

Preventive Controls for Human Food Facilities



FDA FOOD SAFETY
MODERNIZATION ACT

Michigan State Listening Session

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4-24-13



21 CFR Part 117

- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

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

Updated Good Manufacturing Practices

- Protection against allergen cross-contact
- Updated language (e.g., “must”)
- Certain provisions containing recommendations would be deleted
- Comments requested on mandating training and whether rule should require, rather than recommend, certain provisions

Training

- Should FDA replace the current recommendations in the CGMPs for personnel education and experience with requirements?
- If so, what is the appropriate level of specificity?

Other Features of the Rule

- Updates 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

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

Hazard Analysis and Risk-Based Preventive Controls



Exemptions and Modified Requirements -1

- “Qualified” facilities:
 - Very small businesses (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 - 2

- 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 - 3

- Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment
 - Certain packaged food for which refrigeration is required for safety must have temperature controls, monitoring, verification and records

Exemptions and Modified Requirements- 4

- 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

Exemptions and Modified Requirements- 5

- Facilities such as warehouses that store raw agricultural commodities that are fruits and vegetables are NOT exempt from hazard analysis and risk-based preventive controls.
 - They are exempt with respect to CGMPs

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

Inside or Outside the “Farm” Definition?

- Depends on the activities conducted
- Sec. VIII of the PC rule preamble provides information related to on-farm activities
 - Clarifies activities that are included as part of the term “facility”
- Tables 1-5 summarize how activities are classified

When would the PC provisions apply to the produce industry?

- Would apply to manufacturers/processors of produce items (e.g., bagged salads)
- Would apply to off-farm packing houses
- Whether the PC rule would apply on-farm depends on whether activities outside the farm definition are being conducted (“mixed-type facility”)

General Activities Outside the Farm Definition

- Packing and holding food not grown, raised or consumed on that farm (or another farm under the same ownership)
- Manufacturing/processing food not consumed on that farm (or another farm under the same ownership)

Activities of “Mixed-type” Facilities Subject to the PC Requirements

- Manufacturing/processing activities
 - Cutting/coring/chopping/slicing produce
 - Freezing produce
 - Drying that creates a distinct commodity (e.g., drying grapes to make raisins)
 - Artificial ripening

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.

Compliance Dates (cont.)

- **Very Small Businesses**—a business having less than \$250,000 (or alternatively \$500,000 or \$1 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.

Specific Provisions

21 CFR 117 Subpart C

Hazard Analysis and Risk-based
Preventive Controls

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

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?

Hazard Evaluation

- Determine whether the hazards are reasonably likely to occur
 - Including an assessment of the severity of the illness or injury if the hazard were to occur
- Must include an evaluation of whether environmental pathogens are reasonably likely to occur
 - Whenever a ready-to-eat food is exposed to the environment prior to packaging

Hazard Evaluation Considerations

- Formulation of the food
- Facility and equipment
- Raw materials and ingredients
- Transportation practices
- Manufacturing/processing procedures
- Intended or reasonably foreseeable use
- Sanitation, including employee hygiene

Required Preventive Controls

- Process controls
- Food allergen controls
 - Protection against cross contact; labeling
- Sanitation controls
 - Cleanliness of food contact surfaces; prevention of cross-contact and cross-contamination
- Recall plan

Recall plan

- Written procedures that describe steps to
 - Directly notify the direct consignees of the food being recalled;
 - Notify the public when appropriate to protect public health;
 - Conduct effectiveness checks to verify that the recall is carried out; and
 - Appropriately dispose of recalled food

Additional Preventive Controls

- We are seeking comment on a supplier approval and verification program
 - 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

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?

Monitoring

- Facility must have written procedures, including frequency they are to be performed, for monitoring the preventive controls
- Monitoring must be documented in records subject to verification

Corrective Actions

- Facility must establish and implement written corrective action procedures to
 - Identify and correct a problem with implementation of a preventive control
 - Ensure affected food is evaluated for safety
 - Ensure adulterated food is prevented from entering into commerce

Verification Required

- Validation
- Calibration
- Review of records

Reanalysis

- At least every 3 years
- Whenever there is a significant change that creates the potential for a new hazard or a significant increase in one previously identified
- When there is new information about potential hazards associated with a food
- When a preventive control is ineffective

Additional Verification

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

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?

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?

Environmental Monitoring Subpart C

- 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?

Qualified Individual

- Must have successfully completed training in the development and application of risk-based preventive controls
 - At least equivalent to that received under a standardized curriculum recognized as adequate by FDA
- Or be otherwise qualified through job experience to develop and apply a food safety system.

Responsibilities of a Qualified Individual

- Preparation of the food safety plan
- Validation of the preventive controls
- Review of records
- Reanalysis of the food safety plan

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

Rulemaking Process: It Doesn't Happen Overnight

1. FDA proposes rule and requests comments
2. FDA considers comments and considers revising rule
3. FDA issues final rule setting dates for companies to comply



We are here

How to Comment on the Proposed Rules

- www.regulations.gov
- Link to rules on www.fda.gov/fsma
- Comments are due by May 16, 2013 (120 days)
- Comment periods on major FSMA proposals will be coordinated to enable comment on how the rules can best work together.

More Information Available

- Web site:
<http://www.fda.gov/fsma>
- Subscription feature available
- Send questions to FSMA@fda.hhs.gov



The screenshot shows the FDA website's navigation and content for the Food Safety Modernization Act (FSMA). At the top, the FDA logo and name are displayed, along with the tagline "Protecting and Promoting Your Health". A navigation bar includes links for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Radiation. The "Food" section is active, with a breadcrumb trail: Home > Food > Food Safety > Food Safety Modernization Act (FSMA). A table of contents for the FSMA page is visible, listing links for "Food Safety Modernization Act (FSMA)", "About FSMA", "Full Text of the Law", "Implementation & Progress", and "Dockets Open for Comment". The main content area features the heading "The New FDA Food Safety Modernization Act (FSMA)" and a text block explaining that the act was signed into law by President Obama on January 4, 2011, to shift the focus from responding to contamination to preventing it. A red envelope icon and the text "Get FSMA Updates by E-mail" are also present.

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Food Safety
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Full Text of the Law
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The New FDA Food Safety Modernization Act (FSMA)

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

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