Contains Nonbinding Recommendations

Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency: Guidance for Industry

Additional copies are available from:
Office of Food Safety HFS-300
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(Tel) 240-402-2166
or
Center for Veterinary Medicine HFV-200
Food and Drug Administration
7519 Standish Place
Rockville, MD 20855
(Tel) 240-402-6246
http://www.fda.gov/FoodGuidances

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments on the guidance to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket No. FDA-2020-D-1108.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine

Issued MARCH 2020
Updated JUNE 2020

This guidance is intended to remain in effect until November 7, 2023, unless superseded by a revised final guidance before that date. For further information, refer to 88 FR 15477, March 13, 2023.

TABLE OF CONTENTS

Contains Nonbinding Recommendations

Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID-19 Public Health Emergency: Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA, the Agency, or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The purpose of this guidance is to state the current intent of the Food and Drug Administration (FDA, we, or the Agency), in certain circumstances related to the impact of the coronavirus outbreak (COVID-19), not to enforce requirements in three foods regulations to conduct onsite audits of food suppliers if other supplier verification methods are used instead.

The three regulations are Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR part 117) ("part 117") [1], Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR part 507) ("part 507") [2], and Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (21 CFR part 1 subpart L) ("FSVP regulation") [3].

[1] For more information on part 117, including links to guidance that discusses the requirements mentioned in this document, see https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food.

[2] For more information on part 507, including links to guidance that discusses the requirements mentioned in this document, see https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-animal-food.

[3] For more information on the FSVP regulation, including links to guidance that discusses the requirements mentioned in this document, see https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals.

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). This guidance is immediately effective because FDA has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). The agency has made this determination because there are public health reasons for the immediate implementation of the guidance document; in particular, the guidance addresses exigent circumstances related to an ongoing public health threat.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

A. Onsite Audits under Part 117, Part 507, and the FSVP Regulation

This guidance concerns three regulations that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111–353)[4]: part 117, part 507, and the FSVP regulation.

Subparts A, B, and F of part 117 include current good manufacturing practice (CGMP) requirements for manufacturing, packing, or holding human food. Subparts A, C, D, E, F, and G of part 117 include requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d) to conduct a hazard analysis and implement risk-based preventive controls for human food (the human food preventive controls requirements). Subpart G of part 117 establishes requirements for a supply-chain program for those raw materials and other ingredients for which a receiving facility has identified a hazard requiring a supply-chain-applied control.

For domestic and foreign facilities that are required to register, subparts A, B, and F of part 507 include CGMP requirements for animal food, and subparts A, C, D, E, and F of part 507 include requirements to conduct a hazard analysis and implement risk-based preventive controls for animal food (the animal food preventive controls requirements). Subpart E of part 507 establishes requirements for a supply-chain program for those raw materials and other ingredients for which a receiving facility has identified a hazard requiring a supply-chain-applied control.

Under the FSVP regulation, FSVP importers are generally required to develop, maintain, and follow a foreign supplier verification program that provides adequate assurances that imported food meets applicable U.S. food safety standards. The applicable U.S. food safety standards vary depending on the product.

[4] For more information on the Agency's implementation of FSMA, see http://www.fda.gov/fsma.

An FSVP importer that is a receiving facility subject to section 418 of the FD&C Act is deemed to be in compliance with the requirements of the FSVP regulation, except the importer identification requirements in 21 CFR 1.509, if the FSVP importer has established and implemented a risk-based supply-chain program in compliance with 21 CFR part 117, subpart G or part 507, subpart E (21 CFR 1.502(c)(3)).

Part 117 defines a "receiving facility" as a facility that is subject to the human food preventive controls requirements and that manufactures/processes a raw material or other ingredient that it receives from a supplier. Part 117 defines a "supplier" as the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature. Part 117 defines a "supply-chain-applied control" as a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt. Part 507, subpart E, contains similar definitions for "receiving facility," "supplier," and "supply-chain-applied control" for animal food (21 CFR 507.3). The FSVP regulation applies to importers, some of which may be receiving facilities; it also contains similar definitions (21 CFR 1.500).

Among other things, subpart G in part 117 requires the receiving facility to establish and implement a written supply chain-program (21 CFR 117.405(a)-(b)) and approve suppliers for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control (21 CFR 117.415(a)(1)). The receiving facility (or a designee) also must determine and conduct appropriate supplier verification activities (21 CFR 117.425, 21 CFR 117.415(a)(3)(iii)). With some exceptions, one or more supplier verification activities (e.g., onsite audit, sampling and testing, review of food safety records) must be conducted for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter (21 CFR 117.430(a)).

Generally, when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death, the appropriate supplier verification activity is an onsite audit of the supplier, and it must be conducted before using the food and at least annually thereafter (21 CFR 117.430(b)(1)).

Subpart E of part 507 contains comparable supply-chain program requirements for animal food receiving facilities.

Similarly, the FSVP regulation requires importers to conduct a hazard analysis to determine whether there are any hazards that require a control (21 CFR 1.504) and, based on the hazard determine the appropriate type of verification activity as well as the frequency of conducting the activity. The foreign supplier verification activities must provide assurance that the hazards requiring a control in the imported food have been significantly minimized or prevented (21 CFR 1.506(c)). Importers must establish and follow written procedures to ensure they import food only from suppliers they have approved (21 CFR 1.506(a)(1)). Appropriate supplier verification activities may include onsite audits, sampling and testing of a food, and review of the foreign

supplier's relevant food safety records (21 CFR 1.506(d)(1)(ii)). When a hazard in a food is controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will cause serious adverse health consequences or death to humans or animals, the default verification activity is to conduct an annual onsite audit before initially importing the food from the supplier and at least annually thereafter (21 CFR 1.506(d)(2)). In addition, audits may be a verification activity selected by importers of certain dietary supplements, who must determine and document which verification activity or activities, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the foreign supplier is producing the food in accordance with processes and procedures that provide the same level of public health protection as those required under 21 CFR part 111 (21 CFR 1.511(c)(4)(i)-(ii)).

B. Coronavirus

In December 2019, a pneumonia of unknown cause in Wuhan, China was reported to the World Health Organization (WHO). The cause was determined to be a novel coronavirus (now designated as SARS-CoV-2), and the associated disease was labeled COVID-19. The virus spread and by January 30, 2020, the WHO declared a public health emergency of international concern[5] and on March 11, 2020, declared COVID-19 a pandemic[6]. 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, 2020 issued a "Level 3 – Reconsider Travel" advisory for global travel due to the outbreak;[7] and some countries such as Italy instituted restrictions on internal travel[8]. 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.

III. Discussion

FDA does not intend to enforce the requirement for an onsite audit in part 117, part 507, and the FSVP regulation in the following circumstances:

(1) A receiving facility or FSVP importer has determined that an onsite audit is the appropriate verification activity for an approved supplier,[9] as reflected by its written food safety plan or foreign supplier verification program;

---

[5] See generally, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen.
[6] See https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.
[7] See generally, https://travel.state.gov/content/travel/en/traveladvisories/ea/covid-19-information.html.
[8] See https://www.cnn.com/2020/03/09/europe/coronavirus-italy-lockdown-intl/index.html.
[9] This policy does not apply to unapproved suppliers, because Parts 117 and 507 and the FSVP regulation provide for the temporary use of unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use or importation. (See 21 CFR 117.420(b)(2); 21 CFR 507.120(b)(2); 21 CFR 1506(a)(1)).

(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) 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
(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[10] its food safety plan or foreign supplier verification program to incorporate the alternative activity or activities. The alternative verification activity(ies) 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.[11]

Receiving facilities and FSVP importers should resume onsite audits within a reasonable period of time after it becomes practicable to do so, and should update their food safety plans and foreign supplier verification programs accordingly.

FDA intends to provide timely notice about the withdrawal of this policy.

[10] Note that part 117 requires a food safety plan to be signed and dated upon any modification (21 CFR 117.310(b)); part 507 and the FSVP regulation contain similar provisions (21 CFR 507.206 and 21 CFR 1.510(a)(2), respectively).
[11] For importers of dietary supplements, the alternative verification activity(ies) should be designed, in consideration of the temporary unavailability of supplier onsite audits, to provide sufficient assurance that the foreign supplier is producing the dietary supplement in accordance with processes and procedures that provide the same level of public health protection as those required under 21 CFR part 111 during the period of onsite audit delay.