FSMA Facts

FDA FOOD SAFETY MODERNIZATION ACT

Proposed Rule on Protecting Food against Intentional Adulteration

Summary

FDA's proposed rule on food defense would require domestic and foreign facilities to address vulnerable processes in their operations to prevent acts on the food supply intended to cause large-scale public harm. The proposed rule, which is required by the FDA Food Safety Modernization Act, would require the largest food businesses to have a written food defense plan that addresses significant vulnerabilities in a food operation.

The FDA is proposing that the requirements be effective 60 days after the final rule is published in the Federal Register. Recognizing that small and very small businesses may need more time to comply with the requirements, the FDA is proposing tiered compliance dates based on facility size. The proposed rule was published on December 24, 2013, and comments are due by June 30, 2014. The FDA will hold a public meeting on February 20, 2014, to explain the proposal and provide additional opportunity for input.

Background

The FDA Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011, to better protect human and animal health by helping to ensure the safety and security of the food and feed supply. FSMA embraces preventing food safety problems as the foundation of a modern food safety system and recognizes the need for a global approach to food and feed safety. The FDA has proposed five additional rules that are foundational to this preventive approach encompassed by FSMA. In addition to the rule on intentional adulteration, the FDA has proposed preventive controls for human food and separately for animal food; standards for produce safety. FDA has also proposed two rules related to imports: the Foreign Supplier Verification Program for importers, which requires importers to take steps to help ensure that imported human and animal food are as safe as that which is produced domestically, as well as a program for the accreditation of third-party auditors, also known as certification bodies, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce.

Acts of intentional adulteration may take several forms, including those where the intention is to cause large-scale public health harm; acts of disgruntled employees, consumers, or competitors; and economically motivated adulteration. Acts of disgruntled employees, consumers, or competitors are generally directed at attacking the reputation of the company and not at causing public health harm. The primary purpose of economically motivated adulteration is to obtain economic gain, and not to impact public health, although public health harm may occur.

Intentional adulteration of the food supply with intent to cause public health harm is unlikely to occur. However, intentional adulteration could have catastrophic results including human illness and death, loss of public confidence in the safety of food, and significant adverse economic impacts, including trade disruption, all of which can lead to widespread public fear. Efforts to protect against intentional adulteration require a shift in perspective from what is taken for traditional food safety. The FDA proposes an approach that targets certain processes within a facility that are most likely to be vulnerable, rather than targeting specific foods or hazards. The Agency recognizes the inherent challenges faced when creating practical and reasonable regulations to address this kind of intentional adulteration and seeks public input to help refine the approach and scope of the rule.

Who is Covered?

With some exceptions, this proposed rule would apply to both domestic and foreign facilities that manufacture, process, pack, or hold food and are required to register as a food facility under section 415 of the FD&C Act. This rule does not apply to farms or other food facilities not required to register under section 415 of the FD&C Act. More information about exemptions from this proposed rule can be found in the chart at the end of this fact sheet.

Highlights of the Proposed Rule

The subject of this proposed rule is to protect food from intentional adulteration when the intent is to cause large-scale public harm. The FDA has identified four key activities within the food system that are most vulnerable to such forms of adulteration. They include:

- bulk liquid receiving and loading;
- liquid storage and handling;
- secondary ingredient handling (the step where ingredients other than the primary ingredient of the food are handled before being combined with the primary ingredient); and
- mixing and similar activities.

Facilities would be required to review their production system to determine if they have any of these activity types or complete their own vulnerability assessment. Once that is completed, they would need to identify actionable process steps, which are points, steps, or procedures in a food process that will require focused mitigation strategies to reduce the risk of intentional adulteration. Facilities are also required to complete a written food defense plan. Once in place, this proposed rule would establish measures that a food facility would be required to implement to protect against the intentional adulteration of food.

Food Defense Plan

Each facility covered by this rule would be required to prepare and implement a written food defense plan, which would include the following:

- **Actionable process steps:** Identify any actionable process steps, using one of two procedures. The FDA analyzed data from vulnerability assessments conducted using the CARVER+Shock methodology and identified four key activity types, as described above. The FDA has determined that the presence of one or more of these key activity types at a process step indicates a significant vulnerability to intentional adulteration aimed at large-scale public harm. Facilities may identify actionable process steps using the FDA-identified key activity types or conduct their own facility-specific vulnerability assessments.
- **Focused mitigation strategies:** Identify and implement focused mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and that food manufactured, processed, packed, or held by the facility will not be adulterated.
- **Monitoring:** Establish and implement procedures, including the frequency with which they are to be performed, for monitoring the focused mitigation strategies.
- **Corrective actions:** Using corrective actions if focused mitigation strategies are not properly implemented.
- **Verification:** Verification activities would ensure that monitoring is being conducted and appropriate decisions about corrective actions are being made. It would also help ensure that the focused mitigation strategies are consistently implemented and are effectively and significantly minimizing or preventing any significant vulnerabilities. In addition, the rule includes requirements for periodic reanalysis of the food defense plan every three years or under certain conditions.

- **Training:** Personnel and supervisors assigned to the actionable process steps would be trained in food defense awareness and in their responsibilities for implementing focused mitigation strategies.
- **Recordkeeping**: Establish and maintain certain records, including the written food defense plan; records documenting monitoring, verification activities and corrective actions, and documentation related to training of personnel.

Appendix to the Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm

The FDA requested comment on a draft qualitative risk assessment when it announced the proposed rule for preventive controls for human food. The draft qualitative risk assessment is designed to provide a science-based risk analysis of those on-farm activity/food combinations that would be considered not reasonably likely to introduce unintentional hazards that are reasonably likely to cause serious adverse health consequences.

With the announcement of this proposed rule, the FDA is publishing for comment Appendix 4 to the draft RA (the draft RA Appendix). The purpose of the draft RA Appendix is to provide a science-based risk analysis of those food production activities conducted on-farm that would be considered low risk with respect to the risk of intentional adulteration caused by acts of terrorism. We are considering the results of this analysis in determining any specific exemptions or modified requirements. We request comment on whether we should exempt on-farm manufacturing, processing, packing, or holding of the foods identified as having low-risk production practices when conducted by a small or very small business if such activities are the only activities conducted by the business that are subject to section 418 of the FD&C Act.

Effective and Compliance Dates and Definitions for Small and Very Small Businesses

The FDA is proposing the effective date for businesses subject to the new requirements to be 60 days after the final rule is published. Recognizing that small and very small businesses may need more time to comply with the requirements, the compliance dates are adjusted accordingly.

Compliance Dates:

- **Very Small Businesses**—a business that has less than $10,000,000 in total annual sales of food would have to comply within three years after the publication of the final rule.
- **Small Businesses—**a business employing fewer than 500 persons would have to comply two years after the publication of the final rule.
- **Other Businesses—**a business that is not small or very small and does not qualify for exemptions would have to comply one year after the publication of the final rule.

Economic Impact of the Proposed Rule

The proposed rule is aimed at preventing intentional adulteration from acts intended to cause massive public health harm, including acts of terrorism. Such acts could cause illness, death, economic disruption of the food supply including disruption of trade, and loss of public confidence in the food supply. The cost of the proposed rule to both domestic and foreign firms, annualized over 10 years at a 7 percent discount rate, is between $260 million and $470 million. The first-year cost is between $520 million and $860 million. The average annualized cost per firm is about $37,000, with initial costs of $70,000. (This is an average per-firm cost, and firms may have more than one facility. The annualized cost for a one-facility firm with 100 employees is about $13,000.) The expected benefit of preventing a catastrophic terrorist attack on the US food supply is about $130 billion, which means that the benefits of this rule outweigh the costs to Americans if the rule has a 1 in 730 or better annual

chance of preventing such an attack. The document is available at http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM378630.pdf.

Rulemaking Process and How to Submit Comments

The proposed rule, "Focused Mitigation Strategies to Protect Food against Intentional Adulteration," is published in the Federal Register so that the public can review it and submit comments. FDA considers comments received during the comment period on the proposed rule and then considers revising the rule, based on its review of the comments, before issuing a final rule. The proposed rule and supporting documents are filed in the FDA's official docket on http://www.regulations.gov and also can be accessed at www.fda.gov/fsma. Comments are due by June 30, 2014.

The FDA will hold a public meeting on February 20, 2014, in College Park, MD. The FDA will conduct additional outreach during the comment period, which may include additional public meetings.

Assistance to Industry

The FDA will publish within six months of publication of the final rule a guidance document that provides the requirements in plain language to help businesses, particularly small businesses, comply with the identification of actionable process steps and implementation of focused mitigation strategy requirements.

For Additional Information

- FR Notice
- FDA Food Safety Modernization Act web site
- Fact Sheet: Preventive Controls for Human Food
- Fact Sheet: Standards for Produce Safety
- Fact Sheet: Foreign Supplier Verification Program for Importers of Food
- Fact Sheet: Accreditation of Third Party Auditors
- Fact Sheet: Preventive Controls for Animal Food
- The Food Safety Law and the Rulemaking Process: Putting FSMA to Work
- Video: The Rulemaking Process: A Primer by FDA
- Video: FDA Food Safety Modernization Act: A Primer by FDA

Updated: 3/28/14

Exemptions and Modified Requirements for Focused Mitigation Strategies to Protect Food against Intentional Adulteration*

Type of facility or operation	Exempt Status
A very small business (a business that has less than $10,000,000 in total annual sales of food, adjusted for inflation)	Exempt, but would be required to provide to FDA, upon request, documentation relied on to demonstrate that the business is very small.
The holding of food, except the holding of food in liquid storage tanks	Exempt
The packing, re-packing, labeling or re-labeling of food where the container that directly contacts the food remains intact	Exempt
Activities that fall within the definition of "farm"	Exempt
Manufacturing, processing, packing, or holding of food for animals	Exempt
Alcoholic beverages under certain conditions	Exempt

* This chart does not contain all of the information necessary to determine the proposed requirements for compliance in a particular circumstance. Consult the proposed rule for specific requirements.