



DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2017-0016]

Availability of FSIS Compliance Guidelines for Small and Very Small Meat and Poultry Establishments regarding Lethality and Stabilization in Meat and Poultry Products (Previously Referred to as Appendices A and B)

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of Availability and Request for Comment

Summary: The Food Safety and Inspection Service (FSIS) is announcing the availability of and requesting comments on two updated compliance guidelines for small and very small businesses. The new guidelines will assist small and very small meat and poultry establishments understand and comply with the regulatory requirements associated with the destruction of *Salmonella* and other pathogens (lethality) in ready-to-eat (RTE) products and the control of pathogen growth in heat-treated RTE and not-ready-to-eat (NRTE) products during cooling and hot-holding (stabilization). FSIS is including the time-temperature tables and cooling options in these guidelines that were previously in Appendices A and B, originally made available in 1999, along with new recommendations establishments can use to achieve lethality and stabilization of these products.

DATES: Submit Comments on or before [INSERT DATE - 60 DAYS AFTER DATE OF PUBLICATION].

ADDRESSES: Downloadable versions of the compliance guidelines are available to view and print at

<https://www.fsis.usda.gov/wps/wcm/connect/bf3f01a1-a0b7-4902-a2df-a87c73d1b633/Salmonella-Compliance-Guideline-SVSP-RTE-Appendix-A.pdf?MOD=AJPERES> and

<https://www.fsis.usda.gov/wps/wcm/connect/9ac49aba-46bc-443c-856b-59a3f51b924f/Compliance-Guideline-Stabilization-Appendix-B.pdf?MOD=AJPERES> once copies of the guidelines have been published.

FSIS invites interested persons to submit comments on this guidance. Comments may be submitted by one of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov/>. Follow the on-line instructions at that site for submitting comments.

Mail, including CD-ROMs: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street SW., Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small and Very Small Establishments and Revised Appendix B 2017 Compliance Guideline. Comments received will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or to comment received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 164-A, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

For Further Information Contact: Roberta Wagner, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

FSIS is making available an updated compliance guideline regarding the requirements for the destruction of *Salmonella* and other pathogens (lethality) in RTE meat and poultry products,

entitled *FSIS Salmonella Compliance Guideline for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A*. The updated guideline provides clarification regarding options for establishments to support an alternative lethality (i.e., at least a 5-log reduction of *Salmonella*, rather than a 6.5-log reduction) for roast, cooked, and corned beef per 9 CFR 318.17(a)(1); a definition of "pasteurization" and guidance on how establishments can label products as "pasteurized"; and updated information gathered from FSIS Food Safety Assessments (FSAs), which are in-depth assessments of establishments' food safety systems to verify that regulatory requirements are met. The guideline also combines and replaces information from the following previously issued guidance documents:

- Appendix A Compliance Guidelines for Meeting Lethality Performance Standards for certain Meat and Poultry Products.
- Appendix A Guidance on Relative Humidity and Time/Temperature for Cooking/Heating and Applicability to Production of Other Ready-to-Eat Meat and Poultry Products (Appendix A Humidity Guidance).
- Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products.

- FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks (5-log Table).

FSIS also is making available an updated guideline on the control of pathogen growth in heat-treated RTE and NRTE meat and poultry products during cooling and hot-holding (stabilization), entitled *FSIS Compliance Guideline for Stabilization (Cooling and Hot-Holding) of Fully and Partially Heat-Treated RTE and NRTE Meat and Poultry Products Produced by Small with Very Small Establishments and Revised Appendix B*. Hot-holding is the process of holding meat and poultry products at hot temperatures (typically above 130°F) prior to distribution. Although stabilization is commonly associated with RTE products, the concepts and many of the recommendations in this guideline can apply to heat-treated NRTE products as well.

This updated stabilization guideline contains recommendations previously found in FSIS Appendix B: Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization) and FSIS Directive 7110.3, Rev. 1, *Time/Temperature Guidelines for Cooling Heated Products*. It also contains additional guidance not previously found in either document, including:

- The regulatory requirements associated with stabilization (cooling and hot-holding);
- The scientific support documents available to help develop a safe process and product;
- Recommended corrective actions in the event of a cooling deviation; and
- Additional options for cooling meat and poultry products, including requesting a waiver.

Specifically in regard to waivers, this stabilization guideline describes information that establishments may use to request a waiver from the regulatory performance standards in 9 CFR 318.17(a)(2), 318.23(b)(3)(ii)(c), and 381.150(a)(2) to allow up to a 2- $\log_{10}$  multiplication of *C. perfringens* within a product, provided no multiplication of *C. botulinum* occurs. The Agency will evaluate waiver requests and use this information to potentially amend the regulations. Notably, FSIS has determined that establishments do not have to provide data that allowing up to 2- $\log_{10}$  multiplication of *C. perfringens* will result in no multiplication of *C. botulinum* as part of the waiver request.

#### **Small Business Regulatory Flexibility Act Compliance**

Both guidance documents are targeting small and very small establishments in support of the Small Business Administration's initiative to provide small and very small establishments with

compliance assistance under the Small Business Regulatory Flexibility Act (SBRFA). It is important that small and very small establishments have access to the scientific and technical support needed to establish safe and effective HACCP systems. However, all FSIS regulated meat and poultry establishments may be able to apply the recommendations in this guideline.

#### Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices.

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Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410.

Fax: (202) 690-7442.

Email: [program.intake@usda.gov](mailto:program.intake@usda.gov).

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD). Done at Washington, DC on: June 8, 2017.

Alfred V. Almanza,

Administrator

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