

# **FDA Issues Parts 1-5 of 14-Part Draft Guidance for Preventive Controls Final Rule**

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On September 19, the FDA Foods and Veterinary Programs held a webinar to discuss FDA's recent issuance of the preventive controls hazard analysis and risk-based draft guidance (Draft Guidance), which became available for public comment on August 24, 2016.<sup>1</sup> The Draft Guidance provides the first five chapters of a 14-part guidance designed to help businesses comply with the Preventive Controls for Human Food Final Rule<sup>2</sup> by the compliance date of September 19, 2016.

The Draft Guidance explains FDA's current thinking on how to comply with the requirements for hazard analysis and risk-based preventive controls, and includes discussions on establishing a food safety plan, what a hazard analysis entails, appropriate preventive controls for certain food categories, monitoring, corrective actions based on a hazard analysis, verification, and records requirements.

The materials that have been developed and released include the following:

- Introduction and Purpose
- 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 Control Management Components
- Appendix 1: Potential Hazards for Foods and Processes
- Appendix 2: Food Safety Plan Forms

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- Appendix 3: Bacterial Pathogen Growth and Inactivation

Remaining chapters will cover process controls, sanitation controls, food allergen controls, preventive controls for chemical and physical hazards, and recall plans.

The FDA will release additional chapters of the Draft Guidance for public comment as they are completed. The Agency plans on releasing all chapters of the Draft Guidance by early 2018.

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<sup>1</sup>See, *generally*, FDA Draft Guidance for Industry, Hazard Analysis and Risk-Based Preventive Controls for Human Food (August 24, 2016) <http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM517610.pdf>.

<sup>2</sup>The Food and Drug Admin., Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Final Rule

(Sept. 17, 2015) <https://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21920.pdf>.

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