

ALERTS

Food, Drug And Device Law Alert - FDA Extends Compliance Dates For Certain Final Rules Under The Food Safety Modernization Act

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The Food and Drug Administration (FDA) recently issued a [final rule](#) extending certain compliance dates for some of the foundational final rules promulgated pursuant to the Food Safety Modernization Act (FSMA). The extension impacts provisions in these four rules: (1) Preventive Controls for Human Food; (2) Preventive Controls for Food for Animals; (3) Produce Safety Final Rule; and (4) Foreign Supplier Verification Programs (FSVP).

The following summary of important extensions is modified from the FDA website:

Extending compliance dates for certain provisions concerning written customer assurances

- All four rules contain “customer provisions” for modified requirements (or, in the case of the Produce Safety rule, an exemption) when food safety controls re applied downstream and certain conditions are satisfied. For example, the customer provisions in some of the rules allow a manufacturer/processor that does not control a hazard requiring a preventive control to rely on its customer to control the hazard.
- The manufacturer/processor must disclose in documents accompanying the food that it is not processed to control the hazard and must obtain a written assurance from the customer that the customer will manufacture the food in accordance with applicable food safety requirements or sell only to someone that agrees to do so.
- The final rule provides an additional two years to comply with the customer assurance requirements while FDA considers the best approach to address feasibility concerns.
- The compliance dates for these requirements are different for each rule, with the earliest date being September 19, 2018, for large human food facilities.

Extending compliance dates for food contact substances under FSVP rule

- Importers subject to the FSVP rule have an additional two years to meet the requirements of the rule for importing food contact substances. (A food contact substance is any substance intended

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for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if the substance is not intended to have any technical effect on the food).

- The agency will consider how best to address feasibility concerns for the application of FSVP to these substances. In doing so, the FDA noted the relatively rare occurrence of significant safety concerns associated with the manufacture of food contact substances and the agency's existing, extensive premarket approval and review processes for these substances provide some assurances regarding safety during this time.
- The earliest compliance date is May 28, 2019.

Extending compliance dates for facilities that only pack and/or hold raw agricultural commodities that are produce and/or nut hulls and shells

- Compliance dates for facilities that are covered by the two Preventive Controls rules for human and animal food, including CGMPs, and are solely engaged in packing and/or holding raw agricultural commodities (for example, some packing houses) are extended to align with the compliance dates for farms conducting similar activities under the Produce Safety rule.
- This extension includes facilities that hull, shell, pack and/or hold nuts.
- The earliest compliance date is January 26, 2018.

Extending compliance dates for facilities coloring raw agricultural commodities

- Compliance dates for facilities that color raw agricultural commodities are being extended for 16 months to align with the Produce Safety rule. Currently coloring is considered a manufacturing/processing activity that requires food facility registration and is subject to the CGMP and Preventive Controls for Human Food rule.
- FDA is considering future rulemaking to modify the definition of a farm in order to address "coloring" activities.
- The earliest compliance date is January 26, 2018.

The final rule includes extensions of other compliance dates as well, including those for (1) certain facilities that would qualify as secondary activities farms except for the ownership of the facility, (2) CGMP compliance date for Grade "A" milk products, and (3) compliance dates for cotton ginning facilities under animal food rule.

Finally, the final rule also clarifies the timeframe for agricultural water testing compliance under the Produce Safety rule.

The compliance dates vary by size of entity and rule, so the full text of the final rule should be reviewed to determine the compliance date for a particular company.

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