KEY REQUIREMENTS:
FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration

The FDA Food Safety Modernization Act (FSMA) final rule is aimed at preventing intentional adulteration from acts intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply. Such acts, while not likely to occur, could cause illness, death, economic disruption of the food supply absent mitigation strategies.

Rather than targeting specific foods or hazards, this rule requires mitigation (risk-reducing) strategies for processes in certain registered food facilities.

The proposed rule was issued in December 2013. The changes in the final rule are largely designed to provide either more information, where stakeholders requested it, or greater flexibility for food facilities in determining how they will assess their facilities, implement mitigation strategies, and ensure that the mitigation strategies are working as intended.

In developing the rule, FDA interacted with the intelligence community and considered vulnerability assessments conducted in collaboration with the food industry.

While acts of intentional adulteration may take many other forms, including acts of disgruntled employees or economically motivated adulteration, the goal of this rule is to prevent acts intended to cause wide-scale harm. Economic adulteration is addressed in the final preventive controls rules for human and animal foods.

WHO IS COVERED?

With some exceptions listed below, this rule applies to both domestic and foreign companies that are required to register with the FDA as food facilities under the Federal Food, Drug, and Cosmetic (FD&C) Act.

This rule is designed to primarily cover large companies whose products reach many people, exempting smaller companies. There are 3,400 covered firms that operate 9,800 food facilities.

It does not cover farms.

KEY PROVISIONS

While this is the first time that companies are required to create a food defense plan, the FDA has taken an approach similar to Hazard Analysis Critical Control Point (HACCP) system, an approach adopted by industry for the identification, evaluation and control of food safety hazards. The FSMA rules advance and strengthen those safeguards.

Each covered facility is required to prepare and implement a food defense plan. This written plan must identify vulnerabilities and actionable process steps, mitigation strategies, and procedures for food defense monitoring, corrective actions and verification. A reanalysis is required every three years or when certain criteria are met, including mitigation strategies that are determined to be improperly implemented.

- **Vulnerability assessment:** This is the identification of vulnerabilities and actionable process steps for each type of food manufactured, processed, packed or held at the food facility. For each point, step, or procedure in the facility's process, these elements must be evaluated:
  - The severity and scale of the potential impact on public health. This would include such considerations as the volume of product, the number of servings, the number of exposures, how fast the food moves through the distribution system, potential agents of concern and the infectious/lethal dose of each; and the possible number of illnesses and deaths.
  - The degree of physical access to the product. Things to be considered would include the presence of such physical barriers as gates, railings, doors, lids, seals and shields.
  - The ability to successfully contaminate the product.
- **Mitigation strategies:** These should be identified and implemented at each actionable process step to provide assurances that vulnerabilities will be minimized or prevented. The mitigation strategies must be tailored to the facility and its procedures.

- The final rule removes the distinction between "broad" and "focused" mitigation strategies. The original proposal only required "focused" mitigation strategies because "broad" mitigation strategies, such as a fence around the entire facility, did not protect specific points from being attacked by an insider.
- The final rule recognizes that a mitigation strategy, applied in a directed and appropriate way to protect the actionable process step from an insider attack, would sufficiently minimize the risk of intentional adulteration.

- **Mitigation strategy management components:** Steps must be taken to ensure the proper implementation of each mitigation strategy. In each of these areas of food defense, the facilities are given more flexibility in the final rule to establish the actions most appropriate to their operation and product.
  - **Monitoring:** Establishing and implementing procedures, including the frequency with which they are to be performed, for monitoring the mitigation strategies.
  - **Corrective actions:** The response if 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.

- **Training and recordkeeping:** Facilities must ensure that personnel assigned to the vulnerable areas receive appropriate training; facilities must maintain records for food defense monitoring, corrective actions, and verification activities.

COMPLIANCE DATES

- This rule is a first of its kind, so education and outreach is critical. Additionally, FDA recognizes that many of the food facilities covered by this rule will also be meeting the requirements of other FSMA rules. Therefore, FDA is providing a longer timeline in the final rule for facilities to comply with the intentional adulteration rule.

- **Very Small Businesses—**a business (including any subsidiaries and affiliates) averaging less than $10,000,000, adjusted for inflation, per year, during the three-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee). These businesses would have to comply with modified requirements within five years after the publication of the final rule.

- **Small Businesses—**a business employing fewer than 500 persons would have to comply four 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 three years after the publication of the final rule.

EXEMPTIONS

- A very small business. While exempt, the business would be required to provide to FDA, upon request, documentation to demonstrate that the business is very small.

- The holding of food, except the holding of food in liquid storage tanks

- The packing, re-packing, labeling or re-labeling of food where the container that directly contacts the food remains intact

- Activities that fall within the definition of "farm"

- Manufacturing, processing, packing, or holding of food for animals

- Alcoholic beverages under certain conditions

- On-farm manufacturing, processing, packing, or holding by a small or very small business of certain foods identified as having low-risk production practices. The exemption applies if such activities are the only activities conducted by the business subject to the rule. These foods include certain types of eggs, and certain types of game meats.

ASSISTANCE TO INDUSTRY

- FDA has established an Intentional Adulteration Subcommittee with the Food Safety Preventive Controls Alliance to develop food defense training resources for industry and regulators alike.
- The agency intends to publish guidance documents to provide information relevant to the provisions of the final rule, such as conducting a vulnerability assessment, identifying and implementing mitigation strategies, and writing procedures for food defense monitoring, corrective actions and verification.
- In addition, FDA has a number of tools and resources currently available on our website (www.fda.gov/fooddefense) that were developed for our voluntary food defense program.
- The Mitigation Strategies Database is an online, searchable listing of mitigation strategies that can be applied to different steps in a food operation to reduce the risk of intentional adulteration.
- The FDA FSMA Food Safety Technical Assistance Network is already operational and provides a central source of information to support industry understanding and implementation of FSMA. Questions submitted online or by mail will be answered by information specialists or subject matter experts.

MORE INFORMATION

Visit http://www.regulations.gov/

FDA's Food Safety Modernization Act page at www.fda.gov/FSMA