

## ALERTS

# Food, Drug And Device Law Alert - FDA Issues Guidance On Hazard Analysis And Risk-Based Preventive Controls For Human Food

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As regular readers of these alerts know, almost one year ago the Food and Drug Administration (FDA) released its final rule entitled, “Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food,” now found in 21 CFR Part 117. Our summary of the final rule can be [found here](#). To assist food manufacturers with compliance with the final rule, the FDA recently released a partial draft guidance on hazard analysis and risk-based preventive controls.

The current five chapters and three appendices span 185 pages, so the complete document will be more like a book than a typical guidance document. The FDA states that it will announce the availability of each draft chapter for public comment as the chapter becomes available, rather than delaying release of individual draft chapters until all the draft chapters are available.

The FDA states that the guidance is intended to help food manufacturers comply with the following requirements established in subparts C and G of Part 117:

- A written food safety plan (FSP)
- Hazard analysis
- Preventive controls
- Monitoring
- Corrective actions
- Verification
- Associated records

At present, the draft guidance includes the following five chapters and three appendices:

- **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

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- **Appendix 2:** Food Safety Plan Forms
- **Appendix 3:** Bacterial Pathogen Growth and Inactivation

Ultimately, the FDA plans that the guidance will include the following additional chapters and a fourth appendix:

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

The draft guidance is available for download [here](#).

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