

April 22, 2020

FDA Issues Temporary Policy for Certain Requirements under the Accredited Third-Party Certification Program During COVID-19 Public Health Emergency

The U.S. Food and Drug Administration (FDA) is issuing a [guidance](#) to communicate its temporary policy regarding certain requirements under the FDA Food Safety Modernization Act (FSMA) [Accredited Third-Party Certification Program](#) for foreign food entities and their products. The guidance addresses the current challenges with conducting onsite monitoring activities during the COVID-19 public health emergency by providing temporary flexibility so that recognized accreditation bodies (ABs) can maintain the accreditations of certification bodies (CBs), and so that already-issued certifications need not lapse, where certain safeguards are in place.

Recognized ABs are required to monitor the CBs they accredit through a comprehensive assessment of their performance, which includes: a review of the CB's self-assessment; its regulatory audit reports; notifications submitted to the FDA; onsite observations of regulatory audits performed by the CB; and a visit to the CB's headquarters no later than one year after the initial date of accreditation and every two years thereafter for the duration of the CB's accreditation. While certain monitoring requirements can be done remotely, we recognize that it may be temporarily impractical to conduct onsite monitoring activities; therefore, in certain circumstances, the FDA does not intend to enforce the requirements for the onsite monitoring activities.

In addition, CB's accredited under the Accredited Third-Party Certification Program are responsible for conducting regulatory audits when certifying that eligible foreign entities are in compliance with the applicable food safety requirements of the Food, Drug, and Cosmetic Act and FDA regulations. These certifications can be used by importers for participation in the [Voluntary Qualified Importer Program](#), and for import certification when required. These certificates are issued for a term of up to 12 months, and issuing a recertification requires an accredited to CB conduct a new audit.

For certificates that have already been issued (and that therefore have an upcoming expiration date), the FDA understands that current travel restrictions and advisories related to COVID-19 may hinder the ability of accredited CBs to conduct the onsite regulatory audits needed to recertify the foreign entity. Therefore, for already-issued certificates, the agency does not intend to enforce the requirement that the accredited CBs issue the certificates for a term only up to 12 months, in certain circumstances. An accredited CB that has issued a certificate with an upcoming expiration date can contact FDA at FDAthirdpartyprogram@fda.hhs.gov to discuss the term of the current certificates.

For More Information:

- [Food Safety and COVID-19](#)
- [Guidance for Industry: Temporary Policy Regarding Accredited Third-Party Certification Program Onsite Observation and Certificate Duration Requirements During the COVID-19 Public Health Emergency](#)
- [Guidance for Industry: Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During COVID-19](#)
- [FDA to Temporarily Conduct Remote Importer Inspections Under FSVP Due to COVID-19](#)
- [Accredited Third-Party Certification Program](#)
- [Voluntary Qualified Importer Program](#)