Import Alerts Guard Against Unsafe Products

Keeping unsafe foods, drugs, devices and other products from reaching consumers is the Food and Drug Administration's mission.

Among the prevention measures used by FDA is the issuance of import alerts to keep potentially dangerous products from other countries out of the U.S. marketplace.

On Aug. 25, FDA issued a country-wide import alert to detain all shipments of papayas from Mexico. The alert was implemented after Salmonella—bacteria that makes people sick with diarrhea, abdominal cramps and fever—was found in samples of fresh whole papaya collected and analyzed by FDA.

This is the newest import alert but it's not the only one.

Captain Domenic J. Veneziano, director of FDA's Division of Import Operations and Policy (DIOP), says there are currently 264 import alerts. They represent 3100 types of products from more than 11,000 manufacturers in 150 countries and regions. Products include seafood, fruits and vegetables, cheese, rice, cosmetics, drugs, and medical devices.

Before the import alert was issued, samples of Mexican papayas were collected at the Otay Mesa port in California, about one-quarter mile from the U.S./Mexico border. They were analyzed in the FDA Mobile Lab deployed there. Once the import alert goes out, FDA no longer samples and analyzes the product. That burden shifts to the importer, which must prove the safety of its product.

What Is an Import Alert?

An import alert allows FDA to detain, without physically examining, products that either have or potentially could violate the Food, Drug, and Cosmetic Act. That same legislation is what empowers FDA to protect U.S. consumers from unsafe products.

The alert lets FDA field staff know that the agency has enough evidence or other information to refuse admission of future shipments of an imported article.

Veneziano says there are a variety of factors that could lead FDA to place a product, manufacturer, shipper, grower, geographical area, and/or country on import alert. For example, questions could have been raised in an inspection of the manufacturing site or flags could have been raised by a recall of products already on store shelves. There could be a history of problems with no signs that appropriate actions were taken to remedy the cause, or problems related to production, such as harvesting from water that appears polluted.

Once a shipment is refused admission to the U.S., the importer has an opportunity to introduce evidence, within 10 days, to overcome the appearance of a violation. During this time, the product is either held at a warehouse or at the importer's premises and cannot be distributed. If the shipment is not proven to be safe, it must be destroyed or exported within 90 days.

The bottom line is that more responsibility is being placed on importers to verify that the products they import are not contaminated.

When Is an Import Alert Made 'Country-wide' and What Does That Mean?

The alert can be issued for an import from a manufacturer, shipper, grower, geographical area, or country. If the problem or condition exists on a wide scale, federal inspectors would be instructed to detain all products of a certain kind coming from that country.

No matter how many manufacturers, shippers or importers are involved, if the targeted product comes from the targeted country, it is going to be detained and will not be allowed into the country until the agency is assured it is in compliance with U.S. law, says Veneziano.

When Does FDA Decide to Issue an Alert?

The information or request to initiate an import alert can come from FDA's field offices, FDA's centers, other government agencies, state agencies and elsewhere. The request goes to Veneziano. He and his team, working with the appropriate center, review the supporting data and determine if there is sufficient evidence to place a product, manufacturer, shipper, grower and/or country on import alert. His team will also work with the Division of Field Science (DFS) to ensure that laboratory methods identified in the alert are appropriate. Depending on the type of alert, the decision will go through an approval process before being implemented.

How Quickly Does the Import Alert Take Effect?

Once approved and issued, the import alert takes effect immediately. Screening criteria is put in place in FDA's import systems to target shipments and the alert notice is e-mailed to FDA district offices. The alert is also posted on FDA's web page (*www.fda.gov/forindustry/importprogram/importalerts*), which is available to everyone and has various search capabilities.

Does a Recall Accompany an Import Alert for Products Already in the Country?

Recalls and import alerts are two separate actions. But Veneziano says that sometimes an import alert will be issued because of a recall to ensure that no other tainted products of that kind enter the country. Conversely, a recall could follow an import alert.

When Is the Import Alert Lifted?

An imported product, firm, region, or country may remain in this status until evidence or other information is provided that gives FDA confidence that the shipment is safe for consumers and that future shipments will be in compliance with the law. The conditions that the importer has to meet vary depending on the stipulations in the import alert, says Veneziano. For example, sometimes an inspection or testing is required. Other times a number of "clean" shipments will result in a lifting of the order.

Will the Food Safety Modernization Act (FSMA) reduce the number of import alerts?

The verdict is out on that, says Veneziano, but that's the goal. The new food safety law specifically addresses the need to ensure that foods imported from more than 150 countries are safe for U.S. consumers. The new authorities include a requirement that importers verify that their foreign suppliers have preventive controls in place. And if another country denies U.S. investigators access to a food-producing facility, FDA can keep the food from that producer from entering the United States.

The bottom line, says Veneziano, is that more responsibility is being placed on the importers to verify that the products that they import are not contaminated and that their suppliers and customers have preventive controls in place.

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