FDA's Feed and Pet Food Agenda for 2014

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Animal PC

Summary of Requirements

- Establish Good Manufacturing Practices
- 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

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Who is Covered?

- Facilities that manufacture, process, pack or hold animal 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

Other Features of the Rule

- Utilizes the updated definitions in 21 CFR Part 1
  - Clarifies the activities that are included in the definition of the term “facility”
  - This in turn clarifies activities that constitute on-farm manufacturing, processing, packing and holding of food
- Proposes definitions for a small and a very small business

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Human PC vs. Animal PC

- Very similar, both establish new sections in CFR
- Animal PC established CGMPs
- Human PC modifies some CGMPs
- Animal PC does not include allergens as a hazard
- Different definitions of very small business

Good Manufacturing Practices

- Personnel
- Plant and grounds
- Sanitary operations
- Sanitary facilities and controls
- Processes and controls
- Equipment and utensils
- Warehousing and distribution

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Good Manufacturing Practices

- Utilize update language from human PC (e.g., “must”)
- Certain provisions containing recommendations are deleted

Current Good Manufacturing Practices Elements

- Personnel
  - follow good hygiene practices, and protection of food from contamination from personal effects.

Current Good Manufacturing Practices Elements

- Sanitary operations
  - includes maintaining clean and sanitary conditions of food contact surfaces, proper use and storage of toxic cleaning compounds, and exclusion of pests.
- Sanitary facilities and controls
  - such as the plant's water supply, plumbing, and toilet and hand-washing facilities;

Current Good Manufacturing Questions

- Spectrum of animal food producers and production facilities and hazards and risks can vary greatly.
- Requesting comment whether CGMPs similar to those for human food are appropriate for animal food.
- Requesting comment on whether CGMP requirements that would be more appropriate for some types of animal food may not be appropriate for other types, and, if so, how the Agency can or should distinguish between those types during the various stages of animal food processing.

Exemptions and Modified Requirements -1

- "Qualified" facilities:
  - Very small businesses (3 definitions being proposed—less than $500,000, less than $1millon and less than $2.5 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- 2

- Certain storage facilities such as grain elevators and warehouses that store only raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing are exempt from hazard analysis and risk-based preventive controls.
  - Also exempt with respect to CGMPs

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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

- **Small Businesses—**a business employing fewer than 500 persons would have two years after publication.

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Compliance Dates (cont.)

- **Very Small Businesses**—a business having less than $500,000 (or alternatively $1 million or $2.5 million) in total annual sales of food would have three years after publication to comply.
  - Very small businesses are considered “qualified” facilities and subject to modified requirements
- **Other Businesses**—a business that does not qualify for exemptions would have one year after publication of the final rule to comply.

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Preventive Control Elements

Requirements for a food safety plan

- Hazard analysis.
- Preventive controls for hazards that are reasonably likely to occur.
- Plan must be written
- Recall plan for animal food in which there is a hazard that is reasonably likely to occur.
- Monitoring.
- Corrective action.
- Verification.
- Records required for preventive controls.
- Control for supplies

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Hazard Analysis

- Identify known or reasonably foreseeable hazards for each food type to determine whether there are hazards that are reasonably likely to occur.
- Must consider hazards that may occur naturally or may be unintentionally introduced
- Must include biological, chemical, physical and radiological

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Intentional Hazards

- Should FDA include potential hazards that may be intentionally introduced for economic reasons?
- When can an economically motivated adulterant be considered reasonably likely to occur?

Additional Controls and Verification

- We are seeking comment on
  - Supplier verification
  - Review of complaints,
  - Finished product testing and
  - Environmental testing

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Supplier Verification

- Can help ensure that raw materials and ingredient suppliers have appropriate programs to address safety
- Can help provide assurance that suppliers are complying with practices that adequately control hazards

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Supplier Approval and Verification

- Should FDA require supplier approval and verification?
- When and how is a supplier approval and verification program an appropriate preventive control measure?

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Review of Complaints

- Should a facility's review of complaints, including complaints from consumers, customers, or other parties, be required as a way to verify that its preventive controls are effectively minimizing the occurrence of hazards?

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Finished Product Testing

- Should FDA require finished product testing?
- When and how is finished product testing an appropriate means of verifying that hazards are being effectively controlled?

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Environmental Monitoring

- Should environmental testing requirements be included in the final rule?
- When and how is environmental testing an appropriate means of verifying that hazards are being effectively controlled?
- If they are required, what is the appropriate level of specificity?

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Required Records

- Written food safety plan
- Records that document monitoring of the preventive controls
- Records that document corrective actions
- Records that document verification
- Records that document training for the qualified individual

How to Comment on the Proposed Rules

- www.regulations.gov
- Link to rules on www.fda.gov/fsma
- Comments due within 120 days of publishing
- Comment periods for FSVP and 3rd party will be coordinated to enable comment on how the rules can best work together.

Proposed Regulations for Foreign Supplier Verification Programs (FSVPs)

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

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?

- Food that is transshipped or that is imported for future export and not consumed or distributed in the U.S.
- Food imported for research and evaluation purposes

What Is Exempt? (cont.)

FSVP

- Products from facilities subject to FDA's low acid canned food requirements (exempt for microbiological hazards only)
- Food imported for personal consumption
- Importation of juice and seafood whose suppliers are in compliance with HACCP regulations
- Alcoholic beverages

Proposed Rule Accreditation of Third-Party Auditors

Key Principles

- A credible third-party program will allow the agency to leverage industry audits
- A credible third-party program will help to facilitate entry of certain imported food
- A comprehensive third-party program will create a new path for working with foreign governments

How it Would Work

3rd Party

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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.

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

Food

Home › Food › Guidance & Regulation › Food Safety Modernization Act (FSMA)

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
- Full Text of the Law
- Food Facility Registration
- FSMA Rules & Guidance for Industry
- Public Meetings

For Consumers

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

Salmonella CPG

- Generally well received
  - Some concerns expressed that the animal specific serotypes are not the only ones that cause disease in animals
  - Questions on how serotypes could be added to list

Draft text for proposed VFD regulation

- As interim step, comments received on March 2010 ANPRM were used to develop draft text
- Draft text published April 13, 2012
- Provided an additional opportunity for comment on the proposed changes
- Input received is being used to develop a formal proposed rule (which in turn will be subject to comment prior to issuance of final rule)

Current Status/Next Steps

- Proposed VFD rule has been drafted
- Currently undergoing Agency and Department review and clearance
- FDA priority to publish proposed rule in 2013
- Proposed rule would be subject to a public comment period of 90 days
- FDA would review public comments prior to issuing the final regulation

VFD and AMR Strategy

- GFI 213 puts forth mechanism for moving drugs from OTC to VFD
- Comments received on proposed draft and incorporate
- Undergoing Agency and Department review and clearance
- Moving together with the VFD rule

Thank You

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