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FDA HOLDS PUBLIC MEETING ON FSMA PROPOSED RULES FOR FOREIGN SUPPLIER VERIFICATION PROGRAMS AND ACCREDITATION OF THIRD-PARTY AUDITORS/CERTIFICATION BODIES

On September 19 and 20, FDA held a public meeting in Washington, D.C. to discuss the new Food Safety Modernization Act (FSMA) proposed rules on foreign supplier verification programs (FSVPs) and the accreditation of third-party auditors/certification bodies. At the meeting, agency representatives provided an overview of the proposed rules and heard comments from the food industry, consumer advocacy groups, and consumers themselves.

As a general matter, both days of the meeting highlighted concerns – and, at times, confusion – about the two proposed rules, as well as their interplay with the other FSMA proposals that FDA has previously released. The agency representatives indicated that FDA appreciates these stakeholder perspectives and welcomes comments addressing the practical effects of the rules and the merits of various provisions. Below is a brief summary of some of the key issues discussed.

DISCUSSION OF FSVPS

As discussed in our previous client alert, the proposed rule on FSVPs seeks to establish a risk-based framework in which food importers analyze hazards reasonably likely to occur and take measures to verify that these hazards are adequately controlled by the foreign supplier, the importer, or the importer's customer.

The majority of comments, by industry stakeholders and consumer advocacy groups alike, focused on the two options proposed by FDA for steps an importer must undertake to verify that a foreign supplier has controlled an identified hazard. "Option 1" would require, among other things, annual audits for food suppliers for which a serious adverse health consequences or death to humans or animals is reasonably likely to occur. "Option 2," on the other hand, would provide more discretion to importers to choose appropriate verification activities. Consumer advocacy groups voiced strong support for the more prescriptive Option 1 and for on-site audits, arguing that only in-person inspections of foreign suppliers will be sufficient to identify food safety risks. Industry stakeholders expressed concern that the FSVP proposed rule is too prescriptive and not reflective of the food industry's leading practices, arguing instead for the more flexible Option 2.

Some commenters also raised questions about the intersection of FDA's hazard analysis and preventive controls proposal and the FSVP proposed rules. Michael Taylor, the Deputy Commissioner for Foods and Veterinary Medicine, said that FDA envisions supplier verification as part of the final rule on hazard analysis and preventive controls to allow for consistency and alignment between foreign and domestic food supply chains. That proposed rule did not include domestic supplier verification requirements, but in an appendix thereto, FDA discussed its belief that such measures can be beneficial in certain circumstances. A document later released by FDA indicated that an earlier draft of the proposed rule contained supplier verification requirements, but

these were stricken by the Office of Management and Budget during review of the proposal.[1] Mr. Taylor indicated, in response to a stakeholder question, that interested parties would have an opportunity to comment on the inclusion of domestic supplier verification requirements, although he did not provide any details on the process for comment or on the specifics of potential domestic supplier verification requirements. Whether stakeholders will have a meaningful opportunity to comment on a domestic supplier verification requirement has been a matter of interest within the food industry since the proposed rule for preventive controls was released. The agency representatives indicated at last week's meeting that they are mindful of the industry's concern about this issue.

DISCUSSION OF ACCREDITATION OF THIRD-PARTY AUDITORS/CERTIFICATION BODIES

As directed by FSMA, FDA proposes to provide for accreditation of third-party auditors and certification bodies to conduct food safety audits of foreign food entities, including registered foreign food facilities, and to issue food and facility certifications. Under this program, in which participation is voluntary, FDA will recognize accreditation bodies, which will in turn accredit third-party auditors to conduct food safety audits and issue certifications for foreign facilities and food under specified programs.

Consumer advocacy groups and industry stakeholders both made comments about the level of transparency that would be required. Consumer advocacy groups urged FDA to publish a wide range of information about auditors, such as an auditor's conflicts of interest or inspection of a facility linked to a foodborne illness, on the agency's website. Industry stakeholders expressed concern about the scope of the reports required under the rule, suggesting that the results of consultative audits not be subject to the rule's reporting requirements. FDA representatives did not comment on the agency's views on this particular issue.

Another topic of discussion was how the third-party auditor program, which is voluntary, would interact with other FSMA rules. For example, an industry stakeholder asked FDA representatives whether audits conducted outside the scope of the FSVP would be required to comply with third-party auditor reporting requirements. The agency's panelists responded that it will need to find a way to clarify how the rules will work together.

NEXT STEPS FOR FSMA

The comment period for these two proposed rules is open until November 26, 2013.[2] FDA will continue its public meetings in Miami on October 10 and Long Beach on October 22. The agency representatives also indicated at the meeting that it will issue proposed rules on animal feed and pet food, as well as on intentional adulteration, by the end of November 2013; and the proposed rule on sanitary food transport should be published in January 2014.

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Covington & Burling LLP continues to monitor FDA's implementation of FSMA and will keep its clients updated regarding developments and next steps.

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[1] The docket for the hazard analysis and preventive controls rule can be found here.

[2] FDA has also extended, for a second time, the comment period for the proposed Current Good Manufacturing Practice and Hazard Analysis and Preventive Controls for Human Food and Produce Safety Rules. Comments on the proposed rules are due November 15, 2013. Our client alerts for those proposed rules are available here and here.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:

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