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INTERNATIONAL TRADE AND FOOD SAFETY ALERT

UNITED STATES CONGRESS DEBATES THE FOOD AND DRUG IMPORT SAFETY ACT OF 2007 AND MIGHT ENACT RELATED LEGISLATION IN THE NEW CONGRESS

Consumer confidence in imported food has steadily declined in recent years after a series of incidents that put into question the ability of traditional regulators to protect the food supply—pet food, peanut butter, peppers and spinach are just a few imported products that have recently been found to contain deadly chemicals or bacteria. With food imports exceeding $70 billion in 2007, and foreign-grown food making up more than 10 percent of the American diet, the demands on the government systems charged with monitoring the safety of U.S. products are immense. Experts on food safety contend that the United States' oversight of imported foods is "chaotic and inefficient" because of a lack of coordination between the 12 government agencies that share responsibilities for regulating food. Moreover, experts and policy makers have expressed concerns that the Food and Drug Administration (FDA), is underfunded and does not have updated rules to keep pace with a more complicated marketplace.

In the light of these mounting concerns over the safety of food imports, two important developments have occurred. First, in July 2007, President George W. Bush established by Executive Order an interagency working group on import safety, chaired by the secretary of Health and Human Services (HHS). That working group's general mission is to assess and improve existing regulatory enforcement of import safety laws, to strengthen the public and private sector partnership to protect the supply chain and to identify areas where additional regulators might be required. The working group has consulted with public and private sector stakeholders and made important recommendations to improve the security of the imported food supply chain.

Second, in a related but more far-reaching attempt to impose new requirements, the U.S. Congress proposed legislation during the first session of the 110th Congress (entitled the Food and Drug Import Safety Act of 2007 (H.R. 3610)) that would dramatically alter the legal landscape for manufacturers, importers and consumers of food products. The Act attempts to resolve serious concerns that have been raised regarding food and drug imports by increasing the stringency of import requirements, enhancing the government's inspection regime and augmenting current measures used in response to the importation of adulterated food articles.

The purpose of this alert is to discuss the status of that legislation, which, if not passed in 2008, will likely be reintroduced in the 111th Congress and might very well be enacted.

The Food and Drug Import Safety Act would implement several strategies to address the problems with the United States' food import system. First, it provides stricter restrictions on how food can be imported into the country. Originally, the act mandated that "no food shall be permitted entry into the United States" unless it originates from a country with food safety standards "at least as protective" as those in the United States or unless the product is made in a foreign facility that has been certified to comply with U.S. safety standards. Since its introduction, a new "discussion draft" has altered the bill to allow for expedited delivery of food products if facilities along the production chain have been inspected and certified. In addition, the bill requires the importation of food products to occur only in select metropolitan ports of entry that have an FDA field laboratory equipped to test any imports for potential health risks. The latter proposal has engendered quite a bit of controversy in the food importing community—particularly for those food importers that ship products through ports of entry where the FDA does not yet have a presence.

Second, the Food and Drug Import Safety Act attempts to enhance the current inspections regime for food and drug imports. The bill requires the secretary of HHS to provide regulations that increase both random border inspections and research for the development of tests and sampling methodologies for use on imported food. The act also mandates the secretary to submit a plan to reorganize FDA field laboratories and district offices. To defray the costs of the stronger inspection regime, the bill authorizes the assessment of user fees on food imported into the United States, with a maximum of $50 per "line item." Should this legislation ultimately be enacted, it is anticipated that U.S. Customs and Border Protection would conduct random border inspections on behalf of the FDA, and that user fees might collected in addition to harbor maintenance and merchandise processing fees.

Third, the Food and Drug Import Safety Act seeks to improve the government's response to a discovery of tainted foods that have already entered the country. The bill provides the secretary of HHS with the authority to issue mandatory recalls of any products that may cause serious, adverse health consequences or death. Finally, the proposed civil sanctions for manufacturers and importers are significant. The bill increases the civil penalties for a person who introduces "an article of food that is adulterated" to a civil money penalty of up to $500,000 for a single violation.

LEGISLATIVE AND POLITICAL OUTLOOK

Since being introduced in September 2007, the bill has been the subject of several hearings in the House of Representatives. More broadly, 11 hearings have occurred in Congress in the past 16 months on the issue of the safety of imported foods, drugs and devices. Rep. John Dingell's legislation is now being negotiated in several committees in the House. Given the very recent concerns about salmonella-tainted jalapeños and tomatoes imported from Mexico, and the Government Accountability Office's (GAO) recent audit giving poor marks to the U.S. food safety regimes, political pressure is mounting to enact food safety legislation in the near future. With the election looming and the ability of Congress to pass major legislation diminishing, it is a near certainty that this issue will have to wait until the start of the 111th Congress.

Rep. Dingell, chairman of the Energy and Commerce Committee, who introduced the bill, has made it clear that he expects to move legislation in this area during the first session of the new Congress. In order to successfully navigate both chambers of Congress, the legislation will need the active engagement of the new administration, as well as the new FDA commissioner and the secretaries of Agriculture, Commerce and Homeland Security (e.g., U.S. Customs and Border Protection). In response to early industry concerns, the Energy and Commerce Committee released a new

discussion draft of the bill. The areas highlighted in this draft will form the foundation of efforts when the new Congress is seated, and the new administration is sworn in. The accelerating pace of developments in food safety law requires that manufacturers, importers and consumers of food products that originate outside the United States anticipate likely changes in the law and implement strategies to successfully navigate the ever-changing legal atmosphere for product safety.

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