JONES DAY

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FDA MOVES TOWARD INCREASED REGULATION OF IMPORTED FOODS

PROPOSED "FSMA" REGULATIONS WILL IMPOSE HEIGHTENED RESPONSIBILITIES ON IMPORTERS AND WILL ACCREDIT THIRD PARTIES TO AUDIT COMPLIANCE

In 2013, the U.S. Food and Drug Administration ("FDA") has proposed four major sets of regulations designed to implement the **Food Safety Modernization Act** ("FSMA"). The first two, released in January, focused on strengthening the regulations governing manufacturing practices and establishing a new regime of regulations covering farm operations. (Please **click here** to view a summary of these rules.)

Most recently, FDA released another two major proposed rules; these rules concern imported foods and are intended to prevent food safety problems *before* foods arrive on U.S. shores, rather than relying on inspections at U.S. ports of entry as the primary method to catch unsafe foods. The first proposed rule, regarding **Foreign Supplier Verification Programs for Imports of Food for Humans and Animals** ("FSVP"), will make food importers responsible for overseeing their suppliers' compliance with food safety regulations. The second, the proposed rule on **Accreditation of Third-Party Audits/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications**, will establish a program for accreditation of independent auditors of foreign food producers. (For the full text of FSMA and the two proposed rules, follow the embedded hyperlinks above.)

On July 26, FDA published for comment two proposed regulations to implement certain aspects of FSMA: the Foreign Supplier Verification Program rule and the Accreditation of Third-Party Auditors rule. The proposals each include a 120-day formal comment period, closing November 26. FDA proposes the FSVP effective date be 60 days after the date on which the final rule is published. However, the Agency

also proposes to provide additional time for importers to come into compliance, generally setting a compliance date of 18 months after the publication date of the final rule. In many cases, the effective date for food importers will vary depending on the effective dates for other recently proposed rules regarding preventive controls, produce safety, and manufacturing practices.

With respect to the Accreditation of Third-Party Auditors rule, FDA did not specify timing to implementation of a final rule but stated its intent to implement the program as soon as possible after publication of the final rule and associated Model Accreditation Standards.

Note that many more "FSMA" regulations are still in the pipeline. Yet to come are regulations regarding pet food, the sanitary transportation of food, intentional adulteration, and record-keeping requirements for high-risk foods. Congress required FDA to develop these rules, and FDA is under court pressure to accelerate its timetable for issuing the rules.

THE PROPOSED FOREIGN SUPPLIER VERIFICATION PROGRAM RULE

As reported in the proposed rule, about 15 percent of all food consumed in the United States is imported, including approximately 50 percent of fresh fruit and 20 percent of fresh vegetables. Historically, FDA has relied primarily on inspections and customs controls at U.S. points of entry to stop unsafe foods from entering the United States. When finalized, the FSVP rule will change the food import paradigm from governmental attempts to catch a product at the port to preventative efforts undertaken by industry to ensure safety throughout the food supply chain.

The proposed rule, if issued in its current form, will require an importer to develop, maintain, and follow an FSVP for each food product it imports. An *importer* is the U.S. owner or consignee of the food at the time of entry, or, if there is no U.S. owner or consignee at the time of entry, the U.S. agent or representative of the foreign owner or consignee. Each FSVP would include several major requirements:

- Reviewing the compliance status of the food and the foreign supplier for compliance with FDA rules, before importing the food and periodically thereafter;
- Conducting a hazard analysis for each food to identify the hazards reasonably likely to occur and evaluate the hazard's severity should it occur;
- Conducting verification activities that provide adequate assurances that identified hazards are being controlled, which could include on-site auditing, sampling and testing, or other appropriate risk-based procedures, as well as general verification activities such as maintaining supplier lists and establishing adequate written procedures regarding verification activities;
- Taking appropriate corrective action if hazards are not being adequately controlled;
- Periodically reassessing the FSVP, at a minimum of every three years or sooner if the importer becomes aware of new information about potential hazards associated with the foods they import;
- Obtaining a Dun & Bradstreet Data Universal Numbering System ("DUNS") number for their company and ensuring that each food product offered for import in the U.S. has their name and DUNS number provided electronically at the time of filing for entry; and
- Keeping and maintaining certain records pertaining to compliance status reviews, hazard analysis, foreign supplier verification activities, investigations and corrective actions, and reassessments of their FSVPs.

The proposed rule imposes specific requirements and enumerates options for implementation concerning each of these major requirements. Currently, the verification activities requirement leaves to importers' discretion whether to conduct their own on-site audits or to rely on verification documentation from the food supplier. Requiring on-site audits rather than including them as an optional means of implementing an FSVP would significantly increase compliance costs for importers. As written, FDA estimates the new rules on imported food will cost $400 million to $500 million over a 10-year period. FDA's cost analysis assumes these costs will be passed on to U.S. consumers, and the Agency is requesting comment on the extent to which all of those costs will be absorbed by U.S. consumers.

Modified provisions would apply to certain types of importers, including importers of dietary supplements and dietary supplement components who establish and verify compliance with certain statutory specifications, very small food importers and importers of food from very small foreign suppliers (entities with annual food sales of no more than $500,000), and importers of food from foreign suppliers in countries whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, subject to certain conditions.

In addition, the proposed rule exempts certain categories of imported food from FSVP regulations. Those categories include certain juice, fish, and fishery products; food for personal consumption; alcoholic beverages; food that is transshipped, meaning it is transferred between conveyances for reshipment; food that is imported for re-export; and food for research or evaluation.

THE PROPOSED THIRD-PARTY ACCREDITATION RULE

The proposed rule on Accreditation of Third-Party Auditors will establish a program for approving third-party auditors, or certification bodies, to conduct food safety audits and issue certifications of foreign facilities and the foods they produce. Importers are generally not required to obtain certifications. However, FDA may use accredited auditor certifications in deciding whether to admit certain imported foods the Agency determines pose a food safety risk or whether to permit an importer to participate in pilot programs aimed as expediting product entry.

The proposed rule includes eligibility requirements for accreditation bodies and third-party auditors. Both must meet standards for legal authority, competency and capacity, independence, quality assurance, and records procedures. FDA would monitor the accreditation bodies and third-party auditors and could revoke recognition or accreditation for good cause.

Under the proposed rule, an accreditation body, which may be a foreign body or agency or a private third party, is required to:

- Assess third-party auditors for accreditation;
- Monitor performance of the third-party auditors it accredits and notify FDA of changes in, or denials of, accreditation;
- Assess and correct any problems in its own performance;
- Submit reports and other notifications to FDA;
- Protect against conflicts of interest; and
- Maintain and provide FDA with access to records.

An accredited third-party auditor, which may include a foreign government, foreign cooperative, or other third party, would audit and issue certifications for foreign facilities and goods, and is required to:

- Ensure audit agents are competent and objective;
- Conduct rigorous audits;
- Submit reports of regulatory audits to FDA;
- Notify FDA upon finding any condition posing a serious risk to the public health;
- Assess and correct any problems in performance;
- Protect against conflicts of interest; and
- Maintain and provide FDA with access to records.

FDA intends to issue draft model accreditation standards describing the qualifications a certification body must have in order to qualify for accreditation. The draft model accreditation will be subject to public review and comment prior to finalization. As described in the proposed rule, once an accreditation body provides sufficient documentation demonstrating eligibility warranting recognition and receiving such recognition based on the prescribed standards, it may begin conducting accreditation activities under the program and will not be subject to a waiting period.

FDA intends to use certifications issued by accredited third-party auditors to provide food importers with a system upon which they may rely to meet supplier verification requirements under the FSVP.

FDA PERSPECTIVES ON THE TWO NEW RULES

The proposed regulations are related to the preventive controls programs for food manufacturers and processors contained in FDA's recently proposed Current Good Manufacturing Practice rule. FDA views the proposed regulations as a flexible, risk-based approach to foreign supplier verification, focusing on foreseeable food safety risks identified through a hazard assessment process, rather than all risks covered by the adulteration provisions of the Food, Drug, and Cosmetic Act. FDA believes its approach is sufficiently general and flexible to apply to a variety of circumstances, without being unduly burdensome or restrictive of the imported food trade. However, the Agency acknowledges that the costs associated with compliance are considerable and will be at least $400 million to $500 million over a 10-year period. Combined with the third-party accreditation framework, which will create a system of comprehensive oversight to help FDA make admissibility decisions regarding imported foods posing safety risks, the proposed rules provide the government with new tools for holding importers accountable for verifying that the food they import is safe and for doing so in a manner that is transparent to FDA.

INDUSTRY AND CONSUMER IMPACT

FDA believes consumers would benefit from required on-site audits to ensure food suppliers are meeting safety standards, and consumer advocacy groups will undoubtedly push for them to be mandatory under the new rules. Large importers may already have systems in place mirroring the proposed requirements as part of efforts to protect their brands and food safety image. Some importers who have previously implemented robust quality systems may believe that it is unfair for other companies to avoid such costs, especially when a foodborne illness outbreak could dramatically reduce sales in an entire product category.

Importers and suppliers of foreign foods will be affected by the costs of implementing programs to comply with the new rules, and they may also reconsider what records they generate in the first instance in the face of record-keeping requirements. FDA recognizes that food entities and suppliers may have concerns about their trade secrets and confidential or sensitive information becoming public in light of the proposed record requirements, and it encourages industry stakeholders to raise such concerns over records access during the notice and comment period.

Industry stakeholders have also informed FDA of concerns regarding access to sufficient numbers of qualified third-party auditors and certification bodies under current conditions. FDA is encouraging public comment and submission of data concerning the availability of these entities to participate in the program or their ability to scale up their current capabilities, the effect the program may have on foreign and domestic food firms' ability to provide certifications to their customers, whether foreign and domestic firms will be affected to the same degree, and whether capacity issues may be more prevalent in certain areas of the world or with respect to certain types of food firms or products.

OPPORTUNITIES TO SHAPE THE FINAL VERSION OF THE RULES

To learn more of the views of the public, industry, and other stakeholders, FDA has been holding a series of public meetings. In addition, FDA is accepting (and is required to review) written comments.

Businesses potentially affected by the proposed rules should consult an attorney to determine the extent of the new obligations and should begin to determine the costs imposed by the rules' requirements. The public comment period is open until November 26, and interested parties and those likely to be affected by the proposed rules should voice their concerns now. As written here, care should be taken to ensure that the comments are as effective as possible. Even small changes to the proposed rules as written could result in major savings, or costs, to industry stakeholders.

LAWYER CONTACTS

For further information, please contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com.

Harold K. Gordon
New York
+1.212.326.3740
hkgordon@jonesday.com

Jonathan Berman
Washington
+1.202.879.3669
jberman@jonesday.com

Colleen M. Heisey
Washington
+1.202.879.3449
cmheisey@jonesday.com

Kristen E. Scoville
New York
+1.212.326.3763
kscoville@jonesday.com

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