LEGAL ADVISORY

FDA Seeks Importer and Exporter Input on Food Safety Law Changes

Importer Requirements, Foreign Food Safety Systems to be Discussed at Two Meetings

March 11, 2011– U.S. food importers and foreign companies exporting food to the U.S. will soon be subject to important new requirements under the recently-enacted Food Safety Modernization Act, which the Food and Drug Administration has committed to implementing on an aggressive schedule. FDA will hold a March 29 public meeting in which importers and exporters will have an opportunity to voice their views and submit comments on the import safety provisions of the FSMA. Separately, the FDA will hold a public hearing March 30-31 on foreign food safety programs and policies and how they might be used to further enhance the safety of foods and animal feed imported into the U.S.

IMPORTERS

The FSMA, which incorporates the most sweeping changes to U.S. food safety regulation in 70 years, includes numerous provisions that apply to importers of food and food products. These include:

- the Foreign Supplier Verification Program, under which most importers must conduct risk-based foreign supplier verification activities to verify that imported food is not adulterated or misbranded and is produced in compliance with FDA's preventive controls requirements and produce safety standards;

- the Voluntary Qualified Importer Program, a new voluntary, user-fee funded program that will expedite the entry of imported food from eligible, qualified importers;

- mandatory import certification authority, under which FDA will require articles of food offered for import into the U.S. to be accompanied by certifications or other assurances that they comply with relevant food safety laws; and

- a third-party auditor accreditation system, under which FDA will recognize bodies that accredit third-party auditors to issue import safety certifications.

The March 29 meeting is designed to gather public input to assist FDA in its development of regulations and guidance on these and other import-related issues. FDA will provide multiple opportunities for individuals to express their views, including making presentations at the meeting, participating in break-out sessions and submitting written comments afterward. Those wishing to attend the meeting must register by March 22. There will also be an interactive webcast for stakeholders who cannot be present.

FOREIGN FOOD SAFETY SYSTSEMS

The FSMA embodies the principle of prevention by requiring those who produce and import food to have systems of preventive controls in place and empowering FDA to hold them accountable to meet their new responsibilities. Consistent with this mandate, FDA is focusing on preventing problems at appropriate points along the global food supply chain. The March 30-31 public hearing will therefore include a general discussion of FSMA from the perspectives of consumers, industry, legislators and U.S. trading partners; the policies, practices and programs used by foreign regulators to ensure the safety of imported foods and animal feed; and the comparability of foreign food safety systems with that of the U.S.

On the issue of comparability, FDA is proposing a model under which it will consider the food safety system of a foreign country to be comparable to the U.S. food safety system if FDA determines that it (1) is similar, though not identical, to the U.S. food safety system, (2) comprises elements that are analogous to those within the U.S. food safety system, and (3) is a system that FDA has determined provides the same level of public health protection as that of the U.S. FDA has developed a tool it proposes to use in making such assessments, and comments on specific aspects of this tool and the associated process (pros and cons, costs, incentives, etc.) will be solicited at the upcoming hearing. FDA is also interested in insights gained from previous work on the equivalence of domestic and foreign systems (e.g., those made by the Department of Agriculture's Food Safety and Inspection Service).

With respect to foreign policies and practices, FDA wants to learn more about the methods foreign regulators use (e.g., import and export certification programs) to ensure the safety of imported foods and animal feed and how the effectiveness of those methods is measured. For example, FDA seeks to better understand the control systems used by other countries for the importation of ingredients used in processed food as well as the control systems used for the transshipment of products. FDA will use this type of information to determine whether to use the innovations and improvements being adopted in other countries.

Advance registration to attend this hearing is required no later than March 21 and will be accepted on a first come, first served basis. Requests to make an oral presentation at the hearing are due by March 14. Written comments for the docket of this proceeding must be submitted by June 30.

For more information on seeking refunds if revocation is affirmed, please contact:

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