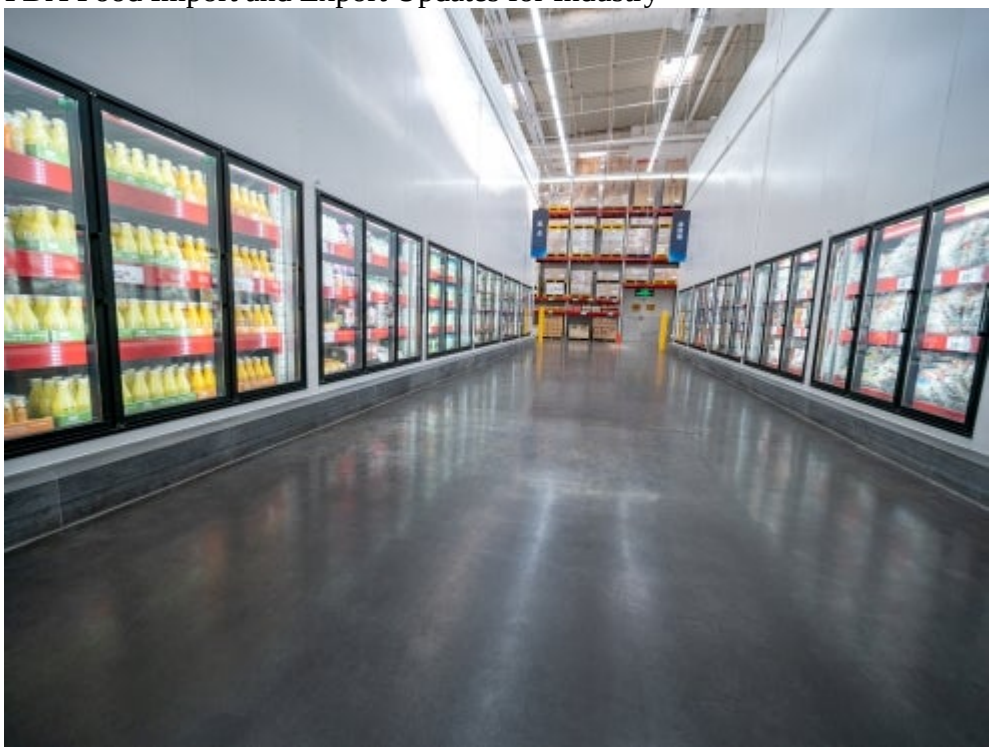
Updates
November 20, 2024
FDA Food Import and Export Updates for Industry



On the heels of launching the Human Foods Program, the U.S. Food and Drug Administration (FDA) has zeroed in on imports and exports, publishing updated guidance for certain importers and a notice of request for information (RFI) for exporters.

- On November 14, 2024, FDA released revised guidance covering the agency's Voluntary Qualified Importer Program (VQIP). FDA offers VQIP participants expedited entry of imports. The noted updates build on stakeholder feedback, aiming to streamline processes, enhance flexibility, and elevate the overall efficiency of the program.
- Earlier this month, on November 8, 2024, FDA issued an RFI seeking stakeholder feedback relating to the listing requirements of other countries and FDA's approach to facilitating U.S. industry compliance with these requirements. The RFI is intended to assist in the continuing development of the export list program for human foods.

Voluntary Qualified Importer Program Revisions

FDA's VQIP stems from the FDA Food Safety Modernization Act (FSMA), which required FDA to establish a voluntary, fee-based program to facilitate expedited review and importation of foods from importers who achieve and maintain a high level of control over the safety and security of their supply chains.

FDA's VQIP guidance, originally published in November 2016, describes FDA's policy regarding participation in the program by importers of food for humans or animals. The agency has modified this guidance from time to time in accordance with FDA's good guidance practice regulation (*i.e.*, 21 CFR 10.115) and in light of the agency's ongoing evaluation of the program's effectiveness.

Key updates noted in the recently revised guidance include:

- A revised inspection approach designed to optimize program efficiency by leveraging other oversight activities, which may reduce user fees. For example, FDA updated its guidance to note that FDA may conduct a VQIP inspection—or a Foreign Supplier Verification Program (FSVP) and/or Hazard Analysis and Critical Control Point (HACCP) inspection in lieu of a VQIP inspection—after a firm's application is approved.
- Flexibility for participants to add new foreign suppliers and foods to their existing program throughout the fiscal year, allowing participants to access more benefits through the program.
- Supporting participants in obtaining a facility certificate from an accredited certification body under the Accredited Third-Party Certification Program by extending the Notice of Intent to Participate and application deadlines.

Request for Information: Export Lists for Human Food

FDA's November 8, 2024, RFI seeks to gather stakeholder feedback in an effort to streamline the agency's approach to managing export certification for human food products.

For context, foreign customers or governments often ask U.S. exporters to supply a "certification" for food products regulated by FDA. Certain countries, for certain products, require export certification in the form of inclusion on a list of establishments that the exporting country's competent authority has certified as complying with applicable food safety requirements. As of August 2024, FDA provides certification in the form of export lists that cover 19 categories of products for six destinations: Chile, China, the European Union, Saudi Arabia, Taiwan, and the United Kingdom. FDA's export certification—in the form of certificates or export lists—provides an official attestation concerning a product's regulatory or marketing status.

To assist the agency with the continued development of its export list program for human foods, FDA invites stakeholder input on the following four questions through January 7, 2025:

1. There are many different types of establishment listing and certification procedures for establishments that produce human food products. Please share your experience with other countries' establishment listing, certification, and registration requirements.
2. FDA requires those on export lists to reapply regularly if they wish to remain listed. Do reapplicants experience any challenges with the renewal process? If you have experienced challenges, how were those challenges resolved?
3. For those included on export lists, please describe any challenges you have experienced with exporting human food products included on the export lists.
4. FDA is authorized to collect up to $175 per certification for each company and its human food products that FDA certifies through inclusion on an export list. For those that would be charged a fee, do you have any specific suggestions about how FDA should approach the implementation of fees? Please provide details relating to any suggestions you might have.

If you have any questions concerning the developments discussed in this Update, please contact members of Perkins Coie's Food Regulatory team.

Authors

Explore more in

Food Regulatory Food & Beverage Food & Consumer Packaged Goods Litigation

Related insights

Update

HHS Proposal To Strengthen HIPAA Security Rule

Update

California Court of Appeal Casts Doubt on Legality of Municipality's Voter ID Law