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

FSIS NOTICE

66-22 | 12/7/22

INSTRUCTIONS FOR VERIFYING THE IMPLEMENTATION OF THE 2021 COOKING GUIDELINE (REVISED APPENDIX A) AND STABILIZATION GUIDELINE (REVISED APPENDIX B)

DO NOT IMPLEMENT THIS NOTICE UNTIL DECEMBER 14, 2022.

I. PURPOSE

This notice provides instructions to inspection program personnel (IPP) on how to verify that establishments are using the revised 2021 versions of *FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A)* and *FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B),* where appropriate. Establishments that currently use the 1999 and 2017 versions of these guidelines as scientific support for their Hazard Analysis and Critical Control Point (HACCP) systems will need to use the 2021 version of the guidelines or identify alternative scientific support, starting December 14, 2022. IPP are to use the instructions in this notice to supplement the instructions in FSIS Directive 5000.6, *Performance of the Hazard Analysis Verification (HAV) Task* and FSIS Directive 7111.1, *Verification Procedures for Lethality and Stabilization*. This notice also provides instructions for Enforcement, Investigation, and Analysis Officers (EIAO) when performing Food Safety Assessments (FSA) in establishments using FSIS' Appendix A or B as scientific support.

II. BACKGROUND

A. FSIS announced the availability of the final revised versions of its cooking (lethality) and stabilization (cooling and hot-holding guidance), referred to as Revised Appendix A and B in the *Federal Register* on December 14, 2021 (86 FR 71007), and that the guidelines are available at:

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

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

B. FSIS provided training on the revised versions of Appendix A and B and a recorded webinar is available on IPP Help, *Media Library, 2021 Revised Appendix A & B*.

C. 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, 9 CFR 381.150(a)(1), and 9 CFR 417 associated with safe production and cooking of ready-to-eat (RTE) products with respect to the destruction of *Salmonella* and other pathogens.

D. FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B) provides information for 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 417 associated with safe production and stabilization of heat-treated RTE and not ready-to-eat (NRTE) meat and poultry products with respect to preventing or limiting the growth of spore-forming bacteria (*e.g.*, *Clostridium perfringens* and *Clostridium botulinum*) and

other pathogens.

E. 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 operational parameters in the revised guidelines. Scientific gaps 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.

F. IPP are to be aware that an establishment producing products using processes that fall under an identified scientific gap, may use older recommendations from the previous guidelines included in the 2021 Revised Appendix A and B as scientific support.

G. Starting December 14, 2022, as explained in this notice, IPP are to begin issuing noncompliance records (NR) if an establishment continues to use the 1999 and 2017 versions of these guidelines as scientific support for their HACCP systems and has not identified alternative support for their cooking and stabilization processes.

H. IPP are to be aware that these documents are guidance, not requirements. Under the regulations, meat and poultry establishments may choose to implement different procedures than those outlined in the 2021 Revised Appendix A and B guidelines, but they would need to validate and support how those procedures are effective.

III. IPP RESPONSIBILITIES

A. During the next routine HAV task performed on or after December 14, 2022, if an establishment uses a cooking or stabilization process for meat and poultry products (either fully cooked or partially heat-treated), IPP are to select one HACCP plan to review using the priority rankings in Table 1 below, with the Fully Cooked/Not Shelf Stable Post-Lethality Exposed category having the highest priority. IPP are to select a different HACCP plan each quarter until all HACCP plans that contain products that are cooked (either fully cooked or partially heat-treated) and cooled have been reviewed. IPP are to verify lethality and stabilization of meat and poultry products when performing the HAV task as described in FSIS Directive 5000.6. After IPP have rotated through the HACCP plans that contain products that are cooked and cooled, they are to resume reviewing HACCP plans following the priority order in FSIS Directive 5000.6. Additional instructions are also provided below to specifically address cooking and cooling procedures that supplement the instructions in FSIS Directive 5000.6 and in FSIS Directive 7111.1.

Table 1: HAV HACCP Category Priority Ranking for FSIS Notice 66-22
Fully Cooked/Not Shelf Stable Post-Lethality Exposed
Fully Cooked/Not Shelf Stable Not Post-Lethality Exposed
Heat Treated/Not Fully Cooked/Not Shelf Stable

B. IPP are to verify that establishments use the 2021 versions of the guidelines or have identified alternative support. IPP are to verify that establishments have reassessed their HACCP system as needed (9 CFR 417.4(a)(3)), and gathered any needed in-plant validation data for changes made to their HACCP system (9 CFR 417.4(a)(1)). If IPP find that the establishment continues to use the 1999 or 2017 versions of Appendix A or B as scientific support, they are to issue an NR for not supporting the decisions in the hazard analysis (9 CFR 417.5(a)).

C. IPP are to verify that the establishment is following all of the critical operational parameters in its supporting documentation when establishments use the 2021 Revised Appendix A and B or other scientific support. 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)).

D. IPP are to be aware that, when verifying an establishment's cooking processes:

1. 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 (*e.g.*, fermented and dried sausage) are not covered by the 2021 Revised Appendix A Guideline.

NOTE: Products listed in D.1. are products where research or human illness outbreaks demonstrate FSIS guidance is insufficient to result in a safe product. These products cannot use FSIS guidance as scientific support and must identify alternative support. Products listed above are different from products covered under a scientific gap described in D.4. below.

2. Relative humidity is a critical operational parameter for most cooking processes, including pork and poultry, unless the establishment can support that humidity does not need to be addressed because the product is:

    a. Completely immersed in a liquid cooking medium throughout the entire cooking process (*e.g.*, unbagged in water, deep fried);

    b. Cooked in a sealed, moisture impermeable bag (*e.g.*, cook-in-bag meat or poultry);

    c. Cooked in a casing that holds moisture (*e.g.*, natural casings, cellulose casings, collagen casings, fibrous casings, and plastic casings (sometimes called "synthetic" casings));

    d. At least 10 pounds and heated in an oven maintained at 250 °F (121 °C) or higher throughout a process achieving one of the time-temperature combinations in the guideline;

    e. Cooked using direct heat (*e.g.*, grilled, broiled with exposure to direct, intense radiant heat), cooked using a heating coil or flame in direct contact with the product, or cooked using certain rotisserie ovens that cook the meat or poultry over the heat source resulting in a product with a grilled quality; or

    f. Produced using processes that fall under a scientific gap that supports relative humidity.

3. If IPP find that establishments have not included humidity as part of their cooking process (as one of the critical limits of a critical control point (CCP) or a prerequisite program) and have not provided support for why humidity would not be needed in the process, then IPP are to issue an NR for not supporting the decisions in the hazard analysis (9 CFR 417.5(a)(1)).

4. Where scientific gaps exist, recommendations from older cooking guidance included in the 2021 Revised Appendix A can be used until research is completed for the following scientific gaps:

    a. Products cooked for short times at high temperatures (Scientific Gap #1);

    b. Products cooked using continuous or non-continuous microwave cooking methods that are not designed to control relative humidity (Scientific Gap #2);

    c. Products cooked using cooking methods that are not designed to control relative humidity other than microwave ovens (Scientific Gap #3);

    d. Other processes that may inherently maintain relative humidity around the meat and poultry filling but cannot follow one of the relative humidity options (Scientific Gap #4);

    e. Processes where the drying step comes before cooking under moist conditions (Scientific Gap #5); and

f. Products with long heating come-up-times (CUT) (*i.e.*, longer than 6 hours) (Scientific Gap #6).

5. Establishments using common cooking processes but which cannot achieve the relative humidity or heating CUT in the revised guidelines may be able to cite one of these scientific gaps as support for not addressing the critical operational parameter. Establishments should refer to Table 5 on pages 43-48 of the 2021 Revised Appendix A to determine if their process falls under one of the scientific gaps.

6. For establishments following recommendations under a scientific gap, if FSIS or the establishment collects an RTE sample that is positive for *Salmonella*, or the establishment is implicated in a food safety investigation related to *Salmonella* (*i.e.*, is associated with reports of illness or outbreak), FSIS would verify, as part of the corrective actions (9 CFR 417.3), whether the establishment is able to support inadequate lethality was not the root cause if it wants to continue to use the older recommendation.

E. When verifying an establishment's cooling processes, IPP are to be aware that:

1. Fish of the Order Siluriformes is not covered by the 2021 Revised Appendix B Guideline.

NOTE: Fish of the Order Siluriformes (*e.g.*, catfish) and products derived from these fish are products where research demonstrate FSIS guidance is insufficient to result in a safe product. These products cannot use FSIS guidance as scientific support and must identify alternative support. Products listed above are different from products covered under a scientific gap described in E.7. below.

2. Cooling options for both RTE and NRTE products that are cooked to lethality are included in Table 1 of the 2021 Revised Appendix B, which incorporates 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 Table 2, which incorporates the previous Option 1 as Option 2.1.

3. Under Option 1.2, establishments should begin cooling product within 90 minutes of when cooking ends. Once the product reaches 120 °F, the product must cool to 80 °F in ≤ 1 hour.

4. Under Option 2.1, for partially cooked products, establishments should limit the heating CUT to ≤ 1 hour between 50 °F and 130 °F.

5. Under 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). Establishments should not mix natural sources of nitrite and ascorbate or erythorbate with purified or synthetic sources.

6. Under Option 1.4, establishments should demonstrate a continuous drop in temperature without the need to demonstrate any particular timeframe is met between 120 °F and 80 °F.

7. Where gaps exist, recommendations from older stabilization guidance included in the 2021 Revised Appendix B can be used until research is completed for the following scientific gaps:

a. Large mass non-intact products (> 8 pounds or > 4.5 inches thick for each single piece) that cannot cool quickly enough to follow the new options in Table 1 of the 2021 Revised Appendix B (Scientific Gap #1);

b. Partially heat-treated, smoked products that contain nitrite and erythorbate or ascorbate and have long heating CUT and cooling times and cannot follow the options in Table 2 of the 2021 Revised Appendix B (Scientific Gap #2);

c. 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 (Scientific Gap #3);

d. 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) (Scientific Gap #4);

e. 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 (Scientific Gap #5); and

f. Scalded offal that cannot cool quickly enough to follow the new options in Table 2 of the 2021 Revised Appendix B (Scientific Gap #6).

8. Establishments using common cooling processes that used the 1999 version of Appendix B but cannot achieve the heating CUT for partially heat-treated products, cooling time-temperature, or pre-cooling conditions in the revised guidelines may be able to cite one of these scientific gaps as support for not addressing the critical operational parameter. Establishments should refer to Table 3 on pages 29-34 of the 2021 Revised Appendix B to determine if their process falls under one of the scientific gaps.

9. For establishments following older recommendations under a scientific gap, if the establishment is implicated in a food safety investigation (*i.e.*, associated with reports of illness or outbreak), FSIS would verify, as part of the corrective actions (9 CFR 417.3), whether the establishment is able to support inadequate stabilization was not the root cause if it wants to continue to use the older recommendation.

10. The 2021 Revised Appendix B Guideline introduced the category of pre-cooling conditions as critical operational parameters. These are conditions that must be met to support cooling product according to that option (9 CFR 417.5(a)(1)). The intent is that critical operational parameters are met with "pre-cooling," but logistically some parameters may be monitored at different points. For example, nitrite and ascorbate/erythorbate levels may be calculated based on the "ingoing" formulated amount. In contrast, brine concentration is calculated from the total salt content and total water content values obtained by a laboratory analysis of cooked and cooled product.

11. If while reviewing the scientific or technical support for cooking and cooling processes, IPP have a concern about a technical aspect of the documentation not covered in this notice, they are to contact their supervisor.

IV. SUPERVISORY RESPONSIBILITIES

A. In the event of a deviation from a lethality or stabilization CCP or prerequisite program, supervisors are to assist IPP in evaluating the establishment's supporting documentation to determine if it supports product safety, and to obtain answers to address IPP concerns and questions regarding the scientific support.

B. To determine whether the lack of scientific support could result in product adulteration, or to determine whether the establishment's corrective actions are sufficient, supervisors are to seek assistance from the District Office to request an EIAO's review or submit an askFSIS question, if necessary.

C. If an establishment does not maintain documents to support the scientific or technical basis for CCPs or prerequisite programs used to support decisions in the hazard analysis related to the lethality or

stabilization of a product and the establishment is not using information from a supportable scientific gap (see Section III.D.4. and Section III.E.7. of this notice for a list of scientific gaps), supervisors are to recommend that IPP issue an NR citing noncompliance with 9 CFR 417.5(a)(1).

1. Supervisors are to assist IPP in verifying that the establishment takes necessary actions to return to compliance with the applicable regulation(s) found noncompliant.

2. If the establishment decides to reclassify the product as NRTE, as part of the response to an NR written for lack of scientific support for their lethality or stabilization process, supervisors are to verify establishments meet applicable requirements, including those related to support for decisions in the hazard analysis (9 CFR 417.5(a)(1)) as directed in FSIS Directive 7111.1 Section X.H.

D. If IPP have obtained information from askFSIS or other resources, supervisors are to be actively engaged with IPP to review the information and to assist IPP in making a final compliance decision.

V. EIAO RESPONSIBILITIES

A. During an FSA, as instructed in FSIS Directive 5100.1, *Food Safety Assessment Methodology*, 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) on file, and that the scientific support is complete and contains methodology and results.

B. If an establishment uses a cooking or stabilization process for meat and poultry products (either fully cooked or partially heat-treated), the EIAO is to verify that the establishment uses the 2021 Revised Appendix A or B or has identified alternative support (9 CFR 417.5(a)(1)). The EIAO is also to verify that the establishment has reassessed its HACCP system as needed (9 CFR 417.4(a)(3), 9 CFR 417.4(b)), and gathered any needed in-plant validation data for changes made to their HACCP system (9 CFR 417.4(a)(1)).

C. The EIAO is to verify the establishment implements the critical operational parameters in the actual production process consistent with the parameters in the scientific or technical support. If the establishment does not use the same critical operational parameters as those in the scientific or technical support, the EIAO is to evaluate whether the establishment provided additional support for the adequacy of the process control measures or interventions. The EIAO is to be aware that:

1. Establishments using common cooking processes that cannot achieve the relative humidity or heating CUT in the revised guidelines may be able to cite one of the scientific gaps described in Section III.D.4 of this notice as support for not addressing the critical operational parameter.

2. Establishments using common cooling processes that used the 1999 version of Appendix B but cannot achieve the heating CUT for partially heat-treated products, cooling time-temperature, or pre-cooling conditions in the revised guidelines may be able to cite one of the scientific gaps described in Section III.E.7 of this notice as support for not addressing the critical operational parameter.

D. Based on the findings of the FSA, the EIAO is to follow the instructions in FSIS Directive 5100.1, Chapter II, Section XII, FSA Recommendations when determining whether to recommend No Further Action, Issuance of NRs, or Enforcement Action.

VI. QUESTIONS

Refer questions regarding this notice to your supervisor or as needed to the Office of Policy and Program Development (OPPD) through askFSIS or by telephone at 1-800-233-3935. When submitting questions, 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