VENABLE LLP

Homeland Security Alert

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FOOD AND BEVERAGE EXPORTERS AND IMPORTERS TO THE U.S. SHOULD BEGIN COMPLIANCE ACTIONS NOW. DEADLINES APPROACH FOR FDA BIOTERRORISM ACT REGULATIONS.

Since January 2003 the U.S. Food and Drug Administration ("FDA") has issued four draft regulations for implementation of the agency's principal mandates under the Bioterrorism Act (The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [P.L. 107-188.], "the Act"). Public comment periods have closed, and the finalized regulations will shortly be issued, with compliance required soon thereafter. The four regulations, and their expected compliance deadlines, are as follows:

Section 303: Administrative Detention: This rule sets out procedures for FDA to order the detention of food upon credible evidence or information indicating a threat of serious adverse health consequences or death to humans or animals. (Draft rule issued May 9, 2003; comment period closed July 8, 2003; final rule to be issued by December 12, 2003; these procedures are expected to be in effect upon publication of the final rule.)

Section 305: Registration of Facilities: This rule specifies requirements for registration with FDA of facilities that manufacture, process, pack, or hold food for human or animal consumption. (Draft rule issued February 3, 2003; comment period closed April 4, 2003; final rule to be issued by October 10, 2003; compliance deadline by December 12, 2003.)

Section 306: Recordkeeping: This rule establishes requirements for the establishment and retention (for up to two years) of records related to food imports. (Draft rule issued May 9, 2003; comment period closed July 8, 2003; final rule to be issued by December 12, 2003; compliance deadline by approximately June 12, 2004, for all but small businesses.)

Section 307: Prior Notice of Imported Food Shipments: This rule sets out requirements for giving FDA prior notice of imported food shipments. (Draft rule issued February 3, 2003; comment period closed April 4, 2003; final rule to be issued by October 10, 2003; compliance deadline by December 12, 2003.)

EXPORTERS AND IMPORTERS TO THE U.S. SHOULD TAKE PROMPT ACTION TO PREVENT AVOIDABLE COSTS

Even before these regulations are finalized by FDA, the agency has been stepping up its border enforcement efforts. Heightened concerns for border security have led to an increase in the number of FDA port inspectors, and they are reviewing imports more carefully. Scrutiny will likely further intensify once the Bioterrorism Act regulations are finalized and enter into force, and the potential for delays in delivery times will increase.

Failure to comply with the new regulations may have serious – and costly – adverse effects on firms exporting food and beverage products to the United States. For this reason, a "wait-and-see" approach to compliance – until *after* exporting and importing firms see if they encounter any problems – is inadvisable. If compliance planning is not addressed until problems arise, exporting and importing companies may incur considerable expense that could have been avoided by timely efforts to conform their operations to FDA's requirements.

The temptation for exporters and importers to hold off initiating compliance planning efforts may in some cases be influenced by the absence to date of difficulties with U.S. inspection authorities, leading to the belief that business risks will not be significantly different than in the past. That belief may not be justified. While FDA earnestly has tried to ease the compliance burden (for example, plans to streamline the process for giving prior notice under Section 307 via the existing Automated Commercial System used by the Department of Homeland Security's Bureau of Customs and Border Protection), exporters and importers should not entertain any illusions about the agency's determination and ability strictly to enforce the new standards. For food and beverage companies used to relatively easy access to the American market, the past may not necessarily be prologue.

WHAT VENABLE CAN BEGIN DOING FOR EXPORTERS AND IMPORTERS NOW

Venable's Homeland Security Group, strategically placed in Washington, DC, draws together specialists experienced in the regulatory procedures affecting food and agriculture, customs and trade, transportation of all modes, ports, government contracts, labor and immigration, and litigation. The Group also includes experienced professionals from our Legislative practice, offering a vital link to enforcement agencies such as FDA, the Department of Homeland Security, and the Department of Agriculture (USDA), as well as to Congress.

While some compliance actions with the new regulations will have to await issuance of the finalized texts (beginning in October 2003), there are some immediate steps exporters and importers can set in motion to help ensure their protection. Among the services Venable can begin providing prior to promulgation of the final regulations are the following:

- Review of company operations to identify likely compliance issues. This would include, for example, assessing properties that would constitute "facilities" – including warehouses, plants, processing centers, and other assets outside the United States – that are required to be registered under the Section 305 regulation.

- Comprehensive review (and where advisable, redrafting) of exporters' and importers' contractual arrangements with shippers, carriers, consignees, NVOCCs, brokers, freight forwarders, insurers, distributors, suppliers, and other business partners to minimize legal exposure and costs in the event goods are detained, or there are delays in delivery, as a result of regulatory enforcement actions, security breaches, or terrorist attacks.

- Review of company liabilities in the event of a security breach or a failure to comply with FDA, Bureau of Customs and Border Protection, or other security-related regulations or requirements.

- Assistance in assessing how participation in U.S. government programs, such as the Customs-Trade Partnership Against Terrorism (C-TPAT), or in industry-wide compliance programs, can help ensure effective compliance with FDA regulations.

- Counseling and training exporters and importers about risks and procedures for detained products, including appeals and release of held or detained products.

- Working with exporters, importers, and outside technical consultants in constructing customized systems and approaches to anticipated compliance.

- Review of current insurance policies and coverages to determine whether sufficient coverage is available to protect the company under risks and liabilities presented by the new regulatory programs.

- Review of labels and labeling on imported products, which may face increased scrutiny at the U.S. port of entry.

Finally, even in advance of issuance of the final regulations, Venable's specialists can assist exporters and importers with building relationships with FDA, Customs, USDA, and other enforcement agencies, and help to acculturate firms to the agencies' outlook and methodologies.

FOR MORE INFORMATION . . .

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