FDA Issues Temporary Guidance on Food Supplier Verification Audit Requirement

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PRACTICES FDA Regulatory and Compliance, Food, Beverage and Restaurant, Healthcare and Life Sciences, Healthcare Transactions and Regulatory, Hospitality

To help prevent disruptions in the food supply-chain during the COVID-19 pandemic, the FDA issued a temporary policy for Food Safety Modernization Act (FSMA) supplier verification onsite audit requirements. The policy states that the FDA will temporarily not enforce FSMA supplier verification onsite audit requirements if other appropriate supplier verification methods are used instead. Other supplier verification methods, such as sampling and testing or a review of food safety records, will be designed to provide sufficient assurance that hazards have been significantly minimized or prevented during the period of onsite audit delay. The following is a list of circumstances in which onsite audit requirements will not be enforced:

- A receiving facility or Food Supplier Verification Program ("FSVP") importer has determined that an onsite audit is the appropriate verification activity for an approved supplier, as reflected by its written food safety plan or foreign supplier verification program;
- The supplier that is due for an onsite audit is in a region or country covered by a government travel restriction or travel advisory related to COVID-19;
- In light of a government travel restriction or travel advisory, it is temporarily impracticable for the receiving facility or FSVP importer to conduct or obtain the onsite audit of the supplier (e.g., a receiving facility or FSVP importer is unable to obtain the services of a qualified auditor in the impacted country or region or travel to the foreign supplier to conduct the onsite audit); and
- The receiving facility or FSVP importer temporarily selects an alternative verification activity or activities, such as sampling and testing food or reviewing relevant food safety records, and modifies its food safety plan or foreign supplier verification program to incorporate the alternative activity or activities. The alternative verification activity(ies) method is designed, in consideration of the temporary unavailability of supplier onsite audits, to provide sufficient assurance that the hazard requiring a supply-chain-applied control (or, for FSVP, the hazard that is being controlled by the foreign supplier) has been significantly minimized or prevented during the period of onsite audit delay.

The FDA will provide timely notice about the withdrawal of this policy, but asks facilities and FSVP importers to resume onsite audits within a reasonable period of time once it becomes practicable to do so. The FDA also instructs facilities and importers to update their food safety plans and foreign supplier verification programs accordingly.