

FDA's Bioterrorism Regulations: Food and Supplement Safety

By Susan Brienza, Esq.¹

Two new FDA regulations go into effect on December 12, 2003, and they directly pertain to both domestic and foreign sellers of *Aloe vera* ingredients and products, and anyone who imports *Aloe vera* into the U.S. In response to 9/11 and concerns for food safety, on June 12, 2002, President Bush signed into law the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002," commonly known as the Bioterrorism Act. In terms of protecting the nation's food supply, the dreaded weapon has changed from the huge aircraft to the microscopic pathogen--equally lethal. This crucial piece of legislation authorizes the Department of Health and Human Services ("HHS") to take specific measures to protect the nation's food and drug supplies against bio-terrorist threats. The Food and Drug Administration ("FDA"), as the primary regulatory arm of HHS for these products, is responsible for implementing those measures.

Title III of the Bioterrorism Act is designed to protect the United States against bio-terrorist threats to its food supply including food from foreign sources. This law has four major provisions:

- Registration of Facilities
- Prior Notice of Imports
- Administrative Detention
- Required Record-keeping

Registration and Prior Notice will have the greatest impact on the importing community, Customs and Border Patrol, and the food and dietary supplement industries. The major purpose is for the FDA to be able to locate, determine, and trace adulterated food (which includes dietary supplements) back to its source.

The FDA was authorized to promulgate "implementing" regulations, to implement the logistics for registration of facilities and prior notice of imports. On October 9, 2003, the FDA issued Interim Final Rules for both of these regulations. Even though the FDA is still reviewing formal Comments, submitted by industry members, and may revise or refine these two rules,

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and even though they are termed “Interim Final Rules,” they are binding--with an effective date of December 12, 2003, set by Congress.

Registration: All facilities, domestic and foreign, that sell *Aloe vera* (or other foods or dietary ingredients) must register with the FDA. This means that all food and supplement facilities will have a registration number, which the FDA can use, if necessary, for tracking purposes. The FDA's main bioterrorism site, containing a wealth of information and FAQs, is <http://www.fda.gov/oc/opacom/hottopics/bioterrorism.html>. More specifically, for practical information on food safety, use <http://www.cfsan.fda.gov/~dms/fsbtact.html>. Then click on the second link, “Electronic Registration Via the Internet,” to register on-line. This means of registration has been available since October 16, but as of last week the American Herbal Products Association estimated that only one-tenth of approximately 400,000 facilities had registered.

In terms of which facilities must register, there are several exemptions, including restaurants and charitable facilities (such as soup kitchens). For example, under 21 C.F.R. (Code of Federal Regulations) section 1.226, farms are exempt from registration. As a hypothetical example, if a manufacturer in Korea obtains aloe ingredients from farms, tests them, and makes finished products which it then sends to your facility in the U.S., then the farmer/suppliers to your Korean manufacturer do not have to register their facilities. A foreign facility is required to register if it manufactures or processes the food (or supplement, or ingredient) without further manufacturing or processing by another foreign facility before exporting that food to the United States.

Furthermore, foreign facilities that are involved in the initial stages of manufacturing/processing of food or supplements are not required to register if another facility further manufactures, processes or packs the food produced at that facility outside the U.S. The general rule is that the last facility to process the food in some way before shipping to the U.S. is the facility which must register under the Bioterrorism Act, unless that final facility merely does some *de minimus* handling of the supplement such as labeling. In that case, the facility before the labeler counts as the last facility and must register. Finally, according to Lesley Frazier of the FDA, the responsibility to register is on the shoulders of the operator of a facility; thus, the FDA would not hold a manufacturer responsible for using an ingredient from an improperly unregistered supplier (if that supplier exported to the U.S.). Ms. Frazier made that statement during the Q & A portion of a Bioterrorism seminar sponsored by the National Natural Foods Association (NNFA), on Oct. 30, 2003.

Prior Notice for Imports: This interim final rule:

- provides some exceptions to certain foods,
- defines who is authorized to submit prior notice,
- defines when prior notice must be submitted to the FDA,
- defines how prior notice must be submitted,
- defines what information must be in a prior notice,
- defines what must be done if information changes after prior notice confirmation has been received from the FDA,

- defines the consequences to food that is imported or offered for import without adequate prior notice, and
- defines the consequences to food that is imported or offered for import from unregistered facilities.

Prior notice for imports of *Aloe vera* shipments also may be given on-line. Please note that there is essentially no “personal use” exception to the requirement for prior notice. For example, if an attendee at Expo Asia or some other overseas trade show brings back to the U.S. some samples of foods and/or supplements, if these are for a commercial purpose, then they constitute “imports” and are subject to the prior notice requirements.

There are different time-tables logically based on the means of transportation of the imported shipment. Notice may be given up to five days in advance of the shipment. The timeframes for minimum prior notice are as follows:

1. If the article of food is arriving by land by road, no less than 2 hours before arriving at the port of arrival;
2. If the article of food is arriving by land by rail, no less than 4 hours before arriving at the port of arrival;
3. If the article of food is arriving by air, no less than 4 hours before arriving at the port of arrival; or
4. If the article of food is arriving by water; no less than 8 hours before arriving at the port of arrival.

Enforcement and Penalties: The FDA cannot be at all places at all times, and has indicated that it will follow a risk-based surveillance and enforcement plan. For example, supplements containing vitamins, minerals, herbs, and other multiple dietary ingredients are judged as at highest risk for adulteration, as opposed to single ingredient products. Also, the FDA will probably adopt the red-flag status of 14 countries as designated by Customs, which includes most of the countries in the Middle East as the country of origin for imports. On the other hand, the FDA realizes that there will be logistical mistakes and bureaucratic snafus even for companies fully intending to be in compliance, and accordingly has stated that in the months immediately after December 12, it will exercise discretion in how strictly to punish merely technical violations. But presumably after this short “breaking in” period, there will be serious consequences and sanctions for violations, and the affected food would be considered adulterated. First, failure to register is a prohibited act, which can be prosecuted either civilly or criminally. A successful civil action will probably result in an injunction (the violating company would be enjoined from selling product). A criminal action would be prosecuted in federal court. Finally, if there is no registration and yet an attempt to import, or if there is no prior notice for import, the food shipment will be held at the port of entry, and the non-compliant company will have to deal with both Customs and with the FDA.

The Future: The FDA’s Bioterrorism web-page reports that the following actions are being taken to intensify its surveillance for adulterated foods:

The Administration has asked Congress for increased FDA resources to build up its food surveillance of both domestic and imported foods through these major actions:

- it will hire 210 additional import inspectors to monitor food as it enters the United States;
- add 100 inspectors to survey points that are critical for product safety in the domestic food production and distribution system;
- add 100 technical analysts to multiply the number of food samples tested for possible contamination.

In addition to a request for increased resources for surveillance, the Administration is seeking further authority to strengthen FDA's oversight of food in the case of an emergency. The increased authority will allow FDA to require information from food producers that will enable the agency to rapidly address possible health hazards by quickly tracing the source and distribution of both domestic and imported food.

These new FDA requirements for facility registration and prior notice are somewhat burdensome for the food and supplement industries, but the end result should be greater confidence of the customer and consumer in the purity and safety of *Aloe vera* and other herbal products.