

This information was presented to the IICA Board of Directors at its Spring 2011 meeting by Clay Detlefsen, vice president, regulatory affairs and counsel. It is provided here for informational purposes.

Food Safety and Imported Ingredients

Issue

The Food Safety Modernization Act (FSMA) contains a special section, Title III, which exclusively deals with the safety of imported food. The provisions could complicate the import process, increase the costs of imports, reduce imports or extend the time it takes to import products. Given that a number of ingredients used in the ice cream industry are imported, this could significantly impact our industry.

New Requirements

Foreign Supplier Verification Program - The owner of a food at the time it enters the United States must have a program to verify that the imported food is produced in accordance with US requirements and is not adulterated or misbranded. FDA is required to issue guidance within one year to assist importers in developing foreign supplier verification programs and must issue regulations establishing the content of the programs. FDA may require lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and preventative control plans of the foreign supplier and periodic testing and sampling of shipments.

Voluntary Qualified Importer Program - Within 18 months FDA, in collaboration with the Department of Homeland Security (DHS), must create a program to allow for expedited review and importation of products from importers that are voluntarily participating in the program. Importers must apply to have the foreign facility certified. FDA will determine whether the facility is eligible using a number of criteria including known safety risks, compliance history of foreign suppliers, the status of the foreign regulatory system and many other factors.

Authority to Require Import Certificates - FDA may require an import certificate as a condition of entry into the United States. FDA may accomplish this by a shipment-specific certificate, by a listing of certified facilities or other manner. FDA will consider a number of factors in making a determination to require a certificate including known food safety risks, known country or regional risks and a finding that the proximate food safety program is inadequate to ensure the food is as safe as a similar U.S. product. Certifying entities may include foreign government officials or other accredited personnel. FDA may require periodic renewal and may refuse to accept a certificate it believes is invalid.

Accreditation of Third-Party Auditors- FDA must create a system to recognize accreditation bodies that will certify third-party auditors within two years. If it has not recognized an accreditation body within two years, it may accredit third-party auditors directly. Recognized accreditation bodies must provide FDA with a list of all accredited

auditors and their audit agents. Within 18 months FDA must develop model accreditation standards including requirements for regulatory audit reports.

Neutralizing Costs and Public Registry- FDA shall establish by regulation a cost-neutral user fee program whereby third-party auditors and audit agents reimburse FDA for the costs of establishing and maintaining an accreditation system. FDA shall establish and maintain a publicly available registry of accreditation bodies and accredited third-party auditors, including contact and other necessary information.

IDFA Actions

IDFA has and will participate in FDA meetings, discussions and the rule making process over the foreseeable future and will keep the membership informed. For matters concerning this issue contact Clay Detlefsen at (202) 220-3554 or at cdetlefsen@idfa.org.