



Proposed Rule to Protect Food Against Intentional Adulteration

<http://www.fda.gov/fsma>

**FDA FOOD SAFETY
MODERNIZATION ACT**





Proposed Regulations for Focused Mitigation Strategies to Protect Food Against Intentional Adulteration

Key Terms and Phrases

- Types of Intentional Adulteration
 - Acts intended to cause massive public health harm
 - Acts of disgruntled employees, consumers, or competitors
 - Economically motivated adulteration

Key Terms and Phrases

- Actionable process steps
- Focused mitigation strategies

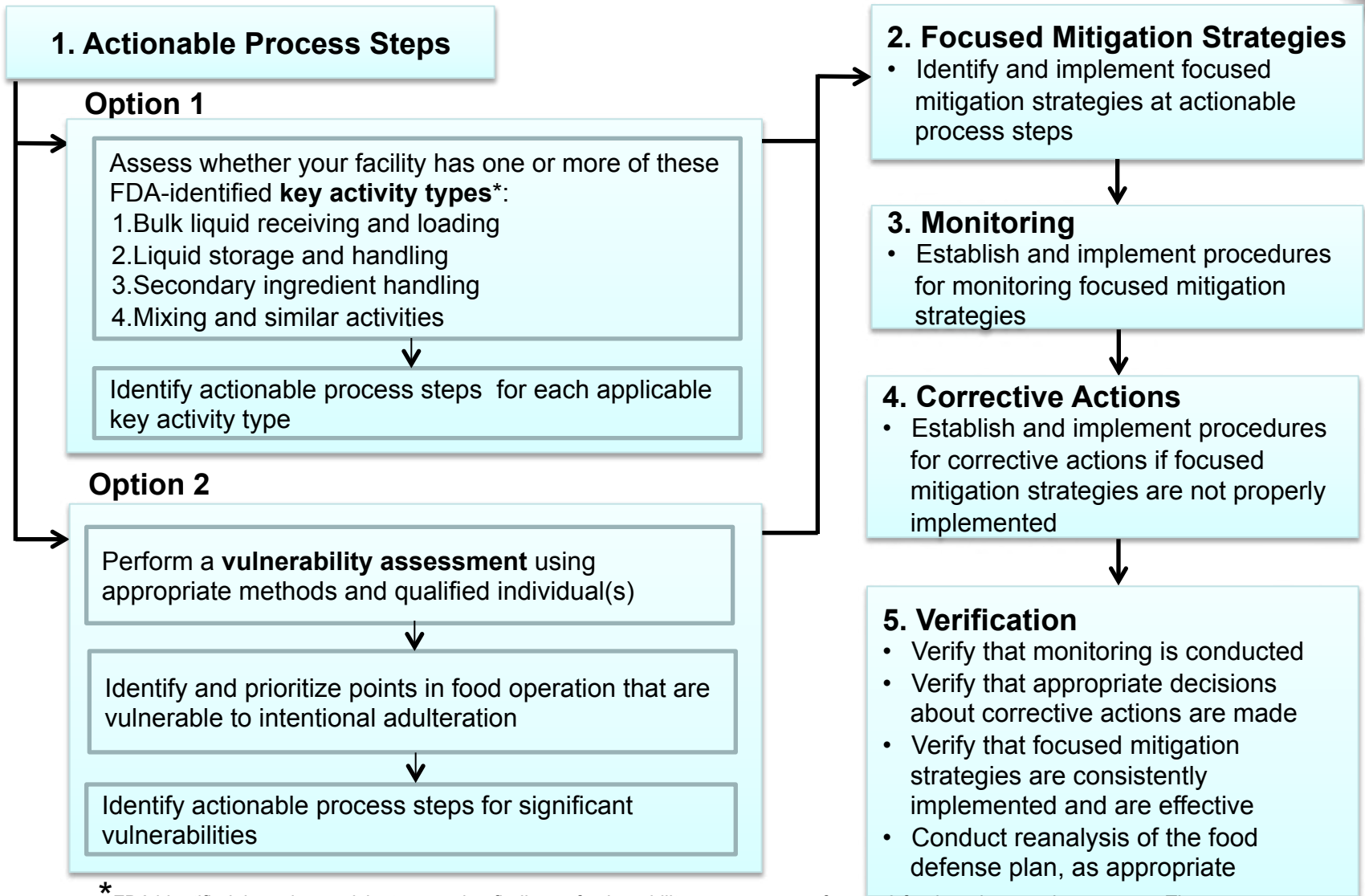
Key Principles

- Prevention of acts intended to cause widespread public health harm
- Considers vulnerabilities and risks related to intentional adulteration
- Risk-based and flexible

Summary of Requirements

- Written food defense plan, including
 - Actionable process steps
 - Focused mitigation strategies
 - Monitoring
 - Corrective actions
 - Verification
- Training

Proposed Requirements



* FDA identified these key activity types using findings of vulnerability assessments of over 50 food products and processes. These activity types commonly rank high in vulnerability based on various factors, including the ability to physically access the food or

process and the potential to adulterate a sufficient quantity of product in order to cause massive public health harm.

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

Exemptions

- Manufacturing, processing, packing, or holding food for animals
- Farms
- Holding of food, except bulk liquid
- Packing, repacking, labeling, or relabeling of food where the container that directly contacts the food remains intact
- Alcoholic beverages at certain facilities (under specified conditions)

Modified Requirements

- “Qualified” facilities:
 - Very small businesses (less than \$10 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

Effective and Compliance Dates

- Effective date
 - 60 days after the final rule is published
- Compliance dates
 - **Small Businesses** – employing fewer than 500 persons would have two years after publication

Compliance Dates continued

- **Very Small Businesses** – having less than \$10 million in annual sales of food would have three years after publication to comply with modified requirements
 - Very small businesses are considered qualified facilities and subject to modified requirements
- **Other businesses** –that do not qualify for exemptions would have one year after publication of the final rule to comply

How to Comment on the Proposed Rules

- <http://www.regulations.gov>
- Link to rules on <http://www.fda.gov/fsma>
- Comment period closes on June 30, 2014
- Comment periods on major FSMA proposals will be coordinated to enable comment on how the rules can best work together

Outreach and Technical Assistance Will Continue

- Public meetings
- Presentations
- Listening sessions
- Guidance documents



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 bar with the logo and tagline "U.S. Food and Drug Administration Protecting and Promoting Your Health". Below the navigation bar, the "Food" section is highlighted. The main content area features a "Guidance & Regulation" sidebar with links to "Food Safety Modernization Act (FSMA)", "The Law, Rules & Guidance", "How to Comment on FSMA", "Fact Sheets", "Frequently Asked Questions", "Speeches, Videos, & Webinars", and "FDA Actions to Date". The main content area is titled "FSMA Proposed Rule for Focused Against Intentional Adulteration" and includes a "Preventive Standards under the FSMA Main Page" section with a link to "Stay connected with FSMA E-mail updates!". Below this, there is a section for downloading a fact sheet in PDF (252KB) with links for French, Spanish, Chinese, Italian, Portuguese, and Arabic. The "Proposed Rule" section lists several links: "View the full Proposed Rule", "Federal Register Notice", "Summary & Highlights", "Exemptions and Modified Requirements", and "Explanatory Diagrams (PDF: 646KB)".