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

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-2017-N-6908 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).

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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 the intent of the Food and Drug Administration (FDA, we, or the Agency) not 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 Human Food" (21 CFR part 117); "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" (21 CFR part 507); "Standards for Growing, Harvesting, Packing, or Holding of Produce for Human Consumption" (21 CFR Part 112); and "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (21 CFR Part 1, Subpart L).

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)).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's 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 Agency guidances 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 four 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 (i.e., part 117, part 507, the produce safety regulation, and the FSVP regulation). 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

Title and Regulatory Citation	Abbreviation Used in This Document	Docket No. and Key Publications in the *Federal Register*[1]
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR part 117)	part 117	• Docket No. FDA–2011–N–0920 • Proposed rule: 78 FR 3646, January 16, 2013 • Supplemental notice of proposed rulemaking: 79 FR 58524, September 29, 2014 • Final rule: 80 FR 55908, September 17, 2015 • Final rule; extension and clarification of compliance dates for certain provisions: 81 FR 57784, August 24, 2016
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR part 507)	part 507	• Docket No. FDA–2011–N–0922 • Proposed rule: 78 FR 64736, October 29, 2013 • Supplemental notice of proposed rulemaking: 79 FR 58476, September 29, 2014 • Final rule: 80 FR 56170, September 17, 2015 • Final rule; extension and clarification of compliance dates for certain provisions: 81 FR 57784, August 24, 2016
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (21 CFR part 112)	produce safety regulation or part 112	• Docket No. FDA–2011–N–0921 • Proposed rule: 78 FR 64736, October 29, 2013 • Supplemental notice of proposed rulemaking: 79 FR 58434, September 29, 2014 • Final rule: 80 FR 74354, November 27, 2015 • Final rule; extension and clarification of compliance dates for certain provisions: 81 FR 57784, August 24, 2016
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (21 CFR Part 1, Subpart L)	FSVP regulation	• Docket No. FDA–2011–N–0143 • Proposed rule: 78 FR 45730, July 29, 2013 • Supplemental notice of proposed rulemaking: 79 FR 58574, September 29, 2014 • Final rule: 80 FR 74226, November 27, 2015 • Final rule; extension and clarification of compliance dates for certain provisions: 81 FR 57784, August 24, 2016

[1] 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.

In a final rule published in the *Federal Register* of August 24, 2016 (81 FR 57784; the "compliance date final rule"), we extended the compliance dates for certain provisions in the four FSMA rules listed in the table above, to address concerns about the practicality of compliance, consider changes to the regulatory text, and better align compliance dates across the rules (81 FR 57784). As relevant to this guidance, we extended the compliance dates for:

- Specific facilities subject to part 117 and/or part 507:
    - Facilities solely engaged in packing and/or holding produce raw agricultural commodities (RACs) and/or nut hulls and shells that are used in animal food;
    - 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 RACs under part 117;
    - Facilities solely engaged in the ginning of cotton under part 507;
- Written assurances under the "customer provisions" in part 117 and related rules; and
- Importation of food contact substances under the FSVP regulation.

As discussed more fully below, we intend to exercise enforcement discretion with regard to these facilities or requirements. In addition, since the compliance date final rule we have become aware of additional circumstances in which we now intend to exercise enforcement discretion. Those are also described fully below.

In this document we use the term "facility" to refer to a facility required to register under the section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d) registration requirements. A facility that is currently required to register must still do so, regardless of whether the facility is covered by the enforcement policy that applies to the preventive controls requirements, the CGMP requirements, or both. In addition, we use the phrase "farm-related activities" to refer to activities included within the "farm" definition if performed by a farm. Farm-related activities include manufacturing/processing activities allowed within the "farm" definition (e.g., drying/dehydrating RACs to create a distinct commodity, treating RACs to manipulate ripening, and packaging and labeling RACs and RACs that have been dried/dehydrated to create a distinct commodity or treated to manipulate ripening). Finally, we use the term "farm mixed-type facility" to refer to an establishment that is a farm but also conducts activities outside the "farm" definition that require the establishment to be registered under section 415.

III. Discussion

A. Enforcement Policy for Specific Facilities Subject to Part 117 and/or Part 507

1. General

a. Rulemakings to establish part 117, part 507, and revise the "farm" definition

Among other things, the rulemaking to establish part 117 amended our CGMP 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. In the preamble of the final rule establishing part 117, we stated that the rule is effective November 16, 2015, and provided for compliance dates of 1 to 3 years from the date of publication in most cases (see Table 53 in the preamble of the final rule establishing part 117, 80 FR 55908 at 56128).

The rulemaking to establish part 117 also amended the "farm" definition in our regulations implementing section 415 of the FD&C Act (the section 415 registration regulations are at 21 CFR part 1, subpart H). The purpose of the amendment was to clarify the scope of the exemption from registration requirements provided for "farms" and, in so doing, to clarify which human food establishments are subject to the human food preventive controls requirements, and which human food establishments are exempt from those requirements because they are "farms." The "farm" definition also impacts the applicability of the CGMP requirements because farms are exempt from CGMPs (21 CFR 117.5(k)(i)).

The rulemaking to establish part 507 included new requirements for CGMPs, 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). The part 507 requirements apply to domestic and foreign facilities that are required to register under the section 415 registration regulation. Thus, the "farm" definition that we amended as part of the rulemaking to establish part 117 also clarifies which animal food establishments are subject to the part 507 requirements, and which animal food establishments are exempt from those requirements because they are "farms." In the preamble of the final rule establishing part 507, we stated that the rule is effective November 16, 2015 (80 FR 56170). We provided for compliance dates of 1 to 3 years from the date of publication in most cases for compliance with the CGMP requirements, with an additional year beyond that for compliance with the animal food preventive controls requirements.

b. Why the enforcement policy is needed

As discussed in more detail below, a threshold question to determine whether and how the regulatory framework provided by parts 117 and 507 applies to an entity is whether the entity is a "farm" as that term is defined in § 1.227 of the section 415 registration regulation. Feedback from regulated entities has raised complex questions about factors, such as farm-related activities and farm ownership, that impact the determination of whether an entity is a "farm." In addition, we have previously stated our belief that certain activities conducted on produce RACs are similar regardless of where they happen and that an off-farm packinghouse that is subject to the human food preventive controls requirements in part 117 will be able to draw from the provisions of the produce safety regulation in developing its food safety plan and establishing preventive control management components that are appropriate in light of the nature of the preventive controls and their role in the facilities' food safety system. Feedback from regulated entities has emphasized the need for additional regulatory guidance or changes to the regulatory text to enable this goal to be achieved. In the compliance date final rule, we described these and other questions and extended compliance dates for requirements in part 117 and part 507 as they apply to certain facilities and activities, to consider changes to the regulatory text and better align compliance dates across the regulations.

FDA intends to initiate a rulemaking that could change the applicability of the preventive controls and CGMP requirements to some entities that conduct farm-related activities. In the remainder of this guidance, we refer to this rulemaking as the "future rulemaking related to farm 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. Under the current regulatory framework, a farm is not subject to the preventive controls or CGMP requirements but may be subject to the produce safety regulation, depending on the food and activities involved. We do not anticipate that changes to the regulatory text would result in an entity that currently is a "farm" becoming subject to the preventive controls or CGMP requirements for human or animal food.

To provide sufficient time to pursue the future rulemaking related to farm activities and other solutions to the concerns regarding the applicability of parts 117 and 507, we intend to exercise enforcement discretion with regard to the preventive controls requirements (and, in some cases, the CGMP requirements) of parts 117 and 507 for the facilities identified in sections III.A.2 through III.A.5 of this guidance until completion of the future rulemaking related to farm activities. In sections III.A.2 through III.A.5, we describe the facilities, the activities that they conduct, and the specific regulatory requirements for which the enforcement policy for specific facilities subject to part 117 and/or part 507 applies. If we adopt any approaches to the concerns described in the document that do not require rulemaking, we may announce those approaches, and any timeframe for compliance with the applicable requirements, via a communication other than the future rulemaking related to farm activities, such as a guidance document.

Regardless of our intent to exercise enforcement discretion, the statutory prohibition against the introduction or delivery for introduction into interstate commerce of adulterated food (section 301(a) of the FD&C Act (21 U.S.C. 331(a)) applies. For example, under section 402(a)(4) of the FD&C Act (21 U.S.C. 342(a)(4)), a food shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

c. The enforcement policy applies to facilities and mixed-type facilities

The enforcement policy for part 117 and/or part 507 applies to facilities and farm mixed-type facilities. For example, an operation that is devoted to holding and packing RACs but is not a secondary activities farm because it does not meet the ownership requirement is a facility addressed in section III.A.2. An operation that grows and harvest oranges but also colors them is a farm mixed-type facility that would be entirely a farm if it did not color RACs and is a facility addressed in section III.A.3.

Farm mixed-type facilities that engage in manufacturing/processing activities not within the "farm" definition and not addressed in this guidance remain subject to the compliance dates listed in Table 53 of the final rule establishing part 117 (for human food) (80 FR 55908 at 56128) and the compliance dates listed in Table 32 of the final rule establishing part 507 (for animal food) (80 FR 56170 at 56329) for those activities that require the entity to register.

d. The enforcement policy applies to associated requirements

The enforcement policy in this guidance for the primary subparts for CGMP and preventive controls requirements also applies to the associated subparts. Thus, when we state our intent to exercise enforcement discretion with regard to the preventive controls requirements, that intent also applies to the associated requirements. Likewise, when we state our intent to exercise enforcement discretion with regard to the CGMP requirements, that intent also applies to the associated requirements. For example, the requirements in § 117.4(b)(2) in part 117, subpart A, and in § 507.4(b)(2) in part 507, subpart A to ensure that all individuals who manufacture, process, pack, or hold human or animal food receive training in the principles of food hygiene and food safety are part of the CGMP requirements in parts 117 and 507. We intend to exercise enforcement discretion with regard to these training requirements in part 117 or part 507 in those circumstances where we state our intent to exercise enforcement discretion with regard to the CGMP requirements of part 117 or part 507, respectively.

e. The enforcement policy applies even if a facility is subject to two categories

Section III.A. describes four categories of facilities that are subject to FDA's enforcement policy for parts 117 and 507. A facility might not be included in the enforcement policy if each category is considered alone but may qualify if two or more of the categories are considered together. For example, FDA intends to exercise enforcement discretion for a human food facility that packs, colors, and holds RACs and that would fail to be a secondary activities farm both because it does not meet the ownership requirement (section III.A.2) and because it colors RACs (section III.A.3).

f. Application of the enforcement policy to preventive controls and CGMP requirements

The enforcement policy for part 117 and part 507 applies to all human and animal food preventive controls requirements, all animal food CGMP requirements, and to human food CGMP requirements for non-produce RACs. The enforcement policy for human food CGMPs

does not include activities conducted on produce RACs, many of which have long been subject to CGMP requirements in part 110. To the extent the activities on produce RACs were exempt from part 110 under § 110.19, they continue to be exempt under § 117.5(k). Further, unlike non-produce RACs, produce RACs on farms are subject to part 112. Note that some off-farm produce packinghouses and warehouses that will continue to be subject to human food CGMPs have the option to comply with the human food CGMP requirements or with the applicable requirements for packing and holding in the produce safety regulation (see § 117.8).

g. Facilities that currently are exempt from preventive controls requirements or CGMP requirements will continue to be exempt from those requirements

Some facilities currently are exempt from the preventive controls or CGMP requirements or both. Exemptions from the regulations are codified in 21 CFR 117.5 and 507.5. The enforcement policy in this guidance does not affect those exemptions. For example, establishments solely engaged in the holding and/or transportation of one or more RACs and establishments solely engaged in hulling, shelling, drying, packing and/or holding nuts are exempt from CGMPs (21 CFR 117.5(k)(iii) and (v), 21 CFR 507.5(h)(1) and (2)).

h. Summary of the enforcement policy for specific facilities subject to part 117 and/or part 507

Tables 2 and 3 summarize the enforcement policy in section III.A as it relates to human and animal food, respectively. For a complete description of the enforcement policy, see the discussions in sections III.A.2 through III.A.5.

Table 2. Summary of the Enforcement Policy With Regard to Human Food

Section	Description of Facilities and Activities Conducted by the Facilities	Does Enforcement Discretion Apply for Human Food Preventive Controls Requirements?	Does Enforcement Discretion Apply for Human Food CGMPs?
III.A.2	Facilities That Would Qualify as Secondary Activities Farms Except for the Ownership of the Facility	Yes	• No, for farm-related activities conducted on produce RACs. • Yes, for farm-related activities conducted on non-produce RACs.
III.A.3	Facilities That Would Qualify as Farms If They Did Not Color RACs	Yes	• No, for coloring produce RACs. • Yes, for coloring non-produce RACs.
III.A.4	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	Yes	• No, for produce RACs. • Yes, for non-produce RACs.

Table 3. Summary of the Enforcement Policy With Regard to Animal Food

Section	Description of Facilities and Activities Conducted by the Facilities	Does Enforcement Discretion Apply for Animal Food Preventive Controls Requirements?	Does Enforcement Discretion Apply for Animal Food CGMPs?
III.A.2	Facilities That Would Qualify as Secondary Activities Farms Except for the Ownership of the Facility	Yes	Yes
III.A.3	Facilities That Would Qualify as Farms If They Did Not Color RACs	Yes	Yes
III.A.4	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	Yes	Yes
III.A.5	Farm Mixed-Type Facilities Making Silage Food for Animals	• N/A for small and very small businesses (because they are exempt from animal food preventive controls requirements under § 507.5(f)(4)) • Yes, for businesses that are not small or very small.	Yes

2. Facilities that Would Qualify as Secondary Activities Farms Except for the Ownership of the Facility

Part 117 and Part 507

The rulemaking to establish part 117 created a "secondary activities farm" definition within the "farm" definition (in 21 CFR 1.227) to cover certain operations that are not located on a primary production farm but are sufficiently related to a primary production farm so that it is appropriate to consider the operations to be farms. (See Response 25, 80 FR 55908 at 55928 to 55929.) A secondary activities farm is devoted to harvesting, packing, and/or holding of RACs (such as produce, grains, and eggs) and may also conduct those additional activities allowed on a primary production farm (i.e., farm-related activities). Further, a secondary activities farm must be majority-owned (singly or jointly) by the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm (§ 1.227).

In the compliance date final rule, we explained that we had received multiple questions on whether certain operations would qualify as secondary activities farms as defined in § 1.227. These questions described a variety of business structures that may satisfy our intent with the final rule to require a close relationship between primary and secondary activities farms, but the business structures did not meet the ownership requirement as codified in the "farm" definition. In the compliance date final rule, we extended the compliance dates for facilities that would

qualify as secondary activities farms except for the ownership of the facility but limited to extension to circumstances where the operation was under common ownership with the primary production farm(s) that grew, harvested, and/or raised the majority of the RACs harvested, packed, and/or held by the operation. (See Table 3, 81 FR 57784 at 57790.)

To provide sufficient time to pursue the future rulemaking related to farm activities and other solutions to address these questions about ownership of secondary activities farms, we intend to exercise enforcement discretion for facilities that would be secondary activities farms except for the ownership of the facility. In contrast to the compliance date final rule, our intent to exercise enforcement discretion is not contingent upon an operation being under common ownership with the primary production farm(s) that grew, harvested, and/or raised the majority of the RACs harvested, packed, and/or held by the operation. As explained in section III.A.1.f, we intend to exercise enforcement discretion for this category for all of the human and animal food preventive controls requirements, all animal food CGMP requirements, and for human food CGMP requirements for non-produce RACs.

Because of the change regarding ownership, some of the facilities identified separately in the compliance date final rule are now included in this category. Specifically, because our intent to exercise enforcement discretion applies to any operation (not located on a primary production farm) that is dedicated to harvesting, packing, and/or holding RACs, it applies to facilities solely engaged in packing and/or holding activities on produce RACs and/or nut hulls and shells. For similar reasons, it applies to facilities solely engaged in the ginning of cotton. Listed below are examples of the types of facilities likely to fit within this category:

- Facilities engaged in farm-related activities on produce RACs (e.g., produce packinghouses and warehouses)
- Facilities engaged in farm-related activities on non-produce RACs (e.g., egg packinghouses and grain elevators)
- Facilitates engaged in nut hulling/shelling operations
- Facilitates engaged in the ginning of cotton; and
- Facilities engaged in conditioning seed for cultivation that solely pack and hold seed for use in animal food

3. Facilities that Would Qualify as Farms If They Did Not Color RACs

a. Part 117

The definition of RAC in section 201(r) of the FD&C Act includes "fruits that are … colored … in their unpeeled natural form prior to marketing." (21 U.S.C. 321(r)). As discussed in the compliance date final rule (81 FR 57784 at 57791-57792), we previously described coloring a RAC as an example of an activity that is manufacturing/processing but does not transform a RAC into a processed food (78 FR 3646 at 3678 to 3679, January 16, 2013). Generally, an establishment that conducts manufacturing/processing activities other than those specified as being within the "farm" definition is a facility that is required to register and is subject to the preventive controls requirements.

Unlike treating RACs to manipulate ripening and packaging and labeling RACs, we did not include coloring RACs as a manufacturing/processing activity within the "farm" definition. Therefore, coloring a RAC intended for use in human food brings an operation outside the "farm" definition and triggers the requirements for human food preventive controls and CGMPs (except where other exemptions apply). In the compliance date final rule, we extended the compliance dates for facilities that would be farms if they did not color RACs for use in human food. (See Table 4, 81 FR 57784 at 57791.)

To provide sufficient time to pursue the future rulemaking related to farm activities and other solutions that fully consider whether and how coloring RACs could be within the "farm" definition, we intend to exercise enforcement discretion for this category with regard to all of the human food preventive controls requirements; as well as the human food CGMP requirements for activities conducted on non-produce RACs.

b. Part 507

Some facilities that would be farms if they did not color RACs generate by-product for use as animal food as a result of their coloring operations. Some of these facilities simply pack and hold the by-product for distribution, while other facilities may further manufacture/process the by-product for use as animal food. These packing, holding, and manufacturing/processing activities are subject to part 507, unless an exemption applies. To provide sufficient time to pursue the future rulemaking related to farm activities and other solutions to fully consider whether and how coloring RACs could be within the "farm" definition, we intend to exercise enforcement discretion with regard to the animal food preventive controls and CGMP requirements for facilities that would be farms if they did not color RACs and that generate by-product for use as animal food as a result of their coloring operations.

4. 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

a. Part 117

The "farm" definition provides for a farm to dry/dehydrate RACs to create a distinct commodity. Further, it provides for a farm to pack, package, label, and/or hold the processed food (e.g., raisins, dried herbs) resulting from the drying/dehydrating. An operation that solely packs, packages, labels, and/or holds dried/dehydrated RACs that have become a distinct commodity cannot be a primary production farm because it is not devoted to growing or harvesting RACs. Further, such an operation cannot be a secondary activities farm because it is not devoted to harvesting, packing, and/or holding RACs, since the dried/dehydrated RACs are processed food. Thus, even though it is solely engaged in farm-related activities, such an operation does not meet the definition of a farm.

In addition, since issuing the final rules establishing part 117 and the produce safety regulation, our Technical Assistance Network (TAN) has received questions seeking clarification on

whether dried "beans"[1] are considered produce RACs. In the preamble to the final rule establishing the produce safety regulation, we stated that dried beans are a processed food (i.e., a distinct commodity). In addition, in §117.5(g)(2)(i) we referred to "dried legumes" as a processed food product for the purposes of the exemptions in §§ 117.5 (g)(3) and (h)(3) for specific low-risk packing/holding manufacturing/processing activity/food combinations conducted by small and very small on-farm businesses. However, in a previous *Federal Register* notice of policy interpretation entitled "Legal and Policy Interpretation of the Jurisdiction Under the Federal Food, Drug, and Cosmetic Act of the Food and Drug Administration and the Environmental Protection Agency Over the Use of Certain Antimicrobial Substances," beans were included within a group of commodities (i.e., hay, nuts, rice, beans, corn, other grasses, legumes, and grains) that remain RACs even though they may have undergone some drying (63 FR 54532 at 54542, October 9, 1998).

To provide sufficient time to pursue the future rulemaking related to farm activities and to further consider the status of dried beans (which currently are considered a processed food), we intend to exercise enforcement discretion with regard to all of the human food preventive controls requirements for facilities that would qualify as secondary activities farms except that they pack, package, label, and/or hold processed food that consists only of dried/dehydrated RACs that have become a distinct commodity until completion of the future rulemaking related to farm activities. In addition, we intend to exercise enforcement discretion for those facilities with regard to the human food CGMP requirements for non-produce RACs.

b. Part 507

Some facilities that would be 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 may provide the commodity (e.g., dried beans) for use as animal food or generate by-product for use as animal food as a result of their operations. Some of these facilities simply pack and hold the by-product for distribution, while other facilities may further manufacture/process the by-product for use as animal food. These packing, holding, and manufacturing/processing activities are subject to part 507, unless an exemption applies. While we are pursuing the future rulemaking related to farm activities and resolving the inconsistency relating to dried beans, we intend to exercise enforcement discretion with regard to the animal food preventive controls and CGMP requirements for facilities that would qualify as secondary activities farms if they did not pack, package, label, and/or hold processed food that consists only of dried/dehydrated RACs that have become a distinct commodity, and that generate by-product for use as animal food, until completion of the future rulemaking related to farm activities.

[1] In the produce safety regulation, we classify several types of "beans" as produce. Examples of beans that the produce safety regulation classifies as produce are black beans, cowpea beans (also called black-eyed peas), great northern beans, kidney beans, lima beans, navy beans, pinto beans. (See §§ 112.1(b)(1), 112.2(a)(1), and the definition of produce in § 112.3.) The produce safety regulation classifies soybeans as a food grain. (See the definition of "produce" in § 112.3.)

5. Farm Mixed-Type Facilities Making Silage Food for Animals

Part 507

Silage is food for animals made by storing and fermenting green forage plants (e.g., corn stalks, bean plants, grass), sometimes in a silo. Silage is primarily made on a farm following harvest. When a farm makes silage and the silage is consumed on that farm or another farm under the same management, the farm is exempt from part 507. If the silage enters commerce (e.g., is donated or sold to another farm or animal food manufacturer), the silage-making farm becomes a mixed-type facility (see section III.A.1.c). Mixed-type facilities are required to register under section 415 of the FD&C Act and are subject to part 507 for the animal food activities that require registration.

A farm that is a mixed-type facility and also a small or very small business is exempt from the animal food preventive controls requirements if the farm's only manufacturing/processing activities fall into specific low-risk manufacturing/processing activity/animal food combinations. See § 507.5(f). Ensiling, including making silage, is an activity that is exempt from the animal food preventive controls requirements when conducted on-farm by a small or very small farm mixed-type facility (§ 507.5(f)(4)). This exemption is based on our determination that making silage for animal food is a low-risk manufacturing/processing activity/animal food combination. A farm mixed-type facility making silage for distribution in commerce is subject to the CGMP requirements of part 507.

We have received feedback through the TAN from farmers that they consider making silage to be an extension of harvesting and that FDA should consider making silage to be a "harvesting" activity. The harvesting definition includes "cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g. foliage, husks, roots or stems)" (§ 507.3). For animals, the crop plant, foliage, husks, roots, and stems are also edible. When these parts of the plant are used for silage, they are cut and trimmed in the field during harvesting.

To provide sufficient time to pursue the future rulemaking related to farm activities and other solutions that fully consider whether and how making silage could be within the "harvesting" definition, we intend to exercise enforcement discretion with regard to the animal food CGMP requirements for a farm that is a mixed-type facility only because it is making silage that enters commerce (i.e., is not fed on the farm or another farm under the same management) until completion of the future rulemaking related to farm activities. A farm mixed-type facility that is a small or very small business is exempt from the animal food preventive control requirements for its ensiling (see § 507.5(f)(4)) and will continue to be exempt. We intend to exercise enforcement discretion with regard to the animal food preventive controls requirements applicable to ensiling for farm mixed-type facilities that are not small or very small businesses, until completion of the future rulemaking related to farm activities.

B. Enforcement Policy for the Written Assurances in the "Customer Provisions" in Part 117 and Related Rules

Among other requirements, subpart C of part 117 requires a facility that manufactures/processes human food to conduct a hazard analysis to determine whether there are any hazards that require a preventive control (§ 117.130) and identifies several types of possible preventive controls (§ 117.135(c)). In addition, subpart C of part 117 includes several provisions that apply when a manufacturer/processor of human food identifies a hazard requiring a preventive control ("identified hazard"), does not control the identified hazard, and relies on an entity in its distribution chain to control the identified hazard (§§ 117.136(a)(2) through (4) and 117.137). A manufacturer/processor that complies with these provisions is not required to implement a preventive control for the identified hazard before distributing the food. As discussed in the final rule to establish part 117 (80 FR 55908 at 56036-56037), the combination of three requirements in these provisions was intended to provide assurance that food for further processing will be processed to control the identified hazard before it reaches consumers:

- Documentation provided by the manufacturer/processor to its direct customer that the food is "not processed to control [identified hazard]" (the disclosure statement requirements; current § 117.136(a)(2)(i), (3)(i), and (4)(i));
- Written assurance provided by the customer to the manufacturer/processor that the identified hazard will be controlled (the written assurance requirements; current § 117.136(a)(2)(ii), (3)(ii), and (4)(ii)); and
- A provision specifying that a facility that provides a written assurance under the customer provisions must act consistently with the assurance and document its actions taken to satisfy the written assurance (the accountability requirements; current § 117.137).

In these provisions, "customer" means a commercial customer, not a consumer.

Part 117 includes several provisions applicable to records associated with the written assurances (the written assurance recordkeeping requirements):

- Section 117.136(b)(2), (3), and (4) requires that you must document the written assurances; and
- Subpart F of part 117 specifies requirements applying to all records that must be established and maintained to comply with part 117 and includes the elements to be included in the written assurances required by § 117.136(a)(2)(ii), (3)(ii), and (4)(ii). (See § 117.335(b).)

We refer to the collective provisions of §§ 117.136(a)(2) through (4), 117.136(b)(2) through (4), 117.137, and 117.335(b) as the "customer provisions" of part 117.

Among other requirements, subpart C of part 507 requires a facility that manufactures/processes food for animals to conduct a hazard analysis to determine whether there are any hazards that require a preventive control (§ 507.33) and identifies several types of possible preventive controls (§ 507.34(c)). Subpart F of part 507 specifies requirements applying to all records that must be established and maintained to comply with part 507.
As with part 117, part 507 includes "customer provisions" as follows:

- Subpart C of part 507 includes provisions for disclosure statements and written assurances that apply when a manufacturer/processor of food for animals identifies a hazard requiring a preventive control, does not control the identified hazard, and relies on an entity in its distribution chain to control the hazard (§§ 507.36(a)(2), (3), and (4), 507.36(c), 507.36(d), and 507.37). A manufacturer/processor that complies with these provisions of part 507 is not required to implement a preventive control for the identified hazard. The combination of these requirements was intended to provide assurance that the food will be processed to control the identified hazard before it reaches the consumer feeding the food to animals.
- Subpart F of part 507 specifies the elements to be included in the written assurances required by § 507.36(a)(2)(ii), (3)(ii), and (4)(ii). (See § 507.215(b).)

The FSVP regulation includes "customer provisions" that apply when an importer imports a food for which the hazards are controlled after importation (§ 1.507). As with the customer provisions in part 117 and part 507, the requirements in the customer provisions of the FSVP regulation were intended to provide assurance that the food will be processed to control the identified hazard before it reaches the humans or animals that would consume the food.

The produce safety regulation applies to "covered produce" as set forth in §§ 112.1 and 112.2. Produce that would otherwise be covered is eligible for an exemption from most of the requirements of the produce safety regulation if: (1) The produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance (§ 112.2(b)(1)); and (2) certain other conditions are met, including requirements for disclosure statements and written assurances analogous to the requirements for disclosure statements and written assurances in the "customer provisions" required by part 117, part 507, and the FSVP regulation (§ 112.2(b)(2) through (4) and (6)).

FDA has received feedback from industry expressing concern that certain product distribution chains would require vastly more written assurances (and consequently resources to comply with the requirement) than anticipated by FDA during the rulemaking process (Ref. 1). For example, a manufacturing facility may sell food products subject to the customer provisions to a distributor, who may sell numerous items requiring assurances to multiple restaurants, cafeterias, delicatessens, and other distributors. It is estimated that this could result in hundreds or even thousands of written assurances needed by a single distributor (Ref. 1). After considering this feedback from industry, we stated our belief that the requirement for written assurance in the customer provisions of part 117 significantly exceeds the current practices of even the largest facilities; compliance by those facilities by September 19, 2016, may not be feasible; and it is appropriate to extend the compliance dates for 2 years for the written assurance requirements for part 117, part 507, the FSVP regulation, and the produce safety regulation while we considered the best approach to address feasibility concerns (81 FR 57784 at 57786).

FDA intends to initiate a rulemaking that takes into consideration the complex supply chain relationships and resource requirements. To provide sufficient time for us to pursue that rulemaking, we are exercising enforcement discretion with regard to the written assurance requirements of part 117, part 507, part 112, and the FSVP regulation until completion of that rulemaking process. In the meantime, entities with disclosure duties under part 117, part 507,

part 112, or the FSVP regulation are still required to make necessary disclosures. Subsequent entities in the distribution chain will continue to be subject to applicable requirements related to food adulteration in Federal and/or state and local laws and regulations, e.g., part 117, part 507, and the Retail Food Code.

C. Enforcement Policy for Importation of Food Contact Substances Under the FSVP Regulation

The FSVP regulation requires food importers to develop, maintain, and follow an FSVP that provides adequate assurances that the foreign supplier uses processes and procedures that provide the same level of public health protection as those required under the preventive controls or produce safety provisions of FSMA (if applicable) and regulations implementing those provisions, as well as assurances that the imported food is not adulterated and that human food is not misbranded with respect to allergen labeling (21 CFR 1.502(a)). Among other things, the FSVP regulation (21 CFR 1.500-1.514) requires most food importers to do the following:

- Analyze the hazards for the foods they import (21 CFR 1.504);
- Evaluate the performance of their potential foreign suppliers and the risk posed by the foods to be imported (21 CFR 1.505); and
- Determine and conduct appropriate foreign supplier verification activities, such as onsite auditing of foreign suppliers, sampling and testing, and review of supplier food safety records (21 CFR 1.506).

The FSVP regulation applies (with certain exceptions) to the importation of food as defined in section 201(f) of the FD&C Act (see 21 CFR 1.500). Food contact substances are included in the definition of "food" for purposes of the FSVP regulation (21 CFR 1.500). However, for the reasons stated below, we intend to exercise enforcement discretion for importers of food contact substances with respect to the FSVP regulation.

A food contact substance is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food (section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)); 21 CFR 170.3(e)(3)). The term "food" is defined in section 201(f)(3) of the FD&C Act to include articles used as components of food. In the preamble to the FSVP final rule, we stated that the definition of "food" for purposes of FSVP includes food contact substances that are considered "food" in section 201(f) of the FD&C Act (80 FR 74225 at 74233). Therefore, the FSVP regulation applies to importers of food contact substances that meet the definition of "food" in section 201(f).

In the compliance date final rule, we extended the compliance date for the importation of food contact substances by 2 years so that we could consider how best to address concerns raised about the feasibility of importers of food contact substances meeting the FSVP requirements (81 FR 57784 at 57792-57793). As a result of this extension, the earliest that an importer would be required to comply with FSVP for the importation of food contact substances would be May 28, 2019.

Upon consideration of comments and information provided by industry and other interested parties and the issues involved, we have concluded that, because of certain characteristics related to the nature of food contact substances, FDA's premarket review/oversight of food contact substances, and the regulatory framework for such substances, it is appropriate to consider the exercise of our enforcement discretion to not require importers of food contact substances to meet FSVP requirements. Because by definition food contact substances are not intended to have a technical effect in food, food contact substances generally result in relatively low levels of migration to food. Consequently, consumer exposure to food contact substances is frequently less than exposure to other types of food substances. In addition, FDA has extensive premarket review processes for these substances under the food contact notification (FCN) process and the food additive petition process. Section 309 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) amended section 409 of the FD&C Act to establish the FCN process (codified in 21 CFR 170.100 through 170.106) as the primary method by which we regulate food additives that are food contact substances. Before FDAMA, many food additives that are now authorized through the FCN process required premarket approval by the Agency through the submission of food additive petitions and publication of regulations authorizing their intended use.

Both the FCN process and the food additive approval process require the notifier or petitioner to demonstrate that the intended use of the food contact substance is safe within the meaning of section 409(c)(3)(A) of the FD&C Act. If the information in the food additive petition or notification does not support the safety of the substance, FDA will act so that this use is not authorized: for food additive petitions, we can deny the petition; for FCNs, we can object to the notification within 120 days from the date of receipt of the notification so that it does not become effective (21 CFR 170.104)(c)). For an authorized use of a food contact substance, the food additive regulation or effective notification establishes, among other things, specifications (including purity or physical properties) for the substance and any limitations on the conditions of use. A substance is not authorized for use in contact with food in the United States unless it complies with all such criteria. Further, we note that food contact substances are not subject to the supply-chain program requirements in the human food preventive controls regulation. Under that regulation, the supply-chain program requirements only apply to hazards requiring a supply-chain applied control, and FDA has determined that there are no hazards associated with food contact substances that are hazards requiring a supply-chain applied control under 21 CFR 117.405(a)(1).

For the reasons above, we intend to exercise enforcement discretion for these food contact substances with regard to the FSVP requirements. However, importers of food contact substances remain subject to the statutory prohibition against the introduction or delivery for introduction into interstate commerce of adulterated food (section 301(a) of the FD&C Act (21 U.S.C. 331(a)). In addition, we will consider revising our exercise of enforcement discretion if, for example, new information becomes available regarding safety concerns associated with food contact substances

D. Enforcement Policy for Certain Human Food By-Products for Use as Animal Food that is Further Manufactured/Processed

The final rule establishing part 507 included two provisions that streamline the requirements for human food facilities subject to and in compliance with part 117 for the manufacturing, processing, packing, and holding of human food by-products for use as animal food.

One provision applies to human food facilities subject to and in compliance with part 117, subpart B and all applicable human food safety requirements of the FD&C Act that do not further manufacture/process their human food by-products for use as animal food after separation from the human food (see § 507.12). These facilities are only subject to the limited holding and distribution CGMP requirements located in § 507.28 and duplicated in § 117.95. The other part 507 CGMP requirements and the animal food preventive controls requirements do not apply to their human food by-products for use as animal food.

The second provision applies to human food facilities subject to part 117 that are further manufacturing/processing their human food by-products for use as animal food after separation from the human food (see § 507.1(d)). These facilities are subject to all the requirements in part 507 for their human food by-products for use as animal food unless an exemption applies. However, the facility has the choice to comply with the CGMP requirements and the hazard analysis and risk-based preventive controls requirements from either part 117 or part 507.

In August 2016, we published Draft Guidance for Industry (GFI) #239, "Human Food By-Products for Use as Animal Food" that further explains these streamlined provisions for human food by-products for use as animal food. In the draft guidance, we identified some activities that we do not consider to be further manufacturing/processing when determining whether the human food facility is subject to just the limited holding and distribution CGMPs, as opposed to the full part 507 CGMP and animal food preventive controls requirements. These activities include:

- passive dewatering
- holding by-products at a particular temperature to facilitate transportation (e.g., keeping a syrup or oil warm to maintain liquidity or holding frozen blocks of by-product).

After the publication of the final rule establishing part 507 and release of draft GFI #239: Human Food By-Products for Use as Animal Food, we were made aware of concerns about how the requirements in part 507 apply to certain activities that are frequently performed in part to facilitate the storage and transportation of human food by-products for use as animal food, including: combining different ingredients (e.g., vegetable culls and trimmings or liquid juice and dairy by-products), drying/dehydrating, evaporating, chopping, mixing, pressing, heating, cooling, trimming, and washing (Refs. 2, 3, 4). For example, some alcoholic beverage manufacturers dry spent grains to facilitate transportation of these grains to farms or animal food manufacturers a greater distance from the facility. Some beverage manufacturers have a single tank where they commingle liquid by-products from dairy and juice manufacturing to be sent to animal food manufacturers or farmers for use as animal food. Fruit and vegetable processors may commingle trimmings and culls from different types of fruits and vegetables that were processed at the same time and perform chopping on these fruits and vegetables to reduce bulk for storage or transportation. We note that typically trimming and washing activities are done to

the human food before it has been separated from the by-product and thus would not be considered further manufacturing/processing of the human food by-product for use as animal food.

Generally, we do not expect that these manufacturing/processing activities will change the safety profile of human food by-products for use as animal food if they are done in compliance with the CGMP requirements in part 507, subpart B or part 117, subpart B. In contrast, manufacturing/processing activities that are more complex activities performed on human food by-products, such as heating or cooling to address pathogens, pelleting, extruding, and formulating, may introduce hazards or change the animal food safety profile in a way that could require the implementation of preventive controls. We do not intend to exercise enforcement discretion for manufacturing/processing activities that may impact safety as described below.

To provide sufficient time to consider the application of animal food preventive controls requirements to certain manufacturing/processing activities on human food by-products for use as animal food, we intend to exercise enforcement discretion with regard to the animal food preventive control requirements for human food facilities meeting the qualifications in § 507.12(a)(1)(i) or (ii), if the manufacturing/processing activities that are performed on the human food by-products for use as animal food are limited to the following activities and circumstances:

- drying/dehydrating, evaporating, pressing, chopping, and similar activities to reduce weight, bulk, or volume, and/or
- mixing (e.g., combining different vegetable culls and trimmings, combining juice and dairy by-products, stirring), centrifuging, and similar activities to combine ingredients or separate components (e.g., water and solids), and
- these activities are not performed to prevent or significantly minimize animal food hazards and do not introduce animal food hazards.

This enforcement discretion is being provided because we do not expect that these types of activities done for the purposes of reducing weight, bulk, or volume, and/or separating components, or combining ingredients will change the food safety profile of the animal food. This enforcement discretion does not extend to a human food facility that performs other manufacturing/processing activities on its human food by-products for use as animal food.

IV. References

1. Grocery Manufacturers Association, "21 CFR 117.136. Industry Impacts from Disclosure and Written Assurance Requirements," 2016.
2. Comment from American Frozen Food Institute to FDA Docket FDA-2016-D-1220.
3. Comment from Midwest Food Processors Association to FDA Docket FDA-2016-D-1220.
4. Comment from Northwest Food Processors Association to FDA Docket FDA-2016-D-1220.