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MEMORANDUM

From: Joseph A. Levitt
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Date: May 30, 2018

Re: **FSMA Implementation Update: FDA Releases New Supplier Verification Tool to Assist with FSMA Compliance and Provides Update on VQIP**

The Food and Drug Administration (FDA) recently made two notable announcements regarding implementation of the FDA Food Safety Modernization Act (FSMA). First, FDA released a tool to assist companies with meeting supplier verification requirements under FSMA. A new section of the FDA's Data Dashboard will help companies that perform supplier verification under FSMA by functioning as a "one stop shop" for identifying compliance and enforcement information related to specific suppliers. 1/ Second, FDA announced that the Voluntary Qualified Importer Program (VQIP) will not launch until the Fiscal Year (FY) 2020 benefit year—i.e., October 1, 2019. VQIP is a voluntary, fee-based program that offers expedited review and entry of food into the United States.

FDA Releases New Tool for Searching Supplier Compliance Data

As background, there are three FSMA regulations that contain supplier verification requirements – the Foreign Supplier Verification Programs (FSVP) rule, the Preventive Controls for Human Food (PCHF) rule, and the Preventive Controls for Animal Food (PCAF) rule. Among other things, each of these regulations requires the party responsible for performing supplier verification (i.e., the "importer" or "receiving facility") to evaluate a supplier's performance and the risk associated with the food, which includes evaluating a supplier's compliance with FDA regulations. In particular, there is a requirement to determine whether a supplier has been subject to an FDA Warning Letter, Import Alert, or other FDA compliance action related to food safety and to consider the supplier's compliance with U.S. food safety laws and regulations.

Previously, FDA hosted a website that included links to several separate databases (e.g., Warning Letters, Import Alerts, Recalls) that needed to be individually reviewed to assess a supplier's compliance history and legal compliance. 2/ Now, the FDA Data Dashboard compiles all of the information from those databases in one location, allowing users to perform one search and receive results from multiple databases. The FDA Data Dashboard retrieves information regarding warning

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1/ The FDA Data Dashboard is available at https://datadashboard.fda.gov/ora/index.htm. Select "FSMA Data Search" followed by "Firm/Supplier Evaluation Resources" to reach the main searching portal.

2/ FDA Supplier Evaluation Resources, available at https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm516330.htm.

letters, import alerts, recalls, import refusals, inspection classification, and other firm-specific compliance and enforcement actions. The information is displayed through user-friendly graphics.

The updated FDA Data Dashboard should be a helpful tool for companies performing supplier verification under FSMA, as well as for companies performing diligence on their business partners. Note that all of the information available through the FDA Data Dashboard was previously available, but now simply is more readily accessible.

FDA Announces VQIP Will Start in 2019

VQIP is a voluntary, fee-based program that offers expedited review and entry of food into the United States. Among other things, to qualify for VQIP, food must be produced in a foreign facility or on a foreign farm that is certified by an auditor accredited through FDA's Accredited Third-Party Certification Program. 3/ FDA has recognized the American National Standards Institute (ANSI) and ANSI-ASQ National Accreditation Board (ANAB) as accreditation bodies under FDA's voluntary Accredited Third-Party Certification Program. ANAB and ANSI will be assessing and accrediting certification bodies, which will take some time, and so currently no certification bodies have been accredited through this program. Certification bodies will conduct food safety audits of foreign facilities and issue the certifications that importers need to participate in VQIP.

The VQIP application portal is open annually from January 1 through May 31 for the following benefit year. In a recent Constituent Update, FDA announced that although the VQIP application portal opened in January 2018, "FDA does not anticipate that importers will be able to apply during this application cycle while certification bodies (also known as third-party auditors) receive their accreditation under the Accredited Third Party Certification Program." 4/ Because the audits required to apply for VQIP have not been conducted yet, FDA does not expect importers to be able to participate in VQIP for the FY 2019 benefit year (i.e., October 1, 2018 – September 30, 2019).

Due to the time needed to accredit certification bodies, FDA is considering an early opening for the FY 2020 application portal later in the 2018 calendar year, once certification bodies have been accredited under FDA's Accredited Third Party Certification Program. This would allow importers to submit their completed applications early for the FY 2020 benefit year.

FDA also is encouraging importers to submit a "notice of intent to participate" in order to help FDA gauge the necessary resources for review of VQIP applications. Importers also are encouraged to begin the application process now to prepare for next year and to provide FDA with feedback on the process to help increase efficiency in next year's application cycle.

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We will continue to monitor FDA's implementation of FSMA. Please let us know if you have any questions.

3/ *See* Hogan Lovells memorandum dated February 8, 2018, *FDA Begins Accepting VQIP Applications and Recognizes First Accreditation Body under FSMA's Accredited Third-Party Certification Program.*

4/ FDA Constituent Update, May 25, 2018, available at https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm608009.htm.