

TECHNICAL AND BUSINESS SERVICES, LLC
2011 REGULATORY UPDATE

Questions and Answers on the Food Safety Modernization Act*

Questions Addressed:

- How serious is foodborne illness in this country?
- Why was the law needed at this time?
- What are the major elements of the law?
- Does this law only apply to large companies?
- How long will it take before the food system is made safer?
- How does the law protect our imported food?
- How does the new law change the way FDA regulates food?

How serious 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 health burden that is largely preventable.

Why was the law needed at this time?

Foodborne illness is largely preventable if individuals and companies that are part of the global food chain were held responsible and accountable at each step for controlling hazards that can cause illness. Under the new law, FDA will require new prevention-focused tools and a clear regulatory framework to help make substantial improvements in our approach to food safety. Some of us may recognize this prevention tool as part of HACCP programs. Now, for the first time, FDA has a legislative mandate to require comprehensive, preventive-based controls across the food supply chain. At this point it appears that anyone **operating a food facility (excluding farms and restaurants) that manufactures, processes, packs, or holds** food in that facility is required to implement a risk assessment and to implement effective controls against food safety risk. 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

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from other countries each year. Technical and Business Services, LLC is a provider of risk analysis training, preparation of documentation and records required to comply with the new law, and HACCP-based food safety program validation services. Check our website for further information.

What are the major elements of the law?

The elements can be divided into five key areas:

- **Preventive controls** – This is covered under Title I of the new regulation. The Food Drug and Cosmetic Act (21 U.S. C. 350(c)(a) was amended to incorporate a new Section - 418. For the first time, FDA has a legislative mandate to require written, comprehensive, prevention-based controls (HACCP) across the food supply. Such written plans must be made available for inspection during a site examination by a duly authorized representative of the FDA. Small or very small businesses (i.e., those with less than \$500,000 total food sales) may be exempt for the requirements of the Section 418 but there is still work to be done to clarify what types and sizes of food facilities may be exempt from the new law.
- **Inspection and Compliance-** The legislation recognizes that inspection is an important means of holding industry 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. This will include the
- **Imported Food Safety-** FDA has new tools to ensure that imported foods meet US standards and are safe 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 the 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. For instance, FDA must develop regulations further defining the specific scientific criteria to be considered when performing food handling risk analysis. Additionally, the FDA must clarify by about September 2012, how on-farm manufacturing and other small entity food handling activities must comply with Sec 418 of the new law (preventive risk assessments). FDA is committed to implementing the requirements through an open process with opportunity for input from all stakeholders.

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. New 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 World 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 production 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 control plan, provide for the monitoring of the performance of those controls, and specify the corrective actions the facility will take when necessary.

*Technical and Business Services, LLC acknowledges the U.S. Food and Drug Administration as the source of the information in this update. However, some elements of the Food Safety Modernization Act are still in development at this time or will be part of a rule making process over the next several months at the time that this update was posted on 1/5/2011. Technical and Business Services, LLC assumes no responsibility or liability for interpretation, accuracy, or other information posted in this update, nor was this update written, edited, or examined by a legal authority.