News & Events

Questions and Answers on the Food Safety Modernization Act

Questions on This Page:

How big a problem is foodborne illness in this country?

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 healt burden that is largely preventable.

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Why is this law needed?

Foodborne illness is largely preventable if everyone in today's global food chain could be held responsible and accountable at each step for controlling hazards that can cause illness. Under the new law, FDA will now have new prevention-focused tools and a clear regulatory framework to help make substantial improvements in our approach to food safety. For example, for the first time, FDA has a legislative mandate to require comprehensive, preventive-based controls across the food supply chain. Preventive controls include steps that a food facility would take to prevent or significantly minimize the likelihood of problems occurring. The new law also significantly enhances FDA's ability to achieve greater oversight of the millions of food products coming into the United States from other countries each year.

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What are the major elements of the law?

The elements can be divided into five key areas:

- **Preventive controls-** For the first time, FDA has a legislative mandate to require comprehensive, prevention-based controls across the food supply. [Or, we could insert the definition of preventive controls here (i comes from the Consumer Update.]
- **Inspection and Compliance-** The legislation recognizes that inspection is an important means of holding industr accountable for its responsibility to produce safe food; thus, the law specifies how often FDA should inspect food producers. FDA is committed to applying its inspection resources in a risk-based manner and adopting innovative inspection approaches.
- **Imported Food Safety-** FDA has new tools to ensure that those imported foods meet US standards and are saf for our consumers. For example, for the first time, importers must verify that their foreign suppliers have adequate preventive controls in place to ensure safety, and FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with U.S. food safety standards.
- **Response-** For the first time, FDA will have mandatory recall authority for all food products. FDA expects that it will only need to invoke this authority infrequently since the food industry largely honors our requests for voluntary recalls.

- **Enhanced Partnerships-** The legislation recognizes the importance of strengthening existing collaboration among all food safety agencies—U.S. federal, state, local, territorial, tribal and foreign--to achieve our public health goals. For example, it directs FDA to improve training of state, local, territorial and tribal food safety officials.

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How long will it take before our food system is made safer?

A long-term process will be needed to build a new food safety system based on prevention. Congress has established specific implementation dates in the legislation. Some authorities will go into effect quickly, such as mandatory recall authority, and others require FDA to prepare and issue regulations and guidance documents. FDA is committed to implementing the requirements through an open process with opportunity for input from all stakeholders.

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Does FDA have sufficient funding to implement the new rule?

The funding we have available through the annual budget cycle and fees impacts the number of FTEs we have and will b a factor in the way that FDA handles its significant and far-ranging activities, including the way that this legislation is implemented. For example, the inspection schedule in the legislation would increase the burden on FDA's inspection functions. Without additional funding, FDA will be challenged in implementing the legislation fully without compromising other key functions. We look forward to working with Congress and our partners to ensure that FDA is funded sufficientl to achieve our food safety and food defense goals.

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How will this law make imported food safer?

U.S. consumers enjoy the benefit of imported foods from more than 150 countries. The Food Safety Modernization Act (FSMA) gives FDA new tools to ensure that those imported foods meet US standards and are safe for US consumers. Nev authorities under the Act include:

- importer accountability - importers must verify that their foreign suppliers have adequate preventive controls in place to ensure safety
- third party certification - FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with US food safety standards;
- high risk foods - FDA now has the authority to require that high-risk imported foods be accompanied by a credible third-party certification as a condition of admission into this country
- Additional resources are directed toward foreign inspections
- FDA now has the authority to refuse entry into the US of a food that has refused U.S. inspection.

FDA expects to hold briefings on the new legislation for its colleagues in embassies in Washington, and to brief the Worl Trade Organization on the new legislation.

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How does this Act change the way FDA regulates foods?

This new law puts prevention up front for FDA. For the first time, FDA will have a legislative mandate to require comprehensive, science-based preventive controls across the food supply. Under the Act, implementation of mandatory preventive controls for food facilities and compliance with mandatory produce safety standards will be required. FDA is in the process of developing a proposed rule that will establish science-based minimum standards for the safe productior and harvesting of fruits and vegetables and will address soil amendments, worker health and hygiene, packaging, temperature controls, water, and other issues. Food facilities will be required to implement a written preventive contro plan, provide for the monitoring of the performance of those controls, and specify the corrective actions the facility will take when necessary.

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