President Signs Major Food Safety Bill

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Federal food safety laws will undergo a substantial overhaul now that President Obama has signed the Food Safety Modernization Act (FSMA) into law. The FSMA greatly increases FDA authority and places more responsibility on the food industry. According to FDA Commissioner Margaret Hamburg, the Act focuses on prevention, and will provide the FDA with much more effective enforcement tools to promote food safety. Support for the legislation was spurred by several nationwide food recalls over the last two years involving peanuts, tomatoes, spinach and eggs. It was passed by Congress at the eleventh hour in late December and signed by Obama on Tuesday, January 4, 2011.

Important provisions of the new law include:

Mandatory Recall Authority: The FDA may now order a mandatory food recall when the agency determines there is a reasonable probability that an article of food is adulterated or misbranded, and that the use of the food will cause serious adverse health consequences or death to humans or animals. Prior to ordering a recall, the FDA must give the responsible company the opportunity to conduct a voluntary recall.

Mandatory Hazard Analysis and Risk-Based Preventative Controls (HARPC): All food facilities (any company that engages in manufacturing, processing, packing, or holding food for consumption in the U.S.) will be required to prepare and implement a HARPC plan. HARPC requirements are very similar to Hazard Analysis and Critical Control Points (HACCP) plans that are already required for facilities involved in the production of foods such as seafood, juice and low-acid canned foods. Under FSMA, all facilities must implement these HACCP-type plans that will identify and evaluate potential hazards, develop preventative controls, monitor the effectiveness of controls and take appropriate corrective actions. The HARPC plan requirement becomes effective 180 days after enactment of FSMA.

Increased Records Inspection Authority: The FDA may now inspect and copy all records related to an article of food if it reasonably believes that the article is likely to be adulterated or cause serious adverse health consequences. "Records" are broadly defined to include all records in any format and at any location relating to the manufacture, processing, packing, distribution, receipt, holding or importation of the suspect article of food.

Whistleblower Protection: Employees of food facilities are now protected from retaliation by their employer when the employee (A) provides the employer, the U.S. government, or state attorney general information relating to any violation or any act or omission that the employee reasonably believes to be in violation of the Food, Drug & Cosmetic Act, (B) testifies or is about to testify in a proceeding concerning such violation, (C) assisted or participated or is about to assist or participate in such a proceeding, or (D) objected to, or refused to participate in any activity, policy, practice or assigned

task that the employee reasonably believed to be in violation. Employers are prohibited from discharging such employees, or otherwise discriminating against the employees with respect to compensation, terms, conditions or privileges of employment.

Increased Frequency of Facility Inspections: FDA is now required to complete inspections of what it deems to be "high-risk facilities" at least once every three years. Non-high-risk facilities must be inspected once every five years.

Import Verification: Two years after enactment, food importers will be required to implement verification programs and perform certain activities to verify the safety of food purchased from foreign suppliers.

The FSMA also mandates that the Secretary of Health and Human Services:

- Establish science-based minimum food standards for produce and other foods;
- Enhance the FDA's ability to detect and trace adulterated and misbranded food articles; and
- Improve education and training of state and local food safety officials.

Implementing the sweeping new law will cost an estimated $1.4 billion in federal funding.

If you would like more information about the FSMA or have questions about FDA compliance, please contact Chris Predko (616.752.2190 or cpredko@wnj.com) at the law firm of Warner Norcross & Judd LLP.