

Bioterrorism's New Rules: Are You Ready?

by Loren Israelsen

By now, everyone engaged in any aspect of the food and dietary supplement industry should be preparing to comply with the Food and Drug Administration's (FDA) bioterrorism regulations, which become effective Dec. 13, 2003. As a reminder, this legislation—officially known as the “Public Health Security and Bioterrorism Preparedness and Response Act of 2002” (PL107-188)—was passed in June 2002 to enhance efforts to protect the U.S. food supply from potential acts of bioterrorism or adulteration. Given the high degree of urgency placed on food security, Congress mandated FDA have this new law in effect by December 2003.

The key elements of PL107-188 are as follows:

Food Facility Registration: Every food facility worldwide that is engaged in manufacturing, processing, packaging or holding foods for consumption in the United States must register each of its facilities, foreign and domestic. This includes an estimated 100,000 foreign facilities, as well as all companies making foods, food ingredients, dietary supplements, colors, flavors and excipients. *All* herbs, vitamins, minerals, amino acids, probiotics, marine products, etc., that are labeled or sold as dietary ingredients or dietary supplements in the United States are subject to this requirement.

Products (herbal extracts, for example) regarded as drugs in China or Europe but sold as “foods” under the Dietary Supplement Health and Education Act (DSHEA) in the United States trigger all of the requirements of the bioterrorism legislation. Companies should not mistakenly believe that foreign drug status of an ingredient exempts the company or ingredient from this legislation. In addition, each foreign company must designate an agent to act on its behalf as part of this registration process. After the effective date in December, any food or food ingredient offered for importation into the United States will be denied entry unless the foreign firm and importer are properly registered. I believe, based on a recent round-the-world trip and extensive correspondence with colleagues on all continents, a huge number of foreign companies are completely unaware of this mandatory requirement and will only find out when their goods are held up at the U.S. border on or after Dec. 13. All food and supplement companies are urged to be in close contact with their suppliers to avoid costly disruption and business interruption that would follow the refusal and delay of goods into the United States.

Prior Notice Submission to FDA: The second key element is a new procedure whereby all shipments of foods entering the United States after Dec. 13 must be accompanied by a submission to FDA of a notice providing the identity of the food or food ingredient and

other specific details about the source, origin, the goods and U.S. port of entry. An estimated 20,000 shipments per day will be subject to this requirement. All notices must be sent electronically and must be received by FDA within a very narrow window of time prior to arrival of the products into the United States. Any incomplete or incorrect submission will cause delays in the food's entry into the United States.

FDA's Detention Authority and Inspection of Records: The third key element grants FDA expansive new administrative detention authority to stop "suspicious goods" if FDA "reasonably believes" the goods are adulterated and present a threat of serious adverse health consequences or death to humans or animals. While this legislation and implementing regulations define adulteration as "intentional" adulteration, many observers believe FDA will likely interpret this to include any type or form of adulteration from any cause or source, not just intentional acts of adulteration. This could dramatically affect a number of products currently shipped into the United States. Botanicals from China, India, Eastern Europe or other regions of the world, for example, may be exposed to various industrial pollutants, contaminants, herbicides or pesticides that would render such herbs adulterated but heretofore have not been inspected or closely examined by FDA at the port of entry.

It is becoming clear that a higher standard of quality, cleanliness and purity is urgently needed for all inbound dietary ingredients sold in the U.S. market. Substantial funds have been allocated by Congress to allow FDA to hire new inspectors and to dramatically increase the number of food inspections both at the ports and at domestic facilities. Dietary supplement companies should not be surprised to see an FDA inspector in the coming months or to have those inspectors requesting access to records which heretofore have not been available to them under prior food law. FDA now has expansive authority based on a new but very broad definition of adulteration to detain goods at the port of entry or elsewhere to protect public health. Provisions are made for appeals to release goods held under detention. It has already become clear that goods entering the United States are being held longer and without any clear reason before being released.

Record Maintenance and Inspection: The fourth element involves maintenance and inspection of records for foods. FDA will now have access to a wide range of records where there is a reasonable belief that a food or dietary supplement is adulterated. This rule applies to all records relating to the manufacturing, processing, packaging, distribution, receipt, holding or importation of such foods or supplements. Farms and restaurants are excluded, as is information such as recipes, financial data, personnel records, research data and sales data. However, FDA inspectors may now ask for all records relative to the shipment, receipt, holding, storage or resale of any food, food ingredient or supplement.

Given the seriousness with which Congress and FDA take bioterrorism and food security, food and dietary supplement companies are well advised to take all possible precautionary steps to comply with the registration and prior notice requirements as soon as possible. FDA is frantically trying to develop and issue final regulations for this law by

mid-October, and it is unclear whether FDA will grant any extensions of time for facility registration or prior notice submissions beyond the statutory date of Dec. 13, 2003.

In short, within a few months, the food, dietary supplement, dietary ingredient and excipient industries worldwide will be operating under a new and far stricter regulatory environment that will affect thousands of products entering the United States. Many foreign suppliers are, understandably, fearful of the U.S. legal and regulatory process and may be uneasy about filing official papers with the U.S. government. Although time is short, U.S. companies should contact their foreign suppliers to assure them that all necessary registration and prior notification submissions are being attended to. Many companies are also taking the precautionary step of building a safety inventory in the fourth quarter of 2003 to avoid interruption of critical raw materials and supplies.

The time to prepare for these major changes is now!

Loren Israelsen, president of LDI Group Inc., has 20 years of experience in the supplement, phytomedicine and functional food fields. His background includes serving as president of Nature's Way, dietary supplement issue manager to the Trans Atlantic Business Dialogue (TABD), and advisor to the Office of Dietary Supplements on botanical research priorities. His work as executive director of the Utah Natural Products Alliance (UNPA) was instrumental in the introduction and passage of DSHEA.