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Client Alert

International Trade Practice Group and Food & Drug Practice Group

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FDA Food Safety Modernization Act Imposes New Requirements on Imported Food

On January 4, 2011, President Obama signed into law the FDA Food Safety Modernization Act (S. 510) (FSMA), which amends the Federal Food, Drug, and Cosmetic Act (the FDC Act). The FSMA shifts the focus of the Food and Drug Administration (FDA) from reacting to outbreaks to preventing them by (1) augmenting FDA's ability to require food manufacturers to employ protective food safety systems and enhancing FDA's ability to police those systems; (2) improving FDA's ability to detect and respond to food safety "problems;" and (3) helping to better assure the safety of imported food.

To accomplish its aim of ensuring food safety, the FSMA imposes significant requirements on both FDA and all food manufacturers and suppliers. Because the requirements of the FSMA apply to almost all food manufacturers, the impact on importers of food will be significant as well.

FDA estimates that 15 percent of the U.S. food supply is imported. The FSMA enhances FDA's ability to ensure that imported food complies with U.S. requirements. Although provisions in the FSMA that apply to food importers do not take effect immediately, domestic and foreign food producers need to begin taking steps now if they wish to avoid the potentially harsh consequences of non-compliance. The following summary focuses on the impact of the FSMA on importers of food.

Foreign Supplier Verification Program

A key aspect of the FSMA is the requirement in new Section 805 of the FDC Act that importers verify that their foreign suppliers have controls in place to ensure that U.S. food safety standards are being complied with. To this end, importers will need to institute risk-based foreign supplier verification programs to assure that imported food is produced in compliance with the requirements of new Sections 418 and Section 419 (discussed below), as applicable, and is not adulterated under current Section 402 and is in full compliance with the allergen labeling requirements found in Section 403(w). If an importer fails to maintain a foreign supplier

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verification program for a given food, the imported food will be refused admission.

Under the FSMA, FDA is required within one year after the enactment of the legislation, to "promulgate" regulations providing for the content of foreign supplier verification programs. It is highly unlikely FDA will meet this deadline. FDA likely will, however, issue proposed regulations within the next 12 to 18 months. Although Section 805 does not become effective until January 4, 2013, importers should not wait for agency guidance before beginning to develop compliant verification programs. We expect that developing a compliant import verification program will not be a "one size fits all" task and, as a result, the more varied an importer's foreign suppliers and products are, the more demanding the task of developing a comprehensive program will be.

Section 418: Hazard Analysis and Risk-Based Preventive Controls

As noted above, importers will be required to verify that foreign food suppliers have instituted controls similar to those required by hazard analysis and critical control points (HACCP) systems. Seafood, juice, and low-acid canned food facilities already are subject to HACCP-controls and, therefore, are exempt from the FSMA hazard analysis and risk-based preventive controls. A small business may also be exempted as a "qualified facility."

We note that Section 418 of the FDC Act requires that "the owner, operator, or agent in charge of a facility" identify and evaluate known or reasonably foreseeable hazards, develop a written analysis of the hazards, and implement preventive controls for significantly minimizing or preventing the identified hazard (including hazards intentionally introduced). Classic HACCP components of effectiveness monitoring, corrective actions, verification, written plan and documentation, and recordkeeping are all required. Moreover, subsection 418(i) requires the re-analysis of the propriety of preventive controls whenever a change at the facility creates a reasonable potential for a new hazard or significantly increases the potential of a previously identified hazard. Even if no such changes occur, a re-analysis of possible hazards must be conducted at least once every three years.

Section 418(n) requires FDA to promulgate within 18 months after the enactment of legislation "regulations" establishing "science-based minimum standards" for HACCP compliance. FDA also must issue a guidance document explaining hazard analysis and preventive control principles and requirements. The failure to operate a facility in a manner consistent with the minimum standards established by FDA will result in refused admission of the imported food.

Section 419: Standards for Produce Safety

New Section 419 of the FDC Act reflects the recognition that fruits and vegetables that are raw agricultural commodities merit special attention. Accordingly, FDA is required to propose within one year after the enactment of the legislation "science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables … that are raw agricultural commodities" and for which FDA has determined that such standards will minimize the risk of "serious adverse health consequences." In light of the inherent difficulties in policing the safety of such raw agricultural commodities, the legislation requires that any proposed rulemaking "provide sufficient flexibility to be applicable to various types of entities

engaged in the production and harvesting of fruits and vegetables." To this end, Section 419 requires FDA to prioritize the implementation of regulations based on the known risks accompanying certain types of raw agricultural commodities. Past food-borne outbreaks and their severity are suggested as valuable touchstones to consider in any effort at prioritization. The criteria to be employed in developing the regulations must focus on minimizing the risk of serious adverse health consequences and include procedures, processes, and practices reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards. For "small businesses" and "very small businesses" (terms to be defined by FDA by regulation), the effective date of any regulation is to be delayed by one year and two years, respectively.

A state or foreign country from which food is imported may request a variance from FDA from any of the regulation-based requirements. The grant of a variance hinges on whether the requested variance increases the likelihood that the food for which the variance is requested will be adulterated under Section 402 and whether the variance provides the same level of public health protection as the requirements of the regulations adopted under Section 419.

Section 420: Protection Against Intentional Adulteration

Section 106 of the legislation, new Section 420 of the FDC Act, empowers FDA to promulgate regulations regarding food the agency determines carries a "high risk" of "intentional contamination" that could cause "serious adverse health consequences." The section also requires that the agency issue guidance documents related to protecting consumers against the intentional adulteration of food and develop litigation strategies and/or measures to guard against such adulteration. The regulations and guidance must be periodically reviewed and updated by the agency. The failure of an imported food to comply with a regulation adopted under Section 420 is a prohibited act and will result in refused admission of the imported food.

Records Access

FDA is authorized to require that an importer maintain, for not less than two years, records confirming the importer's foreign supplier verification program. The records must be made available "promptly" to a duly authorized agent of FDA. It is a prohibited act to import and even "offer" for import a food for which an importer does not have a compliant foreign supplier verification program in place. If an importer is unable to provide records regarding its foreign supplier verification program upon request, the imported food will be refused admission.

Registration of Food Facilities

Section 102 of the FSMA imposes a requirement for renewal every two years of a facility's registration. More importantly, the amendment empowers FDA to suspend a registration should the agency conclude that food manufactured, processed, packed, received, or held in a registered facility carries, to a "reasonable probability," the potential of causing "serious adverse health consequences." Under such circumstances, the agency can issue an order suspending the registration of the facility "responsible" for creating the potential or that had reason to know of the potential. The legislation provides a procedure for seeking an opportunity

for a hearing before the agency on the suspension order and for a post-hearing corrective action plan for addressing the problematic conditions. The effect of a suspension of registration is profound: food from a facility whose registration has been suspended cannot be introduced into interstate or intrastate commerce and cannot be imported or exported.

Importer Certifications

In cases where FDA concludes that the imported food is high-risk or that the food safety programs in a country or territory are inadequate to ensure that the food at issue is as safe as a similar article of food manufactured in the United States, Section 303 of the FSMA authorizes FDA to require, as a condition of granting admission to a food offered for import, a certification assuring compliance with the "applicable requirements." Such certification may be obtained from either (1) an agency or representative of the government of the country from which the food is being imported or (2) an accredited third-party auditor. In a further effort to help strengthen FDA's authority over the safety of imported food, Section 304 of the FSMA requires that FDA be notified prior to import of any food, if the food has been refused entry into any other country and, in such a case, FDA be informed of the identity of the country refusing entry.

The FSMA mandates that FDA establish a system for recognizing accreditation bodies that accredit third-party auditors to issue certifications. A third-party auditor may issue a food certification or a facility certification to a foreign food supplier after conducting an audit and finding that the food or facility complies with all FDA regulations. If the auditor determines that the food or facility is not in compliance, the auditor must notify FDA or risk losing accreditation. Third-party certifications are permissible only with respect to foreign entities.

Although importer certification requirements are likely to have little immediate impact, importers and foreign food suppliers must begin focusing on the adequacy of their practices under FDA standards. For example, compliance may require that foreign food suppliers cooperate with their governments in order to obtain certification. At a minimum, foreign food suppliers should expect to be audited by importers to ensure that the requirements are met.

Inspection of Foreign Food Facilities

Section 201 of the legislation requires that, with respect to foreign facilities, FDA must inspect no fewer than 600 facilities in the initial one year period following enactment. In each of the subsequent five years, FDA must inspect "not fewer" than twice the number of foreign facilities inspected during the previous year.

Section 306 of the legislation authorizes FDA to enter into "arrangements" or "agreements" with foreign governments in an effort to facilitate the inspection of foreign facilities registered under Section 415 of the FDC Act. More significantly, FDA may refuse admission of imported food from a foreign factory, warehouse, or other establishment if U.S. inspectors or agents request to inspect such foreign factory, warehouse, or other establishment and are refused entry and the opportunity to inspect.

Enhancing Tracking and Tracing of Food and Recordkeeping

Section 204 of the legislation requires FDA to establish a product tracing system to receive information and improve the capacity of the agency to "effectively and rapidly" track and trace food that is in the United States or that is offered for import. Failure of a foreign company to abide by any recordkeeping requirement established under Section 204 of the legislation is a basis for refusal of food produced at such facility when the food is offered for import.

The FSMA in its entirety may be found here.

If you have any questions or wish to comment on the FSMA, please contact Fred Degnan at +1 202 626 3742 or Jeffrey M. Telep at +1 202 626 2390.

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