

MEMORANDUM

From: Joseph A. Levitt
Maile Gradison Hermida
Elizabeth Barr Fawell
Leigh G. Barcham

Date: August 15, 2019

Re: FDA Issues First Warning Letter for Foreign Supplier Verification Program Violations under FSMA

The U.S. Food and Drug Administration (FDA) recently issued the first Warning Letter addressing violations of the Foreign Supplier Verification Program (FSVP) rule, one of the seven major FDA Food Safety Modernization Act (FSMA) regulations.^{1/} Under the FSVP rule, importers must take steps to verify that their foreign suppliers produce food that satisfies U.S. food safety standards. FDA issued the Warning Letter to the importer of tahini implicated in a recent *Salmonella* outbreak. According to FDA, the importer did not have an FSVP in place for the imported tahini. This memorandum summarizes the Warning Letter and provides analysis of the key takeaways for FSVP enforcement.

Summary of Warning Letter

Brodt Zenatti Holdings LLC (Brodt Zenatti) is the FSVP importer for tahini from Karawan Tahini and Halva (Karawan), located in the West Bank, which was implicated in a multi-state *Salmonella Concord* outbreak earlier this year. Brodt Zenatti recalled the tahini on May 23, 2019, and according to FDA, the company voluntarily agreed to stop importing the product. FDA placed the Karawan tahini under detention without physical examination (DWPE) per Import Alert 99-19 on May 30, 2019, as a consequence of being found contaminated with *Salmonella*.

As part of its outbreak investigation, FDA conducted an FSVP inspection of Brodt Zenatti on May 17, 2019, resulting in FDA issuing a Form FDA 483a, FSVP Observations (483a), to the company.^{2/} In the Warning Letter dated July 30, 2019, FDA states that the company did not respond to the 483a and that its recall of the tahini did not address the company's FSVP violations.

The Warning Letter states that Brodt Zenatti's significant deviation is that the company "did not develop an FSVP" for the Karawan tahini, and that if the company does not take prompt action to correct the violations, FDA may take further enforcement action. In particular, FDA warns: "Our inspection revealed that you were not familiar with FSVP requirements, and without evidence of corrective action we may conclude that you appear to be in violation of FSVP requirements for all

^{1/} The Warning Letter is available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/brodt-zenatti-holdings-llc-583679-07302019>.

^{2/} A Form 483a is the FSVP equivalent of a Form 483 for a food facility inspection.

food you import.” FDA also cautions that if the company does not promptly correct the violation, the agency may place food that the company imports on DWPE.

As with all Warning Letters, the company now has 15 working days to respond to the agency with plans to correct the violation or evidence that the company has corrected the violation.

Analysis

The issuance of this Warning Letter is consistent with the FSVP enforcement approach that FDA has expressed since the first compliance date arrived in May 2017. FDA has explained that its approach is “to educate while it regulates” to create a culture of compliance, and its initial enforcement priorities will be on food safety problems that pose an imminent public health risk. FDA has said that because of the agency’s mandate to protect public health, “when appropriate, the agency will act swiftly.” ^{3/}

To that end, it is noteworthy that this FSVP inspection was performed in connection with an outbreak investigation, meaning that it was associated with human illnesses. This confirms that FDA is giving its highest enforcement priority to situations that raise a public health issue. It also signals that importers of foods associated with an outbreak should expect to be subject to FSVP inspections.

FDA’s statements in conjunction with issuance of the Warning Letter underscore that the agency plans to increase FSVP enforcement in the future. In a press release, FDA states that in the future the agency “will take more steps to ensure compliance with FSVP, including reinspecting importers that had deficiencies in previous inspections and by acting immediately when FSVP deficiencies are found that pose an imminent public health risk.” ^{4/} Indeed, implementation of the FSVP rule is a key component of Strategy for the Safety of Imported Food, announced in February 2019, which aims to increase the safety of imported food. ^{5/}

In addition, the Warning Letter reveals further potential consequences for importers lacking adequate FSVPs. Even though FDA’s inspection may focus only on one product, the Warning Letter suggests that FDA could place all the importer’s foods on DWPE (i.e., Import Alert) if this is warranted based on the inspectional findings.

Finally, the Warning Letter reinforces one of the underlying core principles of FSMA, which is to add accountability to the entire supply chain. In this case, even though the supplier was responsible for the outbreak, FDA is holding the importer accountable for failing to engage in oversight of the supplier that potentially could have prevented the outbreak from occurring. Accordingly, FDA is sending a signal to all food companies and importers about the increased importance FDA is placing on supplier verification responsibilities under FSMA.

* * *

Please contact us if you have any questions or if we can be of assistance.

^{3/} See, e.g., “What Do Importers Need to Know about FSVP?: A Conversation with Sharon Mayl” available at <https://www.fda.gov/food/conversations-experts-food-topics/what-do-importers-need-know-about-fsvp>.

^{4/} FDA In Brief: FDA issues first warning letter to the importer of tahini implicated in recent Salmonella outbreak under the Foreign Supplier Verification Programs (Aug. 13, 2019), available at <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-issues-first-warning-letter-importer-tahini-implicated-recent-salmonella-outbreak>.

^{5/} Available at <https://www.fda.gov/media/120585/download>.