

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

07-20

2/11/20

EXTENSION OF DELAYED IMPLEMENTATION OF VERIFICATION OF REVISED APPENDIX A AND B

I. PURPOSE

This notice reissues the contents of FSIS Notice 01-19 in its entirety and informs inspection program personnel (IPP) that establishments that use FSIS Appendix A and B as scientific support for lethality and stabilization procedures may continue to use the 1999 or 2017 versions until further notice. This notice also provides instructions for Enforcement, Investigation, and Analysis Officers (EIAOs) when performing Food Safety Assessments (FSAs) in establishments using FSIS Appendix A and B as scientific support. In 2020, FSIS will announce in the *Federal Register* the availability of updated versions of the lethality (Appendix A) and stabilization (Appendix B) guidance, respond to comments on the 2017 versions of this guidance, and announce dates when FSIS will begin to verify that those establishments that choose to use the safe harbors provided in this guidance as scientific support for their validated Hazard Analysis and Critical Control Point (HACCP) systems are using the information in the 2020 versions of the guidance.

II. BACKGROUND

A. In 2017, FSIS issued revised versions of Appendix A and Appendix B:

1. [FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce RTE Products and Revised Appendix A.](#)
2. [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.](#)

B. FSIS made changes to the 1999 versions of Appendix A and Appendix B to clarify the Agency's cooking and cooling recommendations in response to commonly asked questions and more current scientific information.

C. FSIS is in the process of responding to comments received on the 2017 versions of Appendix A and B and will announce the response to comments and revisions to this guidance in the *Federal Register* when they are available. Further instructions will be provided to FSIS personnel at that time regarding verification in establishments that use FSIS Appendix A and B as scientific support.

D. Establishments may choose to adopt different procedures than those outlined in the Appendix A and Appendix B guidelines, but they would need to support why those procedures

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are effective. Additional types of scientific support establishments may use include other published processing guidelines, journal articles, results of pathogen modeling programs, challenge studies, and advice from processing authorities that includes reference to scientific data.

III. IPP RESPONSIBILITIES

A. If an establishment uses Appendix A or B as scientific support for the lethality and stabilization procedures the establishment uses, IPP are to discuss this notice during the next weekly meeting with establishment management and are to inform the establishment that:

1. It may continue to use the 1999 or 2017 versions of FSIS Appendix A and B as scientific support for lethality and stabilization procedures until further notice; and
2. In 2020, FSIS will announce in the *Federal Register* the availability of updated Appendix A and Appendix B guidance (2020 versions), respond to comments received on the 2017 versions of Appendix A and Appendix B guidance, and announce the date when FSIS will begin to verify that establishments are using the 2020 versions of the guidance (Appendix A and Appendix B) as scientific support for their validated HACCP systems if they choose to use the safe harbors provided in this guidance.

B. Until further notice, IPP are not to issue a noncompliance record (NR) solely because the establishment uses the 1999 version of Appendix A or B as scientific support for its process, even if the establishment is using sections of the 1999 guidance that were updated in the 2017 guidance (see Attachment).

C. IPP are to verify that the establishment is following all of the critical operational parameters in its supporting documentation when the establishment maintains as its scientific support the 1999 or 2017 versions of Appendix A and B. If IPP find that the establishment has not followed all of the critical operational parameters in its scientific support, they are to issue an NR for not supporting the decisions in the hazard analysis ([9 CFR 417.5\(a\)\(1\)](#)) as instructed in [FSIS Directive 7111.1](#), *Verification Procedures for Lethality and Stabilization*, Section VI.B.1.

IV. EIAO RESPONSIBILITIES

A. During an FSA, as instructed in [FSIS Directive 5100.1](#), *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology*, Chapter V, Section VI, an EIAO is to evaluate whether the establishment has adequate scientific support for the design of its HACCP system (e.g., critical control point, prerequisite program, or other program design), and whether in-plant validation data demonstrate that the establishment can implement its system as designed.

B. Until further notice, EIAOs are not to recommend issuance of an NR or an enforcement action solely because the establishment uses the 1999 version of Appendix A or B as scientific support for its process, even if the establishment is using sections of the 1999 guidance that were updated in the 2017 guidance (see Attachment).

V. QUESTIONS

Direct all questions regarding this notice to the Office of Policy and Program Development through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the **Submit a Question** tab, and enter the following information in the fields provided:

Subject Field: Enter **Notice 07-20**.

Question Field: Enter question with as much detail as possible.

Product Field: Select **General Inspection Policy** from the drop-down menu.
Category Field: Select **HACCP Validation** from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



Assistant Administrator
Office of Policy and Program Development

Attachment: Summary of the major changes to the 1999 versions of Appendix A and B

For the 2017 version of Appendix A, FSIS has re-emphasized that the humidity recommendations apply to all cooked products (including poultry), unless the establishment can support that humidity does not need to be addressed. FSIS has not changed the humidity recommendations other than re-emphasizing that they apply to all products. The time temperature tables previously found in Appendix A also have not changed.

For the 2017 version of Appendix B, FSIS has specified that:

Option 1 applies to both partially cooked small mass products and fully cooked products while other stabilization options apply only to fully cooked products.

Option 1 also now includes a recommended come up time to the final heating temperature for partially cooked products of ≤ 1 hour to ensure the cumulative growth of *C. perfringens* and *C. botulinum* over the course of the partial cooking and cooling process is limited to acceptable levels.

Option 2 includes multiple parts to the recommendation: Chilling should begin within 90 minutes after the cooking cycle is completed. All product should be chilled from 120°F to 80°F in 1 hour and from 80°F to 55°F in 5 hours (6 hours total cooling time), followed by continuous chilling until the product reaches 40°F.

To use Option 3, establishments should incorporate at least 250 ppm sodium erythorbate or ascorbate, along with at least 100 ppm ingoing sodium nitrite (either from a purified or natural source such as celery powder).

Option 4 was added to incorporate guidance that had been in FSIS Directive 7110.3 (cancelled by [FSIS Directive 7111.1](#)). The recommendations in this option no longer apply to products with ≥ 120 ppm sodium nitrite and a brine concentration of $\geq 3.5\%$.