The Food and Drug Administration has more than 250 active import alerts that prevent potentially violative products from entering U.S. commerce by subjecting them to detention without physical examination. Before shipping into the U.S., importers should be aware of whether or not their product is listed on an import alert.

[Click here for ST&R’s on-demand webinar on how to avoid costs and delays from FDA import alerts.]

FDA import alerts on the following have been modified in the past week.

- produce (due to human pathogens)
- dietary supplement products
- imported food products that appear to be misbranded
- surgeon’s and patient examination gloves
- food and seafood products (due to the presence of salmonella)
- dried peppers from Mexico
- food products (due to the presence of aflatoxin)
- seafood and seafood products from specific manufacturers/shippers due to decomposition and/or histamines
- mushrooms from Hong Kong and China
- foods containing illegal and/or undeclared colors
- firms refusing FDA foreign establishment inspection
- products marketed as foods that contain an active pharmaceutical ingredient
- gel candles containing konjac

- processed foods and raw agricultural products for pesticides

Importers of FDA-regulated goods are responsible for ensuring that such imports are in compliance with FDA laws and regulations. Import alerts inform FDA field staff that the agency has enough evidence or other information to allow a product that appears to be in violation of those laws and regulations to be detained without physical examination at the time of entry (e.g., a product contains illegal colors or food additives or a foreign firm refused an FDA inspection). Import alerts may cover products from designated countries or areas (including from all foreign countries), manufacturers, or shippers.

Firms and/or products on the “red list” of an import alert are subject to DWPE, while firms and/or products on the “green list” are not because they have met the criteria for exclusion. Some import alerts include a “yellow list” of firms, products, and/or countries subject to intensified surveillance because the nature of the violations may warrant further field examinations of individual entries and/or additional analyses. In addition, depending on the specific import alert, shipments of products subject to DWPE may still be imported into the U.S. if the importer has demonstrated that the shipment is in compliance.

If a product is detained without physical examination the importer has the right to provide evidence to the FDA in an attempt to overcome the appearance of the violation. If no such evidence is submitted, or if the evidence provided is insufficient to overcome the appearance of the violation, the product will be subject to refusal of entry into the U.S.

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