FDA Facts:
Food Safety Modernization Act

The Food Safety Modernization Act (FSMA)—passed by Congress on December 21, 2010, and signed into law by President Obama on January 4, 2011—empowers the FDA to implement a science-based system to address food safety hazards. The law shifts the focus of federal regulators from responding to contamination to preventing it.

The FDA's food safety efforts involve three of the agency's strategic priorities.

- Advance regulatory science and innovation
- Strengthen the safety and integrity of the global supply chain
- Strengthen compliance and enforcement activities to support public health

Key Points

- The FDA regulates about 80 percent of U.S. food supply—$602 billion in domestic food and $64 billion in imported food each year—nearly everything we eat except for meat, poultry, and some egg products that are regulated by the U.S. Department of Agriculture.
- The FDA has oversight of more than 166,000 registered domestic food facilities, including manufacturers, processors, warehouses, storage tanks, and grain elevators.
- About 252,000 registered foreign facilities manufacture, process, pack, or hold food consumed by Americans.

FSMA Overview

FSMA provides the FDA with new authorities to enforce prevention- and risk-based food safety standards. These new authorities also enable the agency to better trace and contain outbreaks of foodborne illnesses.

The FDA will have more authorities in its efforts to hold imported foods to the same standards as domestic foods. This is important because other countries now supply half of fresh fruit, 21 percent of vegetables, and at least 85 percent of seafood consumed in the United States.

Under FSMA's mandate, the agency will continue to build an integrated national food safety system that involves state and local authorities. Some FSMA authorities will go into effect quickly, and others require the FDA to prepare and issue regulations and guidance documents. The FDA now has a mandated inspection frequency that will increase the agency's regulatory presence in food facilities.

Examples of FSMA Provisions Now in Effect

- **Expanded administrative detention:** The FDA has begun using its expanded authority to prevent the sale or distribution of potentially harmful foods, while the agency determines whether other actions are warranted.
- **Suspension of registration:** The law authorizes the FDA to suspend the registration of a food facility—and its ability to legally distribute or sell food from the facility in the United States—if there is a reasonable probability that food manufactured, processed, packed, received, or held by the facility presents a serious health hazard and certain other criteria are met.
- **Mandatory recall:** Under certain circumstances, the FDA can order the recall of a potentially harmful food if the responsible party does not voluntarily cease distribution and recall the food after being provided with an opportunity to do so by the FDA.
- **Recall search engine:** Consumers can quickly and easily check on new and recent recalls by using a new search engine at *www.fda.gov/Safety/Recalls.*
- **Product tracing pilots:** Two pilot projects—one for processed foods and one for produce—are exploring how the FDA and the food industry can quickly trace foods responsible for foodborne illness outbreaks.
- **Anti-smuggling strategy:** The FDA is working with the Department of Homeland Security on a strategy to identify and prevent smuggled foods from entering the United States

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and posing a threat to national security and consumer safety.

- **Draft dietary supplement guidance:** The FDA has issued draft guidelines clarifying agency expectations for the dietary supplements industry on new dietary ingredients to ensure that consumers are not exposed to unnecessary public health risks from new ingredients with unknown safety profiles.
- **Declaration of food previously refused by any country:** The FDA requires prior notice before food is imported or offered for import into the United States. Under FSMA, submitters of this prior notice are now required to identify any country that has refused entry to the food. The new information can help the FDA evaluate the potential risks of imported food.
- **Seafood guidance:** The FDA has issued its updated guide to the seafood industry on hazards associated with fish and fishery products and appropriate controls for those hazards.
- **Mandated inspection frequency:** FSMA establishes a mandated inspection frequency, based on risk, for domestic food facilities. All high-risk domestic facilities must be inspected within five years of enactment and no less than every three years, thereafter. FSMA also establishes a mandated inspection frequency for foreign facilities.
- **Records access:** The law expands the FDA's access to establishment records about potentially harmful foods.
- **Authority to deny entry:** If a food producer in another country does not permit the FDA to inspect its facility, the agency may refuse to allow food from that facility into the United States.

FSMA Provisions in the Works

- **Preventive controls for human food and animal food facilities:** Human and animal food facilities will be required to evaluate the hazards in their operations, implement and monitor effective control measures to significantly minimize or prevent the hazards, and take corrective actions when necessary. The FDA will have access to the facility's food safety plan and records documenting its implementation.
- **Produce safety standards:** The FDA is working on rulemaking to establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables on farms.
- **Foreign Supplier Verification:** Importers will need to verify that the food they are importing is as safe as domestically produced food.
- **Enhanced partnerships:** FSMA will enhance collaboration with other government agencies. The FDA must develop and implement strategies to leverage and enhance the food safety and defense capacities of state and local agencies. In addition, the law directs the FDA to develop a plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments, and their respective food-producing industries that export food to the United States.
- **Voluntary Qualified Importer Program:** FSMA directs the FDA to establish a voluntary program designed to expedite the entry of products from importers based on the risk of the food.

For More Information

Resources available at *www.fda.gov/FSMA* include:

- the full text of the law;
- links to recalls, market withdrawals and safety alerts;
- news about implementation and progress; and
- videos, webinars, interviews and speeches.

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