FDA Food Safety Modernization Act

FDA Proposed Rules & OTA Draft Comments

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OTA Webinar | October 2013

FDA Proposed Preventive Control Rule

Webinar Objectives

- Gather feedback from members on OTA's Draft Comments
- Provide members with the resources to learn more about the proposed regulations and how to submit comments

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FDA Proposed Rules

Produce Safety and Preventative Control Rule

"Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption"

[**Produce Rule**] – Released Jan 2013

- Focuses on produce safety and mandates the on-farm adoption of various risk-prevention measures by growers, farms, and mixed-type facilities

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

[**Preventive Control Rule**] **–** Released Jan 2013

- Mandates the adoption, implementation, and ongoing documentation of the operation of a science-based preventive food safety system for most processing, handling, and warehousing operations

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Preventive Controls Required

Presentation of OTA's Draft Comments

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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

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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

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Exemptions and Modified Requirements

Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment – modified requirement

Certain storage facilities such as grain elevators that store only raw agricultural commodities intended for further distribution or processing

Facilities that are subject to the Proposed Produce Rule

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Exemptions and Modified Requirements

"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

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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.
- **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.

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Questions or Comments?

FEEDBACK REQUESTED

Which one of the proposed definitions for a small business makes the most sense:

- less than **$250,000**;
- less than **$500,000**; or
- less than **$1 million** in total annual sales

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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
    - Hazard Analysis & Preventive Controls
    - Monitoring
    - Corrective Actions
    - Verification
    - Record Keeping
    - Recall Plan
- Updated Good Manufacturing Practices

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OTA Draft Comments - General

- Many handlers currently use and understand voluntary auditing programs such as HACCP and GFSI.

- It is neither operationally sound nor efficient to create a separate inspection framework for FSMA program without taking steps to provide integration with currently existing food safety programs.

OTA recommends that FDA re-evaluate the proposed rules, compare them with existing programs, and identify where current programs may be adequate and where programs need upgrading.

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OTA Draft Comments - HACCP

- The preamble to the proposed rule makes clear that these new requirements would be based largely on Hazard Analysis and Critical Control Points (HACCP) principles.

- FDA tentatively concludes for several reasons that HACCP is the appropriate framework to reference in interpreting and implementing section 103 of FSMA.

- OTA urges FDA to formally recognize operations that have an established HACCP Program and HACCP Plan. OTA requests that FDA recognize HACCP and its corresponding prerequisite programs as **equivalent**.

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Questions or Comments?

FEEDBACK REQUESTED

Please type in the number one aspect of the proposed preventive control rule that you are concerned with.

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Verification Required

- Validation
- Calibration
- Review of records

In addition, FDA is seeking comment on review of complaints, finished product and environmental **testing**.

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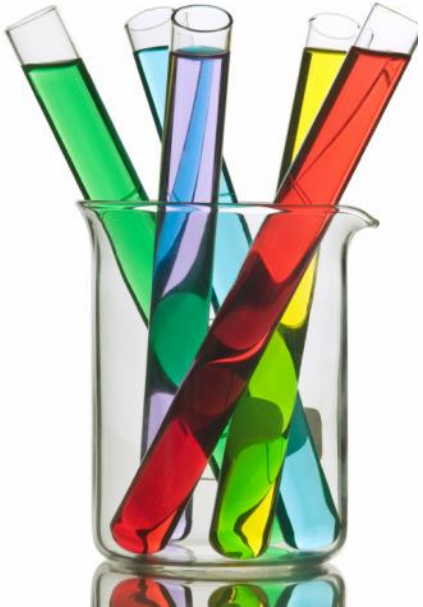
OTA Draft Comments on Testing

- Testing is an important verification measure to ensure that preventive controls are effectively controlling hazards
- Urge FDA to focus on ensuring that preventive measures are properly designated and effective, instead of relying on environmental or product testing
- Request FDA to express the importance and provide guidance on best practices and methods for monitoring and testing protocols.



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Questions or Comments?

FEEDBACK REQUESTED

Do you agree that environmental and product testing should not be required in the regulation?

Should there be any level of testing required?

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"Farm" vs. "Mixed-Type Facility"

Farm: One general physical location and devoted to growing and harvesting of crops. Includes facilities that:

- Pack or hold food provided all is grown, raised, or consumed on that farm or another farm under the same ownership
- Facilities that manufacture or process provided:
  - Provided all food is consumed on that farm or another farm under the same ownership

Mixed Type Facility: Engaged in both activities that are within the definition of a farm and activities outside the definition of a farm.

Preventive Control Rule = Registration w/ FDA under Bioterrorism Act

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"Farm" vs. "Mixed-Type Facility"

Harvesting:

- Activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. This includes gathering, washing, trimming outer leaves, removing stems and husks, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities (RAC) **grown on the farm or another farm under the same ownership.**

Mixed-Type Facilities

OTA Draft Comments

- We agree with the definition of “harvesting” **EXCEPT** for the condition that the RACs be grown on the farm or another farm **under the same ownership**.
- Food pathogens do not care whether they come from your farm or your neighbors farm!
- OTA requests that FDA, as mandated, focus on food safety risk and prevention measures taken to ensure safe food.
- OTA requests that FDA focus on supplier verification. Suppliers should be either covered by the Produce Safety Rule or in compliance with other recognized food safety programs.

FDA Proposed Preventive Controls

Questions or Comments?

FEEDBACK REQUESTED

When should on-farm harvesting and packing be required to meet the preventive control rule?

Is there a level of processing complexity that would require a HACCP plan?

Should a supplier verification program be required for domestic production and processing?

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FDA FSMA & Proposed Rules

Next Steps

- The organic sector must support and ensure food safety in all organic systems
- We must stay **engaged in the rulemaking process** and ensure that requirements do not duplicate, conflict or put undue burden on organic operations
- FDA is requesting feedback – your voice matters!

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FDA Food Safety Rules

OTA Resources

www.ota.com/regulatory/foodsafety.html

Food Safety Overview

Print this page

Food safety is at the forefront of consumers' food concerns. The food recalls issued in recent years, along with pressure from consumer groups and constituents, caused Congress to take up legislation to ensure the safety of America's food supply.

On January 4, 2011, President Obama signed into law the FI Act (FSMA). The Act amends the Federal Food, Drug, and C safety of the food supply and is aimed at helping the U.S. Fo (FDA) prevent food safety problems by shifting the focus from prevention. This amendment is the most significant reform to addition to giving FDA new enforcement authorities and new foods, the Act requires food facilities to identify potential food develop and implement preventive control plans. It also requir vegetable harvesting standards.

Read more about FSMA

FDA Releases Proposals for Two Key Rules Under FSMA

Two years later, FDA has released for public comment its proposed rule to establish science-based standards for growing, harvesting, packing and holding produce on domestic and foreign farms. A proposed rule for preventive controls for human food was published at the same time. These are two of the proposed rules that are key to the preventive food safety approach established by FSMA.

View the home site for the new rules

View OTA's summary presentation on the two new proposed rules

The **Preventive Controls for Human Food Rule** would require food companies—whether they manufacture, process, pack or store food—to put in place better controls to minimize and reduce the risk of contamination. The rule proposes each covered facility to prepare and implement a written food safety plan to to identify potential hazards, similar to Hazard Analysis and Critical Control Points (HACCP) systems that are required by FDA for juice and seafood.

View the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Proposed Rule.

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FDA Food Safety Rules

How to Comment on the Proposed Rules

www.regulations.gov

Link to rules on
www.fda.gov/fsma

Comment period ends
November 15th 2013

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Thank You

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