

# **Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions**

## **Guidance for Industry**

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the 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 number FDA-2021-D-0563, listed in the notice of availability published in the *Federal Register*.

For questions regarding this document, you may contact the FSMA Technical Assistance Network online at <https://www.fda.gov/food/guidanceregulation/fsma/ucm459719.htm>, by mail at Food and Drug Administration; 5001 Campus Drive; Wiley Building, HFS-009; Attn: FSMA Outreach; College Park, MD, 20740, or by phone at 1-888-SAFEFOOD (1-888-723-3366).

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

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## **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 document is to state that the Food and Drug Administration (FDA, we, or the Agency), at this time and based on our current understanding of the risks, does not intend to enforce certain regulatory requirements as they currently apply to certain entities and/or activities. The applicable requirements are established in our regulations entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals” (21 CFR Part 507); “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” (21 CFR Part 117); “Foreign Supplier Verification Programs for Importers of Food for Humans and Animals” (21 CFR Part 1, Subpart L (FSVP)); “Mitigation Strategies to Protect Food Against Intentional Adulteration” (21 CFR Part 121); and “Standards for Growing, Harvesting, Packing, or Holding of Produce for Human Consumption” (21 CFR Part 112).

Section II of this document describes certain enforcement discretion policies that were issued previously and are relevant to the enforcement policies discussed in sections III.B and III.C. Section III describes new or extended enforcement discretion policies. Section III.A describes our extension of FDA’s enforcement discretion in certain circumstances when a receiving facility that is a contract manufacturer/processor not in compliance with certain supply-chain program requirements for food manufactured for a brand owner. Section III.B describes that we do not intend to enforce requirements of the Intentional Adulteration regulation for facilities under the preexisting farm-activity related enforcement policy. Section III.B also announces that FDA

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does not intend to enforce the Intentional Adulteration regulation’s requirement for reanalysis in certain circumstances—for example, when there is a single failure that is addressed through implementation of corrective action procedures. Section III.C describes that FDA does not intend to enforce the supplier approval and verification requirements in part 117, part 507, and the FSVP regulation with regard to supplier compliance with requirements that are already associated with an enforcement discretion policy.

We are issuing this guidance consistent with our good guidance practices 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)), on the basis that the guidance presents a less burdensome policy that remains consistent with FDA’s public health mission. As with all guidance documents, the public can comment on the guidance at any time (21 CFR 10.115(g)(5)). If FDA receives comments on the guidance document, FDA will review those comments and revise the guidance document when appropriate (21 CFR 10.115(g)(3)(ii)).

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

In this guidance, pronouns such as “you” refer to entities that are covered by this guidance.

## **II. Background**

See Table 1 for information about the rulemakings to establish five regulations as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353) and for the abbreviations that we use in this document for these regulations. You can access the listed *Federal Register* publications and other information about these regulations from our FSMA website (<https://www.fda.gov/fsma>) and from the Docket No. (listed in Table 1) established for each rulemaking (available at <https://www.regulations.gov>).

Table 1. The Regulations That Are Relevant to This Guidance Document

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<b>Title and Regulatory Citation</b>	<b>Abbreviation Used in This Document</b>	<b>Docket No. and Key Publications in the <i>Federal Register</i><sup>1</sup></b>
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR part 507)	part 507	<ul style="list-style-type: none"> <li>• Docket No. FDA–2011–N–0922</li> <li>• Proposed rule: 78 FR 64736, October 29, 2013</li> <li>• Supplemental notice of proposed rulemaking: 79 FR 58476, September 29, 2014</li> <li>• Final rule: 80 FR 56170, September 17, 2015</li> <li>• Final rule; extension and clarification of compliance dates for certain provisions: 81 FR 57784, August 24, 2016</li> </ul>
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR part 117)	part 117	<ul style="list-style-type: none"> <li>• Docket No. FDA–2011–N–0920</li> <li>• Proposed rule: 78 FR 3646, January 16, 2013</li> <li>• Supplemental notice of proposed rulemaking: 79 FR 58524, September 29, 2014</li> <li>• Final rule: 80 FR 55908, September 17, 2015</li> <li>• Final rule; extension and clarification of compliance dates for certain provisions: 81 FR 57784, August 24, 2016</li> </ul>
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (21 CFR Part 1, Subpart L)	FSVP regulation	<ul style="list-style-type: none"> <li>• Docket No. FDA–2011–N–0143</li> <li>• Proposed rule: 78 FR 45730, July 29, 2013</li> <li>• Supplemental notice of proposed rulemaking: 79 FR 58574, September 29, 2014</li> <li>• Final rule: 80 FR 74226, November 27, 2015</li> <li>• Final rule; extension and clarification of compliance dates for certain provisions: 81 FR 57784, August 24, 2016</li> </ul>
Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR Part 121)	IA regulation or part 121	<ul style="list-style-type: none"> <li>• Docket No. FDA-2013-N-1425</li> <li>• Proposed rule: 78 FR 78014, December 24, 2013</li> <li>• Final rule: 81 FR 34166, May 27, 2016</li> </ul>
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (21 CFR part 112)	Produce Safety regulation or part 112	<ul style="list-style-type: none"> <li>• Docket No. FDA–2011–N–0921</li> <li>• Proposed rule: 78 FR 64736, October 29, 2013</li> <li>• Supplemental notice of proposed rulemaking: 79 FR 58434, September 29, 2014</li> <li>• Final rule: 80 FR 74354, November 27, 2015</li> <li>• Final rule; extension and clarification of compliance dates for certain provisions: 81 FR 57784, August 24, 2016</li> </ul>

Since issuing the regulations listed in Table 1, FDA has issued three enforcement policy guidances relevant to this guidance document that recognize that industry is still in the process of coming into compliance with a requirement or that FDA is considering options to address

<sup>1</sup> During each rulemaking listed in Table 1, we also issued several notices extending the comment period or announcing a public meeting to discuss the proposed rule. For the complete history of *Federal Register* publications associated with each rulemaking, see the applicable final rule.

concerns raised by stakeholders.<sup>2</sup> Below we identify and describe several enforcement discretion policies from those guidances that are relevant to the new enforcement discretion policies discussed later in this guidance in section III. The enforcement policies identified and described in sections II.A and II.B are unchanged.

## **A. Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds**

In a notice published in the *Federal Register* of March 28, 2019 (84 FR 11644), we announced the availability of a guidance for industry entitled “Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds: Guidance for Industry” (the produce commodity guidance) (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-enforcement-policy-entities-growing-harvesting-packing-or-holding-hops-wine-grapes>). The produce commodity guidance announced our intent not to enforce part 112 for entities growing, harvesting, packing, or holding almonds, hops, pulse crops, or wine grapes while we consider rulemaking to address the unique circumstances of these commodities.

## **B. Enforcement Policy for Certain Entities Subject to CGMP and Preventive Controls, Produce Safety, and/or FSVP Requirements**

In a notice published in the *Federal Register* of January 5, 2018 (83 FR 598), we announced the availability of a guidance for industry entitled “Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry” (the January 2018 enforcement policy guidance) (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-policy-regarding-certain-entities-subject-current-good-manufacturing-practice-and>). The January 2018 enforcement policy guidance announced our intent not to enforce certain requirements, as follows:

- Part 117 and/or part 507 as applied to specific facilities that conduct farm-related activities:
  - Facilities that would qualify as secondary activities farms except for the ownership of the facility;
  - Facilities that would qualify as farms if they did not color raw agricultural commodities (RACs);
  - Facilities that would qualify as secondary activities farms except that they pack, package, label, and/or hold processed food that consists only of RACs that have been dried/dehydrated to create a distinct commodity;
  - Farm mixed-type facilities making silage food for animals;

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<sup>2</sup> Those guidances are: (1) “Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds: Guidance for Industry,” (2) “Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs,” and (3) “Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food: Guidance for Industry,” all available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

- Written assurances requirements in the “customer provisions” in part 117, part 507, the Produce Safety regulation, and the FSVP regulation;
- FSVP requirements as applied to the importation of food contact substances; and
- Animal food preventive control requirements as applied to human food facilities, for certain human food by-products for use as animal food that are further manufactured/processed.

### **1. Specific facilities subject to part 117 and/or part 507 that conduct farm-related activities**

In the January 2018 enforcement policy guidance, we stated that to provide sufficient time to pursue rulemaking related to farm-related activities and other solutions to the concerns regarding the applicability of part 117 and part 507, we intended for the enforcement policy to remain in effect until the completion of the future rulemaking related to farm-related activities. Only certain facilities that conduct farm-related activities but are subject to part 117 and/or part 507 are covered by the January 2018 enforcement policy guidance; those entities are listed in the sub-bullets (arrows) above. Until we complete the rulemaking related to farm-related activities, we intend to exercise enforcement discretion regarding: (1) the part 117 and/or part 507 preventive controls requirements for the listed entities; (2) the part 507 current good manufacturing practice (CGMP) requirements for the listed entities that are subject to the part 507 CGMPs; or the part 117 CGMP requirements with regard to non-produce RACs for the listed entities. Note that as indicated in the January 2018 enforcement policy guidance, for human food CGMPs applicable to produce RACs, we intend to enforce the requirements per our usual policies.

### **2. Written assurances in the “customer provisions”<sup>3</sup> in part 117 and related rules**

In the January 2018 enforcement policy guidance, we explained that industry provided us with feedback indicating that certain distribution chains would require vastly more written assurances than FDA had anticipated. We stated that we intend to initiate a new rulemaking that takes into consideration complex supply chain relationships and resource requirements. Until the completion of such a rulemaking, we intend to exercise enforcement discretion regarding the requirements related to written assurances in part 117, part 507, the FSVP regulation section 1.507, and the Produce Safety regulation. The written assurance provisions are 21 CFR 117.136(a)(2)(ii), (3)(ii), and (4)(ii); 21 CFR 507.36(a)(2)(ii), (3)(ii), and (4)(ii); 21 CFR 1.507(a)(2)(ii), (3)(ii), and (4)(ii) (FSVP regulation); and 21 CFR 112.2(b)(3) (Produce Safety regulation).

### **3. Certain human food by-products for use as animal food**

In the January 2018 enforcement policy guidance, we explained that we would be considering the application of part 507 preventive controls requirements to certain manufacturing/processing activities conducted on human food by-products, after separation from the human food, for use as animal food (e.g., drying/dehydrating to reduce weight, bulk, or volume of the food). While we consider that issue, we intend to exercise enforcement discretion regarding the part 507 preventive controls requirements related to human food by-products if after separation from the human food the entities are performing one of a limited number of manufacturing/processing

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<sup>3</sup> The customer provisions of part 117, part 507, 21 CFR 1.507, and the Produce Safety regulation are listed in the January 2018 enforcement policy guidance at pp. 15-16.

activities identified in the January 2018 enforcement policy guidance.<sup>4</sup> This policy applies to human food facilities meeting the qualifications in 21 CFR 507.12(a)(1), including that their manufacturing/processing activities are conducted under CGMP requirements. A human food facility conducting the limited activities on human food by-products has the option to utilize either the part 117 or part 507 CGMP requirements.

### **III. Discussion**

As discussed below, we intend to extend the duration of the enforcement policy for supply-chain program requirements for co-manufacturers (section III.A), and we anticipate continuing this policy until such time as FDA's deliberations are complete, which may occur when a related rule is finalized. In addition, we intend to exercise enforcement discretion regarding the IA regulation for certain entities and activities (section III.B), and the supplier approval and verification requirements in part 117, part 507, and the FSVP regulation with regard to supplier compliance with requirements already associated with an enforcement discretion policy (section III.C).

#### **A. Extension of Enforcement Policy for Supply-Chain Program Requirements Applicable to Co-Manufacturers of Human Food and Animal Food**

As discussed in the co-manufacturer guidance (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-supply-chain-program-requirements-and-co-manufacturer-supplier-approval-and>), industry has expressed concerns that the supply-chain program requirements would require revisions to contracts between brand owners and their suppliers to allow brand owners to share certain information (e.g., audits of suppliers) with the brand owners' contract manufacturers/processors, and that establishing new contracts would take a significant period of time, impeding their ability to meet compliance dates. Therefore, FDA announced that under certain circumstances and on a temporary basis, we do not intend to take enforcement action regarding a receiving facility that is a contract manufacturer/processor, and that is not in compliance with certain supply-chain program requirements for food manufactured for the brand owner, until November 6, 2019.

In September 2019, industry submitted a request for an extension of the co-manufacturer enforcement discretion policy, contending that the supplier verification and approval challenges related to co-manufacturing cannot all be addressed by revising contracts, and suggesting that approaches utilized in other FSMA implementation contexts may be applied to find solutions to these challenges. (Refs. 1, 2). FDA has determined that it should continue to consider the additional practical challenges related to compliance with these provisions.<sup>5</sup>

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<sup>4</sup> Those activities are drying/dehydrating, evaporating, pressing, chopping and similar activities to reduce weight, bulk, or volume, and/or mixing, centrifuging, and similar activities to combine ingredients or separate components (e.g., water and solids), as long as these activities are not performed to prevent or significantly minimize animal food hazards and do not introduce animal food hazards.

<sup>5</sup> FDA issued a constituent update on November 6, 2019, that announced our intent to issue an extension of the enforcement discretion policy for certain supply-chain program requirements applicable to receiving facilities that are co-manufacturers, available at: [FDA Continues Enforcement Discretion Policy Relevant to Certain Co-Manufacturers under FSMA | FDA](#).



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As FDA's deliberations proceed, we do not intend to take enforcement action regarding certain supply-chain program requirements for food manufactured for the brand owner by a receiving facility that is a contract manufacturer/processor, as described in the co-manufacturer guidance and restated in this section. Specifically, we do not intend to take enforcement action regarding 21 CFR 117.410(d) and 117.415(a)(3), and 21 CFR 507.110(d) and 507.115(a)(3) in the circumstances described below for "Supplier Approval" and for "Supplier Verification." Furthermore, we do not intend to take enforcement action under the FSVP regulation regarding an importer who is relying on 21 CFR 1.502(c)(3) but whose supply-chain program is under an enforcement discretion policy regarding 21 CFR 117.410(d) and 117.415(a)(3) or 21 CFR 507.110(d) and 507.115(a)(3) in the circumstances described below for "Supplier Approval" and for "Supplier Verification." We anticipate continuing the enforcement policy until deliberations are complete, which may occur when a related rule is finalized.

For co-manufacturers under this policy that are also FSVP importers, we intend to enforce the importer identification requirements in 21 CFR 1.509 per our usual policies. Under 21 CFR 1.509(a), for each line entry of food product offered for importation into the United States, the importer must provide its name, electronic mail address, and unique facility identifier recognized as acceptable by FDA electronically when filing entry with U.S. Customs and Border Protection. For more information on the unique facility identifier, see FDA's guidance "Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation" (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-compliance-providing-acceptable-unique-facility-identifier-foreign-supplier>).

### Supplier Approval

As noted above, until its deliberations are complete, FDA does not intend to take enforcement action under the following circumstances: (1) a brand owner conducts supplier approval activities, (2) the co-manufacturer describes these activities in its food safety plan, and (3) the co-manufacturer conducts any necessary supplier approval activities not conducted by the brand owner. For example, FDA does not intend to take enforcement action when a brand owner (rather than the co-manufacturer) evaluates supplier performance as part of approving a supplier, the co-manufacturer's food safety plan states that the brand owner will consider supplier performance before a supplier is approved, and the co-manufacturer conducts any other necessary supplier approval activities (e.g., hazard analysis of the food). However, our usual enforcement policies apply with respect to the requirements that a co-manufacturer follow written procedures for receiving raw materials and other ingredients, and document use of the procedures (21 CFR 117.420 and 507.120).

### Supplier Verification

Until its deliberations are complete, FDA also does not intend to take enforcement action under the following circumstances: (1) a brand owner determines and/or conducts supplier verification activities for its co-manufacturer, (2) the co-manufacturer describes these activities in its food safety plan, and (3) the co-manufacturer conducts any necessary supplier verification activities not conducted by the brand owner. For example, FDA does not intend to take enforcement action when an audit is determined to be the appropriate supplier verification activity but a co-

manufacturer does not independently obtain a supplier audit or review the conclusions of a supplier audit obtained and reviewed by the brand owner, the co-manufacturer's food safety plan states that the brand owner will obtain and review audits of the supplier, and the co-manufacturer conducts any other necessary supplier verification activities (e.g., sampling and testing of the raw material or other ingredient).

## **B. Enforcement Policy for Certain Entities and Requirements Under the Mitigation Strategies to Protect Food<sup>6</sup> Against Intentional Adulteration Regulation**

FDA published the IA rule in the Federal Register of May 27, 2016. The IA regulation includes requirements for food defense measures against intentional adulteration and can be found in 21 CFR part 121. Specifically, the IA regulation requires covered facilities to identify significant vulnerabilities and implement mitigation strategies, including mitigation strategy management components and related activities, such as reanalysis, to establish a proactive and systematic food defense program to protect food from intentional adulteration intended to cause wide scale public health harm.

### **1. Enforcement policy for IA requirements for facilities covered by the January 2018 enforcement policy related to farm-related activities**

The IA regulation does not apply to activities of a farm that are subject to section 419 of the FD&C Act (Standards for Produce Safety) (21 CFR 121.5(d)). Therefore, a threshold question to determine whether the IA regulation applies to an entity is whether the entity is a "farm" as that term is defined in 21 CFR 1.227 of the section 415 registration regulation.

As mentioned in section II, we previously announced our intent to exercise enforcement discretion regarding part 117 for certain facilities that would qualify as farms except for some fact or circumstance discussed in the January 2018 enforcement policy guidance (e.g., facilities that would be farms except for ownership of the facility; facilities that would be farms if they did not color RACs). As explained above, we intend to pursue rulemaking and other solutions to the farm-related activity concerns that have been raised. This rulemaking could change the applicability of the intentional adulteration requirements to some entities that conduct farm-related activities. For example, a change to the "farm" definition could change the status of an entity from a facility required to register to a farm, and consequently change its status under the IA regulation from covered to exempt.

While we pursue the rulemaking and other solutions to address concerns related to facilities that conduct farm-related activities, FDA does not intend to enforce the requirements of the IA regulation for those facilities that are under the farm-activity related enforcement policy described in the January 2018 enforcement policy guidance.

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<sup>6</sup> The IA regulation does not apply to the manufacturing, processing, packing, or holding of food for animals other than man.

## **2. Enforcement policy with regard to the requirement for reanalysis in 21 CFR 121.157(b)(3)**

The IA regulation requires reanalysis of the food defense plan (FDP) in certain circumstances, including whenever a mitigation strategy, a combination of mitigation strategies, or the FDP as a whole is not properly implemented (21 CFR 121.157(b)(3)). Improper implementation of mitigation strategies is also addressed by taking food defense corrective actions. Specifically, covered entities are required to establish and implement written food defense corrective actions procedures that must be taken if mitigation strategies are not properly implemented (21 CFR 121.145(a)(1)). The corrective actions procedures must describe the steps to be taken to ensure that: (1) appropriate action is taken to identify and correct a problem that has occurred with implementation of a mitigation strategy; and, (2) appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur (21 CFR 121.145(a)(2)).

In light of the requirement to take corrective actions to address an implementation failure, in certain circumstances, FDA does not intend to enforce the requirement for a reanalysis of all or part of the FDP. Specifically, FDA does not intend to enforce the requirement for reanalysis in 21 CFR 121.157(b)(3) when improper implementation of a mitigation strategy or combination of mitigation strategies is addressed through implementation of corrective actions procedures that correct the problem and reduce the likelihood of recurrence.

For example, an FDP provides that a mitigation strategy for a bulk liquid storage tank is to use a lock to secure the access hatch when unattended or not in use. A monthly food defense verification review of monitoring records indicates that the mitigation strategy was not properly implemented once during the month (i.e., the hatch on the liquid storage tank was left unlocked). Corrective actions records indicate that the cause of the problem was employees working at the tank not locking the access hatch after filling the tank. Corrective actions records also indicate that the problem was corrected by relocking the lock and retraining the employees and the supervisors working at this actionable process step. FDA does not intend to enforce the requirement for reanalysis under this circumstance.

The next month, a verification review of food defense monitoring and corrective actions records shows that the lock was still not consistently being placed on the access hatch to the storage tank (i.e., the hatch on the tank was left unlocked on multiple days). Now it is clear that the corrective actions procedures are not sufficiently reducing the likelihood of recurrence. In this situation, FDA intends to apply its usual enforcement policies with respect to the requirement that the facility perform a reanalysis of the mitigation strategy. As a result, the facility might determine that a new mitigation strategy is needed (e.g., restrict access to the bulk liquid storage tank to authorized personnel).

FDA also intends to enforce, per its usual policies, the requirement in 21 CFR 121.157(b)(3) to conduct a reanalysis when the FDP as a whole is not properly implemented. For example, a facility identifies background checks as a mitigation strategy to be used in combination with other mitigation strategies for all actionable process steps within the facility. The monitoring procedure is to assess whether the checks were completed prior to assigning the employee to an actionable process step. The corrective actions procedure is to conduct the check prior to

assigning the employee to an actionable process step if the check has not yet been conducted and to reassign an employee who has been assigned to an actionable process step without a background check. A manager discovers that there are no monitoring or corrective actions records for the background checks and determines the background check program was never implemented. Further, the manager determines it is no longer feasible to implement the program. In this example, FDA intends to enforce the requirement that the entire FDP be reanalyzed per its usual policies, because the mitigation strategies at each actionable process step were determined to be adequate based on the inclusion of background checks which were not conducted. Without the implementation of background checks, the mitigation strategies may not be adequately minimizing or preventing the significant vulnerabilities at each actionable process step.

### **C. Enforcement Policy for Supplier Approval and Verification Requirements in Part 117, Part 507, and the FSVP Regulation**

Among other things, the rulemaking to establish part 117 amended our current good manufacturing practice regulation for manufacturing, packing, or holding human food to modernize it and establish it in new part 117, primarily in subpart B, with associated requirements in subparts A and F (the human food CGMP requirements). Part 117 also includes new requirements for domestic and foreign facilities that are required to register under section 415 to establish and implement hazard analysis and risk-based preventive controls for human food (the human food preventive controls requirements). The human food preventive controls requirements are primarily in subparts C and G, with associated requirements in subparts A, D, E, and F. Specifically, 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. In certain circumstances FDA's supply-chain program provisions require a facility to conduct supplier approval and verification activities to provide assurance that raw materials and other ingredients were produced in compliance with a FSMA regulation, such as part 117 or the Produce Safety regulation.

The rulemaking to establish part 507 included new requirements for CGMPs for food for animals, primarily in subpart B, with associated requirements in subparts A and F (the animal food CGMP requirements) and requirements for hazard analysis and risk-based preventive controls for food for animals, primarily in subparts C and E, with associated requirements in subparts A, D, E, and F (the animal food preventive controls requirements). Specifically, 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. In certain circumstances FDA's supply-chain program provisions require a receiving facility to conduct supplier verification activities.

The FSVP regulation requires importers to develop, maintain, and follow an FSVP that, among other things, provides adequate assurance that foreign suppliers are producing food in compliance with processes and procedures that provide at least the same level of public health protection as those required under the Produce Safety regulation, part 117, or part 507, as

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applicable, and that the food is not adulterated or misbranded with respect to allergens.<sup>7</sup> In certain circumstances FDA's FSVP provisions require an importer to conduct supplier approval and verification activities to provide this assurance.

As described above in sections II and III, FDA has stated it does not intend to take enforcement action regarding certain regulatory requirements under the Produce Safety regulation, part 117, and part 507. When FDA does not intend to take enforcement action regarding a provision in one of those regulations for a particular entity, we also do not intend to take enforcement action regarding the requirement for an importer or receiving facility to verify the entity's compliance with that provision. Stated differently, FDA intends for its enforcement discretion policy to extend to any requirement (under FSVP or the preventive controls supply-chain program requirements) for an importer or receiving facility to verify a supplier's compliance with a FSMA requirement which itself is associated with an enforcement discretion policy. For example, we do not intend to take enforcement action regarding the requirement for an FSVP importer of pulse crops to verify that the pulse crop grower produced the crop in compliance with the Produce Safety regulation, because FDA has stated its intent to exercise enforcement discretion regarding the requirements of the Produce Safety regulation for entities growing pulse crops.

The enforcement discretion policy for importers and receiving facilities is intended to cover the period during which the underlying enforcement discretion policy for the supplier applies. That is, when FDA intends to exercise enforcement discretion regarding a supplier's compliance with the Produce Safety regulation, part 117, or part 507, FDA also intends to exercise enforcement discretion regarding the importer's or receiving facility's obligation to verify the supplier's compliance with those provisions.

Importantly, this enforcement discretion policy does not apply to all supplier verification requirements under FSVP or the supply-chain program requirements. An FSVP importer must develop an FSVP that complies with applicable FSVP requirements, and FDA's usual enforcement policies apply for FSVP requirements that are not associated with an enforcement discretion policy. As stated above, the importer's FSVP must ensure that the foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under the Produce Safety regulation, part 117, or part 507, as applicable, and that the food meets the requirements of sections 402 (regarding adulteration) and 403(w) (if applicable, regarding misbranding of human food with respect to labeling for the presence of major food allergens) of the FD&C Act. Consequently, even though FDA does not intend to enforce the FSVP importer's obligation to verify a supplier's compliance with Produce Safety, part 117, or part 507 requirements when an enforcement discretion policy applies for the supplier's compliance with those provisions, FDA intends to enforce the requirements, per its usual policies, for an FSVP importer to develop and follow an FSVP that will ensure that the food imported from that foreign supplier is not adulterated or misbranded with respect to allergen labeling.

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<sup>7</sup> Allergen-related requirements are not applicable to animal food. See comment/response 259 in the part 507 rule preamble, 80 FR 56170 at 56244 (Sept. 17, 2015).

## **IV. References**

1. Request for Extension from Grocery Manufacturers Association to FDA Docket FDA-2017-D-5996.
2. Comment from Grocery Manufacturers Association to FDA Docket FDA-2017-D-5996.