



FEBRUARY 2003

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Homeland Security ALERT

Proposed FDA Regulations under the Bioterrorism Act to Impact Food, Beverage, Transportation Service Providers, Ports, and Related Sectors

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188), enacted June 12, 2002, popularly known as the Bioterrorism Act (the "Act"), substantially broadens the Food and Drug Administration's ("FDA") responsibilities over the U.S. food supply. It will likely affect every part of food and food-related industry sectors, both in the U.S. and abroad, including specifically those involved in transportation and trade. Pursuant to mandates in the Act, FDA recently proposed two important new regulations, which are analyzed in this *Homeland Security Alert*. More action in this area can be expected.

Venable's Homeland Security Group can help companies understand this dramatically changed regulatory environment and comply with a host of new requirements. Venable's group, strategically based in Washington, D.C., 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 specialists from Venable's legislative practice, offering clients a vital link to Congress, as well as to the executive branch agencies and departments, including the newly authorized Department of Homeland Security, that are tasked with enforcement of these and other regulations.

The Proposed FDA Food Registration Rule

On February 3, 2003, FDA published a proposed regulation issued pursuant to section 305 of the Act, which requires domestic and foreign food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the agency by December 12, 2003.¹ FDA intends to finalize this regulation by October 12, 2003, so that registrations can be completed before December 12th. However, all non-exempted facilities will be required to register by December 12, 2003, regardless of whether FDA's regulation is final.

In the case of imported foods, *if a non-exempted facility does not register by the deadline, then any foods imported will be held at the port of entry. In such case, the cost of detention would be borne by the purchaser, owner, importer, or consignee. Refusal of entry or detention at a port will impact carriers such as ships and trucks delivering or picking up cargoes.*

The official deadline for the public to submit comments and suggestions to the Food and Drug Administration is April 4, 2003. However, FDA will unofficially accept comments and suggestions after this date.¹ The regulation would require certain actions by foreign and domestic facilities. High-

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¹ Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5378 (Feb. 3, 2003) (to be codified at 21 C.F.R. pt.1).



lights of the proposed regulation are described below.

- FDA would require U.S. food facilities as well as *foreign food facilities* to register with the FDA by December 12, 2003. Except for specific exemptions, the new regulation would apply to all facilities for all foods and animal feed products regulated by FDA, including dietary supplements, infant formula, beverages (including alcoholic beverages),² and food additives.
- Registering includes providing the name and address of each facility at which, and trade names under which, the registrant conducts business. Facilities must also include the categories of food the facility handles. Foreign and U.S. facilities must include the name of a U.S. agent for the facility.
- FDA expects that most registrations will be made and responded to electronically.
- If facilities do not register by the December 12 deadline, FDA can seek an injunction against the persons who failed to register or bring a criminal action to prosecute persons who fail to do so.
- The regulation exempts farms, restaurants and other retail food establishments, food establishments where food is prepared or served to consumers, certain fishing vessels, facilities exclusively under the jurisdiction of the U.S. Department of Agriculture (USDA), and certain foreign facilities from the registration process altogether.
- The regulation applies to U.S. facilities regardless of whether they enter into interstate commerce.

The “Prior Notice” Regulation and its Customs and Transportation Implications

Pursuant to section 307 of the Act, FDA also proposed on February 2, 2002, a regulation that would require U.S. importers to give prior notice to FDA of all “food” imports.³ Therefore, the transportation industry, including ports and airports, should expect new compliance requirements. Detailed information must be provided in the notice. Some key parts of the proposed regulation are described below.

- If prior notice is not provided to FDA, the food will be refused admission into the U.S. and held in secure location at the importer’s expense. Therefore, the transportation industry should also expect and prepare for significant compliance issues.
- Prior notice must be submitted “no later than 12:00 p.m. of the day before the food will arrive at the border crossing.”
- The only exemptions from the “prior notice” requirement are for foods carried into the U.S. by individuals as part of their personal baggage and products subject to the exclusive jurisdiction of the United States Department of Agriculture (i.e., meat, poultry and egg products).
- With respect to articles that can be used for food and non-food uses, such as certain vegetable oils, prior notice is required if the article is being imported for use as a food.

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¹ Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5378 (Feb. 3, 2003) (to be codified at 21 C.F.R. pt.1).

² The Bioterrorism Act does not specifically address beverages, alcoholic or otherwise. Most federal enforcement regarding alcoholic beverages falls under the jurisdiction of the U.S. Customs Service (newly transferred to the Department of Homeland Security) and the Bureau of Alcohol, Tobacco, and Firearms (Department of Justice). FDA (Department of Health and Human Services) has jurisdiction over some wine-containing products, including cider beverages with less than seven percent alcohol by volume, but not over wine and distilled spirits with higher alcohol content.

³ Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5428 (Feb. 3, 2003) (to be codified at 21 C.F.R. pt. 1) (“FDA Prior Notice.”)



- While FDA and U.S. Customs are authorized to jointly prescribe regulations to enforce the Act, it is possible that companies, both foreign and U.S., will be subject to two different reporting requirements. Therefore, unless otherwise changed by new regulations issued by the U.S. Customs Service, companies will remain subject to its existing advance notice requirements.
- Information that must be provided to avoid a refusal of admission includes the identity of each carrier that transports the article of food from the exporting country to the United States. For example, the Standard Carrier Abbreviation Code for each importation will be required. The identification of the carrier is one factor considered by FDA and U.S. Customs to target food imports for inspection or detention when the food arrives at the first U.S. port. Further, FDA distinguishes a “carrier” (e.g., the shipper or transport company) from the shipper (that is, the company that has ownership of the imported goods). Currently, carrier and other pertinent information is received by the U.S. Customs Service in advance of entry, which subsequently transmits it to FDA.

What is “Food” Within These Regulations?

Under the “prior notice” rule, FDA is proposing to define “food”⁴ as: “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” FDA also is proposing to provide examples of products in the rule that will be considered to be “food” within the scope of this regulation. Examples listed to date include: fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supple-

ments and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water); live food animals (such as hogs and elk); bakery goods, snack foods, candy, and canned foods. FDA already receives some import information on all of these products.

The Trade Impacts on Food Facilities and the Transportation Industry

In the case of imported foods, if a non-exempted facility does not register by the deadline and if an importer does not provide adequate “prior notice,” then any foods imported will be held at the port of entry until complete information is provided. In such case, the cost of detention would be borne by the purchaser, owner, importer, or consignee. Further, food refused for admission in the U.S. also cannot be delivered under bond; rather, it must be held at the port or face reexport or, ultimately, destruction. Refusal of entry or detention at a port will impact carriers such as ships, rail carriers, and trucks delivering or picking up cargoes.

In addition to adding requirements to companies seeking to import food products into the United States, the prior notice regulation may raise significant issues with trading partners. The regulation states: “In establishing and implementing this proposed rule, FDA will comply fully with its international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement (“NAFTA”). For example, we believe this proposed rule is not more trade restrictive than necessary to meet the objectives of the Bioterrorism Act.”⁵ This may not be as clear to some of America’s trading partners, who may question whether these regulations meet the standard of national treatment afforded to parties under these multilateral agreements.

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⁴ This definition of “food” is consistent with the term used in section 201(f) of the Federal Food Drug and Cosmetic Act (FFDC Act).

⁵ Prior Notice at 5429.

***For More Information. . .***

The two regulations will impact food facilities in the U.S. and abroad. Venable's team can help companies anticipate how these regulations could affect their operations; communicate issues to the U.S. government, including Congress; and help with their implementation. Moreover, Venable can help companies formulate alternative ideas to submit to FDA and other government agencies that influence this process for their consideration.

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