Proposed Rules under the FDA Food Safety Modernization Act

http://www.fda.gov/fsma

Five Proposed Rules Establish Food Safety Framework

- **Produce Safety Standards –**
  Published Jan. 2013
- **Preventive Controls for Human Food -**
  Published Jan. 2013
- **Foreign Supplier Verification Program –**
  Published July 2013
- **Accredited Third Party Certification –**
  Published July 2013
- **Preventive Controls for Food for Animals -**
  Published October 2013

FDA

Five Proposed Rules – Comment Period

- **Produce Safety Standards – Comment period extended to Nov. 15, 2013**
- **Preventive Controls for Human Food – Comment period extended to Nov. 15, 2013**
- **Foreign Supplier Verification Program – Comments due Nov. 26, 2013**
- **Accredited Third Party Certification – Comments due Nov. 26, 2013**
- **Preventive Controls for Food for Animals - Comments due Feb. 28, 2014**

Preventive Controls for Human Food

Key Principles

- Confirms industry's primary role on food safety
- Prevention of hazards
- Risk-based

Summary of Requirements

- **Hazard Analysis and Risk-Based Preventive Controls**
  - **Each facility would be required to implement a written food safety plan that focuses on preventing hazards in foods**
- **Updated Good Manufacturing Practices (proposed 21CFR Part 117)**

Who is Covered?

- Facilities that manufacture, process, pack or hold human food
- In general, facilities required to register with FDA under sec. 415 of the FD&C Act
- Applies to domestic and imported food
- Some exemptions and modified requirements are being proposed

Preventive Controls Required

- Process controls
- Food allergen controls
- Sanitation controls
- Recall plan
- In addition, seeking comment on supplier approval and verification program

Verification Required

- Validation
- Calibration
- Review of records
- In addition, seeking comment on review of complaints, finished product testing and environmental testing

Updated Good Manufacturing Practices

- Protection against allergen cross-contact
- Updated language; certain provisions containing recommendations would be deleted
- Comments requested on mandating training and whether rule should require, rather than recommend, certain provisions

Exemptions and Modified Requirements

- "Qualified" facilities:
  - Very small business (3 definitions being proposed—less than $250,000, less than $500,000 and less than $1 million in total annual sales)

OR

  - Food sales averaging less than $500,000 per year during the last three years AND sales to qualified end users must exceed sales to others

Exemptions and Modified Requirements

- Foods subject to low-acid canned food regulations (microbiological hazards only)
- Foods subject to HACCP (seafood and juice)
- Dietary supplements
- Alcoholic beverages

Exemptions and Modified Requirements

- Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment
- Certain storage facilities such as grain elevators that store only raw agricultural commodities intended for further distribution or processing

Farm-Related Exemptions

- Activities within the definition of "farm," including farm activities that are covered by the proposed produce rule
- Certain low-risk manufacturing/processing, packing and holding activities conducted by small/very small businesses on farms for specific foods

Effective and Compliance Dates

Effective date:

60 days after the final rule is published

Compliance Dates

- Large Business - 1 year after publication
- Small Business (employs fewer than 500 personnel) - 2 years after publication
- Very Small Business (i.e. a “qualified” facility) – 3 years after publication. A “qualified” facility is also subject to modified requirements

PCR & PMO Published Q&A's

- **Do facilities operating under the PMO meet the requirements of the proposed preventive controls rule?**

  The preventive controls provision of FSMA (section 103) does not exempt dairy facilities that are required to register with FDA. FDA is interested in receiving comment on whether and how a facility complying with the PMO would be in compliance with the requirements of the proposed PC rule.

PCR & PMO Published Q&A's (cont.)

- **If a firm implements the PMO's voluntary HACCP program, will the preventive controls requirements of FSMA be satisfied? If not, what are the additional requirements?**

  Beginning on page 3662 of the preamble of the proposed Preventive Controls Rule, FDA discusses the voluntary HACCP program of Appendix K in the PMO in relation to other HACCP programs. Beginning on page 3785, Section XVI. B discusses the comparison of hazard analysis and preventive controls standards;

PCR & PMO Published Q&A's (cont.)

this comparison includes the PMO HACCP Appendix. The proposed rule would require a food safety plan, and outlines specific components that are very similar but not identical to the requirements for a HACCP plan in the PMO HACCP Appendix. FDA is interested in receiving comment on the comparison of requirements under the proposed Preventive Controls Rule and the PMO HACCP Annex and any specific differences, as well as whether and how the PMO voluntary HACCP program satisfies the proposed rule's requirements.

PCR & PMO Published Q&A's (cont.)

- **After the Preventive Controls Rule becomes effective, when FDA conducts a Grade A milk plant inspection, what inspection criteria will be used - Preventive Controls, PMO or both sets of rules?**

Grade A milk plants currently inspected under the PMO would be required to meet any additional requirements of the Preventive Controls Rule. FDA would like to receive comments on how the requirements of the PMO and the Preventive Controls Rule can be implemented in a way that avoids duplication and makes sense with respect to ensuring food safety.

PCR & PMO Published Q&A's (cont.)

- **Does the Preventive Controls Rule apply to dairy farms?**

  Dairy farms that conduct manufacturing/processing activities on food not consumed on that farm or that pack or hold food not grown, raised or consumed on that farm are subject to registration under section 415 of the FD&C Act and would be subject to requirements of the Preventive Controls Rule unless a specific exemption applies.

PCR & PMO Published Q&A's (cont.)

- **What environmental and finished product testing for milk and dairy products is required under FSMA and the proposed Preventive Controls Rule?**

  The proposed Preventive Controls Rule did not include requirements for environmental monitoring or finished product testing. Instead, the proposed rule discusses FDA's current thinking and poses a number of questions seeking input on when and how

PCR & PMO Published Q&A's (cont.)

such testing is appropriate in verifying that hazards are being effectively controlled. We encourage the submission of comments on when it would be appropriate to use environmental monitoring and/or finished product testing for milk and dairy products.

Proposed Rules to Help Ensure the Safety of Imported Food

http://www.fda.gov/fsma

FSMA's Import Tool Kit

- **New authorities and mandates work together to create integrated import safety system**
  - **Foreign supplier verification programs (FSVP) (sec. 301) – proposed rule published July 2013**
  - **Voluntary qualified importer program (VQIP) (sec. 302) – in progress with a work group**
  - **Mandatory certification (sec. 303) – in progress with a work group**
  - **Enhancements to prior notice (sec. 304) – final rule published May 2013**

FSMA's Import Tool Kit (cont.)

- **New authorities and mandates work together to create integrated import safety system (cont.)**
  - Building capacity of foreign governments (sec. 305) – **plan published February 2013**
  - Improved enforcement authorities (sec. 306) – **i.e. Administrative Detention (Final Rule for criteria used published February 2013; Small Entity Compliance Guide published March 2013)**
  - Accreditation of third-party auditors (sec. 307) – **proposed rule published July 2013**
  - Foreign offices (sec. 308) – **ongoing activity**

Trade Agreements

- **Section 404, Compliance with International Agreements, explicitly notes that FSMA must be consistent with our agreement with the World Trade Organization (WTO) and any other treaty or international agreement.**

Proposed Rules Implement Preventive Framework

- Safety standards established by FDA
  - Standards for produce safety
  - Preventive controls for human food
  - Preventive controls for food for animals
- Industry must verify standards are met
  - Foreign supplier verification program (FSVP)
  - Accreditation of third-party auditors
- Draft guidance will be forth-coming

FSVP

Proposed Rule for Foreign Supplier Verification Program (FSVP)

FSVP

Key Principles

- Importers would be responsible for ensuring that the food they bring into the U.S. meets FDA safety standards
- The requirements provide flexibility based on the risk of the food

Overview of FSVP

- Importers would be required to develop, maintain, and follow an FSVP for each food imported, unless an exemption applies.
- The requirements vary based on:
  - Type of food product
  - Category of importer, such as very small
  - Nature of the hazard identified in the food
  - Who is to control the hazard

FSVP

Who Is Covered?

- An importer is a person in the U.S. who has purchased the food being offered for import
  - If there is no U.S. owner at the time of entry, the importer is the U.S. consignee
  - If no U.S. owner or consignee at time of entry, the importer is the U.S. agent or representative of the foreign owner or consignee.

FSVP

What Is Exempt?

- Importation of juice and seafood whose suppliers are in compliance with HACCP regulations
- Food imported for research and evaluation purposes
- Food imported for personal consumption
- Alcoholic beverages

FSVP

What Is Exempt? (cont.)

- Food that is transshipped or that is imported for future export and not consumed or distributed in the U.S.
- Products from facilities subject to FDA's low acid canned food requirements (exempt for microbiological hazards only)

FSVP Requirements

- **In general, importers would need to conduct the following activities as part of their FSVP:**
  - **Compliance status review of foods and suppliers**
  - **Hazard analysis**
  - **Supplier verification activities**
  - **Corrective actions (if necessary)**
  - **Periodic reassessment of the FSVP**
  - **Importer identification at entry**
  - **Recordkeeping**

FSVP

Control of Hazards

- **The proposed requirements for supplier verification are primarily based on who is to control the hazards that are reasonably likely to occur.**

Importer or Customer Controls Hazard

FSVP

- If the importer will be responsible for controlling a hazard identified as reasonably likely to occur, the importer would be required to document, at least annually, that it has established and is following procedures that adequately control the hazard.

FSVP

Importer or Customer Controls Hazard (cont.)

- If the importer's customer will be controlling a hazard, the importer would need to obtain written assurance, at least annually, that its customer has established and is following procedures that adequately control the hazard.

Hazard Controlled by Foreign Supplier or Its Supplier

FSVP

- FDA is proposing two options for supplier verification activities when:
  - The foreign supplier is to control a hazard or
  - The foreign supplier verifies that its raw material or ingredient supplier is controlling a hazard
- The options differ based on approach to hazards that can cause serious adverse health consequences or death to humans or animals (SAHCODHA)

Modified FSVP Requirements

FSVP

- Dietary supplements and dietary supplement components
- Food imported by a very small importer or from a very small foreign supplier
- Food from a foreign supplier in good compliance standing with a food safety system that FDA has officially recognized as comparable or equivalent

Effective and Compliance Dates

FSVP

- Effective date expected to be 60 days after publication of the final rule
- Compliance dates
  - Generally 18 months after publication; or
  - Six months after the importer's foreign supplier is required to comply with the new preventive controls or produce safety regulations.

3rd Party

Proposed Rule for Accreditation of Third-Party Auditors/Certification Bodies

Overview

3rd Party

- FDA must establish voluntary program for accrediting third-party auditors/certification bodies to conduct food safety audits of foreign facilities and their foods
- FDA will recognize accreditation bodies, which will in turn accredit third-party auditors/certification bodies under the program
  - FDA can directly accredit third-party auditors in limited circumstances

Are Third-Party Audits Required?

3rd Party

- Importers will not generally be required to obtain certifications
- In certain circumstances FDA would use certifications in determining:
  - Whether to admit certain imported food into the U.S. that FDA has determined, based on FSMA criteria, poses a food safety risk, or
  - Whether an importer is eligible to participate in the Voluntary Qualified Importer Program (VQIP)

How it Would Work

3rd Party

FDA

FDA would recognize accreditation bodies based on certain criteria such as competency and impartiality.

Accreditation Bodies

Accreditation bodies would in turn accredit qualified third-party auditors.

Third-Party Auditors or Certification Bodies

Third-party auditor s/certification bodies would audit and issue certifications for foreign facilities and foods.

Foreign Facility

Foreign facilities may choose to be audited by an accredited auditor /certification body.

Eligibility for Recognition of Accreditation Bodies (ABs)

3rd Party

- Foreign government agencies or private organizations
- Must meet requirements on authority, competency, capacity, impartiality, quality assurance, and records

Eligibility for Accreditation- Third Party Auditors/ Certification Bodies

3rd Party

- Foreign government or government agency; a foreign cooperative or other private third party
- Must meet requirements regarding authority, competency, capacity, conflict of interest, quality assurance and records

Requirements for Accredited Auditors

3rd Party

- Audit agent competency
- Audit protocols
- Notifications
- Audit reports
  - Consultative audit
  - Regulatory audits (these are not FDA inspections)

Use of Certifications Issued by Accredited Third-Party Auditors

3rd Party

- In meeting eligibility requirements for VQIP for expedited review and entry of food
- In providing certification or other assurances of compliance as a condition of entry for food determined by FDA to pose a safety risk under FSMA criteria

Ongoing Activities

- For comment on proposed rules go to www.regulations.gov or www.fda.gov/fsma
- Preparation of an Environmental Impact Statement on Proposed Produce Rule
- FDA held 2 public meetings on the FSVP and Accreditation of Third Party Auditors Proposed Rules in Sept. and Oct.
- FDA will hold 3 public meetings on the Proposed Rule for Food for Animals (first will be held in College Park, MD on Nov. 21)

Ongoing Activities

- Guidance documents pertaining to the proposed rules are currently being drafted
- IT development
- FDA will continue outreach to stakeholders through webinars, listening sessions, other meetings
- Subscription feature available
- Send questions to FSMA@fda.hhs.gov

Web Page: http://www.fda.gov/fsma

Food

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Guidance & Regulation

- Food Safety Modernization Act (FSMA)
- The Law, Rules & Guidance
- How to Comment on FSMA
- Fact Sheets
- Frequently Asked Questions
- Speeches, Videos, & Webinars
- FDA Actions to Date

Resources for You

- FSMA Blog
- The Rulemaking Process (a video tutorial)
- FSMA 101 (a video tutorial)
- Translations of Key FSMA Resources
- Foodborne Illness Outbreaks

FDA Food Safety Modernization Act (FSMA)

The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

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Spotlight

FDA Answers Farmers' Questions on the Proposed Rule for Produce Safety
Q&A with Mike Taylor, Deputy Commissioner for Foods and Veterinary Medicine

What's New

Strengthening the Oversight of Imported Foods
FDA issues two proposed rules under the Food Safety Modernization Act (FSMA) aimed at strengthening assurances that imported food meets the same safety standards as food produced domestically.

- Proposed Rule on Foreign Supplier Verification Programs for Importers of Food for Humans and Animals
- Proposed Rule on Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications

Most Popular

- FSMA Information by Topic
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- What Does the New Food Safety Law Mean for You?
- FDA Strengthening Our Food Safety Foundation
- Foreign Exporters Study Food Safety Law
- Fact Sheets