

Regulatory Alert: FDA Publishes Final ACE Rule

Submission of FCE/SID Data in Entries Required

December 6, 2016

On Friday, November 29, 2016, the U.S. Food and Drug Administration (FDA) published in the Federal Register a final rule entitled “Submission of Food and Drug Administration Import Data in the Automated Commercial Environment”¹ (“Final Rule”). The Final Rule establishes requirements for the electronic filing of entries of FDA-regulated products in the Automated Commercial Environment (ACE). ACE is the new, mandatory system for electronic filing of customs entries among other things.

The Final Rule requires certain new data elements to be submitted in entries for food, food contact substances, human drugs, animal drugs, radiation-emitting electronic products, biological products (including human cells and tissues), tobacco products and cosmetics. These requirements are in addition to the current requirements for FDA-regulated entries. This regulatory alert focuses on the food and food contact substances requirements. Please note that retailers importing glasses and sunglasses with impact resistant lenses should be aware that an Affirmation of Compliance with impact resistance is now required to be submitted in entries.

What are the data elements FDA is requiring that must be submitted for food contact substances?

For food contact substances, the following information must be submitted (“Product identifying information”):

- **FDA Country of Production:** The country where the article was last manufactured, processed, or grown (including harvested, or collected and readied for shipment to the U.S.). The FDA Country of Production for an article that has undergone any manufacturing or processing is the country where that activity occurred, provided that the manufacturing or processing had more than a minor, negligible, or insignificant effect on the article.
- **Complete FDA Product Code:** The FDA Product Code must be consistent with the invoice description of the product.
- **Full Intended Use Code**

¹ 81 Fed. Reg. 85854 (November 29, 2016).

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- Importer of record contact information: the telephone and email address of the importer of record.

What are the data elements required for food?²

- FCE/SID: For low-acid canned foods and acidified foods, the ACE Filer must submit at the time of filing entry the Food Canning Establishment Number and the Submission Identifier, and can dimensions or volume. This information is not required to be submitted if the article is imported or offered for import for laboratory analysis only and will not be taste tested or otherwise ingested.

Please note that for purposes of the ACE Rule, the term owner or consignee is defined as the person who “makes entry under the provisions of section 484 of the Tariff Act of 1930 (19 U.S.C. 1484) namely, the “importer of record.”” This definition differs from that under the Food Safety Modernization Act Foreign Supplier Verification Program (FSVP) Rule. The FSVP importer is the U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under the FSVP regulations.

Please contact Erik Lieberman at elieberman@usfoodimports.com or 202.765.1800 if you have questions or would like additional information.

² Excluding food contact substances.