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Practice Groups:**Food, Drugs, Medical
Devices, and
Cosmetics (FDA)****Food Industry**

FSIS Seeks Comments on Second Draft of HACCP Validation Guidance

By Robert G. Hibbert, Anthony T. Pavel, Jr., and Zachary A. Rothstein

On May 9, 2012, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS or Agency) published a notice in the Federal Register requesting comments on the Agency's revised draft guidance on the requirements for validation of an establishment's Hazard Analysis and Critical Control Points (HACCP) system (Compliance Guideline).¹ This is the second draft of the Compliance Guideline; the first draft was released in March 2010.

FSIS will require HACCP validation to consist of two parts: First, an establishment must gather scientific or technical support for the judgments it makes in designing its HACCP system. Second, the establishment must gather evidence from its HACCP system while it is operating to demonstrate that the establishment is able to implement the "critical operational parameters necessary to achieve the results documented in the scientific or technical support" that form the basis of its HACCP system.²

The Compliance Guideline recommends that scientific or technical support used in designing a HACCP system be from one of the following sources: Published processing guidelines; a scientific article from a peer-reviewed journal; a challenge or inoculated pack study that is designed to determine the lethality or stabilization of a process; data gathered in-house; or regulatory performance standards.³ In order for the scientific or technical support to be considered effective, it must identify: (1) The hazard that the measures are intended to address; (2) the expected level of hazard reduction or prevention that the measures will achieve; (3) the critical operational parameters, such as time, temperature, humidity, and pH, that must be met for the measures to be effective; (4) the processing steps necessary to achieve the specified level of hazard reduction or prevention; and (5) how the processing steps can be monitored.⁴

- The use of an established processing guideline, such as Appendix A of the final rule on "Performance Standards for the Production of Certain Meat and Poultry Products," as scientific support will be considered a "safe harbor" process. When relying on a safe harbor process, the establishment will still need to collect in-plant data to demonstrate that it is achieving the critical operational parameters documented in the processing guideline.⁵
- FSIS has provided a list of scientific and technical support on its website to aid establishments in designing their HACCP systems.⁶ FSIS has also included an Appendix in the Compliance

¹ HACCP Systems Validation, 77 Fed. Reg. 27135 (May 9, 2012); FSIS Compliance Guideline, HACCP Systems Validation (April 2012), available at http://www.fsis.usda.gov/PDF/HACCP_Systems_Validation_Draft_Guidance_0412.pdf.

² 77 Fed. Reg. at 27136.

³ 77 Fed. Reg. at 27139; see also Compliance Guideline at pp. 10-12.

⁴ *Id.*; see also Compliance Guideline at p. 8.

⁵ 77 Fed. Reg. at 27138.

⁶ See http://www.fsis.usda.gov/Science/HACCP_Validation_Articles/index.asp

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Guideline to assist establishments in understanding scientific and technical journal articles and identifying critical operational parameters.⁷

After an establishment gathers the requisite scientific or technical support for its HACCP system, it must ensure the adequacy of the various components of its HACCP system in controlling identified hazards.⁸ This includes information and data that demonstrates the HACCP system will perform as expected and will routinely meet the critical operating parameters identified in the HACCP system under in-plant conditions.⁹

- An establishment will be required to meet all *critical* operational parameters – those that have been shown to influence the effectiveness of an intervention when variations occur – described by the scientific and technical support that form the basis of the establishment’s HACCP system.¹⁰ The March 2010 draft did not distinguish between critical and non-critical operational parameters.
- In contrast to the March 2010 draft, FSIS will not require in-plant microbiological testing as a necessary component of the HACCP validation process. FSIS will, however, review the adequacy of a HACCP system if “regulatory samples analyzed by the Agency show non-compliance with microbiological standards.”¹¹

Comments must be submitted to FSIS by **July 9, 2012**. Please let us know if you would like additional information, or would like to discuss submitting comments.

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⁷ Compliance Guideline at p. 24, Appendix 1: Guidance to Identify Critical Operational Parameters from Supporting Documentation.

⁸ See 9 C.F.R. § 417.4(a)(1).

⁹ 77 Fed. Reg. at 27136-37.

¹⁰ *Id.*; Compliance Guideline at p. 14.

¹¹ 77 Fed. Reg. at 27138; Compliance Guideline at p. 13.

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