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MEMORANDUM

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Re: **FDA Extends Several FSMA Compliance Deadlines**

The Food and Drug Administration (FDA) recently published a final rule extending several compliance deadlines for specific provisions in four of the seven major FDA Food Safety Modernization Act (FSMA) final rules. 1/ The extensions affect provisions of the Preventive Controls for Human Food, Preventive Controls for Animal Food, Foreign Supplier Verification Program (FSVP), and Produce Safety rules. The extensions each address specific issues that were brought to the agency's attention by industry. Importantly, these are limited extensions for particular issues, rather than blanket extensions of the compliance date for the entire regulations.

The extensions address the compliance dates for the following:

1. The requirement to obtain written customer assurances when controls are applied downstream in the distribution chain under the Human and Animal Food Preventive Controls rules, the FSVP rule, and the Produce Safety rule;
2. Facilities solely engaged in packing and/or holding raw agricultural commodities (RACs) that are produce and/or nut hulls and shells;
3. Facilities that would qualify as secondary activities farms except for the ownership of the facility;
4. Certain facilities that color RACs;
5. Facilities solely engaged in ginning cotton;
6. Imports of food contact substances;
7. Current Good Manufacturing Practices (cGMPs) requirements under Part 117 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); and
8. Certain provisions related to agricultural water testing under the Produce Safety rule.

This memorandum explains each of the extended compliance deadlines. Appendix 1 to this memorandum summarizes the previous and revised compliance dates for each of the provisions affected by the final rule.

1/ 81 Fed. Reg. 57784 (Aug. 24, 2016).

1. Extension of Compliance Dates for Customer Assurance Provisions

FDA is delaying by two years the deadlines for compliance with provisions in the Preventive Controls rules, the FSVP rule, and the Produce Safety rule that require companies to obtain written assurances from their customers that hazards are being controlled further down the distribution chain. As explained in more detail below, FDA is not extending the compliance date for the corresponding regulations requiring written disclosure of such hazards.

As background and in summary, 21 CFR § 117.136 of the Preventive Controls for Human Food regulations provides that a manufacturing or processing facility is not required to implement a preventive control if it identifies a hazard requiring a preventive control and this hazard is controlled downstream by a commercial customer, provided the facility:

(1) Provides documentation to its direct customer that the food is "not processed to control [identified hazard]" (the disclosure statement requirement); and
(2) Receives written assurance from its customer that the customer or an entity further down the supply chain will control the hazard (customer assurance requirement).

There are similar provisions in the Preventive Controls for Animal Food rule (§ 507.36) and FSVP rule (§ 1.507). Likewise, the Produce Safety rule provides that farms are exempt from the rule if the produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided that a similar disclosure statement requirement and customer assurance requirement are met (§ 112.2).

FDA explains in the preamble that it learned from the Grocery Manufacturers Association (GMA) that compliance with the customer assurance requirements under each rule would require "vastly more written assurances and consequently resources" than FDA had anticipated. After considering information presented by GMA, FDA recognized that the customer assurance requirement "significantly exceeds the current practices of even the largest facilities," such that compliance by September 19, 2016 "may not be feasible." Accordingly, FDA is extending the compliance dates for the customer assurance requirements by 2 years in each of these rules. 2/ The compliance dates for corresponding requirements contingent upon the customer assurances (e.g., §§ 117.137 and 117.335 in the Preventive Controls for Human Food rule) also are extended by two years. This additional time will allow FDA to consider "the best approach to address feasibility concerns."

Notably, however, FDA has not extended any of the compliance deadlines for the disclosure statement requirements. This means that the Preventive Controls for Human Food disclosure requirement for companies with 500 or more full-time equivalent employees takes effect on September 19, 2016. FDA plans to issue draft guidance on the disclosure statement provisions soon.

2. Facilities Solely Engaged in Packing and/or Holding Produce RACS and/or Nut Hulls and Shells

FDA is extending the compliance dates by approximately 16 months for facilities solely engaged in packing and/or holding raw agricultural commodities that are produce (produce RACS) and facilities

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2/ Some FSVP compliance dates are benchmarked off of the supplier's own compliance date. In these instances, the new compliance date for the customer assurance requirement is based on the supplier's original compliance date for the relevant regulations (i.e., the other changes FDA is making to compliance dates will not impact when an FSVP importer must comply with the customer assurance requirements).

that hull, shell, pack, and/or hold nuts. These facilities are covered by the Preventive Controls rules, so the extension will align their compliance date with the Produce Safety rule compliance date.

Certain off-farm operations, such as facilities that hull, shell, pack and/or hold nuts, are subject to the Preventive Controls rule, rather than the Produce Safety rule (e.g., an operation that does not meet the definition of "secondary activities farm"). FDA has advised that although it feels the statute prevents it from considering these facilities to be farms (because they do not have a sufficient connection to a farm), these operations should be able to "draw from the provisions of the [P]roduce [S]afety regulation in developing [their] 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." Thus, if such an operation is considered a "facility," it needs the same types of food safety practices under its Food Safety Plan as it would be required to implement under the Produce Safety rule.

Because of the nexus between the Preventive Controls and Produce Safety rules for these facilities, FDA is extending the compliance date by approximately 16 months for "facilities" that are solely engaged in packing and/or holding produce RACs and/or nut hulls and shells. The extension will align the compliance date for these facilities with the compliance dates for operations under the Produce Safety rule. There are corresponding revisions to the compliance dates under Part 507 (Preventive Controls for Animal Food).

Notably, the extended compliance dates do not apply to facilities that also engage in manufacturing or processing of nuts, or of nut hulls and shells. For example, if a facility grinds nut shells to make an animal food ingredient, it would not be subject to this extension.

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

FDA is extending the compliance dates for Part 117 by approximately 16 months for certain operations that would qualify as "secondary activities farms" except that they do not meet the ownership criterion of the definition. The Preventive Controls for Human Food rule established a "secondary activities farm" definition that would incorporate into the "farm" definition operations that are not located on a primary production farm but are sufficiently related to a primary production farm such that it is appropriate to consider the operations to be farms. Secondary activities farms include farms devoted to harvesting (such as hulling or shelling), packing, and/or holding of RACs. To qualify as a secondary activities farm, a majority interest in the secondary activities farm must be majority owned by the primary production farm or farms that grow, harvest, and/or raise the majority of the RACs that the secondary activities farm harvests, packs, and/or holds.

FDA received comments alerting the agency that a number of different business structures satisfy the agency's intention to require a close relationship in ownership between the primary and secondary activities farms, even though they do not satisfy the ownership requirements in the farm definition. In order to align the compliance deadline for such business with those for comparable businesses subject to the Produce Safety rule, FDA is extending the compliance date for certain operations that would qualify as secondary activities farms except that they do not meet the ownership criterion of the definition. 3/

This extension will only apply to operations meeting three requirements:

(1) the operation is not located on the primary production farm;

3/ FDA's action only delays the compliance date for these operations; it does not amend the "farm" definition to reclassify these operations as secondary activities farms. These operations are still required to comply with part 117.

(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 that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the operation. 4/

For operations that satisfy these criteria, FDA also is making a parallel 16-month extension for compliance with Part 507 under the Animal Food Preventive Controls rule. FDA is considering future rulemaking to modify the definition of a farm to address ownership issues.

4. Facilities that Color RACs

FDA has delayed compliance with Part 117 for approximately 16 months for facilities that color RACs. FDA explains that coloring RACs triggers registration and compliance with the Preventive Controls for Human Food requirements in Part 117.

FDA currently is considering whether to modify the "farm" definition to include coloring RACs. In the meantime, FDA's extension aligns the deadline for those facilities that would qualify as "farms" if they did not color RACs with the compliance dates for comparable facilities subject to the Produce Safety rule. The compliance deadline for facilities that engage in additional manufacturing/processing activities outside the "farm" definition remains the same.

5. Facilities Solely Engaged in the Ginning of Cotton Under Part 507

FDA is extending by approximately 16 months the preventive controls requirements under Part 507 for facilities solely engaged in ginning cotton. FDA is taking this action because the cotton industry has expressed concern that cotton ginners that perform the same activities are subject to different requirements depending on whether they meet the "farm" definition. FDA currently is considering whether and how to address these concerns and consequently has extended the deadline for these operations to make their deadlines match the other extension dates that relate to the "farm" definition. The extension does not apply to 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 those facilities must come into compliance with the animal food preventive controls requirements as a result of those other activities.

6. Importers of Food Contact Substances Under FSVP

FDA is extending compliance with the FSVP rule for importers of food contact substances for two years to allow the agency time to address feasibility concerns with this requirement. The food packaging manufacturing industry has explained to FDA 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. In addition, the industry contends that the hazards associated with food contact substances already are addressed adequately through the food additive petition and food contact substance notification processes.

4/ 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). Another example is 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).

After considering the information industry has presented, FDA believes that compliance with the FSVP regulation for food contact substances by May 30, 2017 might not be feasible. FDA consequently is extending the deadline by two years for imports of food contact substances to allow the agency time to consider "how best to address the feasibility concerns."

7. Facilities that Produce Grade A Milk

For PMO-regulated facilities, FDA is clarifying that September 17, 2018 is the compliance date for subparts B, C, and G (cGMPs, preventive controls, and the supply-chain program). This creates a single compliance date for Grade "A" milk and milk products covered by the PMO. FDA also reinforces its earlier statement that the extension does not apply to manufacturing, processing, packing, or holding of other food produced in PMO-regulated facilities. 5/

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

FDA also clarifies its intent regarding the meaning of the compliance dates for certain agricultural water testing requirements in the Produce Safety rule. Specifically, farms are allowed discretion as to both the number of samples they take in their initial survey to develop a microbial quality profile for untreated surface water directly applied to growing produce, provided that the total is 20 or more samples. They also are allowed discretion as to the time period over which the samples are taken, provided that it is at least two years and no more than four years. The Federal Register notice provides a detailed explanation and examples of how these requirements apply in order to mitigate confusion that has arisen in industry. FDA's explanation warrants careful review by anyone who is covered by this requirement.

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We will continue to monitor FDA's implementation of FSMA. Should you have any questions, please do not hesitate to contact us.

5/ 80 Fed. Reg. 71934 (Nov. 18, 2015).

APPENDIX A
EXTENSION OF COMPLIANCE DATES 6/

	Previously Announced Compliance Date	Compliance Date With Extension
Compliance with Customer Assurance Provisions in Part 117 and Related Rules		
Human Food – § 117.136(a)(2)(ii), (3)(ii), and 4(ii)		
Small businesses	September 18, 2017	September 18, 2019
Business that is neither small or very small	September 19, 2016	September 19, 2018
Animal Food – § 507.36(a)(2)(ii), (3)(ii), and (4)(ii)		
Small Business	September 17, 2018	September 17, 2020
Business that is neither small or very small	September 18, 2017	September 18, 2019
FSVP – § 1.507(a)(2)(ii), (3)(ii), and (4)(ii)		
Latest 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 all covered produce except sprouts	January 27, 2020	January 26, 2022
Small businesses relying on the exemption in § 112.2(b) for all covered produce except sprouts	January 28, 2019	January 26, 2021
All other businesses relying on the exemption in § 112.2(b) for all covered produce except sprouts	January 26, 2018	January 27, 2020
Compliance Dates for Parts 117 and 507 for Facilities Solely Engaged in Packing and/or Holding Produce RACS and/or Nut Hulls and Shells		
Human Food – Facilities solely engaged in packing and/or holding activities on produce RACs (part 117)		
Very small businesses	September 17, 2018	January 27, 2020
Small businesses	September 18, 2017	January 28, 2019

6/ For brevity, definitions of these categories are not provided. Likewise, provisions specific to sprouts are omitted.

	Previously Announced Compliance Date	Compliance Date With Extension
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	September 17, 2018 (cGMPs) September 17, 2019 (preventive controls)	January 27, 2020 (cGMPs) January 26, 2021 (preventive controls)
Small businesses	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
Compliance Dates for Certain Facilities That Would Qualify as Secondary Activities Farms Except for Ownership of the Facility		
Human Food – Facilities that would qualify as secondary activities farms except for ownership of the facility (part 117)		
Very small businesses	September 17, 2018	January 27, 2020
Small businesses	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	September 17, 2018 (cGMPs) September 17, 2019 (preventive controls)	January 27, 2020 (cGMPs) January 26, 2021 (preventive controls)
Small businesses	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)
Compliance Dates in Part 117 for Certain Facilities That Color RACs		
Human Food – Facilities that color RACs under part 117		
Very small businesses	September 17, 2018	January 27, 2020
Small businesses	September 18, 2017	January 28, 2019
Other businesses	September 19, 2016	January 26, 2018
Compliance Dates for Facilities Solely Engaged in the Ginning of Cotton Under Part 507		
Animal Food – Facilities solely engaged in the ginning of cotton under part 507		
Very small businesses	September 17, 2019	January 26, 2021
Small businesses	September 17, 2018	January 27, 2020
Other businesses	September 17, 2017	January 28, 2019
Compliance Dates for Importation of Food Contact Substances Under the FSVP Regulation		
No sooner than 18 months after the publication of the final rule	May 30, 2017 (earliest compliance date)	May 28, 2019 (earliest compliance date)
Compliance Dates for Modified cGMPs in Part 117 for PMO Facilities		
PMO facilities	---	September 17, 2018