FSMA Facts

Background on the FDA Food Safety Modernization Act (FSMA)

About 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama on Jan. 4, enables FDA to better protect public health by strengthening the food safety system. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives FDA important new tools to hold imported foods to the same standards as domestic foods and directs FDA to build an integrated national food safety system in partnership with state and local authorities.

Building a new food safety system based on prevention will take time, and FDA is creating a process for getting this work done. Congress has established specific implementation dates in the legislation. Some authorities will go into effect quickly, such as FDA's new authority to order companies to recall food, and others require FDA to prepare and issue regulations and guidance documents. The funding the Agency gets each year, which affects staffing and vital operations, will also affect how quickly FDA can put this legislation into effect. FDA is committed to implementing the requirements through an open process with opportunity for input from all stakeholders.

The following are among FDA's key new authorities and mandates. Specific implementation dates specified in the law are noted in parentheses:

Prevention

For the first time, FDA will have a legislative mandate to require comprehensive, science-based preventive controls across the food supply. This mandate includes:

- **Mandatory preventive controls for food facilities**: Food facilities are required to implement a written preventive controls plan. This involves: (1) evaluating hazards that could affect food safety, (2) specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards, (3) specifying how the facility will monitor these controls to ensure they are working, (4) maintaining routine records of monitoring, and (5) specifying the actions the facility will take to correct problems that arise. *(Final rule due 18 months following enactment)*
- **Mandatory produce safety standards**: FDA must establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables. Those standards must consider naturally occurring hazards, as well as those that may be introduced either unintentionally or intentionally, and must address soil amendments (materials added to the soil such as compost), hygiene, packaging, temperature controls, animals in the growing area and water. (*Final regulation due about 2 years following enactment)*
- **Authority to prevent intentional contamination**: FDA must issue regulations to protect against the intentional adulteration of food, including the establishment of science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points. (*Final rule due 18 months following enactment).*

Inspection and Compliance

The FSMA recognizes that preventive control standards improve food safety only to the extent that producers and processors comply with them. Therefore, it will be necessary for FDA to provide oversight, ensure compliance with requirements and respond effectively when problems emerge. FSMA provides FDA with important new tools for inspection and compliance, including:

- **Mandated inspection frequency**: The FSMA establishes a mandated inspection frequency, based on risk, for food facilities and requires the frequency of inspection to increase immediately. All high-risk domestic facilities must be inspected within five years of enactment and no less than every three years thereafter. Within one year of enactment, the law directs FDA to inspect at least 600 foreign facilities and double those inspections every year for the next five years.
- **Records access**: FDA will have access to records, including industry food safety plans and the records firms will be required to keep documenting implementation of their plans.
- **Testing by accredited laboratories**: The FSMA requires certain food testing to be carried out by accredited laboratories and directs FDA to establish a program for laboratory accreditation to ensure that U.S. food testing laboratories meet high- quality standards. *(Establishment of accreditation program due 2 years after enactment)*

Response

The FSMA recognizes that FDA must have the tools to respond effectively when problems emerge despite preventive controls. New authorities include:

- **Mandatory recall**: The FSMA provides FDA with authority to issue a mandatory recall when a company fails to voluntarily recall unsafe food after being asked by the FDA.
- **Expanded administrative detention**: The FSMA provides FDA with a more flexible standard for administratively detaining products that are potentially in violation of the law (administrative detention is the procedure FDA uses to keep suspect food from being moved).
- **Suspension of registration**: FDA can suspend registration of a facility if it determines that the food poses a reasonable probability of serious adverse health consequences or death. A facility that is under suspension is prohibited from distributing food. *(Effective 6 months after enactment).*
- **Enhanced product tracing abilities**: FDA is directed to establish a system that will enhance its ability to track and trace both domestic and imported foods. In addition, FDA is directed to establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or control a foodborne illness outbreak. *(Implementation of pilots due 9 months after enactment).*
- **Additional Recordkeeping for High Risk Foods**: FDA is directed to issue proposed rulemaking to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that the Secretary designates as high-risk foods. *(Implementation due 2 years after enactment).*

Imports

The FSMA gives FDA unprecedented authority to better ensure that imported products meet U.S. standards and are safe for U.S. consumers. New authorities include:

- **Importer accountability**: For the first time, importers have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe. *(Final regulation and guidance due 1 year following enactment)*
- **Third Party Certification**: FSMA establishes a program through which qualified third parties can certify that foreign food facilities comply with U.S. food safety standards. This certification

may be used to facilitate the entry of imports. *(Establishment of a system for FDA to recognize accreditation bodies due 2 years after enactment).*

- **Certification for high risk foods**: FDA has the authority to require that high-risk imported foods be accompanied by a credible third party certification or other assurance of compliance as a condition of entry into the U.S.
- **Voluntary qualified importer program**: FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Eligibility is limited to, among other things, importers offering food from certified facilities. *(Implementation due 18 months after enactment).*
- **Authority to deny entry**: FDA can refuse entry into the U.S. of food from a foreign facility if FDA is denied access by the facility or the country in which the facility is located.

Enhanced Partnerships

The FSMA builds a formal system of collaboration with other government agencies, both domestic and foreign. In doing so, the statute explicitly recognizes that all food safety agencies need to work together in an integrated way to achieve our public health goals. The following are examples of enhanced collaboration:

- **State and local capacity building:** FDA must develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies. The FSMA provides FDA with a new multi-year grant mechanism to facilitate investment in State capacity to more efficiently achieve national food safety goals.
- **Foreign capacity building:** The law directs FDA to develop a comprehensive plan to expand the capacity of foreign governments and their industries. One component of the plan is to address training of foreign governments and food producers on U.S. food safety requirements.
- **Reliance on inspections by other agencies:** FDA is explicitly authorized to rely on inspections other Federal, State and local agencies to meet its increased inspection mandate for domestic facilities. The FSMA also allows FDA to enter into interagency agreements to leverage resources with respect to the inspection of seafood facilities, both domestic and foreign, as well as seafood imports.

Additional partnerships are required to develop and implement a national agriculture and food defense strategy, to establish an integrated consortium of laboratory networks, and to improve foodborne illness surveillance.

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