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

FSIS NOTICE

17-18 | 03/22/18

DELAYED IMPLEMENTATION OF VERIFICATION OF REVISED APPENDIX A AND B

I. PURPOSE

This notice informs inspection program personnel (IPP) and Enforcement, Investigation, and Analysis Officers (EIAOs) that FSIS is providing establishments that use the 1999 versions of FSIS Appendix A and B as scientific support for lethality and stabilization procedures one year from the date of this issuance to review the revised lethality and stabilization guidance issued in 2017 and determine whether additional documentation or changes are needed to support their process (9 CFR 417.5(a)(1)), and to then validate any changes made to follow the new guidelines or additional support over 90 calendar days (9 CFR 417.4(a)(1)).

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 (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 (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. A summary of the major changes to the 1999 versions of Appendix A and B follows.

1. For Appendix A, FSIS has re-emphasized that the humidity recommendations apply to all cooked products (including poultry) unless the establishment can support 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.

2. For Appendix B, FSIS has specified that:

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

b. Option 1 also now includes a recommended come up time to the final heating temperature for partially cooked products of ≤ 1 hour.

c. 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.

d. 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).

e. 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 3.5%.

D. Establishments may choose to adopt different procedures than those outlined in the revised *Appendix A* and *Appendix B* guidelines, but they would need to support why those procedures 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 maintains the 1999 version of 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, to assure the establishment is aware that the guidelines have been updated and of the major changes described in Section II.C of this notice.

B. IPP are to inform establishments that they have one year from the date of the issuance of this notice to determine whether they need to gather new support or make changes to their HACCP system in response to the revised *Appendix A* and *Appendix B* and then to validate any changes made to follow the new guidelines or additional support over 90 calendar days (9 CFR 417.4(a)(1)).

C. IPP are to document the notes from the meeting in a Memorandum of Interview (MOI) as described in FSIS Directive 5010.1 Food Safety Related Topics for Discussion during Weekly Meetings with Establishment Management Section IV.

D. 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 have been updated in the 2017 guidance.

E. IPP are to continue to verify that the establishment is following all of the critical operational parameters in its supporting documentation when the establishment maintains the 1999 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 a NR for not supporting the decisions in the hazard analysis (9 CFR 417.5(a)(1)) as instructed in FSIS Directive 7111.1 Verification of Lethality and Stabilization Procedures Section VI.B.1.

V. EIAO RESPONSIBILITIES

A. During a Food Safety Assessment (FSA), as instructed in FSIS Directive 5100.1, 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., CCP, prerequisite program, or other program design), and whether in-plant validation data demonstrates that the establishment can implement its system as designed.

B. If an establishment is using the 1999 version of Appendix A or B and is using one of the sections with major changes described in Section II.C. of this notice, but the establishment has not made changes to its support or process, the EIAO is to note this fact in the FSA but is not to use the lack of support for the lethality and stabilization procedures as the only reason for recommending the issuance of an NR or an enforcement action until one year from the date of issuance of this notice.

VI. QUESTIONS

Direct all questions regarding this notice to the Risk, Innovations, and Management Staff through *ask*FSIS at http://askfsis.custhelp.com 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 17-18**
Question Field:	Enter question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.
Category Field:	Select **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.

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