

FDA Revises Bioterrorism Plan

BY DOUG CLARK

All of us want to protect our nation's food supply. But overzealous efforts to prevent bioterrorism threaten the supply chain with counterproductive regulations. Some proposals would subject carriers that transport food products to the same scrutiny and licensing as hazardous materials carriers. That's unrealistic when you consider that exempt transportation haulers don't even have to possess operating authority to transport fresh produce or other food-related exempt commodities.

Where's this new push coming from? The National Preparedness for Bioterrorism and Response Act of 2002 requires the secretary of health and human services, through the Food and Drug Administration, to administer new food safety regulations. Sections 301 to 315 of Title III: Protecting Safety and Security of Food and Drug Supply, Subtitle A — Protection of Food Supply apply to the food industry and are aimed at preventing or responding to attacks on our food supply.

Four specific regulations will result, and they will require:

- **Registration of food producers, processors, importers and distributors.** Owners, operators or agents in charge of domestic or foreign facilities that manufacture, process, pack or hold food for human or animal consumption in the United States must register with the FDA, even if they previously registered for another purpose with the FDA or with the Department of Agriculture under the Perishable Agricultural Commodities Act. Manufacturing and processing is defined as combining one or more ingredients into a food product; packing is placing food into a container without changing the form of the food; and holding is storing food, such as in a warehouse, silo or grain elevator.

Specific exemptions to the registration requirement include facilities dealing exclusively with meat, poultry and eggs under the USDA; farms and retail food operations that sell food directly to consumers; restaurants and cafeterias; and grocery stores and nonprofit organizations. If a grocery warehouse sells food directly to consumers and also sells food to other retailers such as a "mom and pop" shop, it must register. All processors of produce, including farmers who turn their fruit into juice, for example, must register.

Registrants must provide the name of the facility, full address, phone number, fax number and an e-mail address, as well as the same information for a parent corporation, if any. Also required is an emergency contact. These requirements also apply to cold storages, warehouses and outlets like Sam's Clubs and Costco.

- **Notice of shipments coming into the country.** The Bioterrorism Act requires more information when you are importing product. If there are three different commodities in a container,

all three have to be listed. If it is the same product from different shippers, each shipper has to specify its commodity and register with the FDA. The shipper or exporter is required to list the U.S. agent for the commodity. The U.S. agent has to specify what he is receiving; it has to be identical to what the exporter has shipped. If the foreign facility ships directly to a retail facility, he must specify a U.S. agent as the receiver. To qualify as a U.S. agent, the agent must have a residence in the United States or maintain a place of business here. Obviously, the agent will have to be registered as well.

(Under the original proposed regulations, all of the shipping and receiving information had to be provided to the FDA before it could enter the United States or be manufactured and delivered domestically. The FDA appears to have relaxed its "prior notice" requirement and instead will require registrants to keep that information available on request from the FDA.)

- **Record keeping.** The FDA requires record of shipments to be maintained for one to two years in paper or electronic form. The FDA states: "If an article of food is reasonably believed to be adulterated and presenting a threat of serious adverse health consequences, firms would be required to provide these and other records to the FDA within four hours during certain business hours, or eight hours at other times." Trucking companies, private delivery carriers, railroads and airlines also would be required to keep similar documentation but will not have to register with the FDA.

- **Detention authority.** An FDA official with rank of at least district director can order detention of food products for up to 30 days. The owner of the product has two to four days to appeal the detention.

These proposals raise lots of questions. If a carrier is in transit and the shipper or receiver is not registered, what is the compensation to the carrier for being detained? If a carrier is directed to a port to pick up a container and the container is seized, what is the compensation to the carrier? The FDA says that when an article is held by the FDA for noncompliance, "the owner, purchaser, importer or consignee must pay transportation and storage costs." It makes no reference to what fair cost is or how to determine which party is negligent. If the FDA breaks container or trailer seals for spot inspections, will it replace the seals with government seals and document that change for the shipper?

The comment period for most of the proposed regulations ended on April 4. The proposal to allow detention authority is open for comments and suggestions until July 8. The FDA will publish the final rules by Dec. 12. Registration with the FDA will begin sometime between Oct. 12 and Dec. 12.

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