Food Safety Modernization Act

San Jose, Costa Rica
May 18, 2016
• Final Rule: Preventive Controls for Human Food
• Final Rule: Foreign Supplier Verification Programs
Final Rules

Preventive Controls for Human Food

http://www.fda.gov/fsma

THE FUTURE IS NOW
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

• Hazard Analysis and Risk-Based Preventive Controls
  • Each facility is required to implement a written food safety plan that focuses on preventing hazards in foods.

• Updated Good Manufacturing Practices

• Revised Definition of a ‘Farm’
Who is Covered by PCHF?

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
– Not farms or retail food establishments

Applies to domestic and imported food

Some exemptions and modified requirements apply
The final Preventive Controls for Human Food rule clarified the definition and expanded it to cover two kinds of farming operations:

- Primary production farm
- Secondary activities farm
An **operation under one management** in one general, **but not necessarily contiguous**, location

Devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities

– The definition has been expanded to include operations that just grow crops and operations that just harvest crops.
In addition to these activities, a primary production farm can:

– Pack or hold RACs (regardless of who grew or raised them)

– Manufacture/process, pack, or hold processed foods so long as:
  • all such food is consumed on that farm or another farm under the same management; or
  • the manufacturing/processing falls into limited categories
Drying/dehydrating RACs to create a distinct commodity (e.g., drying grapes to produce raisins)

Treatment to manipulate the ripening of RACs (e.g., treating produce with ethylene gas)

Packaging and labeling RACs
Secondary Activities Farm

• An operation not located on a primary production farm that is devoted to harvesting, packing, and/or holding RACs.
• The primary production farm(s) that grow, harvest, and/or raise the majority of those RACs must own or jointly own a majority interest in the secondary activities farm.
• Can do the same manufacturing/processing as a primary production farm
Exemptions and Modified Requirements for Preventive Controls

Qualified facilities (very small businesses)

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

Certain low-risk manufacturing/processing, packing and holding activities conducted by small/very small businesses on farms for specific foods

- Making jams/jellies/preserves from acid fruit
- Milling grains
- Extracting oils from grains (e.g., sunflower seeds) and fruits/vegetables (e.g., olives)
Food Safety Plan

Hazard analysis

Preventive controls

Supply-chain program

Recall plan

Procedures for monitoring

Corrective action procedures

Verification procedures
Hazard identification must consider known or reasonably foreseeable biological, chemical and physical hazards.

- These could occur naturally, be unintentionally introduced, or be intentionally introduced for economic gain.
Evaluation of hazards must include:

- consideration of severity of illness/injury and probability of occurrence in absence of preventive controls
- evaluation of environmental pathogens for ready-to-eat foods exposed to the environment
- consideration of effect of factors such as formulation and processing of food, facility, equipment, ingredients, intended use
Measures required to ensure that hazards are significantly minimized or prevented. These include:

- Process controls
- Food allergen controls
- Sanitation controls
- Supply-chain controls
- Recall plan
Include controls at critical control points (CCPs), if any, and controls other than those at CCPs that are appropriate for food safety.

Not required when hazard is controlled by another entity later in the distribution chain.

- Disclose that food is for further processing
- Obtain assurances hazard will be controlled
Preventive Control Management Components

Monitoring
Corrective Actions
Verification

As appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility’s food safety system.
Food Safety Plan - Verification

Includes (as appropriate to the facility, food and nature of the preventive control):

– Validation of preventive controls

– Verification of monitoring and corrective actions

– Calibration of process monitoring and verification instruments

– Product testing, environmental monitoring

– Records review and reanalysis
Supply-Chain Program

Manufacturing/processing facilities must have a risk-based supply-chain program to ensure control of hazards in raw materials and other ingredients when the control is applied before receipt ("supply-chain applied control").
Supplier

• The establishment that manufactures/ processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a **de minimis** nature.
Supply-Chain Program

Use of approved suppliers
Determine, conduct and document appropriate supplier verification activities
When applicable, obtain documentation of verification by another entity
Compliance with FSVP requirements meets the PC supplier verification requirements
Supplier Verification Activities

Onsite audits (default for most serious hazards)

Sampling and testing

Review of relevant food safety records

Other as appropriate
Onsite Audits

Must be performed by a qualified auditor

– Government employee
– Third-party (e.g., agent of a certification body)
– Employee of receiving facility
– Another entity in the supply chain

Inspection may substitute for audit in certain cases
<table>
<thead>
<tr>
<th>Element</th>
<th>HACCP Plan</th>
<th>Added in Food Safety Plan</th>
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<tbody>
<tr>
<td>Hazard analysis</td>
<td>Biological, chemical, physical</td>
<td>Chemical hazards to include radiological; consider econ. motivated adulteration</td>
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<tr>
<td>Preventive controls</td>
<td>CCPs for processes</td>
<td>Process CCPs + controls at other points that are not CCPs</td>
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<tr>
<td>Parameters and values</td>
<td>Critical limits</td>
<td>Parameters and minimum/maximum values (= Critical limits for process controls)</td>
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<tr>
<td>Monitoring</td>
<td>Required for CCPs</td>
<td>Required as appropriate for preventive controls</td>
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<td>Corrective actions or Corrections</td>
<td>Corrective actions</td>
<td>Corrective actions or corrections, as appropriate</td>
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<tr>
<td>Verification</td>
<td>For process controls</td>
<td>As appropriate for all preventive controls; supplier verification required when supplier controls a hazard</td>
</tr>
<tr>
<td>Records</td>
<td>For process controls</td>
<td>As appropriate for all preventive controls</td>
</tr>
<tr>
<td>Recall plan</td>
<td>Not required in the plan</td>
<td>Required when a hazard requiring a preventive control is identified</td>
</tr>
</tbody>
</table>
Qualified Facilities

Very small businesses are qualified facilities exempt from the full requirements for hazard analysis and risk-based preventive controls (but have some modified requirements).

– Average less than $1M per year ($2.5M animal food) in both sales of human food plus the market value of human food manufactured, processed, packed or held without sale
Compliance Dates for Businesses

Very small businesses (less than $1 million in annual food sales): Three years (except for certain records).

Small businesses (a business with fewer than 500 full-time equivalent employees): Two years

All other businesses: One year

Separate compliance dates for the supply chain program
Separate compliance dates have been established for the supply-chain program provisions to accommodate compliance dates for suppliers of different sizes and subject to different rules (e.g., Produce Safety Standards).
Planned Guidances

Hazard analysis and preventive controls

Environmental monitoring

Food allergen controls

Validation of process controls

Supply-chain program

A Small Entity Compliance Guide
Plans include

– Collaborating with the Food Safety Preventive Controls Alliance on capacity building through its International Subcommittee

– Working with regulatory counterparts and multinational organizations

– Developing and disseminating outreach, education, and technical materials

– Developing guidance documents

– Establishing network call center to provide information
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

- Originally proposed: October 29, 2013
- Supplemental proposal: September 29, 2014
- Public comments: More than 2,400 for the original proposal; more than 140 for the supplemental proposal
- Final rule: September 17, 2015
Who is Covered?

In general, facilities that manufacture, process, pack or hold animal food

- Facilities required to register with FDA under sec. 415 of the FD&C Act
- Not farms

Applies to domestic and imported food

There are some exemptions and modified requirements for certain facilities
Establish Current Good Manufacturing Practices (CGMPs)

Hazard Analysis and Risk-Based Preventive Controls

– Each facility is required to implement a written food safety plan that focuses on preventing hazards in animal foods

Revised Definition of a ‘Farm’
Good Manufacturing Practices

Personnel
Plant and grounds
Sanitation
Water supply and plumbing
Equipment and utensils
Plant operations
Holding and distribution
Holding and distribution of human food by-products for use as animal food
## Compliance Dates

<table>
<thead>
<tr>
<th>Business Size</th>
<th>CGMP Compliance</th>
<th>PC Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other Businesses</td>
<td>1 year</td>
<td>2 years</td>
</tr>
<tr>
<td>Small Business*</td>
<td>2 years</td>
<td>3 years</td>
</tr>
<tr>
<td>Very Small Business◊</td>
<td>3 years</td>
<td>4 years</td>
</tr>
</tbody>
</table>
Planned Guidances

Current Good Manufacturing Practices

Human Food By-Products for Use as Animal Food

Hazard Analysis and Preventive Controls

A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule
Web site: www.fda.gov/fsma
Subscription feature available
To submit a question about FSMA, visit www.fda.gov/fsma and go to Contact Us
Final Rule on Foreign Supplier Verification Programs

http://www.fda.gov/fsma
FSMA Sec. 301 requires importers to have FSVPs and FDA to issue regulations.

Proposed rule: July 29, 2013

Supplemental proposal: Sept. 29, 2014

Public comments: 300+ for proposed rule and 100+ for supplemental

Final rule issued: Nov. 13, 2015
Key Principles of FSVP Rule

Requires importers to share responsibility for ensuring safety of imported food

Risk-based (according to types of hazards, importers, and suppliers)

Flexibility in meeting requirements (assessing activities conducted by others)

Alignment with PC supply-chain provisions
Purpose of FSVPs

To provide adequate assurances that:

– Foreign suppliers produce food using processes and procedures providing same level of public health protection as FSMA preventive controls or produce safety provisions

– Food is not adulterated or misbranded (as to allergen labeling)
Who Must Comply?

“Importer” is U.S. owner or consignee of a food at time of U.S. entry.

If no U.S. owner or consignee at entry, importer is U.S. agent or representative of the foreign owner or consignee, as confirmed in signed statement of consent.
Exemptions from FSVP

Firms subject to juice or seafood HACCP regulations

Food for research or evaluation

Food for personal consumption

Alcoholic beverages and ingredients (when importer uses them to make an alcoholic beverage)
FSVP Exemptions (cont.)

Food transshipped through U.S.

Food imported for processing and export

“U.S. food returned”

Meat, poultry, and egg products subject to USDA regulation at time of importation
Importers in Compliance with Preventive Controls

Importers are deemed in compliance with most of FSVP when they:

– Comply with PC supply-chain provisions

– Implement preventive controls under PC regulation for hazards in food they import

– Are not required to implement a preventive control under certain PC provisions
Use of Qualified Individuals

Must use a qualified individual to perform all required FSVP tasks

– Must have education, training, or experience (or combination thereof) necessary to perform the activity

– Must be able to read and understand the language of any records reviewed in performing an activity
Hazard Analysis

Evaluate known or reasonably foreseeable hazards to determine if they require a control

- Biological, chemical (including radiological), and physical hazards
- Naturally occurring, unintentionally introduced, or intentionally introduced for economic gain

May assess another’s hazard analysis
To approve suppliers and determine appropriate supplier verification activities

Consider:

- Risk posed by the food (hazard analysis)
- Entities controlling hazards or verifying control
- Supplier characteristics (procedures, processes, and practices; FDA compliance; food safety history)
Supplier Verification Activities

Procedures to ensure food is obtained from approved suppliers

May use unapproved suppliers on temporary basis when subject food to verification

Written procedures for verification activities
Determine appropriate verification activities (and frequency) based on food and supplier evaluation

- Activities may include: onsite auditing; sampling and testing; review of supplier records; other appropriate measures

Annual onsite auditing is default approach when a food has a SAHCODHA hazard.
May rely on another entity’s determination or performance of appropriate verification activities (e.g., farm audits conducted by produce distributor)

Must review and assess results of verification activities (importer’s own or others on which it relies)
Onsite audits:

– Must be conducted by “qualified auditor”; may be government employee

– Consider applicable FDA food safety regulations (or laws and regulations of country with comparable or equivalent food safety system)

– Substitute results of inspection by FDA or food safety authority in comparable or equivalent food safety system
Food cannot be consumed without application of control (e.g., coffee beans)

Hazard controlled by importer’s customer or subsequent entity in US distribution

- Disclosure statement
- Written assurance

Importer establishes other system to ensure control of hazard at subsequent distribution step
Other FSVP Requirements

Corrective actions

Importer identification at entry

Recordkeeping
Most standard requirements do not apply when an imported dietary supplement component or packaging meets specifications established in accordance with dietary supplement CGMPs.

Other dietary supplements (including finished supplements): hazard analysis not required; verification standard is compliance with CGMPs.
Very Small Importers and Food from Certain Small Suppliers

Very small importer (VSI)

– Less than $1 million/yr. in human food sales

– Less than $2.5 million/yr. in animal food sales

Food from certain small suppliers

– Qualified facility

– Produce from certain small suppliers that are not covered farms

– Shell egg producers with < 3,000 laying hens
An annnually document eligibility

Verification: Written assurances from suppliers

Additional requirements for food from small suppliers:

- Evaluate supplier compliance history
- Approve suppliers
- Ensure food is from approved suppliers
Compliance Dates

Importers will be required to comply with FSVP no earlier than 18 months after issuance of final rule (i.e., May 2017)

If foreign supplier is subject to preventive controls or produce safety regulations, importer must comply with FSVP 6 months after supplier must comply with the relevant regulations
Guidance and Outreach

Developing FSVP draft guidance for industry

Food Safety Preventive Controls Alliance will develop course materials for FSVP

Webinars and meetings
Web site: www.fda.gov/fsma
Subscription feature available
To submit a question about FSMA, visit www.fda.gov/fsma and go to Contact Us
Thank you very much for your attention!
Questions / Discussion