3-17-20 FDA Publishes Temporary COVID-19 Policy for FSMA Supplier Verification Onsite Audit Requirements

From: U.S. Food and Drug Administration
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To: Donna Schaffner, Food Innovation Center at Rutgers
Subject: FDA Publishes Temporary COVID-19 Policy for FSMA Supplier Verification Onsite Audit Requirements

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Today, the U.S. Food and Drug Administration issued guidance to communicate FDA's intention to temporarily not enforce supplier verification onsite audit requirements for receiving facilities and importers under the FDA Food Safety Modernization Act (FSMA) in response to the global pandemic of COVID-19. FDA does not intend to enforce the onsite audit requirements if other supplier verification methods are used instead.

Three of the regulations created to implement FSMA - the Preventive Controls for Human Food (PC Human Food) rule, Preventive Controls for Animal Food (PC Animal Food) rule, and Foreign Supplier Verification Programs (FSVP) rule– require receiving facilities and importers to conduct supplier verification activities based on the hazard analysis conducted as part of their written Food Safety Plan or FSVP. These verification activities generally include onsite audits, sampling and testing, or a review of food safety records.

Governments across the globe have instituted travel restrictions and advisories in an effort to curb the spread of the COVID-19 coronavirus. For example, the U.S. government issued a "Level 4 – Do Not Travel" advisory (the highest level) for China and on March 11 the government issued a "Level 3 – Reconsider Travel" advisory for global travel due to the pandemic, and some countries such as Italy instituted restrictions on internal travel. Following these travel advisories and restrictions may impact the ability of receiving facilities and FSVP importers to conduct or obtain onsite audits of their suppliers.

When receiving facilities and importers develop their Food Safety Plans or FSVP they sometimes determine onsite audits to be the most appropriate supplier verification activity. However, the travel restrictions and advisories associated with the novel coronavirus may make some audits temporarily impractical to conduct. Therefore, the guidance released today outlines the circumstances under which FDA does not intend to enforce the requirement to conduct or obtain an onsite audit of a food supplier when the food supplier is in a country or region covered by a government travel restriction or advisory related to COVID-19.

Specifically, FDA does not intend to enforce the requirement for an onsite audit in the following circumstances:

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1. A receiving facility or 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 FSVP;
2. 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;
3. Because of the 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; and
4. 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 FSVP to incorporate the alternative activity or activities. The alternative verification activity or activities are designed to provide temporary 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.

FDA anticipates that receiving facilities and FSVP importers will resume onsite audits within a reasonable period of time after it becomes practicable to do so, and update their food safety plans and FSVPs accordingly. FDA intends to provide timely notice before withdrawing this policy.

Additionally, the FDA plans to conduct a phone briefing to discuss the impacts of the COVID-19 public health emergency with the food industry later this week.

For More Information

- FDA COVID-19 Information