VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS
FOOD SAFETY CONSUMER PROTECTION DIVISION
MONTPELIER, VT
Anson Tebbetts, Secretary

MIS NOTICE **Adopted from FSIS Notice 59-21**	59-21	12/21/21

AVAILABILITY OF 2021 COOKING GUIDELINE (REVISED APPENDIX A) AND STABILIZATION GUIDELINE (REVISED APPENDIX B) AND EXTENSION OF DELAYED IMPLEMENTATION OF VERIFICATION

I. PURPOSE

This notice provides instructions for inspection program personnel (IPP) to notify establishments that revised versions of *FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A)* (see Appendix A) and *FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B)* (see Appendix B) are now available. This notice also provides instructions for IPP to notify establishments that the Agency is providing establishments that use the 1999 and 2017 versions of these guidelines as scientific support for their Hazard Analysis and Critical Control Point (HACCP) System until December 14, 2022 to begin using the 2021 guidelines or identify alternative support for their cooking and stabilization processes, making changes to their HACCP system as needed. FSIS is not issuing instructions for new verification activities. IPP are to continue to verify validation requirements following the instructions in VT Directive 5000.6, *Performance of the Hazard Analysis Verification (HAV) Task* and VT Directive 7111.1, *Verification Procedures for Lethality and Stabilization*, 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's Appendix A or B as scientific support.

II. BACKGROUND

A. FSIS issued revisions of its cooking (lethality) and stabilization (cooling and hot-holding) guidance in 2017, referred to as Appendices A and B. The guidelines were originally issued in 1999. The revisions considered new and emerging technologies, processes, and science while ensuring that the guidance results in safe food production, when applied correctly.

B. In 2021, FSIS revised these guidelines in response to comments. In addition, the guidelines have been revised to include recommendations from previous versions and new updates based on up-to-date science. The guidelines were also renamed and include other changes to improve readability. The revised guidelines were announced in the *Federal Register* 86 FR 71007 and are now available online:

1. FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A).
2. FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B).

III. IPP RESPONSIBILITIES

A. If an establishment uses a cooking or stabilization process for meat and poultry products (either fully cooked or partially heat-treated), IPP are to make establishment management aware of these revised guidance documents at the next weekly meeting.

B. IPP are to be aware these documents are guidance, not requirements. IPP are to make compliance determinations based on the regulatory requirements.

C. IPP are to inform establishment management that:

1. The 2021 Cooking and Stabilization Guidelines are available on the FSIS website at the links provided in Section II.B. of this notice.

2. The new guidelines provide the following information:

    a. *FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A)* provides information for complying with Agency regulatory requirements in 9 CFR 318.17(a)(1), 9 CFR 318.23, 381.150(a)(1), and 9 CFR part 417 associated with safe production of ready-to-eat (RTE) products with respect to the destruction of *Salmonella* and other pathogens using cooking.

    b. *FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B)* provides information on complying with the Agency regulatory requirements in 9 CFR 318.17(a)(2), 9 CFR 318.23(c)(1), 9 CFR 381.150(a)(2), 9 CFR 381.150(b), and 9 CFR part 417 associated with safe production of heat-treated ready-to-eat (RTE) and not-ready-to-eat (NRTE) meat and poultry products with respect to preventing or limiting the growth of spore-forming bacteria (*Clostridium perfringens* and *Clostridium botulinum*) and other pathogens.

3. The *FSIS Cooking Guideline (Revised Appendix A)* includes a summary of Changes from the Previous Versions. IPP are to be aware that a summary of changes from previous versions of the FSIS Cooking Guideline are also included in Attachment 1.

4. The *FSIS Stabilization Guideline (Revised Appendix B)* includes a summary of Changes from the Previous Versions. IPP are to be aware that a summary of changes from previous versions of the FSIS Cooking Guideline are also included in Attachment 2 of this notice.

5. The 2021 guidelines include recommendations from older cooking and stabilization guidance for products and processes considered “Scientific gaps”. “Scientific gaps” are common cooking and stabilization processes for which establishments have used Appendix A and B as support in the past, even though these processes cannot achieve the critical operating parameters included in the revised guidelines. These are also processes for which there is no evidence of imminent food safety concerns resulting from the continued application of the older recommendations to these processes.

6. Establishments may continue to use the 1999 and 2017 versions of these guidelines until December 14, 2022, at which time those versions will be considered no longer adequate scientific support for the HACCP system because they are out of date.

7. FSIS is providing establishments that use the 1999 and 2017 versions of these guidelines as scientific support for their HACCP System until December 14, 2022 to:

    a. Begin using the 2021 guidelines or identify alternative support for their cooking and stabilization processes, making changes to their HACCP system as needed (9 CFR 417.5(a)(1)); and

b. Gather any needed in-plant validation data for changes made to their HACCP system (9 CFR 417.4(a)(1)).

D. IPP are to continue to verify that establishments are following all of the critical operating parameters in their supporting documentation.

1. Until December 14, 2022, IPP are not to issue a noncompliance record (NR) solely because the establishment uses the 1999 or 2017 versions of the Cooking Guideline (Appendix A) or Stabilization Guideline (Appendix B) as scientific support for its process.

2. 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, Section VI.B.1.

E. Further instructions will be provided to IPP before the implementation date (December 14, 2022). These instructions will describe the verification procedures IPP are to follow in relation to the revised 2021 guidelines, including verification procedures for processes within a defined scientific gap.

IV. EIAO RESPONSIBILITIES

A. EIAOs are to review and familiarize themselves with the information in the 2021 Cooking and Stabilization guidelines because they represent the most current scientific research and critical operating parameters related to cooking (lethality) and stabilization (cooling).

B. During an FSA, as instructed in FSIS Directive 5100.1, *Enforcement, Investigations, and Analysis Officer Comprehensive Food Safety Assessment Methodology*, Chapter V, Section VI, EIAOs are 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.

C. Until further notice, if an establishment is using the 1999 or 2017 versions of the Cooking Guideline (Appendix A) or Stabilization Guideline (Appendix B), the EIAO is to note this fact in the FSA. However, EIAOs are not to use this information as the only reason for recommending the issuance of an NR or an enforcement action until December 14, 2022.

D. When performing outreach activities, EIAOs are to make establishment management aware of the 2021 Cooking and Stabilization guidelines. EIAOs are to provide technical assistance as part of the compliance assistance resources they provide according to the instructions in FSIS Directive 5100.1.

E. FSIS will provide further instructions to EIAOs prior to the implementation date (December 14, 2022). These instructions will describe the verification procedures EIAOs are to follow in relation to the 2021 Cooking and Stabilization guidelines, including verification procedures for processes within a defined scientific gap.

V. QUESTIONS

Refer questions regarding this notice to your supervisor or as needed to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select HACCP Deviation & Validation as the Inquiry Type.

NOTE: Refer to FSIS Directive 5620.1, *Using askFSIS*, for additional information on submitting questions.

Assistant Administrator
Office of Policy and Program Development

Attachment 1. Changes from the Previous Versions of "*FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A)*"

The 2021 *FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A)* dated December 14, 2021, is final and will replace the 1999 and 2017 versions on December 14, 2022. FSIS will update the guideline, as necessary, should new information become available. Establishments that used previous versions of Appendix A as support should either:

- Update to the 2021 FSIS Cooking Guideline (Revised Appendix A); or
- Identify alternative support by **December 14, 2022**.

FSIS made the following changes to this guideline to reflect the comments received on the previous version during the comment period and to include additional scientific information.

For Appendix A, FSIS made changes to specify:

- The following products are not covered by the guideline: Fish of the Order Siluriformes, pork rind pellets, rendered lard and tallow, dried products processed under dry conditions, partially heat-treated NRTE products, and RTE multi-hurdle products.

- The food safety significance of FSIS's recommendations for relative humidity.

- That relative humidity should be addressed for all cooked products (including poultry) unless the establishment can support that humidity does not need to be addressed. FSIS has not changed the relative humidity options other than re-emphasizing that they apply to all products.

- Additional resources for selecting a relative humidity option when following FSIS's cooking guidance.

- The situations when relative humidity does not need to be addressed including by providing more information about situations considered to be direct heating (*e.g.,* by clarifying that relative humidity does not need to be addressed for meat patties cooked using FSIS's time-temperature table for meat, if the patties are cooked using direct heat). Previous guidance indicated it did not need to be addressed for meat patties with the assumption all meat patties are cooked using direct heat, which is no longer the case.

- That natural casings become semipermeable during cooking, maintaining moisture in the product, so that additional documentation to address relative humidity is not needed.

- More detailed information for evaluating product safety following a heating deviation. The revision also removes the recommendation for using the ComBase model for *Staphylococcus aureus* growth (which was not validated) because of the development and validation of the Danish Meat Research Institute (DMRI) Staphtox model in 2018.

- Where gaps exist, recommendations from its older cooking guidance can be used until research is completed for:

    1. Products cooked for short times at high temperatures.

    2. Products cooked using microwave cooking methods that are not designed to control relative humidity.

3. Products cooked using cooking methods that are not designed to control relative humidity.

4. Other processes that may inherently maintain relative humidity around the meat and poultry filling but cannot follow one of the relative humidity options.

5. Processes where the drying step comes before cooking under moist conditions.

6. Products with long heating CUTs.

- That information is included about a listeriosis outbreak associated with a cooked country-cured ham product and recommendations for establishments that cook a similar product once.

For Appendix A, FSIS removed:

- Information about how establishments could remove poultry rolls from the cooking medium before product has achieved the target endpoint temperature and immediately apply another heating or processing method (64 FR 732). Since FSIS has clarified that limiting heating CUT is a critical operating parameter for applying any of FSIS cooking guidance (including these older options), the parameter to "immediately fully cook" poultry rolls subject to multiple heating mediums and processes has been removed.

- Specific recommendations for conducting a *Salmonella* baseline study on raw source materials as support for using cooking critical operating parameters that achieve a 5-Log reduction in *Salmonella* for meat products instead of a 6.5 or 7-Log reduction. This information was removed since it was interpreted to apply to all establishments when it was only intended for establishments that wanted to support a lower level of pathogen reduction from cooking. In addition, FSIS is not aware of any establishments that have pursued such baseline sampling.

In addition to these changes, the guideline format was restructured to make it easier to use.

Attachment 2. Changes from the Previous Versions of "*FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B)*"

The 2021 *FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B)* dated December 14, 2021, is final and will replace the 1999 and 2017 versions on December 14, 2022. FSIS will update the guideline as necessary should new information become available. Establishments that used previous versions of Appendix B as support should either:

- Update to the 2021 FSIS Stabilization Guideline (Revised Appendix B); or
- Identify alternative support by **December 14, 2022**.

FSIS made the following changes to this guideline to reflect the comments received on the previous version during the comment period and to include additional scientific information.

For Appendix B, FSIS made changes to specify:

- Cooling options for both RTE and NRTE products that are cooked to lethality are included in Table 1 and incorporate the previous options, 1, 2, 3 and 4 as options 1.1, 1.2, 1.3 and 1.4.

- Cooling options for partially cooked products are included in a separate table (Table 2) and include former Option 1 as Option 2.1.

- Tables 1 and 2 list the critical operating parameters for each option.

- One additional option for partially cooked products, Option 2.2.

- That cooling in stage 1 of option 1.2 from 120 to 80 °F should occur in ≤ 1 hour.

- That the heating come-up-time (CUT) in Option 2.1 for partially cooked products should be limited to ≤ 1 hour between 50 and 130°F. FSIS extended the CUT up to 3 hours in Option 2.2 for partially cooked products, if the product meets the critical operating parameters for concentrations of salt, nitrite, and a cure accelerator sufficient for purpose.

- New options 1.5 – 1.8 that provide additional cooling time during the first stage of cooling.

- That to use Option 1.3, 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).

- That natural sources of nitrite and ascorbate should not be mixed with purified or synthetic sources.

- FSIS removed the recommendation to cool from 120 to 80ºF in 2 hours and replaced it with the critical operating parameter that the process cause a continuous drop in product temperature.

- To support all the cooling options, additional research and modeling results using up-to-date validated cooling models to support all of the cooling options are included in Attachment B3, FSIS' Predictive Microbial Modeling Support for 1-Log Cooling Options.

- To support common bacon and scrapple processes, FSIS updated references in Attachment B8, Using Journal Articles to Support Alternative Stabilization or Cooling Procedures to address comments requesting support for these processes.

- Practical recommendations for improving product cooling in Attachment B4, Steps an Establishment Can Take to Cool Products More Rapidly.

- Where gaps exist, recommendation from its older cooling guidance can be used until research is completed for:

    1. Large mass non-intact products that cannot cool quickly enough to follow the new options in Table 1.

    2. Partially heat-treated, smoked products that contain nitrite and erythorbate or ascorbate and have long heating come-up and cooling times and can't follow the options in Table 2.

    3. Smoked bacon that contains nitrite and erythorbate/ascorbate that cannot use Option 1.3 because lethal time and temperature combination is achieved but relative humidity is not addressed.

    4. Immersion or dry-cured products that contain nitrite and use equilibration time instead of erythorbate or ascorbate but cannot meet cooling options without nitrite in Table 1 (for products cooked to full lethality) or Table 2 (for products not cooked to full lethality).

    5. Products that contain nitrite and use equilibration time instead of erythorbate or ascorbate, but do not have a brine concentration of ≥ 6% to meet Option 1.4.

    6. Scalded offal that cannot cool quickly enough to follow the new options in Table 2.

For Appendix B, FSIS removed:

- Specific recommendations for obtaining a waiver to permit 2-Log growth of *C. perfringens* during cooling. This information was removed since it was interpreted to apply to all establishments when it was only intended for establishments that wanted to support a lower level of spores in their source product. In addition, FSIS has not received any waiver requests, but establishments may request a waiver in the future (9 CFR 303.1(h) and 9 CFR 381.3(b)).

In addition to these changes, the guideline format was restructured to make it easier to use.