may designate or as may be required by law.

Portia Wu

Assistant Secretary for Employment and Training.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 11, 16, 106, 110, 111, 112, 114, 117, 120, 123, 129, 179, 211, and 507

[Docket Nos. FDA–2011–N–0920, FDA–2011–N–0921, FDA–2011–N–0922, FDA–2011–N–0143]

RIN 0910–AG10, 0910–AG35, 0910–AG36, 0910–AG64

The Food and Drug Administration Food Safety Modernization Act; Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; extension and clarification of compliance dates for certain provisions.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the dates for compliance with certain provisions in four final rules. We are extending the compliance dates to address concerns about the practicality of compliance with certain provisions, consider changes to the regulatory text, and better align compliance dates across the rules. In addition, we are clarifying certain compliance dates in the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption rule.

DATES: This final rule is effective August 24, 2016. See sections III.C, IV.A.2, IV.B, and V through VIII for the extended compliance dates.

FOR FURTHER INFORMATION CONTACT:

For questions relating to Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2166.

For questions relating to Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals: Jeanette Murphy, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6246.

For questions relating to Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: Rebecca Buckner, Office of Food and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4576.

For questions relating to Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Samir Assar, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1636.

SUPPLEMENTARY INFORMATION:

I. Background: The Four Related Rules Implementing the FDA Food Safety Modernization Act

This extension and clarification of compliance dates concerns four of the seven foundational rules that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111–353). The four final rules are entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food'' (published in the **Federal Register** of September 17, 2015, 80 FR 55908) (*http://www.fda.gov/fsma*); ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals'' (published in the **Federal Register** of September 17, 2015, 80 FR 51670) (*http://www.fda.gov/fsma*); ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals'' (published in the **Federal Register** of November 27, 2015, 80 FR 74226) (*http://www.fda.gov/fsma*); and ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' (published in the **Federal Register** of November 27, 2015, 80 FR 74354) (*http://www.fda.gov/fsma*).

In part 117 (21 CFR part 117), we have established our regulation entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food'' (80 FR 55908, September 17, 2015). Among other things, the rulemaking to establish part 117 amended our current good manufacturing practice (CGMP) regulation for manufacturing, packing, or holding human food to modernize it and establish it in new part 117, subparts A, B, and F. Part 117 also includes new requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d) in subparts A, C, D, E, F, and G to establish and implement hazard analysis and risk-based preventive controls for human food (the human food preventive controls requirements). 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). In the rulemaking to establish part 117, we also amended the ''farm'' definition in our regulations implementing section 415 of the FD&C Act (the section 415 registration regulation; 21 CFR part 1, subpart H) 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.''

In part 507 (21 CFR part 507), we have established our regulation entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals'' (80 FR 56170, September 17, 2015). Among other things, the rulemaking to establish part 507 established new requirements for CGMPs in subparts A, B, and F (CGMP requirements) and also established requirements for hazard analysis and risk-based preventive controls for food for animals in subparts A, C, 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 and, 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 (see table 32 in the preamble of the final rule establishing part 507, 80 FR 56170 at 56329).

In part 1, subpart L (21 CFR part 1, subpart L), we have established our regulation entitled ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals'' (the FSVP regulation; 80 FR 74226, November 27, 2015). The FSVP regulation requires importers to establish foreign supplier verification programs to verify that their foreign suppliers are using processes and procedures that provide the same level of public health protection as those required under the provisions on hazard analysis and risk-based preventive controls and standards for produce safety in the FD&C Act, that the imported food is not adulterated, and that food is not misbranded with respect to food allergen labeling. In the preamble of the final rule establishing the FSVP regulation, we stated that the rule is effective January 26, 2016, and provided for varying compliance dates based in part on the size of the foreign supplier, the nature of the importer, and whether the foreign supplier is subject to certain other FSMA regulations (80 FR 74226 at 74332 to 74333, as corrected in a technical amendment (81 FR 25326, April 28, 2016)).

In part 112 (21 CFR part 112), we have established our regulation entitled ''Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption'' (the produce safety regulation; 80 FR 74354, November 27, 2015). Among other things, the rulemaking to establish the produce safety regulation set forth in a new part 112 procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. The produce safety regulation applies to certain produce farms, and does not apply to activities of facilities that are subject to part 117 (as established in part 117). In the preamble of the final rule establishing the produce safety regulation, we stated that the produce safety regulation is effective January 26, 2016, and provided for compliance dates of 1 to 6 years from the effective date depending on the commodity and the provision(s) (see table 30 in the preamble of the final rule establishing the produce safety regulation, 80 FR 74354 at 74527, as corrected in a technical amendment at 81 FR 26466, May 3, 2016). (Some of the compliance dates identified in the technical amendment fall on weekends (*i.e.,* January 26, 2019, is a Saturday and January 26, 2020, is a Sunday) and should therefore be read as referring to the next business day (*i.e.,* January 28, 2019, and January 27, 2020, respectively). We use the latter dates throughout this document.)

II. Summary of Compliance Date Extensions in This Rule

We are extending the dates for compliance with certain provisions in four final rules to address concerns about the practicality of compliance with certain provisions, consider changes to the regulatory text, and better align compliance dates across the rules. First, we are extending the compliance dates for certain related provisions concerning customer assurances when controls are applied downstream in the distribution chain in all four rules. Second, we are extending the compliance dates for part 117 and part 507 for facilities solely engaged in packing and/or holding activities conducted on raw agricultural commodities (RACs) that are produce and/or nut hulls and shells and for certain facilities that would qualify as secondary activities farms except for the ownership of the facility. Third, we are extending the compliance dates for part 117 for certain facilities that color RACs. Fourth, we are extending the compliance dates for part 507 for facilities solely engaged in the ginning of cotton. Fifth, we are extending the compliance dates for the FSVP regulation for importation of food contact substances. Sixth, we are extending the date for certain facilities producing Grade ''A'' milk and milk products covered by the National Conference on Interstate Milk Shipments (NCIMS) under the Pasteurized Milk Ordinance (PMO) to comply with the CGMP requirements of part 117.

Finally, we are clarifying how we interpret the compliance dates for certain provisions related to agricultural water testing in the produce safety regulation.

III. Extension of Compliance Dates for ''Customer Provisions'' in Part 117 and Related Rules

A. Background

In a supplemental notice of proposed rulemaking for part 117 (79 FR 58524, September 29, 2014), we proposed several exceptions to the requirement for a manufacturer/processor to establish and implement a supply-chain program. Under one proposed exception, a receiving facility would not have been required to have a supply-chain program if it relied on its customer to control the hazard and annually obtained from its customer written assurance that the customer had established and was following procedures (identified in the written assurance) that would significantly minimize or prevent the hazard (see the discussion in the preamble of the final rule at 80 FR 55908 at 56036; see the proposed regulatory text at 79 FR 58524 at 58565).

After considering comments, we replaced this proposed provision with several provisions (§§ 117.136(a)(2) through (4) and 117.137) (referred to collectively as ''customer provisions'') that apply when a manufacturer/processor 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 address the hazard (80 FR 55908 at 56037 to 56039). (In these provisions, ''customer'' means a commercial customer, not a consumer.) A manufacturer/processor that complies with the customer provisions is not required to implement a preventive control for the identified hazard. The combination of three requirements in the customer provisions is intended to provide assurance that the food 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 provisions; § 117.136(a)(2)(i), (3)(i), and (4)(i));
- Written assurance provided by the customer to the manufacturer/processor that the customer is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements (the written assurance provisions; § 117.136(a)(2)(ii), (3)(ii), and (4)(ii)); and
- Provisions relating to accountability for written assurances (the accountability provision; § 117.137).

We established similar requirements in three other FSMA rules (''related rules''): Part 507 (§§ 507.36 (a)(2) through (4) and 507.37); the FSVP regulation (§§ 1.507(a)(2) through (4), and 1.507(c)); and the produce safety regulation (§ 112.2(b)(2) through (4), and (6)).

B. Written Assurances From Customers

On March 23, 2016, FDA met with the Grocery Manufacturers Association (GMA) at their request to listen to concerns regarding the customer

provisions in the part 117 rule (Ref. 1). GMA provided examples of product distribution chains that would require vastly more written assurances and consequently resources to comply with the requirement than anticipated by FDA. For example, a manufacturing facility may sell such foods to a distributor, who may sell numerous items requiring assurances to multiple restaurants, cafeterias, delicatessens, and other distributors. GMA estimated that this could result in hundreds or even thousands of written assurances needed by a single distributor. A similar concern exists for the related rules.

After considering the information presented by GMA, FDA believes 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 and the related rules while FDA considers the best approach to address feasibility concerns.

We believe it continues to be appropriate to provide for an entity earlier in the distribution chain to disclose that a hazard has not been controlled and rely on a subsequent entity to control a hazard in human or animal food. For example, it would not make sense to require a facility that chops nuts to have a preventive control for *Salmonella* if the nuts are going to be used by customers in baked goods in accordance with a process validated to adequately control the hazard. In addition, it would not make sense to require a facility that manufactures a rendered meat ingredient for pet food to have a preventive control for *Salmonella* when the final pet food will go through an extrusion process at a customer's facility to control *Salmonella.* A manufacturer/processor under part 117 or part 507 that relies on a customer to control a hazard will continue to be required to comply with the disclosure statement provisions and disclose that the food has not been processed to control the hazard on the compliance date originally specified (we note that FDA will soon be making available for public comment draft guidance on the disclosure statement provisions). 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. Extension of Compliance Dates

Table 1 provides a summary of the revised compliance dates.

TABLE 1—EXTENSION OF COMPLIANCE DATES FOR THE WRITTEN ASSURANCES IN THE CUSTOMER PROVISIONS IN PART 117 AND RELATED RULES

	Previously announced compliance date	Compliance date with extension
Human Food—§ 117.136(a)(2)(ii), (3)(ii), and (4)(ii)		
Small Business (a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees).	September 18, 2017	September 18, 2019.
Business that is neither small or very small (a business (including any subsidiaries and affiliates) averaging less than $1 million, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale (*e.g.* held for a fee)).	September 19, 2016	September 19, 2018.
Animal Food—§ 507.36(a)(2)(ii), (3)(ii), and (4)(ii)		
Small Business (a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees).	September 17, 2018	September 17, 2020.
Business that is neither small or very small ((a business (including any subsidiaries and affiliates) averaging less than $2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed or held without sale (*e.g.,* held for a fee or supplied to a farm without sale)).	September 18, 2017	September 18, 2019.
FSVP—§ 1.507(a)(2)(ii), (3)(ii), and (4)(ii))		
Latest date of:		
18 months after the publication of the final rule	May 30, 2017	May 28, 2019.
Importers of food from foreign supplier subject to preventive controls regulation for human food, the preventive controls or CGMP requirements in part 507, or the produce safety regulation:	6 months after supplier is required to comply with the relevant regulations.	30 months after previously announced compliance date for the relevant regulations.
Produce Safety—§ 112.2(b)(3)		
Very small businesses relying on the exemption in § 112.2(b) for sprouts that would otherwise be subject to subpart M (those with more than $25,000 but no more than $250,000 in average annual produce sales during the previous three year period).	January 28, 2019	January 26, 2021.
Small businesses relying on the exemption in § 112.2(b) for sprouts that would otherwise be subject to subpart M (those with more than $250,000 but no more than $500,000 in average annual produce sales during the previous three year period).	January 26, 2018	January 27, 2020.
All other businesses relying on the exemption in § 112.2(b) for sprouts that would otherwise be subject to subpart M.	January 26, 2017	January 28, 2019.

TABLE 1—EXTENSION OF COMPLIANCE DATES FOR THE WRITTEN ASSURANCES IN THE CUSTOMER PROVISIONS IN PART 117 AND RELATED RULES—Continued

	Previously announced compliance date	Compliance date with extension
Very small businesses relying on the exemption in § 112.2(b) for all other produce that would otherwise be covered (those with more than $25,000 but no more than $250,000 in average annual produce sales during the previous three year period).	January 27, 2020	January 26, 2022.
Small businesses relying on the exemption in § 112.2(b) for all other produce that would otherwise be covered (those with more than $250,000 but no more than $500,000 in average annual produce sales during the previous three year period).	January 28, 2019	January 26, 2021.
All other businesses relying on the exemption in § 112.2(b) for all other produce that would otherwise be covered.	January 26, 2018	January 27, 2020.

We are extending the compliance date by 2 years for the written assurance requirement in the customer provisions in part 117. With the extension, facilities that are small businesses must comply with § 117.136(a)(2)(ii), (3)(ii), and (4)(ii) by September 18, 2019, and other facilities subject to the requirements must comply with those provisions by September 19, 2018. As a result of the extension, the compliance date for certain associated requirements that are contingent on the specified delayed provisions are also delayed (*i.e.,* the recordkeeping requirements in §§ 117.136(b)(2) through (4) and 117.335 and the requirements in § 117.137 for a facility that provides a written assurance under § 117.136(a)(2), (3), or (4)). We are not extending the compliance date for qualified facilities (including very small businesses) as defined in § 117.3 because they are not subject to the requirements in § 117.136(a)(2)(ii), (3)(ii), and (4)(ii).

We are also extending the compliance date by 2 years for the written assurance requirement in the customer provisions in part 507. With the extension, facilities that are small businesses must comply with § 507.36(a)(2)(ii), (3)(ii), and (4)(ii) by September 17, 2020, and other facilities subject to the requirements must comply with those provisions by September 18, 2019. As a result of the extension, the compliance dates for certain associated requirements that are contingent on the specified delayed provisions are also delayed (*i.e.,* the recordkeeping requirements in §§ 507.36(b)(2) through (4) and 507.215 and the requirements in § 507.37 for a facility that provides a written assurance under § 507.36(a)(2), (3), or (4)). We are not extending the compliance date for qualified facilities (including very small businesses) as defined in § 507.3 because they are not subject to the requirements in § 507.36(a)(2)(ii), (3)(ii), and (4)(ii).

In addition, we are extending the compliance date under the FSVP regulation for complying with the written assurance requirements in § 1.507(a)(2)(ii), (3)(ii), and (4)(ii) by 2 years beyond the dates established in the final rule (as corrected in the technical amendment). In the preamble of the final rule, as corrected by the technical amendment, we stated that importers would need to comply with the FSVP regulation by the latest of the following:

- 18 months after the publication of the final rule;
- For importers of food from a foreign supplier that is subject to part 117, the CGMP requirements or the preventive controls requirements for animal food in part 507, or the produce safety regulation, 6 months after the supplier was required to comply with the relevant regulations; or
- For an importer subject to the supply-chain program provisions of the human or animal food preventive controls regulations, the date the importer, as a receiving facility, was required to comply with the supply-chain program provisions of the relevant regulation.

As a result of this extension, the earliest that an importer would be required to comply with the written assurance requirements in the customer provisions in § 1.507 would be May 28, 2019. When an importer's compliance date is determined by when the foreign supplier must comply with the preventive controls regulation for human food, the preventive controls or CGMP requirements in part 507, or the produce safety regulation (*i.e.,* when the importer must comply with FSVP 6 months after the foreign supplier is required to come into compliance), the importer's compliance date for the written assurance requirements in § 1.507 will be 2 years and 6 months after the previously-announced compliance dates for the relevant regulations. That is, the other changes we are making to compliance dates for the human and animal food preventive controls and produce safety regulations will not impact when an FSVP importer must comply with the written assurance requirements in the customer provisions in § 1.507. For example, although this rule extends the compliance dates for part 117 and part 507 for facilities solely engaged in packing and/or holding activities conducted on RACs that are produce that would qualify as secondary activities farms except for the ownership of the facility, an importer whose foreign supplier is such a facility will be required to comply with the assurance requirements in § 1.507 2 years and 6 months after the foreign supplier would have been required to comply with part 117 or part 507 under the final rules published on September 17, 2015 (80 FR 55908; 80 FR 56170). The importer's compliance date for the assurance requirements in § 1.507 is not 2 years and 6 months after the newly-established part 117 and part 507 compliance dates announced in this rule. As a result of the extension, the compliance dates for certain associated requirements that are contingent on the specified delayed provisions are also delayed (*i.e.,* the requirements in § 1.507(c) for a customer or subsequent entity that provides a written assurance under § 1.507(a)(2), (3), or (4)).

Finally, we are extending by 2 years the compliance dates for the written assurance requirements in the customer provisions of the produce safety regulation in § 112.2(b)(3). With the extension, sprout operations wishing to rely on the exemption in § 112.2(b) with respect to sprouts that would otherwise be subject to subpart M of part 112 must comply with the written assurances provisions in § 112.2(b)(3) by January 26, 2021 (very small businesses); January 27, 2020 (small businesses); and January 28, 2019 (all other businesses). With the extension, operations wishing

to rely on the exemption in § 112.2(b) with respect to other types of produce that would otherwise be covered must comply with the written assurances provisions in § 112.2(b)(3) by January 26, 2022 (very small businesses); January 26, 2021 (small businesses), and January 27, 2020 (all other businesses). As a result of the extension, the compliance dates for certain associated requirements that are contingent on the specified delayed provisions are also delayed (*i.e.,* § 112.2(b)(4) and (6)).

IV. Extension of Certain Compliance Dates for Both Part 117 and Part 507

A. Facilities Solely Engaged in Packing and/or Holding Activities Conducted on Produce RACs and/or Nut Hulls and Shells

Some facilities that are subject to part 117 are solely engaged in packing and/or holding RACs that are produce (''produce RACs''). These activities are similar to packing and holding activities commonly conducted on produce RACs by farms subject to the produce safety regulation. Examples of such facilities are produce packinghouses, warehouses that hold produce RACs, and facilities that hull, shell, pack and/or hold nuts (nuts are produce RACs and hulling and shelling may be considered ''packing'' when done for safe or effective packing). (We note that FDA will soon be making available for public comment a draft guidance on classification of activities as harvesting, packing, holding, or manufacturing/processing for farms and facilities). During the rulemaking to establish part 117, we received comments asking us to revise the regulatory text to ensure that similar activities would be treated similarly under either the produce safety regulation or part 117. (See Comment 25, 80 FR 55908 at 55927 to 55928.)

We received comments that expressed concern about how the requirements in part 117 for environmental monitoring and product testing would apply to off-farm facilities that pack or hold produce RACs. (See Comment 524, 80 FR 55908 at 56062.) In responding to those comments, we stated that we were considering developing a separate guidance on packing and holding operations for produce RACs in light of the questions we have received regarding similarities and differences for off-farm packing and holding compared to on-farm packing and holding. In a letter to us dated April 19, 2016, the United Fresh Produce Association and 21 other organizations (UFPA et al.) noted that such guidance has not been issued, and the September 19, 2016, compliance date for part 117 is approaching (Ref. 2).

1. Similarities of Packing and Holding Activities Conducted on Produce RACs

In the preamble of the final rule establishing part 117, we described several changes to the regulatory text in response to comments asking us to consider revisions to ensure that similar activities would be treated the same way under either the produce safety regulation or part 117. (See Response 25, 80 FR 55908 at 55928 to 5929.) For example, we revised the ''farm'' definition to provide for two types of farms: (1) A primary production farm and (2) a secondary activities farm (see §§ 1.227 and 117.3). With the added definition of ''secondary activities farm,'' some packinghouses that are managed by a business entity (such as a cooperative) that is different from the business entity growing crops (such as individual farms) can be within the ''farm'' definition and, thus, not be subject to the human food preventive controls requirements. We also established a new provision to allow off-farm establishments that package, pack, and hold produce RACs to comply with the CGMPs in part 117 by complying with the relevant requirements for packing and holding in the final produce safety regulation (see § 117.8).

In responding to these comments, we noted that the revised ''farm'' definition did not, as requested, provide for all off-farm operations such as certain packinghouses and hulling/shelling operations to be subject to the produce safety regulation rather than part 117. We explained that the statutory framework does not provide for entities such as packinghouses and hulling/shelling operations that do not have a sufficient connection to a farm to be subject to the requirements of the produce safety regulation. However, we stated that we continued to believe 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 facility's food safety system. For example, we stated our expectation that the food safety plan for an off-farm packinghouse would focus on a few key preventive controls, including some that would have counterparts in the produce safety regulation, such as maintaining and monitoring the temperature of water used during packing (which would have counterparts under § 112.48(c) in the produce safety regulation). We also expected that an off-farm packinghouse would establish sanitation controls to address the cleanliness of food-contact surfaces (including food-contact surfaces of utensils and equipment) and the prevention of cross-contamination from insanitary objects and from personnel to food, food-packaging material, and other food-contact surfaces. On-farm packinghouses would be subject to similar, but not identical, requirements (see, *e.g.,* §§ 112.111(b) and 112.123(d)(1) for cleanliness of food-contact surfaces, and §§ 112.113 and 112.132 for protection against contamination).

We agree that certain activities conducted on produce RACs are similar regardless of where they happen. Therefore, facilities for which the packing and/or holding of produce RACs is subject to the human food preventive controls requirements may nonetheless still be able to draw from the provisions of the produce safety regulation in developing their food safety plans and establishing preventive control management components that are appropriate in light of the nature of the preventive controls and their role in the facility's food safety system. We acknowledge that we have not yet issued guidance with specific recommendations for how packinghouses subject to the human food preventive controls requirements could comply with those requirements.

2. Extension of Compliance Dates for Facilities Solely Engaged in Packing and/or Holding Produce RACs and/or Nut Hulls and Shells

Table 2 provides a summary of the revised compliance dates.

TABLE 2—EXTENSION OF COMPLIANCE DATES FOR BOTH PART 117 AND PART 507 FOR FACILITIES SOLELY ENGAGED IN PACKING AND/OR HOLDING PRODUCE RACS AND/OR NUT HULLS AND SHELLS

	Previously announced compliance date	Compliance date with extension
Human Food—Facilities solely engaged in packing and/or holding activities on produce RACs (part 117)		
Very Small Businesses (a business (including any subsidiaries and affiliates) averaging less than $1 million, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale (e.g. held for a fee)).	September 17, 2018	January 27, 2020.
Small Businesses (a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees).	September 18, 2017	January 28, 2019.
Other Businesses	September 19, 2016	January 26, 2018.
Animal Food—Facilities solely engaged in packing and/or holding activities on produce RACs and/or nut hulls and shells that are used as animal food (part 507)		
Very Small Businesses (a business (including any subsidiaries and affiliates) averaging less than $2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed or held without sale (e.g., held for a fee or supplied to a farm without sale)).	September 17, 2018 (CGMPs) September 17, 2019 (preventive controls).	January 27, 2020 (CGMPs) January 26, 2021 (preventive controls).
Small Businesses (a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees).	September 18, 2017 (CGMPs) September 17, 2018 (preventive controls).	January 28, 2019 (CGMPs) January 27, 2020 (preventive controls).
Other Businesses	September 19, 2016 (CGMPs) September 18, 2017 (preventive controls).	January 26, 2018 (CGMPs). January 28, 2019 (preventive controls).

We published the final rule establishing part 117 more than 2 months before we published the final rule establishing the produce safety regulation and, thus, the compliance dates for the produce safety regulation had not yet been established. To provide facilities that are solely engaged in packing and/or holding activities on produce RACs the same time to understand the applicable provisions of the produce safety regulation as farms that conduct similar packing and holding activities, and to enable such facilities to develop a food safety plan that builds on the requirements of the produce safety regulation, where applicable, we are extending the date for facilities that are solely engaged in packing and/or holding activities on produce RACs to comply with part 117 by approximately 16 months to make the compliance dates the same as for businesses in the same size categories in the produce safety regulation. For example, the new compliance date for a facility that is a small business under part 117 is the compliance date for a small business under the produce safety regulation, regardless of whether the facility subject to part 117 would be considered a small business under the produce safety regulation. (Note that the produce safety regulation has different compliance dates associated with sprouts but for the purposes of this extension we are not establishing different dates for sprouts.) This will match the other extended compliance dates that relate to the ''farm'' definition or the produce safety regulation in this document.

With the extension, eligible facilities that are very small businesses must comply with part 117 by January 27, 2020; eligible facilities that are small businesses must comply by January 28, 2019, and all other eligible facilities must comply by January 26, 2018. We are extending compliance dates for very small businesses because, although they are not required to comply with subparts C and G (*e.g.,* they are not required to have food safety plans), one of their options for compliance includes identifying the potential hazards associated with the food being produced, implementing preventive controls to address the hazards, and monitoring the performance of the preventive controls to ensure that such controls are effective (21 CFR 117.201(a)(2)(i)).

To maintain the intended alignment between part 117 and part 507, we also are making a parallel extension to the dates for facilities that are solely engaged in packing and/or holding activities on produce RACs that are used as animal food to comply with part 507 requirements. While there may be limited facilities that pack and hold produce RACs exclusively for animal food, the by-products, such as culls, from packing and holding of produce RACs for human food are often used as animal food. The rulemaking to establish part 507 included a provision for certain human food by-products used as animal food (§ 507.12). To qualify for § 507.12, the human food facility whose packing or holding of produce results in by-products for use as animal food must be in compliance with the part 117 CGMPs or in compliance with the applicable requirements for packing and holding in part 112. The extension of compliance dates allows for facilities that are providing by-products for use as animal food time to implement the applicable part 117 or part 112 requirements. The parallel 16 month compliance date extension for part 507 is staggered to allow time for such operations to first comply with the part 507 CGMP requirements, including the related requirement in § 507.12. With the extension, eligible facilities that are very small businesses must comply with the CGMP requirements of part 507 by January 27, 2020, and with the preventive controls requirements of part 507 by January 26, 2021; eligible facilities that are small businesses must comply with the CGMP requirements of part 507 by January 28, 2019, and with the preventive controls requirements of

part 507 by January 27, 2020, and all other eligible facilities must comply with the CGMP requirements of part 507 by January 26, 2018, and with the preventive controls requirements of part 507 by January 28, 2019.

In addition, nut hulls and shells are used for animal food and result from some activities performed by those facilities that are receiving an extension to comply with part 117. Therefore, we are extending the compliance dates for animal food preventive controls requirements for facilities solely engaged in packing and/or holding activities conducted on nut hulls and shells. Facilities that are solely engaged in hulling, shelling, drying, packing, and/or holding of nuts and hulls are exempt from the part 507 CGMP requirements (§ 507.5(h)(2)) and will continue to remain exempt. With the extension, eligible facilities that are very small businesses must comply with animal food preventive controls requirements by January 26, 2021; eligible facilities that are small businesses must comply by January 27, 2020, and all other eligible facilities must comply by January 28, 2019.

The extended compliance dates do not apply to facilities that manufacture/process produce RACs or nut hulls and shells in addition to packing and/or holding produce RACs or nut hulls and shells, because such facilities must come into compliance with part 117 and part 507 with respect to their manufacturing/processing as well as their packing and holding. Examples of facilities to which the extended compliance dates apply are packinghouses that solely pack and/or hold produce RACs; and facilities that solely hull, shell, pack, and/or hold nuts (nuts are produce RACs and hulling and shelling may be considered ''packing'' when done for safe or effective packing). Examples of manufacturing/processing facilities to which the extended compliance dates do not apply are a ''fresh-cut'' processing facility, such as a facility that produces bagged salad mixes or packages of sliced fruit, and a facility that grinds nut shells to make an animal food ingredient.

B. Certain Facilities That Would Qualify as Secondary Activities Farms Except for the Ownership of the Facility

Table 3 provides a summary of the revised compliance dates.

TABLE 3—EXTENSION OF COMPLIANCE DATES FOR CERTAIN FACILITIES THAT WOULD QUALIFY AS SECONDARY ACTIVITIES FARMS EXCEPT FOR OWNERSHIP OF THE FACILITY

	Previously announced compliance date	Compliance date with extension
Human Food—Facilities that would qualify as secondary activities farms except for ownership of the facility (part 117)		
Very Small Businesses (a business (including any subsidiaries and affiliates) averaging less than $1 million, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale (*e.g.,* held for a fee)).	September 17, 2018	January 27, 2020.
Small Businesses (a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees).	September 18, 2017	January 28, 2019.
Other Businesses	September 19, 2016	January 26, 2018.
Animal Food—Facilities that would qualify as secondary activities farms except for ownership of the facility (part 507)		
Very Small Businesses (a business (including any subsidiaries and affiliates) averaging less than $2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed or held without sale (*e.g.,* held for a fee or supplied to a farm without sale)).	September 17, 2018 (CGMPs) September 17, 2019 (preventive controls).	January 27, 2020 (CGMPs). January 26, 2021 (preventive controls).
Small Businesses (a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees).	September 18, 2017 (CGMPs) September 17, 2018 (preventive controls).	January 28, 2019 (CGMPs). January 27, 2020 (preventive controls).
Other Businesses	September 19, 2016 (CGMPs) September 18, 2017 (preventive controls).	January 26, 2018 (CGMPs). January 28, 2019 (preventive controls).

The rulemaking to establish part 117 created a ''secondary activities farm'' definition within the ''farm'' definition 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 (§ 1.227). A secondary activities farm is devoted to harvesting (such as hulling or shelling), packing, and/or holding of RACs (such as produce, grains, and eggs). Further, a majority interest in 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).

We have received questions via our Technical Assistance Network regarding whether certain operations qualify as secondary activities farms under part 117 and part 507. These questions describe a variety of business structures that may satisfy our intention to require a close relationship regarding ownership of the primary and secondary activities farms but the business structures do not meet the ownership requirement as codified in the ''farm'' definition. For example, some operations that might otherwise qualify as secondary activities farms own the primary production farm, rather than being owned by the primary production farm as currently required. Other operations that might otherwise qualify as a secondary activities farm are operations that are not owned by (and do not own) the primary production farm but are majority owned by the same entity as the primary production farm. For example, Farm A is a primary

production farm. Facility B is a produce packinghouse that packs only produce from Farm A. Farm A and Facility B are both part of Corporation C. Despite the close relationship, Facility B is not a secondary activities farm under the current definition because Farm A does not own a majority interest in Facility B.

We are extending the compliance dates for certain operations that would be secondary activities farms except that they do not meet the ownership criterion in the definition. The extension is applicable only to an operation satisfying all of the following requirements: (1) The operation is not located on a primary production farm; (2) the operation is devoted to harvesting, packing, and/or holding of RACs (including operations that hull, shell, and/or dry nuts without additional manufacturing); and (3) the operation is under common ownership with the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the operation. Examples of common ownership include an operation that is owned by (or that owns) one or more primary production farms (*e.g.,* a packinghouse owned by a cooperative of individual farms) and an operation under common ownership with a primary production farm, such as operations that are managed within the same business structure as the primary production farm (*e.g.,* the farm and packinghouse are separate operations owned by parents and their children, respectively, and both operations are part of the same business jointly owned by the parents and children). Other limitations on secondary activities farms remain. For example, feed mills manufacturing animal food for contract farms would not qualify because, among other reasons, those feed mills are conducting manufacturing/processing outside the farm definition.

We are extending the compliance dates for part 117 for operations satisfying all of the requirements by approximately 16 months to match the compliance dates for businesses in the same size categories in the produce safety regulation (note that the produce safety regulation has different compliance dates associated with sprouts but for purposes of this extension we are not establishing different dates for sprouts). This will match the other extended compliance dates that relate to the ''farm'' definition or the produce safety regulation in this document. With the extension, eligible facilities that are very small businesses must comply with part 117 by January 27, 2020; eligible facilities that are small businesses must comply by January 28, 2019, and all other eligible facilities must comply by January 26, 2018.

The parallel 16 month compliance date extension for part 507 is staggered to allow time for operations satisfying all of the requirements to first comply with the CGMP requirements. With the extension, eligible facilities that are very small businesses must comply with the CGMP requirements of part 507 by January 27, 2020, and with the preventive controls requirements of part 507 by January 26, 2021; eligible facilities that are small businesses must comply with the CGMP requirements of part 507 by January 28, 2019, and with the preventive controls requirements of part 507 by January 27, 2020, and all other eligible facilities must comply by with the CGMP requirements of part 507 by January 26, 2018, and with the preventive controls requirements of part 507 by January 28, 2019.

V. Extension of Compliances Dates for Certain Facilities That Color RACs Under Part 117

Table 4 provides a summary of the revised compliance dates.

TABLE 4—EXTENSION OF COMPLIANCE DATES IN PART 117 FOR CERTAIN FACILITIES THAT COLOR RACS

	Previously announced compliance date	Compliance date with extension
Human Food—Facilities that color RACs under part 117		
Very Small Businesses (a business (including any subsidiaries and affiliates) averaging less than $1 million, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale (*e.g.,* held for a fee)).	September 17, 2018	January 27, 2020.
Small Businesses (a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees).	September 18, 2017	January 28, 2019.
Other Businesses	September 19, 2016	January 26, 2018.

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 we noted in the proposed rule to establish part 117 (78 FR 3646 at 3678 to 3679, January 16, 2013), FDA does not consider the activity of coloring a RAC to result in the transformation of the RAC into a processed food. However, this does not mean that coloring a RAC is not manufacturing/processing. The activity classification ''manufacturing/processing'' is broader than just activities that transform a RAC into a processed food. It includes most food-handling activities because it is satisfied by any degree of ''making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food'' (§ 1.227). In contrast, transforming a RAC into a processed food generally requires meeting a threshold of altering the general state of the commodity. In the proposed rule, coloring was provided 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).

An establishment that conducts manufacturing/processing activities other than those specified as being within the ''farm'' definition generally is a facility that is required to register and is subject to the human food preventive controls requirements in part 117. The ''farm'' definition provides for farms to do several manufacturing/processing activities, including treating RACs to manipulate ripening and packaging and labeling RACs. These are all manufacturing/processing activities that do not transform a RAC into a processed food. However, FDA did not include coloring, another manufacturing/processing activity that does not transform a RAC into a processed food, within the ''farm'' definition. Therefore, currently coloring triggers the

registration requirement and application of the human food preventive controls requirements in part 117 (except where other exemptions apply). We are considering whether future rulemaking to modify the ''farm'' definition is appropriate to address the issue.

Therefore, we are extending the compliance dates for facilities that would qualify as farms if they did not color RACs. We are extending the compliance dates for such operations by approximately 16 months to match the compliance dates for businesses in the same size categories in the produce safety regulation. (Note that the produce safety regulation has different compliance dates associated with sprouts but for purposes of this extension, we are not establishing different dates for sprouts.) This will match the other extended compliance dates that relate to the ''farm'' definition or the produce safety regulation in this document. With the extension, eligible facilities that are very small businesses must comply with part 117 by January 27, 2020; eligible facilities that are small businesses must comply by January 28, 2019, and all other eligible facilities must comply by January 26, 2018. We are not extending the compliance dates for facilities that engage in additional manufacturing/processing activities currently outside of the ''farm'' definition because we expect such facilities to come into compliance with part 117 as a result of those other activities.

VI. Extension of Compliances Dates for Facilities Solely Engaged in the Ginning of Cotton Under Part 507

Table 5—provides a summary of the revised compliance dates.

TABLE 5—EXTENSION OF COMPLIANCE DATES FOR FACILITIES SOLELY ENGAGED IN THE GINNING OF COTTON UNDER PART 507

	Previously announced compliance date for part 507	Compliance date for part 507 with extension
Animal Food—Facilities solely engaged in the ginning of cotton under part 507		
Very Small Businesses (a business (including any subsidiaries and affiliates) averaging less than $2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed or held without sale (*e.g.,* held for a fee or supplied to a farm without sale)).	September 17, 2019	January 26, 2021.
Small Businesses (a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees).	September 17, 2018	January 27, 2020.
Other Businesses	September 18, 2017	January 28, 2019.

Cotton ginning is considered part of harvesting and thus within the ''farm'' definition when done on a farm (and when done for safe or effective packing, it may also be considered a packing activity on a farm). When done off-farm, cotton ginning is either a packing activity (if done for safe or effective packing), or a manufacturing/processing activity, depending on the circumstances. Ginning cotton does not transform a RAC into a processed food but results in component RACs, some of which (*e.g.,* cotton seed, lint, gin trash) are used for animal food. Therefore, currently off-farm cotton ginning in the production of animal food generally triggers the food facility registration requirement and application of the animal food preventive controls requirements in part 507 (facilities solely engaged in the ginning of cotton remain exempt from the CGMP requirements in part 507). Since publication of the final rule establishing part 507, we have received communications from the cotton industry expressing concern that the part 507 rule does not apply to the vast majority of cotton ginners that are part of a farm, while it does apply to the minority of cotton ginners that do not meet the ''farm'' definition, despite the fact that both types of operations perform the same activities (Ref. 3). We are considering whether and how FDA should address these concerns.

Therefore, we are extending the compliance dates for animal food preventive controls requirements for facilities subject to part 507 that solely engage in the ginning of cotton. We are extending the compliance dates for such operations by approximately 16 months to match the other extension dates that relate to the ''farm'' definition. With the extension, eligible facilities that are very small businesses must comply with the animal food preventive controls requirements of part 507 by January 26, 2021; eligible facilities that are small businesses must comply with the animal food preventive controls requirements of part 507 by January 27, 2020, and all other eligible facilities must comply with the animal food preventive controls requirements of part 507 by January 28, 2019. We are not extending the compliance dates for facilities that engage in additional animal food manufacturing/processing activities of cotton currently outside of the ''farm'' definition (*e.g.,* crushing cotton seed to make cotton seed oil) because we expect such facilities to come into compliance with the animal food preventive controls requirements of part 507 as a result of those other activities.

In addition, some cotton ginners may be operations that would be secondary activities farms except that they do not meet the ownership criterion in the current ''farm'' definition. For further discussion of the compliance date extension for these types of operations see section IV.B. Certain Facilities That Would Qualify as Secondary Activities Farms Except for the Ownership of the Facility.

VII. Extension of Compliance Dates for Importation of Food Contact Substances Under the FSVP Regulation

Table 6 provides a summary of the revised compliance dates.

TABLE 6—EXTENSION OF COMPLIANCE DATES FOR IMPORTATION OF FOOD CONTACT SUBSTANCES UNDER THE FSVP REGULATION

	Previously announced earliest compliance date	Earliest compliance date with extension
Importation of Food Contact Substances under the FSVP Regulation ..	May 30, 2017	May 28, 2019.

In the preamble of the final rule establishing the FSVP regulation, we stated that the definition of ''food'' for purposes of FSVP (§ 1.500) includes food contact substances that are considered ''food'' in section 201(f) of the FD&C Act. 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 (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. Therefore, we concluded that importers must have an FSVP for a food contact substance that they import that meets the definition of ''food'' in section 201(f) of the FD&C Act (80 FR 74226 at 74233).

Since we published the final rule establishing the FSVP regulation, our Technical Assistance Network has received inquiries regarding the applicability of the FSVP regulation to food contact substances. In addition, on June 16, 2016, FDA met with representatives of the food packaging manufacturing industry at their request to listen to concerns regarding the applicability of the FSVP regulation to the importation of food contact substances (Ref. 4). The industry representatives stated that the supply chain associated with imported substances used to manufacture food contact substances is highly complex and very different from other foods subject to the FSVP regulation. The industry representatives also asserted that the hazards associated with food contact substances are already adequately addressed through the food additive petition and food contact substance notification processes under section 409 of the FD&C Act (21 U.S.C. 348).

After considering the information presented by the industry representatives, FDA believes that compliance with the requirement to conduct verification activities under the FSVP regulation for food contact substances by May 30, 2017, might not be feasible. Accordingly, we are extending the compliance date for the importation of food contact substances by 2 years so that we can consider how best to address the feasibility concerns. We note the relatively rare occurrence of significant safety concerns associated with the manufacture of food contact substances and FDA's extensive premarket approval and review processes for these substances under section 409 of the FD&C Act provide some assurances regarding safety during this time. 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.

VIII. Extension of Compliance Date for the CGMP Requirements of Part 117 for Facilities Producing Grade ''A'' Milk and Milk Products Covered by NCIMS Under the PMO

In the preamble of the final rule establishing part 117, we established a compliance date of September 17, 2018, for ''PMO facilities'' (see Response 214, 80 FR 55908 at 55987 to 55988). As we discussed in Response 214, we agreed that we should make use of the existing system of State regulatory oversight for Grade ''A'' milk and milk products provided through the NCIMS and the food safety requirements of the PMO. We described our reasons for deciding to extend the compliance date for ''PMO-regulated facilities'' to comply with the human food preventive controls requirements to September 17, 2018. Those reasons related to the current provisions of the PMO, the work already begun by NCIMS to modify the PMO to include all of the human food preventive controls requirements established in part 117, and complex implementation issues concerning the interstate movement of milk and milk products and imported milk.

In the **Federal Register** of November 18, 2015 (80 FR 71934), we clarified that the extended compliance date of September 17, 2018, for ''PMO facilities'' applies only to Grade ''A'' milk and milk products covered by NCIMS under the PMO, and not to the manufacturing, processing, packing, or holding of other food produced in such facilities. In the November 18, 2015, clarification, we did not discuss the date for ''PMO facilities'' to be in compliance with the CGMP requirements of part 117. During our outreach activities for implementation of part 117 we have received questions about when ''PMO facilities'' must comply with the modernized CGMP requirements of part 117 (primarily located in subpart B).

We have not established compliance dates for the modernized CGMPs that are different from the general compliance dates for the preventive controls requirements in part 117 with one exception related to ''PMO facilities'' (see table 53 in the preamble of the final rule establishing part 117, 80 FR 55908 at 56128). Specifically, we provided that the extension of the compliance date for ''PMO facilities'' until September 17, 2018, applied only to ''subparts C and G'' (the principal provisions of the human preventive controls requirements) (see Response 214, 80 FR 55908 at 55987 to 55988). In this document, we are extending the date for compliance with the modernized CGMPs by ''PMO facilities'' until September 17, 2018. We will continue to work with the NCIMS to modify the PMO to reflect the modernized CGMPs and the preventive control requirements. The extension will create a single compliance date for the Grade ''A'' milk and milk products covered by the PMO. Note that this extension applies only to Grade ''A'' milk and milk products covered by NCIMS under the PMO, and not to the manufacturing, processing, packing, or holding of other food produced in such facilities.

IX. Clarification of Compliance Dates for Certain Agricultural Water Testing Provisions in Produce Safety Regulation

In this final rule, we are also clarifying our intent regarding the meaning of the compliance dates with respect to certain testing requirements related to agricultural water in the produce safety regulation.

Specifically, in the preamble of the final rule establishing the produce safety regulation (at 80 FR 74354 at 74453 to 74454) we explained that we excluded § 112.46(b)(1), with respect to untreated surface water only, from the 2-year extended compliance period provided for the remainder of § 112.46 because, in order to comply with the microbial quality criteria in § 112.44(b), farms must have developed a microbial water quality profile (MWQP) based on

the initial survey conducted over a minimum of 2 years and not greater than 4 years. We stated that to develop the MWQP prior to the point at which they must comply with all of the requirements of subpart E, covered farms must begin water sampling and subsequent testing not later than 4 years after issuance of the rule for very small farms; not later than 3 years after issuance of the rule for small farms; and not later than 2 years after issuance of the rule for all other farms. As an example we stated that initiating water sampling upon publication of the rule would allow covered farms that are not small or very small to collect 5 samples per year over the next 4 years, sufficient to make up the minimum 20 samples necessary to develop the MWQP required under § 112.46(b) at the point at which they must comply with all of the requirements of subpart E. We also stated that if these covered farms initiated water sampling 2 years after issuance of the rule, the farms would need to collect 10 samples per year over the next 2 years to make up the minimum 20 samples necessary to develop the MWQP.

We want to clarify and correct these earlier statements. We note that § 112.46(b)(1)(i)(A) allows covered farms discretion as to both (1) the number of samples they include in their initial survey, provided that the total must be 20 or more samples; and (2) the time period over which such samples are taken, provided that the period must be at least 2 years and no more than 4 years. For each business size category, the compliance date for § 112.46(b)(1) with respect to untreated surface water testing is 2 years before the compliance date for the § 112.44(b) microbial quality criteria for such water. This does not mean that covered farms have only 2 years in which to conduct their initial surveys for untreated surface water under § 112.46(b)(1) if they begin testing on the compliance date for that provision. Covered farms have 2 to 4 years in which to fulfill that requirement, per § 112.46(b)(1)(i)(A). This means that, for example, a farm that is not small or very small must begin sampling and testing untreated surface water in accordance with § 112.46(b)(1)(i)(A), as applicable, no later than January 26, 2018. The relevant compliance date for the related microbial quality criteria is 2 years later, on January 27, 2020. However, the farm has discretion under § 112.46(b)(1)(i)(A) as to both (1) the number of samples they include in their initial survey, provided that the total must be 20 or more samples; and (2) the time period over which such samples are taken, provided that the period must be at least 2 years and no more than 4 years. Therefore, to provide a few examples, all of the following possible approaches are acceptable for farms that are not small or very small:

- Beginning in 2018, conducting an initial survey consisting of taking 10 samples per year over 2 years (10 in 2018 and 10 in 2019) for a total of 20 samples; calculating the MWQP for the first time upon completing the 20-sample data set (*e.g.,* at the end of 2019, early 2020); and applying any necessary corrective actions under § 112.45(b) as soon as practicable and no later than the following year (*e.g.,* in 2020–2021).
- Beginning in 2018, conducting an initial survey consisting of taking 5 samples per year over 4 years (5 in 2018, 5 in 2019, 5 in 2020, and 5 in 2021) for a total of 20 samples; calculating the MWQP for the first time upon completing the 20-sample data set (*e.g.,* at the end of 2021, early 2022); and applying any necessary corrective actions under § 112.45(b) as soon as practicable and no later than the following year (*e.g.,* in 2022–2023).
- Beginning in 2018, conducting an initial survey consisting of taking 10 samples per year over 4 years (10 in 2018, 10 in 2019, 10 in 2020, and 10 in 2021) for a total of 40 samples; calculating the MWQP for the first time upon completing the 40-sample data set (*e.g.,* at the end of 2021, early 2022); and applying any necessary corrective actions under § 112.45(b) as soon as practicable and no later than the following year (*e.g.,* in 2022–2023).

For small and very small farms, the same approaches are acceptable, and the relevant dates are 1 and 2 years later, respectively.

X. Economic Analysis of Impacts

In the final regulatory impact analysis (FRIA) for part 117, we concluded that extension of the compliance dates would be unlikely to significantly affect the cost estimates made (Ref. 5). In the FRIA for the produce safety regulation, we noted that extended compliance dates would result in a decrease in costs as smaller operations would have additional time to fully and correctly implement the rule's requirements (Ref. 6). We did not quantify the potential impact of extended compliance periods on the costs of part 507 or the FSVP regulation but expect the impacts would be similar to those of part 117 or the produce safety regulation.

We are extending the compliance dates by 2 years for the written assurances in the customer provisions in part 117 and part 507, the produce safety regulation, and the FSVP regulation. Although none of the FRIAs provided a separate cost analysis for the written assurance provisions, based on our general conclusions about the costs of extending compliance dates and because the affected businesses will not be incurring the costs associated with the written assurances during the compliance delay period, we believe that a 2-year delay in the compliance dates for the written assurances in the customer provisions for these rules is unlikely to significantly affect the costs of the rules.

We are extending the compliance dates in part 117 and part 507 for facilities that are solely engaged in packing and/or holding activities on produce RACs and/or nut hulls and shells. The new compliance dates for part 117 are the same as the compliance dates under the produce safety regulation for the same size categories: January 27, 2020 (very small businesses), January 28, 2019 (small businesses), and January 26, 2018 (other businesses). The new compliance dates for part 507 are staggered to allow for compliance with CGMP requirements first followed by the animal food preventive controls requirements 1 year later. The part 507 CGMP compliance dates for these facilities are the same as the compliance dates under the produce safety regulation for the same size categories: January 27, 2020 (very small businesses), January 28, 2019 (small businesses), and January 26, 2018 (other businesses). The part 507 animal food preventive controls requirements for the same size categories are: January 26, 2021 (very small businesses), January 27, 2020 (small businesses), and January 28, 2019 (other businesses). Although the FRIAs for part 117 and part 507 did not provide a separate compliance cost analysis for facilities solely engaged in packing and/or holding activities on produce RACs and/or nut hulls and shells, based on our general conclusions about the costs of extending compliance dates and because the affected businesses will not be incurring the costs associated with compliance during the delay period, we believe that the delay in the compliance dates for these facilities is unlikely to significantly affect the costs of the rules.

We are similarly extending the compliance dates in part 117 and part 507 for certain facilities that would qualify as secondary activities farms except for the ownership of the facility. Although the FRIAs for part 117 and part 507 did not provide a separate compliance cost analysis for these facilities, based on our general conclusions about the costs of extending

compliance dates and because the affected businesses will not be incurring the costs associated with compliance during the delay period, we believe that the delay in the compliance dates for these facilities is unlikely to significantly affect the costs of the rules.

We are similarly extending the compliance dates in part 117 for certain facilities that color RACs. Although the FRIA for part 117 did not provide a separate compliance cost analysis for these facilities, based on our general conclusions about the costs of extending compliance dates and because the affected businesses will not be incurring the costs associated with compliance during the delay period, we believe that the delay in the compliance dates for these facilities is unlikely to significantly affect the costs of the rule.

We are similarly extending the compliance dates in part 507 for facilities that are solely engaged in the ginning of cotton. Although the FRIA for part 507 did not provide a separate compliance cost analysis for these facilities, based on our general conclusions about the costs of extending compliance dates and because the affected businesses will not be incurring the costs associated with compliance during the delay period, we believe that the delay in the compliance dates for these facilities is unlikely to significantly affect the cost of the rule.

We are extending the compliance date for the importation of food contact substances by 2 years, such that the earliest that an importer would be required to comply with the FSVP regulation for the importation of food contact substances would be May 28, 2019. Although the FRIA for the FSVP regulation did not provide a separate compliance cost analysis for importers of food contact substances, based on our general conclusions about the costs of extending compliance dates and because the affected businesses will not be incurring the costs associated with compliance during the delay period, we believe that the delay in the compliance dates for these facilities is unlikely to significantly affect the cost of the rule.

We are extending the compliance date for the CGMP Requirements of part 117 for facilities producing Grade ''A'' milk and milk products covered by NCIMS under the PMO. Although the FRIA for part 117 did not provide a separate compliance cost analysis for these facilities to comply with subpart B of part 117, based on our general conclusions about the costs of extending compliance dates and because the affected businesses will not be incurring the costs associated with compliance during the delay period, we believe that the delay in the compliance dates for these facilities is unlikely to significantly affect the costs of the rule.

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 states the importance of quantifying costs and benefits, reducing costs and burdens, and harmonizing rules. We believe this final rule will not increase compliance costs and will serve an important purpose of providing us an opportunity to consider how to reduce burdens on the public and maintain or improve coordination among the four rules affected. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule only extends various compliance dates for certain provisions and/or certain entities with respect to the four rules discussed here, we have determined that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

XI. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

XIII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XIV. Executive Order 13175

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a tribal summary impact statement is not required.

XV. References

The following references are on display in the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.*

1. Grocery Manufacturers Association, ''21 CFR 117.136. Industry Impacts from Disclosure and Written Assurance Requirements,'' 2016.
2. Letter dated April 19, 2016, from United Fresh Produce Association and 21 other organizations to Michael Taylor and Stephen Ostroff of FDA.
3. Letter dated May 20, 2016, from Roger A. Isom of the California Cotton Ginners Association to Jeanette Murphy of FDA.

4. Letter dated May 3, 2016, from Society of Plastics Industry, Inc., and other organizations to Michael Taylor and Stephen Ostroff of FDA.
5. FDA, ''Part 117. FSMA Final Rulemaking for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food: Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Final Unfunded Mandates Reform Act Analysis, and Final Paperwork Reduction Act Analysis,'' 2015. (*http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM472884.pdf).*
6. FDA, ''Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,'' 2015. (*http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM472330.pdf*).

Dated: August 18, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2016–20176 Filed 8–23–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2016–N–1896]

New Animal Drugs for Use in Animal Feed; Category Definitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, we) is amending the animal drug regulations by revising the definitions of the two categories of new animal drugs used in medicated feeds to base category assignment only on approved uses in major animal species. This revision will preserve the availability of medicated feeds intended for therapeutic use in minor animal species and prevent a significant disincentive for future development of additional minor species therapies.

DATES: This rule is effective December 1, 2016. Submit either electronic or written comments by November 7, 2016. See Section IV for further discussion of the effective date.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–1896 for ''Category Definitions For Minor Species.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: David Edwards, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6205, *david.edwards@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Direct Final Rule

FDA is issuing this direct final rule to revise the definitions of the two categories of new animal drugs used in