

Regulatory Alert: FDA Issues Draft Guidance for Preventive Controls Rule for Human Food, Extends Compliance Dates for FSMA Final Rules
Retailers, Wholesalers and Manufacturers Should Reevaluate Existing Food Safety Plans, Be Aware of Extensions

September 9, 2016

On August 23rd 2016, the U.S. Food and Drug Administration (FDA) released [draft guidance](#) (“Draft Guidance”) to assist industry in complying with the Preventive Controls for Human Food Rule. The agency also announced that it is delaying compliance dates for certain aspects of the PC Rule and other FSMA Rules.

Draft Guidance

The Draft Guidance on the Preventive Controls for Human Food Rule is not complete. It contains only five of a total of fourteen expected chapters. The Draft Guidance is similar to the information in the Food Safety Preventive Controls Alliance (FSPCA) coursebook, but is not identical and differs in certain ways. Consequently, *retailers, wholesalers and manufacturers should reassess their existing food safety plans in light of the Draft Guidance*. It is important to consider that as is generally the case with FDA’s Seafood HACCP Rule, inspectors will be evaluating facilities for compliance with the Preventive Controls for Human Food Rule based on the guidance rather than the FSPCA handbook or other templates. It is therefore critical that food industry businesses closely evaluate the Draft Guidance. Comments are requested by FDA on the Draft Guidance by February 21, 2017.

The five chapters and appendices that have been released at this time include:

- Chapter 1: The Food Safety Plan
- Chapter 2: Conducting a Hazard Analysis
- Chapter 3: Potential Hazards Associated with the Manufacturing, Processing, Packing and Holding of Human Food
- Chapter 4: Preventive Controls
- Chapter 5: Application of Preventive Controls and Preventive Controls Management Components
- Appendix 1: Potential Hazards for Foods and Processes
- Appendix 2: Food Safety Plan Forms
- Appendix 3: Bacterial Pathogen Growth and Inactivation

The outstanding chapters include:

- Chapter 6: Use of Heat Treatments as a Process Control
- Chapter 7: Use of Time/Temperature Control as a Process Control
- Chapter 8: Use of Formulation as a Process Control
- Chapter 9: Use of Dehydration/Drying as a Process Control
- Chapter 10: Sanitation Controls
- Chapter 11: Food Allergen Controls

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- Chapter 12: Preventive Controls for Chemical Hazards
- Chapter 13: Preventive Controls for Physical Hazards
- Chapter 14: Recall Plans
- Appendix 4: Sanitation and Hygienic Zoning

Compliance Date Extensions

On August 24, 2016, FDA published a [final rule](#) in the Federal Register extending the compliance dates for certain provisions in the following rules:

- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Foreign Supplier Verification Program
- Produce Safety Rule

Written Assurances:

All four rules contain provisions requiring written assurances from downstream customers for foods where the hazard is not controlled upstream. For example, in certain rules a manufacturer or processor that does not control a hazard requiring a preventive control is allowed to rely on its customer to ensure the hazard is controlled.

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 it will ensure control of the hazard.

The final rule extends the compliance date for written customer assurances for an additional two years.

The earliest compliance date is extended to **September 19, 2018** (All four rules contain “customer provisions” with varying compliance dates).

Facilities that only pack and/or hold raw agricultural commodities that are produce and/or nut hulls and shells:

The earliest compliance date for these facilities to comply with the Preventive Controls Rules for Human and Animal Food is extended to **January 26, 2018** (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.

Certain facilities that would qualify as secondary activities farms except for the ownership of the facility:

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The earliest compliance date for these facilities to comply with the Preventive Controls for Human and Animal Food Rules is extended to **January 26, 2018**.

The extension is only applicable if: (1) the operation is not located on a primary production farm; (2) the operation is devoted to harvesting, packing, and/or holding of raw agricultural commodities; and (3) the operation is under common ownership with the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities (RACs) harvested, packed, and/or held by the operation.

FDA is considering a future rulemaking to modify the definition of farm in order to address ownership issues.

Compliance dates for facilities coloring raw agricultural commodities:

The earliest compliance date for such facilities to comply with the Preventive Controls for Human Food Rule is extended to **January 26, 2018** (extended 16 months to align with the Produce Safety Rule).

FDA is considering a future rulemaking to modify the definition of a farm in order to address “coloring” activities.

Compliance dates for cotton ginning facilities under the Preventive Controls for Food for Animal Rule:

The earliest compliance date for these facilities is extended to **January 28, 2019** (extended 16 months to comply with rules in the CGMP and Preventive Controls for Animal Food rule).

Compliance dates for food contact substances under the Foreign Supplier Verification Programs Rule:

The earliest compliance date for these facilities is extended to **May 28, 2019** (extended 2 years).

FDA is seeking to address feasibility concerns for applying FSVP to food contact substances (which include items such as cookware and food packaging materials) and has noted the relatively rare occurrence of significant safety concerns associated with the manufacture of food contact substances.

CGMP compliance date for Grade “A” milk products under the Provisions in Preventive Controls for Human Food Rule:

The earliest single compliance date merges the two different dates for the compliance of facilities producing Grade “A” milk and milk products to comply with the CGMPs and the preventive control requirements and is extended to **September 17, 2018**.

Agricultural water testing compliance timeframe under the Produce Safety Final Rule:

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Farms subject to the Produce Safety rule have discretion in how they sample agricultural water to develop a microbial quality profile. They are allowed discretion as to both the number of samples they take in their initial survey, provided that the total is 20 or more samples. And they are allowed discretion as to the time period over which such samples are taken, provided that it is at least two years and no more than four years. The rule provides examples of approaches that farms may consider when collecting water samples and how they relate to compliance dates for the water-related requirements of the Produce Safety rule.

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