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PRODUCT LIABILITY UPDATE**Sweeping Overhaul of FDA Regulation of Food Industry Promises New Challenges**

The Thanksgiving feast may be over, but food is still on Congress' agenda. The United States Senate voted overwhelmingly in favor of the FDA Food and Safety Modernization Act ("FSMA" or "the Act") this week, and the House of Representatives is expected to follow suit – granting the Food and Drug Administration ("FDA") broad authority to monitor food production to prevent food-borne illnesses and to respond more effectively to any outbreaks that do occur.

The Act applies to producers and/or distributors of domestic and imported food products, but does not cover restaurants, which are regulated on a state or local basis, nor producers of meat and poultry, which are regulated by the USDA. Enacted in response to a string of outbreaks of food-borne illnesses involving eggs, lettuce, peanut butter, and spinach, the FMSA is designed to improve the FDA's ability to prevent, detect, and respond to food safety problems and to improve the safety of imported food. The Act empowers the FDA with increased oversight authority of facilities to prevent food contamination and the power to minimize the damage when tainted food enters the stream of commerce.

Since these changes will be implemented pursuant to the Federal Food, Drug, and Cosmetic Act, violation of the proposed rules will carry the risk of civil penalties and imprisonment. Thus, the FDA not only will have the directive to make the food industry safer, they also will have the power to severely penalize those who violate the Act. Some of the key provisions in the Act are as follows:

- ***Mandatory Recalls.*** A substantial provision under the Act gives FDA power to initiate a mandatory recall if it determines that a food facility has sold tainted food products and the company fails voluntarily to recall the foods at the FDA's request. Thus, while FDA previously could only recommend that a company implement a voluntary recall, now it has the authority to ensure that the recall actually occurs.
- ***Inspections.*** The Act mandates an increase in the number of FDA inspections at United States food facilities, and more frequent inspections at facilities with known safety risks. For high-risk facilities (which will be identified based on several factors, including the known safety risks of the facility's food, the facility's compliance history with regard to past food safety violations, and the rigor and effectiveness of the facility's efforts to prevent food-borne illness), FDA will conduct an inspection within five years of the Act's enactment and at least one inspection every three years thereafter. For facilities that are not determined to be high-risk, FDA will conduct one inspection within the first seven years after the Act's enactment and at least one inspection every five years thereafter. In addition, the Act mandates an increase

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in the number of inspections at foreign food facilities. Specifically, it accounts for a ramp-up of foreign facility inspections from 600 total inspections in the first year following the Act's enactment to nearly 20,000 such inspections by the end the sixth year following the Act's enactment. The FDA's inspection authority under the Act, both foreign and domestic, represents a dramatic increase from the FDA's current authority.

- **Hazard Analysis.** Facilities will be required to identify and cure reasonably foreseeable food safety hazards by creating and executing food safety plans aimed at preventing food safety hazards. FDA will have access to such plans and could require facilities to revise the plans if determined to be ineffective at eliminating food safety hazards.
- **Imported Food.** In an effort to hold foreign suppliers accountable under the same standards applicable to United States facilities, food importers will be required to verify the safety of foreign suppliers and imported food. Moreover, FDA may require certification before food produced by high-risk facilities can enter the country and also may bar entry of food that originated from a foreign facility that refused United States inspectors.
- **Traceability.** The Act will increase efforts to track and trace high-risk foods (a list of "high-risk" foods will be created within one year of the Act's enactment, and will be based on several factors, including known safety risks of a particular food, likelihood of contamination, likelihood that consumption of a contaminated food will result in a food-borne illness, and likely severity of a food-borne illness attributed to that food). To establish tracking and tracing guidelines, the Act mandates the creation of a pilot project in coordination with the food industry to explore methods to rapidly and effectively identify recipients and producers of contaminated foods. These provisions are designed to streamline the recall process by eliminating unnecessary products and companies from recalls.
- **Suspension of Registration.** If FDA determines that a facility harbors food that is reasonably likely to cause serious adverse health consequences or death, the FDA may suspend the facility's registration. As a result, the facility would be forbidden from distributing the food in the United States.
- **Whistleblower Protection.** A facility may not discharge or otherwise discriminate against an employee based on that employee's reporting of a violation under the Act. If a facility does so, the Act provides legal protection and enables the employee to seek civil relief. Ultimately, if the employee proves that he was terminated due to his involvement in reporting a violation under the Act, he will be entitled to reinstatement, back pay with interest, and compensation for special damages. If reinstatement is unavailable or impractical, the discharged employee may be entitled to front pay.

The new regulations that will implement the Act are widely anticipated to affect most aspects of food production. Food producers would be well advised to monitor the regulatory process and address the impact on their businesses, which could result in a substantial financial burden. In anticipation of increased oversight from the FDA, food producers should look at their food



production processes to determine whether their food is likely to be viewed as “high-risk” and whether any additional steps should be taken to ensure that the food they produce is safe. This introspective approach particularly is important for food producers that are part of one of the industries that has experienced recalled food in the last few years. Finally, food producers should consider the steps that they should take to ease the transition to what promises to be a more inspection-oriented industry.

FOR MORE INFORMATION

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