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International Trade Alert

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Should I Eat That? New Rules Propose Significant Requirements on Importers of Food and Dietary Supplements

Dietary Supplements Alert

As an ever-increasing amount of food we eat is from overseas, the challenge of assuring that imported food meets the same safety standards as food grown and produced in the United States continues. On July 29, 2013, the U.S. Food and Drug Administration (FDA) published two proposed regulations aimed at addressing this challenge. *Consider how these changes may affect your business, as comments on the Proposed Rules may be submitted until* ***November 26, 2013.***

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

The **first proposed rule** establishes requirements for importers in implementing a Foreign Supplier Verification Program (FSVP).

The FDA's proposed FSVP rule, if ultimately adopted, would require importers to have a plan for imported food, including identifying hazards associated with each food that are reasonably likely to occur. It would also require importers to provide adequate assurances that these hazards are being adequately controlled. The Food Safety Modernization Act (FSMA) had provided for the foreign supplier verification requirements to be effective in January 2013; however, the FDA has announced its intention not to enforce these provisions until after issuance of the final rule and pronouncement of effective dates for those requirements. Thus, enforcement of these requirements is a year or more away. Nevertheless, companies should contemplate how they will meet these requirements, if they have not done so already.

Under the FSVP proposal, importers would need to undertake the following:

- **Compliance Status Review** – Review FDA warning letters, import alerts, etc. concerning the food and potential foreign suppliers before importing the food, and conduct these reviews periodically thereafter;
- **Hazard Analysis** – Identify the hazards reasonably likely to occur and evaluate the consequences if such a hazard were to occur;
- **Verification Activities** – Provide adequate assurances that the hazards identified are adequately controlled. The FDA is proposing two options for implementing verification procedures, although each potentially involves activities such as onsite auditing of foreign suppliers, sampling and testing of the food, and/or review of the supplier's food safety records;
- **Corrective Actions** – Review and investigate complaints concerning the foods they import and take corrective action as appropriate;
- **FSVP Reassessment** – Reassess their FSVPs every three years; and
- **Importer Identification** – Obtain and use a Dun and Bradstreet Data Universal Numbering System (DUNS) number to file with U.S. Customs.

The proposed FSVP requirements vary based on a variety of factors, including the type of food product (*e.g.* processed foods, produce, and dietary supplements), the category of importer, the nature of the hazard in the food, and who is to control the hazard. For example, certain foods are exempted from FSVP procedures, such as food imported for research or evaluation purposes, food imported for further processing and subsequent export, as well as food from the juice and seafood industries, which is already subject to Hazard Analysis Critical Control Point (HACCP) regulations.

Are Imported Dietary Supplements Impacted?

Additionally, modified FSVP requirements apply in certain situations, such as the importation of dietary supplements. For dietary supplements and dietary supplement components, importers who establish

AUTHORS

Lindsay B. Meyer
Ashley W. Craig
Matthew R. Rabinowitz
Claudia A. Lewis
Michelle C. Jackson

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and verify compliance with certain specifications (concerning dietary supplement components, packaging, and labeling) under the dietary supplement CGMP regulations would not be required to comply with most of the standard FSVP requirements, including hazard analysis and standard supplier verification activities. While importers of finished dietary supplements would still be required to comply with most of the standard FSVP requirements, these obligations are modified. Importers would not have to conduct hazard analyses and their supplier verification activities would focus on verifying that the supplier is in compliance with the dietary supplement CGMP regulations, rather than verifying that hazards identified as reasonably likely to occur are being adequately controlled.

Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications

The **second proposed rule** seeks to establish a program for accreditation of third-party auditors, also known as certification bodies, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce. The FDA plans to use such third-party certifications for both its Voluntary Qualified Importer Program (VQIP) and FSVP. Although the FSVP proposal does not require the use of accredited third-party auditors, the FDA anticipates that once the FDA accreditation system is in place, importers may increasingly rely on audits by accredited third parties to meet their supplier verification requirements under FSVP.

If these changes will impact your business operations, you may consider submitting or reviewing comments, which are **due by November 26, 2013**. Otherwise, we anticipate that the final rules will become effective within 60 days of their publication. Please feel free to contact either Venable's **Dietary Supplements, Cosmetics and Functional Foods Practice Group** or **International Trade and Customs Practice Group** with any questions you might have or for assistance in filing responsive comments.