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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2012-0023]

Availability of Microbial Risk Assessment Guideline: Pathogenic Microorganisms with Focus on Food and in Water

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: The Food Safety and Inspection Service (FSIS) and Environmental Protection Agency (EPA) are announcing the availability of a guideline for conducting microbial risk assessment (MRA). The guideline will improve transparency in the way the two Federal agencies conduct MRA and will promote consistency in approaches and methods. The guideline can apply in varied situations and will be a resource for Federal Government risk assessors, their agents, contractors, and other members of the risk assessment community.

DATES: The guideline is effective [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

ADDRESSES: A downloadable version of the guideline and additional related materials, including the external peer review panel's comments and associated responses, is available to view or print at

[http://www.fsis.usda.gov/regulations & policies/Federal Register Notices/index.asp](http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Notices/index.asp). No hard copies of the guideline have been

published.

FOR FURTHER INFORMATION CONTACT: Kerry Dearfield, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Ave SW, Mail Stop 3766, Washington, DC 20250; email: kerry.dearfield@fsis.usda.gov; phone: (202)690-6451; or, Michael Broder, Office of the Science Advisor, Mail Code 8105-R, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; E-mail: broder.michael@epa.gov; phone: (202)564-3393.

SUPPLEMENTARY INFORMATION:

I. Background

Risk assessment is widely recognized as a systematic way to prepare, organize, and analyze information to help make regulatory decisions, establish programs, and prioritize research and development efforts. In 1983, Risk Assessment in the Federal Government; Managing the Process (NRC 1983 report), published by the National Research Council of the National Academics of Science, helped unify the risk assessment process for chemicals in foods and the environment and provided a basic framework that Federal agencies could apply when conducting risk assessments. During the 1990s, it became apparent that the NRC 1983 report had

some shortcomings with respect to conducting a MRA for microorganisms. Agencies conducting quantitative microbial risk assessments had to individually adapt and make adjustments to the method described in the NRC 1983 report to meet their specific needs. As a result, there existed no consistent approach to conducting MRA among Federal agencies.

FSIS and EPA, joined by scientists from other Federal agencies, initiated a collaborative effort to develop guidelines that would improve consistency in the way MRA is conducted. The agencies thought that clear and credible risk assessment methods would leverage limited resources, improve efficiencies, improve transparency with stakeholders, and promote joint interaction. This cross-agency activity generated the MRA Guideline.

The guideline facilitates systematic and transparent consideration of all relevant factors that impact the risk assessment and facilitates reproducible risk evaluation. Using the guidelines, agencies assessing similar media or pathogens are able to more readily compare and contrast the details and assumptions of their assessment to another Agency's assessment. The guideline can apply in varied situations and provides for the flexibility necessary for any Agency that chooses to do so to use it effectively.

EPA released a draft of the document for public comment in

July 2011 (76 FR 44586). EPA received two comments - one from a member of the public and another from a foreign government authority responsible for the assessment of similar health risks in their country. All comments received by the comment period closing date were shared with an external peer review panel for their consideration. The external peer review panel's comments and associated responses are available for review at:

http://www.fsis.usda.gov/regulations_&_policies/Federal_Register/Notices/index.asp.

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Done at Washington, DC, on: July 26, 2012

Alfred V. Almanza,
Administrator.

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