be maintained for two years and be accessible to the FDA.

Third party certification

- ✓ FDA has authority to require third party certification for specific types or sources of imported food based on public health considerations.
- ✓ FDA may refuse admission if certification is not provided.
- ✓ Third parties may be accredited foreign governments or private auditors.

Accreditation process

- ✓ FDA will recognize accrediting bodies which, in turn, are to evaluate and accredit third party auditors.
- ✓ FDA will establish standards for accrediting bodies conflict-of-interest standards for third party auditors.
- ✓ Third party auditors will be required to report directly to FDA any conditions that could cause or contribute to a serious risk to the public health.
- ✓ False statements made by foreign facilities to third party auditors are subject to criminal penalties.

Certified laboratories

- ✓ FDA will be required to recognize accreditation bodies to accredit laboratories including laboratories administered by a Federal agency as well as independent private laboratories.
- ✓ Accredited laboratories will be required to be used when FDA has designated an identified or suspected food safety problem.
- ✓ Laboratory results will be sent directly to the FDA in addition to the importer.

Voluntary qualified importer program

- ✓ FDA will provide for expedited entry (i.e., “fast lane”) for qualified importers who voluntarily participate in the program.
- ✓ Eligibility includes third party certification among other factors.
- ✓ FDA will coordinate with Department of Homeland Security, which operates a similar program from the security perspective.
- ✓ Participation will be subject to a fee (see below).

3. Stronger FDA enforcement powers

More frequent FDA inspections

- ✓ Domestic facilities will be inspected based on risk: high risk facilities at least once every 3 years and low risk facilities at least once every 5 years.
- ✓ Foreign facilities to be inspected with increasing frequency over time: 600 total foreign facility inspections in the first year, to double each year for 5 years, reaching 9,600 foreign facility inspection by 2015.

Mandatory recall authority

- ✓ FDA will be given authority to mandate a food product recall if the company refuses to do so voluntarily and the hazard meets the criteria for a Class 1 recall.
- ✓ Only the FDA Commissioner has authority to mandate a recall, following an opportunity for an informal hearing.
- ✓ A company will face civil money penalties for refusing to conduct a mandatory recall.

Suspension of registration

- ✓ FDA will be given authority to suspend a company's registration, thereby revoking its license to operate, when the food presents a reasonable probability of causing serious adverse health consequences or death.
- ✓ For a company that only packs, received or holds food, there is the added requirement that the company "knew or should have known" of the problem conditions.
- ✓ Only the FDA Commissioner has authority to suspend a company's registration, following an opportunity for an informal hearing.
- ✓ The bill provides a process for subsequent reinstatement based on corrective action.

Enhanced administrative detention authority

- ✓ Standard for administrative detention of food is broadened to “has reason to believe” the food is “adulterated or misbranded.” (Under prior law, detention was limited to where there was “credible evidence” that the food presents a “threat of serious adverse health consequences or death.”).
- ✓ Administrative detention remains a temporary measure, lasting until the agency institutes a formal seizure action in Federal court.

4. New fees on food facilities

Reinspection fees

- ✓ Fees will be assessed to reimburse FDA for reinspection-related costs for domestic facilities and importers.

Recall fees

- ✓ Fees will be limited to the reimbursement of FDA for recall-related costs when a company refuses to conduct a mandatory recall.

Voluntary qualified importer program fees

- ✓ Fees are intended to reimburse FDA for costs associated with operating a voluntary qualified importer program (i.e., fast lane).

Export certificate fees

- ✓ Fees will reimburse FDA for costs associated with providing export certificates to companies that voluntarily request them.
- ✓ This fee has long been assessed against exporters of other FDA-regulated products.