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fda's version of c-tpat

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With passage of the Bioterrorism Act, FDA gained additional authorities related to food safety and security. See e.g., Bioterrorism Act §§ 303-309. More significantly, the Bioterrorism Act amended the Food Drug & Cosmetic Act (FDCA) to require FDA to focus its imported food examinations on shipments where the agency is more likely to discover intentional adulteration of food. Specifically, section 302(a) of the Bioterrorism Act amended section 801 of the FDCA, adding new subsection (h)(1), which states:

The Secretary shall give high priority to increasing the number of inspections under . . . section [801] for the purpose of enabling the Secretary to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food. 21 USC 381(h)(1) (emphasis added).

Furthermore, Congress has mandated that FDA facilitate importation of certain foods into the U.S. BTA section 302(a) also added new subsection (h)(2) to FDCA section 801, which states:

The Secretary shall give high priority to making the necessary improvements to the information management systems of the Food and Drug Administration that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of the Secretary to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is compliance with this Act. 21 USC 381(h)(2) (emphasis added).

Under section 302, foreign food manufacturers and exporters, and U.S. importers, have an argument available to them for the first time to pursue reduced FDA screening rates of their shipments crossing U.S. borders. Quality, safety and security management programs reducing the risk that imported foods violates the FDCA become the basis for seeking facilitation of the importation.

los angeles
t 310.312.2000
f 310.312.3100

new york
t 212.509.3900
f 212.509.7239

washington, dc
t 202.355.7900
f 202.355.7899

Documenting Food Safety/Security Compliance

Many foreign food companies are already in substantial compliance with FDA's requirements in sourcing raw materials, implementing manufacturing standards, routinely assessing and mitigating food security-related risks, and have developed relationships with shipping and transportation companies that enable distribution through secure supply chains. Documenting these controls can provide the basis for FDA to pass over shipments from such companies, as long as the agency is able to distinguish their shipments from unknown shippers/ manufacturers or from those shipments for which the agency can clearly articulate a higher risk.

Documentation may be accomplished through a combination of:

- third party certification by accredited international third party inspection companies to confirm conformance to regulatory requirements;
- verification of compliance through inspections by other U.S. federal agencies (e.g., Department of Defense or USDA);
- integration of independent private laboratory testing as validation of food GMPs, HACCP, and Sanitation SOPs; and
- inspection reports from home government inspectorates.

For example, a 302 program might evaluate:

- a foreign manufacturer's receipt, testing and acceptance of raw materials;
- implementation of food GMPs, Codex Alimentarius standards and guidelines, or HACCP, as applicable;
- review of internal laboratory analysis procedures and quality control systems;
- SSOP and documentation review;
- pre-shipment inspection for quality and security at point of origin prior to export to the U.S.;
- use of C-TPAT certified shippers and transporters;

As these steps are documented and the agency shifts from a transactional import model (reviewing and evaluating entry data or prior notice data only) to a life-cycle risk mitigation approach, FDA will have more reliable data to demonstrate compliance with food safety and security requirements and guidances to justify expedited release upon entry.

While it is true section 302 is focused strictly on food importations, the very elements of FDA's version of C-TPAT can be brought to bear on other products subject to the agency's jurisdiction.

los angeles
t 310.312.2000
f 310.312.3100

new york
t 212.509.3900
f 212.509.7239

washington, dc
t 202.355.7900
f 202.355.7899