



Porter Wright Law Alert

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Food Safety Modernization Act

Every year, one in six Americans gets a food borne illness. Potentially, the new Food Safety Modernization Act (FSMA), signed January 4, 2011, is the most significant strengthening of the Food and Drug Administration (FDA) since 1938.

Who Will Be Affected?

The new law aims at improving the overall quality and safety of the American food supply through a risk-based approach, focusing on increasing inspection of high-risk food production facilities in the U.S. and abroad and mandating comprehensive preventative measures throughout the supply chain. In addition to domestic food producers and distributors, foreign food production and distribution facilities will also be subject to more frequent FDA inspections and food safety compliance procedures. On the other hand, small farms earning less than \$500,000 annually and mainly supplying local end-product consumers (i.e., farmers selling at a farmers market) will not be subject to new FDA regulations. Rather, these small farms will be regulated only through state laws. Although much of the FSMA's momentum was gained because of past food poisoning incidents, such as the recent instances of salmonella in eggs and peanut butter, it is important to note the FSMA does not expand FDA authority to include control over eggs, meat, or poultry, which is still primarily regulated by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS).

Potential Benefits

Currently, food consumed by Americans comes from 150,000 domestic food-processing plants and an additional 250,000 foreign food-processing plants. Lack of FDA funding has caused decades to have gone by without many of these plants having been inspected. Among its many provisions, the FSMA includes adding nearly 2,000 more FDA inspectors to increase inspection and raise industry food safety compliance. Overall, the changes for FDA and the food production industry are intended to create a secure food supply chain based on proactive preventative compliance as opposed to post-incident efforts to curb food illness outbreaks.



Changes You Should Know About

Changes for FDA

- FDA will now have unilateral recall authority to force a recall when food producers do not voluntarily comply with recall requests.
- FDA will be able to suspend a registered food producer from distributing food if a health risk is suspected or if companies fail keep up-to-date with new FDA requirements.
- FDA will set nation-wide standards, based on scientific research, for harvesting fresh fruits and vegetables.
- FDA, in conjunction with the Department of Homeland Security and Department of Agriculture, will create regulations that prohibit food producers from intentionally including illegal additives into food products.
- FDA must establish five new foreign offices and inspect at least 600 foreign food facilities this year and double the number of foreign food inspections every year for the next five years.
- FDA will have more flexibility in applying administrative detentions of food, i.e., preventing the importation and sale of suspect food products.
- FDA must inspect high-risk domestic food production facilities within the next five years and such facilities must be re-inspected at least every three years thereafter.
- FDA must also report annually to Congress about the cost and frequency of inspections.
- FDA will establish guidelines to help importers comply with a new foreign supplier verification program.
- FDA will establish a voluntary expedited review program for food importers.

Changes for Your Business

- Food producers are required to alert the FDA, in writing, of all potentially hazardous current practices and company plans for prevention of such hazards.
- Grocery stores are now responsible for notifying consumers of product recalls.
- Importers will be required to provide assurances to the FDA that food imports meet applicable FDA safety standards and are not misbranded or adulterated.
- Importers that cannot provide food safety certification of high-risk imports will not be able to import such goods.
- Countries that do not allow the FDA to inspect and evaluate food safety procedures will not be able to export food to the United States.
- Whistleblowers will now be protected when reporting information about potential food safety violations.
- Together, FDA and produce companies will collaborate on new track and trace methods for fruits and vegetables to facilitate timely recalls.

Embracing the Changes

In the months ahead, the FDA will issue implementing regulations and the details for the new regulations. Interested parties will have an opportunity to comment on these proposed regulations and to influence the final form of the new FDA enforcement activities. To be placed on a list and to be kept up-to-date on the announcement of new proposed regulations, contact Les Glick at lglick@porterwright.com.

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