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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2017-0016]

FSIS Guidelines for Small and Very Small Meat and Poultry Establishments regarding Cooking 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 response to comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of two updated guidelines for meat and poultry establishments concerning the destruction of *Salmonella* and other pathogens during cooking of ready-to-eat (RTE) meat and poultry products (lethality) and the control of the growth of spore-forming Clostridial pathogens in heat-treated RTE and not-ready-to-eat (NRTE) meat and poultry products during cooling and hot-holding (stabilization). The updated guidelines reflect changes made in response to comments received on the 2017 versions of these guidelines.

DATES: On December 14, 2022, FSIS will verify that establishments that had been using the 1999 and 2017 versions of Appendix A and B are instead using the 2021 updated versions of the guidance or have identified alternative scientific support for their cooking and stabilization processes, making changes to their HACCP systems as needed.

ADDRESSES: Downloadable versions of the guidelines are available to view and print at https://www.fsis.usda.gov/guidelines/2017-

0007 and https://www.fsis.usda.gov/guidelines/2017-0008 once copies of the guidelines have been published.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Background

On June 16, 2017, FSIS announced the availability of and requested comments on revisions to two guidance documents, originally published in 1999: the *FSIS Salmonella Compliance Guideline for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Revised Appendix A* and the *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* (82 FR 27680). These guidelines describe best practices for eliminating *Salmonella* from RTE meat and poultry products (lethality) and for preventing or limiting the growth of spore-forming Clostridial pathogens (stabilization) during the cooling or hot-holding of RTE and NRTE meat and poultry products. After reviewing the comments received, the Agency has again revised the guidelines. The revised guidelines are posted at: https://www.fsis.usda.gov/policy/fsis-guidelines. A summarized list of major changes to the guidelines appears below.

Many establishments use these processing guidelines as scientific support for the lethality and stabilization procedures in their Hazard Analysis and Critical Control Point (HACCP) systems. When adequately applied to ensure food safety, FSIS has accepted the use of both of these guidelines as scientific support for validating that the establishment's HACCP system for these products meets the regulatory performance standards for lethality(9 CFR 318.17(a)(1), 9 CFR 318.23, 381.150(a)(1)) and stabilization (9 CFR 318.17(a)(2), 9 CFR 318.23(c)(1), 9 CFR 381.150(a)(2), 9 CFR 381.150(b)) in cooked and partially-cooked meat and poultry products. In addition, FSIS has accepted these guidelines as scientific support for validating that the establishment's HACCP system for these products and other RTE and NRTE meat and poultry products not covered by the regulations address Salmonella and Clostridial pathogens. Therefore, establishments may include the guidelines as supporting documentation for decisions in the hazard analysis and for validation (9 CFR 417.5(a)(1)) and 9 CFR 417.4(a)), as well as supporting the selection and development of HACCP system controls (9 CFR 417.5(a)(2)). Establishments may choose to adopt different procedures than those outlined in the Appendix A and B guidelines, but they will need to provide scientific support demonstrating why those procedures are effective. Additional types of scientific or technical support can consist of other published processing guidelines, peer-reviewed scientific or technical data or information, expert advice from processing

authorities (provided it does not rely on expert opinion alone), a challenge or inoculated pack study, results of validated pathogen modeling programs, data gathered by the establishment in-plant, or other best practice guidelines.

Industry Use of the 2021 Guidelines

Although FSIS accepts the use of these guidelines as validated support to achieve adequate lethality and stabilization in certain RTE and NRTE poultry products, an establishment's use of the guidelines does not exempt it from required ongoing establishment HACCP verification activities or expanded FSIS verification or required corrective actions should it produce adulterated products. Additionally, although an establishment may use the guidelines as scientific support for their decisions in developing a HACCP system, the establishment still must meet all the regulatory HACCP requirements, including those for validation. Therefore, if they use the guidelines as scientific support, the establishment needs to follow the critical operational parameters in the guidelines applicable to the product they are producing and the process they are following.

FSIS first revised the 1999 guidelines in 2017 and has again revised them to clarify requirements, provide new options to meet the lethality and stabilization requirements, and to address gaps in the scientific knowledge or newly recognized risks. If an establishment has been using previous versions of this guidance in support of its lethality or stabilization

controls, the establishment should review the revisions to the guidance and make any adjustments to its HACCP system necessary to continue producing safe meat and poultry products. Because use of the guidance is voluntary, an establishment can always opt to use alternative sources of scientific support for its lethality and stabilization controls.

As stated above, on [INSERT DATE ONE YEAR FROM DATE OF PUBLICATION], FSIS will verify whether establishments that had been using the 1999 and 2017 versions of Appendix A and B are instead using the 2021 versions of the guidance or have identified alternative scientific support for their cooking and stabilization processes, making changes to their HACCP systems as needed. At this time, FSIS will consider the older versions of the guidance no longer adequate scientific support for HACCP systems because they are out of date. Inspection program personnel (IPP) will verify establishments are no longer using the 1999 and 2017 versions during performance of the next Hazard Analysis Verification (HAV) Task after [INSERT DATE ONE YEAR FROM DATE OF PUBLICATION]. If IPP have concerns about a technical aspect of the documentation, an Enforcement Investigation and Analysis Officer (EIAO) may be assigned to review the scientific support. EIAOs will also verify that establishments are maintaining adequate scientific support for the design of their HACCP systems during the performance of Food Safety Assessments (FSAs). If an establishment continues to use a rescinded version of the guidance, FSIS will determine whether

the establishment has additional supporting documentation that sufficiently supports its decisions concerning the controls in its HACCP system, as well as the HACCP system in operation. In some cases, an establishment may be using portions of the rescinded guidelines that have not changed that continue to be adequate for achieving lethality or stabilization in the products in question.

Processes Not Covered by the Guidelines and Scientific Gaps

Many of the critical operating parameters in these guidelines were originally published as regulatory requirements in the 1980s, then removed from the regulations and revised as guidance in 1999. The original research used to support these critical operating parameters was performed for only a few processed meat and poultry products and was not designed as support for all products and processes. However, FSIS has found that establishments have been broadly applying the critical operating parameters in the guidelines to many products, beyond those they were originally designed to support.

FSIS has determined that the critical operating parameters in the guidelines should not be used as support for some products and processes, because research or outbreaks demonstrate they are insufficient to result in a safe product or because the guidelines were never intended to cover those products (*e.g.,* Fish of the Order Siluriformes). These excluded processes are now clearly identified at the beginning of each document as "Products and Processes Not Covered by the

Guideline." For example, FSIS learned through an investigation of a 2018 listeriosis outbreak (Recall 084-2018;[1] CDC: Outbreak of Listeria Infections Linked to Deli Ham)[2] that an establishment was cooking country-cured hams in a sealed bag multiple times using Appendix A as support for each cooking step. Before being cooked multiple times, the ham was salt-cured and dried, thus lowering its water activity. The draining of juices may have resulted in drier conditions during cooking. The establishment used Appendix A as scientific support that the cooking process achieved lethality of pathogens, including *L. monocytogenes*. However, Appendix A guidance was not intended for lower water activity products cooked under dry conditions or for products cooked multiple times. *L. monocytogenes* may survive cooking under these conditions. Hence, the process may not have been lethal to *L. monocytogenes*.

FSIS has stated in the revised Appendix A that the guidance does not cover dried products cooked under dry conditions, because of the food safety concern. Other products that FSIS has determined should not be processed using the critical operating parameters in the Cooking Guideline/Revised Appendix A include: Fish of the Order Siluriformes (*e.g.*, catfish); pork rind pellets, rendered lard and tallow; partially heat-treated not ready-to-eat products; and ready-to-eat products that rely on multi-hurdle processes other than cooking such as fermentation,

[1] See: https://www.fsis.usda.gov/recalls-alerts/johnston-county-hams-recalls-ready-eat-ham-products-due-possible-listeria.
[2] See: https://www.cdc.gov/listeria/outbreaks/countryham-10-18/index.html.

salt-curing, or drying to achieve lethality. FSIS has included a reference to alternative support establishments may use for many of the processes not covered by the guidelines.

In addition to products clearly not covered by the guidelines, FSIS has identified several common cooking and stabilization processes for which establishments have used Appendix A and B as support, even though these processes cannot achieve the critical operating parameters included in the revised guidelines. Therefore, there is insufficient evidence showing any imminent food safety concern resulting from the continued application of the older recommendations to these processes. For example, during the 2018 listeriosis investigation discussed above, FSIS determined there were establishments cooking salt-cured and dried country cured hams once in the bag without draining the juices. FSIS believes the juices in the bag provide sufficient moisture to rehydrate the surface of the hams and achieve sufficient lethality of pathogens, but there is no research to support this. In addition, FSIS is not aware of *Salmonella* or *Lm* positives or illnesses associated with establishments that use such processes. Therefore, the use of the guidelines for these processes are considered by FSIS to be "scientific gaps." A complete list of the scientific gaps FSIS has identified for each guideline is included in the Summarized List of Changes below.

FSIS is working to fill relevant gaps in the scientific support for these processes and will update the guidelines as data become available. Until such research is complete, an establishment producing products using processes that fall under an identified scientific gap may continue to use the critical operating parameters from older versions of FSIS guidelines that have been included in the revisions. However, the establishment should be aware of a few concerns FSIS has with doing this:

- Use of these critical operating parameters represents a vulnerability because these processes have not been validated to address all hazards of concern.
- If a process deviation occurs for a process that is listed as a scientific gap, it is unlikely an establishment would be able to identify adequate support for product safety without performing product testing.
- If FSIS or the establishment collects a RTE product sample that is positive for a pathogen or the product is implicated in a food safety investigation (i.e., is associated with reports of illness or outbreak), FSIS would verify, as part of the corrective actions (9 CFR 417.3(b)), that the establishment can demonstrate that inadequate lethality or stabilization was not the root cause of the positive sample or the confirmed illness or outbreak, which it would need to do if it wants to continue to use the older recommendation.

Summarized List of Major Changes to the Guidelines

FSIS made the following changes from the 2017 to the 2021 versions of the guidance.

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 *S. aureus* growth (which was not validated) because of the development and validation of the 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 come-up-times (CUTs).
- That information about a listeriosis outbreak associated with a cooked country-cured ham product and recommendations for establishments that cook a similar product.

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. 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.

For Appendix B, FSIS included the following changes and additional information:

- Cooling options for products that are cooked to lethality (both RTE and NRTE) are now included in a table (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 both RTE and NRTE products that are cooked to lethality are included in Table 1.
- Cooling options for partially cooked products are included in a separate table and include former Option 1 as Option 2.1 (Table 2).
- 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 80 ^{0}F in 2 hours in Option 1.4 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 are included in Attachment B3, FSIS's Predictive Microbial Modeling Support for 1-Log Cooling Options.
- To support common bacon and scrapple processes, FSIS updated references to research 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, recommendations 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 cannot 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 specific changes, FSIS reorganized both Appendix A and B for clarity. Both guidelines are organized to provide establishments with an overview of topics related to the safe cooking and cooling of meat and poultry products in the main body of each document, with additional details about each

topic included in attachments. To use the guidelines, FSIS recommends that establishments first read the overview of each of the topic areas and then consult relevant attachments if more detail is needed.

The guidelines also are organized so that the main body contains critical operating parameters that establishments may choose to use as scientific support for their cooking and cooling processes. Additional recommendations, including some alternative options, are provided in the attachments. The information provided in the attachments is not sufficient to use as sole support. Establishments must provide additional documentation. For example, both Appendix A and B include attachments that summarize alternative support, such as journal articles for lethality and stabilization. However, the summaries are not adequate scientific support for validation on their own, because they do not contain the details of each study. Therefore, establishments that choose to use a journal article cited in the guidelines as their scientific support must have the full copy of the article on file to support decisions in the HACCP System. These changes were made so that establishments could more easily find FSIS's cooking and cooling recommendations, while also having access to other options and details, if needed.

Comments and FSIS Responses

FSIS received 52 comments and over 250 askFSIS questions on the 2017 revisions to Appendix A and B from individuals, establishments, trade groups, FSIS personnel, academics, a State government, a food safety consultant, and a food technology consultant. Following is a summary of the issues raised in the comments and FSIS's responses.

General Appendix A and B

Comment: One individual asked if the 1999 versions of Appendix A and B will still be acceptable support for existing HACCP plans and requested more information be provided as to why or why not.

Response: As discussed above, FSIS has rescinded the 1999 and 2017 versions of Appendix A and B. These versions are no longer available on the FSIS website. FSIS will verify, one year from the date of this issuance, whether establishments using the guidelines as scientific support are using the updated 2021 version. One of the reasons FSIS updated the 1999 versions of Appendices A and B was because some of the content was out-of-date and could no longer be supported by scientific information. In addition, some of the recommendations were vague and put establishments at risk of producing unsafe product. FSIS had provided clarifications to the recommendations in other documents, but all establishments may not have been aware of this information.

FSIS has incorporated the still valid information from the 1999 guidance into the 2021 version. Therefore, if an

establishment is following one of the parts of the 1999 guidance that did not change, and it is still supported by the 2021 version, it can continue to use the new guidance as scientific support and will not need to make changes to its HACCP system or gather new initial in-plant validation data (Element 2 to meet validation requirements), because the critical operational parameters of its process have not changed. However, in some cases, establishments will need to make changes to their HACCP system and gather initial validation data, because the critical operational parameters of their process will need to change.

For example, if the establishment is following Option 2 of Appendix B and had not been monitoring the time product dwelled between 120 to 80°F to meet validation requirements, the establishment would need, at a minimum, to gather initial validation data to demonstrate that the product could cool between 120 to 80°F in an hour or less. To meet HACCP plan and verification requirements (including in-plant validation requirements), the establishment should also incorporate these parameters into the critical limits of its Critical Control Point (CCP) and gather data to support that these parameters can continue to be met on an ongoing basis. The one exception is for establishments producing large mass non-intact product greater than 4.5 inches in size or greater than 8 pounds where FSIS has identified a scientific gap. For these processes, establishments can continue to follow the critical operational parameters FSIS has incorporated from the older guidance into the 2021 versions

(cooling occurs from 120 to 55°F in 6 hours or less and chilling is continuous to 40°F) until additional research is complete.

Comment: One individual requested that FSIS address the difference between guidance and requirements.

Response: As is stated in the "Purpose" sections of the guidance, guidance provides best practices establishments can use to produce safe food under FSIS regulations. The guidelines do not represent requirements that must be met. FSIS has also changed the titles of the documents to remove the word "compliance" to better indicate that the document provides recommendations and validated options, not requirements. Therefore, establishments are required to maintain scientific support for their HACCP systems. If establishments use the guidelines as their scientific support, they need to ensure they follow the applicable critical operating parameters in the guidelines.

Comment: One food safety consultant indicated that the introduction should more clearly state what has changed in the revised guidance.

Response: FSIS has added sections to both documents that summarize the changes.

Insufficient Support

Comment: Comments from eight establishments and a State government argue that there is no need for the updated guidelines, as they have been operating without problems using the current guidelines. Two of these commenters stated that they

have been through FSAs with no problems. These commenters questioned the need for the updated guidelines, considering that there have been few *Salmonella* outbreaks in fully cooked, ready-to-eat meat products.

Response: As noted above, some of the guidance was outdated and no longer provided adequate scientific support for establishments' HACCP systems, although establishments have continued to use the guidance as scientific support to validate their HACCP systems.

While it is true that some establishments may have had Food Safety Assessments in the past where no issues were found, FSIS determined that there may have also been confusion among FSIS EIAOs in determining whether establishments were following the recommendations in the guidelines. Therefore, FSIS will be providing updated instructions to IPP and EIAOs for verifying cooking and stabilization processes at establishments producing fully cooked and heat-treated products.

FSIS has determined that some small and very small establishments may not have been applying the recommendations from the 1999 versions of the guidelines correctly. Consequently, some products may not have been produced in a manner consistent with these original safe harbor recommendations. For example, as discussed above, during an investigation of a listeriosis outbreak in 2018 that was associated with cooked country-cured ham product, FSIS determined the establishment applied FSIS Appendix A as support

for a cooking step when the guidance was not designed for processes where the drying step comes before the cooking step (Recall 084-2018;[3] CDC: Outbreak of Listeria Infections Linked to Deli Ham).[4] FSIS also determined through its verification activities that numerous establishments following Option 2 in the 1999 version of Appendix B (now Option 1.2) were taking two to four hours to cool their product between 120 to 80°F. The 1999 version of Appendix B stated that when processes took longer than one hour between 120 to 80°F, "compliance with the performance standard was less certain." However, when pathogen modeling was performed, processes taking two to four hours to cool their product between 120 to 80°F routinely were found to exceed the recommended performance standard of 1-log growth of *C. perfringens*. There has been one outbreak associated with *C. perfringens* from a commercially produced RTE turkey loaf product, the type of product that can take an extended time to cool between 120 to 80°F due to its size.[5] FSIS has updated the guidance to decrease risks of future outbreaks associated with these products.

Comment: Comments from several establishments and a trade group expressed concern that issuing the new guidelines will

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[3] See: https://www.fsis.usda.gov/recalls-alerts/johnston-county-hams-recalls-ready-eat-ham-products-due-possible-listeria.

[4] See: https://www.cdc.gov/listeria/outbreaks/countryham-10-18/index.html.

[5] Centers for Disease Control and Prevention (CDC). 2000. Surveillance of Foodborne-Disease outbreaks – United States, 1993-1997. Morbidity and Mortality Weekly Report, CDC Surveillance Summaries, March 17, 2000. MMWR 49, No. SS-1. Available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/ss4901a1.htm; personal communication, R.F. Woron, N.Y. State Department of Health, August 2002.

cause economic strain on establishments. Some of the commenters claimed that the updated guidelines will cause slaughterhouses to close, increase tax burdens, raise unemployment, limit customer choice, reduce the quality of products, limit organic and artisanal foods, and harm business growth.

Response: FSIS recognizes the concerns about the economic impact of the revisions to its guidance. Some establishments might need to gather additional support for lethality and stabilization procedures because the guidance did not provide adequate scientific support for their processes. In addition, small and very small establishments often do not have the resources to perform challenge studies or develop additional support on their own. In response to comments on the 2017 version of the guidelines, FSIS has identified research needs related to common procedures and is providing its best recommendations in the updated versions of these guidelines, so that establishments may be able to attain product safety using the recommendations in the 2021 version and maintain scientific support for their HACCP systems, while scientific gaps are being filled. The Agency continues to work with researchers and, once additional research is completed, will provide further guidance for those common products with known gaps to assist small and very small establishments that do not have the technical resources to develop the support on their own.

Comment: A food safety consultant questioned how FSIS came up with the recommendation for 500 samples in Appendix A and B

and how it applies to small establishments. The commenter also indicated such sampling would be excessively expensive for small establishments.

Response: FSIS removed from Appendix A 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. In addition, FSIS removed from Appendix B specific recommendations for obtaining a waiver to permit 2-Log growth of *C. perfringens* during cooling including by conducting baseline sampling.

Appendix A Comments

FSA Analysis

Comment: One food safety consultant questioned whether the FSA review (from the section titled "Lessons Learned from RTE *Salmonella* Food Safety Assessments (FSAs)" in the 2017 guideline) was statistically based, since it included only 16 FSAs out of thousands. The commenter also questioned whether any of the FSAs reviewed had insufficient lethality issues since insufficient lethality was not identified in the summary data.

Response: For the 2017 revision of the guideline, FSIS reviewed a large portion (64%) of FSAs that occurred in response to *Salmonella*-positives in RTE product during 2009-2014. As stated on page 6 of the 2017 guideline, there were 25 positive results for *Salmonella* during that time. FSIS reviewed 16 of the

FSAs that were performed in response to the positive results, which represented over half of the FSAs and was the number that was available for analysis. The goal of the analysis was to identify practices that may have been contributing factors to *Salmonella* contamination of RTE products. To look for trends, FSIS categorized practices into broad categories such as sanitation issues, HACCP issues, and cross-contamination issues. Some of the HACCP issues identified included inadequate recordkeeping and lack of validation, which may have contributed to insufficient lethality. The number reviewed were sufficient for purposes of developing the guidance.

6-Hour come-up-time

Comment: A food safety consultant asked for support for the heating come-up-time recommendation and associated illnesses.

Response: FSIS recommends that the heating come-up-time be limited to 6 hours or less between 50 to 130°F primarily to limit outgrowth of *Staphylococcus aureus* (*S. aureus*), which could grow to high levels and produce a heat-stable enterotoxin that would not be destroyed by the cooking step. The six-hour heating come-up-time is supported by pathogen modeling using USDA Agricultural Research Service (ARS) Pathogen Modeling Program and the Therm 2.0 modeling tool. FSIS clarified in the 2021 revision that the six-hour time applies to the time the product is between 50 to 130°F, so the total amount of time for product to reach an endpoint time-temperature may be longer. The University of Wisconsin also has conducted related research for

hams but involving the use of antimicrobials in the formulation of the product. FSIS has included a reference to this research in the revision.

FSIS is aware that establishments preparing some products (*e.g.,* ham or beef brisket) may not be able to follow FSIS's recommendation that the heating come-up-time be limited to 6 hours or less between 50 to 130°F because of the thermodynamics of the heating process. Therefore, FSIS identified long CUT as a Scientific Gap since support does not exist for many common processes and the Agency is not aware of an imminent public health concern. This gap supports the use of any of FSIS's applicable time-temperature combinations and relative humidity, without considering CUT as a critical operating parameter until research can be complete.

Comment: Two trade groups indicated FSIS did not provide support for the statement that normal levels of *S. aureus* in meat are 2-log/gram.

Response: FSIS based its determination that normal levels of *S. aureus* in meat are 2-log/gram on results from several baseline studies conducted from 1994-1998 on market hogs, steers and heifers, cows and bulls, broilers, young turkeys, raw ground chicken, ground turkey, and ground beef. Additional studies that support that normal levels of *S. aureus* in meat being 2-log/gram include research by Waldroup (1996), the Institute of Food

Technologists (2003), and Doyle and Buchanan (2013). FSIS recognizes that some of these citations use older data.

The baseline studies used to determine that normal levels of S. *aureus* in meat include:

1. Nationwide Pork Microbiological Baseline Data Collection Program: Market Hogs. June 1996;
2. Nationwide Beef Microbiological Baseline Data Collection Program: Steers and Heifers. January 1994;
3. Nationwide Beef Microbiological Baseline Data Collection Program: Cows and Bulls. February 1996;
4. Nationwide Broiler Chicken Microbiological Baseline Data Collection Program. April 1996;
5. Nationwide Young Turkey Microbiological Baseline Data Collection Program. August 1998;
6. Nationwide Raw Ground Turkey Microbiological Survey. May 1996;
7. Nationwide Federal Plant Raw Ground Beef Microbiological Survey. April 1996;
8. Nationwide Raw Ground Chicken Microbiological Survey. May 1996;
9. Doyle, M. P., and R. L. Buchanan (ed.). 2013. Food microbiology: Fundamentals and Frontiers—4th ed. ASM Press, Washington, DC.;
10. Institute of Food Technologists (IFT). 2003. Evaluation and Definition of Potentially Hazardous Foods. Comprehensive Reviews in Food Science and Food Safety. Vol. 2 (Supplement, 2003).; and
11. Waldroup, A. L. 1996. Contamination of raw poultry with pathogens. World's Poultry Science Journal. 52:7-25.

Poultry time-temperatures

Comment: One individual asked if there is a holding time of 160°F for cooked poultry rolls and other cooked poultry products (as recommended in the Poultry Time-Temperature tables that were

incorporated into the 2017 *Salmonella* guideline and Revised Appendix A) or if an instantaneous temperature of 160˚F (recommended final temperature from the 1999 version of Appendix A, incorporated into the 2017 *Salmonella* guideline and revised Appendix A) would meet the performance standard to achieve a 7-log reduction in Salmonella 9 CFR 381.150(a)(1). Also, FSIS has received many questions from FSIS personnel and establishments expressing confusion about whether temperatures in the Poultry Time-Temperature tables included in the 2017 revision of the *Salmonella* Compliance Guideline and Revised Appendix A and that have a dwell time of < 10 seconds are considered instantaneous temperatures.

Response: The recommendation from the 1999 version of Appendix A to cook poultry rolls and other cooked poultry products to an instantaneous temperature of 160˚F can be applied to any poultry product (not just cooked poultry rolls and breakfast strips). FSIS has maintained this option because there have not been any reports of illnesses or outbreaks tied to establishments that follow it. However, the options in the Poultry Time-Temperature Tables (which include dwell times at 160˚F that vary based on species and fat content) have been validated with updated research to address species and fat content as critical operating parameters to ensure adequate Log reductions of *Salmonella.* Applying the cooked poultry rolls option (160˚F instantaneous) may achieve the same Log reductions as the time-temperature combinations in the Poultry Time-

Temperature Tables, particularly when applied to a lean product, because the product may be maintained at 160°F for the recommended dwell times (between 13.7 to 26.9 seconds depending on species and fat) during the time it takes to complete temperature monitoring. FSIS recommends establishments monitor the dwell time in the Poultry Time-Temperature Tables as opposed to relying on the older guidance for cooked poultry rolls (160°F instantaneous) to better assure safety. If an establishment is using the older guidance for cooked poultry rolls (160°F instantaneous) and FSIS collects a RTE sample that is positive for *Salmonella* or if the establishment is implicated with a food safety investigation (i.e., is associated with reports of illness or outbreak, FSIS will review and determine the adequacy of the establishment's corrective actions (taken under 9 CFR 417.3) to address process deviations. The establishment will need to show FSIS that inadequate lethality was not the root cause of the process deviation if it wants to continue to follow the cooked poultry rolls option. FSIS continues to consider the temperatures in the Poultry Time-Temperature table with a dwell time of < 10 seconds to be instantaneous. To reduce confusion and to be consistent with the time-temperature guidance for meat products, FSIS has changed the dwell time to zero seconds to indicate those temperatures that are instantaneous.

Lethality Performance Standards and Recommendations

Comment: A trade group, an establishment, and a food safety consultant questioned why the guidance recommends that

establishments, including small and very small processors, identify the reduction of generic *Salmonella* in their process to address foodborne illness hazards. The commenters indicated that not all serotypes of *Salmonella* are known to cause illness and *Salmonella* is naturally occurring in poultry and swine. The commenters also mentioned that receiving a *Salmonella*-positive does not necessarily mean there is potential for human illness.

Response: If FSIS finds viable pathogens of concern, including *Salmonella*, in any ready-to-eat product, FSIS considers that product to be adulterated. The Agency does not make a distinction among serotypes of *Salmonella.* As stated by the commenters, *Salmonella* is naturally occurring in raw products, such as poultry and swine. RTE meat and poultry products should not contain any *Salmonella*, because they have undergone a lethality treatment. As stated in the guideline, finding *Salmonella* in RTE products indicates that under-processing, cross-contamination, or addition of contaminated ingredients after the lethality step may have occurred. Although FSIS has a low rate of *Salmonella*-positives in RTE products, *Salmonella spp.* are the second leading cause of foodborne illness in the United States, and meat and poultry products are often associated with outbreaks from *Salmonella spp.*[6,7]

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[6] Scallan, E., Hoekstra, R.M., Angulo, F.J., Tauxe, R.V., Widdowson, M., Roy, S.L., Jones, J.L., and P.M. Griffin. 2011. Foodborne Illness Acquired in the United States – Major Pathogens. Emerging Infectious Diseases. 17(1): 7-15.

[7] Interagency Food Safety Analytics Collaboration. Foodborne illness source attribution estimates for 2016 for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes*, and *Campylobacter* using multi-year outbreak surveillance data, United States. GA and D.C.: U.S. Department of Health and Human Services, CDC, FDA, USDA-FSIS. 2018.

Comment: A food safety consultant questioned the Agency's determination that a 5-log lethality would not be sufficient for all products, given pathogen levels in source materials, as stated in the guidance. The commenter recommended that FSIS take samples of raw source materials to determine appropriate performance standards for RTE product and recommended a 5-log lethality for all products types.

Response: FSIS has established different pathogen reduction performance standards, both regulatory and recommended, for different products and processes, based on risk assessments. As stated in Appendix A, FSIS requires a 6.5-log reduction of *Salmonella* in cooked beef, corned beef, and roast beef per 9 CFR 318.17, and has recommended that establishments achieve at least a 6.5 log reduction of *Salmonella* in other cooked meat products. The requirements in 9 CFR 318.17 were promulgated based on the results of the 1998 *Lethality and Stabilization Performance Standards for Certain Meat and Poultry Products: Technical Paper.* FSIS also supports its recommendations for products that do not fall under a performance standard using the "Risk Assessment of the Impact of Lethality Standards on *Salmonellosis* from RTE Meat and Poultry Products, 2005 (*Salmonella* Risk Assessment),"[8] which showed that a 5-log reduction of *Salmonella* (instead of a 6.5 log reduction) would result in a greater risk of illness in cooked meat products. The FSIS *Salmonella* Risk

[8] Risk Assessment of the Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products. 2005. Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C.

Assessment also found that there would not be a significant increase in the cases of salmonellosis if the processing of jerky and other shelf-stable products achieved a 5.0-log instead of 7.0-log lethality. Therefore, FSIS recommends a 5.0-log reduction of *Salmonella* in meat and poultry jerky to ensure a safe product. In addition, FSIS has identified various options establishments may use to show that levels of *Salmonella* in product source materials are lower than those found in the FSIS baseline, justifying an alternative lethality other than those required or recommended.

Comment: Two trade groups recommended alternative lethality options should be clear in the text and not just a sidebar and that FSIS should clarify that the codified performance standard requirements allow for an alternative lethality.

Response: FSIS has made the alternative lethality options clearer by moving them from the sidebar into the body of the text. The overview of the lethality requirements for specific RTE products in the guidance also states that the performance standards allow for an alternative lethality.

Ingredients Added Post-Lethality

Comment: One establishment disagreed with recommendations in the guidance related to supporting ingredients added post-lethality are safe and not contaminated. Specifically, the commenter stated that if the ingredients are inspected, they are considered safe and there should be no need for further tests.

Response: FSIS has identified that a common contributing factor to positive pathogen test results, recalls, and outbreaks has been the use of non-meat ingredients added post-lethality to ready-to-eat products. Some non-meat ingredients, such as frozen vegetables, are considered not ready-to-eat by the producing facility and, therefore, should not be added to a ready-to-eat product without support for the safety. FSIS verifies all ingredients and other articles used in the preparation of any meat or poultry product shall be clean, sound, healthful, wholesome and otherwise such as will not result in the product being adulterated (9 CFR 318.6 9 CFR 424.21). To verify that the non-amenable components will not adulterate the product, FSIS verifies that establishments have considered any potential food safety hazards at the step in the process where the non-meat ingredient is received into the food safety system and documents any controls it needs to support its decisions (9 CFR 417.5(a)(1)) about those hazards.[9] To provide this support, establishments have flexibility and do not have to only rely on testing. Alternatively, they can maintain other supporting documentation demonstrating that the ingredients, such as spices, have been treated by processes to kill pathogens (e.g., irradiation, ethylene dioxide, steam treatment of spices), or they can apply a lethality treatment to the ingredients (e.g., cook the sauce of a pork BBQ).

Casing Types

[9] FSIS Directive 7111.1 - Verification Procedures for Lethality and Stabilization (usda.gov).

Comment: Two trade groups questioned FSIS's decision to consider natural casings as permeable, therefore requiring humidity during cooking. One commenter recommended that FSIS define permeability based on water-holding capacity, which would result in natural casings being either semi-permeable or impermeable. Another commenter stated that both cellulose and natural casings are considered permeable.

Response: Natural casings made from animal gastrointestinal tracts are typically considered permeable, and many establishments take advantage of their permeability to produce dried products or smoked products. However, FSIS recognizes that the permeability of natural casings may be reduced depending on how they are used. Most cooking processes likely reduce the permeability of natural casings early in the process so that humidity around the product is inherently maintained throughout cooking and does not have to be added or monitored. According to Sebranek (2010),[10] establishments often apply smoke early in the process while the natural casing is still moist and permeable to the smoke. Prior to smoke application, the casing surface should be "tacky" or "sticky." After smoke deposition and color development, further cooking denatures the proteins in the casing, reducing permeability to the point that later cooking can be applied without great moisture loss from the product. However, most drying processes use lower temperatures and address relative humidity to maintain casing permeability so

[10] Sebranek (2010). Natural vs. Artificial Casings: Evaluating Which is Best for Your Product. Meatingplace.

that moisture can evaporate. This information has been included in the 2021 guidance. In addition, FSIS revised the 2021 guidance to indicate cooking product in any casing that holds moisture (*e.g.*, natural casings, cellulose casings, collagen casings, fibrous casings and plastic casings (sometimes called "synthetic" casings)) is considered a situation when relative humidity does not need to be addressed.

Although most cooking processes likely result in reduced permeability of natural casings early in the cooking process, little research has been performed to study the critical operational parameters that impact the reduction of permeability, such as the length of the initial smoke application step, cooking temperature, total cooking time, use of steam, size of casings, composition of sausage batter, etc. Therefore, without additional research, the log reduction of *Salmonella* is less certain if meat or poultry products in natural casings are cooked using one of the time-temperature parameters in Appendix A without following one of the humidity options. Therefore, FSIS has identified this issue as a research priority and, if additional data becomes available, FSIS may change the recommendation that establishments do not need to address relative humidity when products are cooked in a natural casing.

Relative Humidity

Comment: FSIS has received several questions from FSIS personnel and establishments concerning the need for adding

humidity to the process for all products covered in the cooking guideline. Several commenters stated that no *Salmonella* outbreaks have occurred recently, so the recommendation to apply relative humidity to all products is unfounded.

Response: FSIS agrees that humidity does not always need to be added and identifies situations in the updated guidance where relative humidity does not need to be addressed. These situations have now been incorporated into the 2021 guidance. For example, establishments producing products that weigh 10 pounds or more that are cooked in an oven that is 250°F or higher, or products that are cooked-in-bag where moisture is inherently maintained, would not need to apply humidity. However, FSIS considers maintaining relative humidity to be an important critical operational parameter for many processes to achieve surface lethality of pathogens. In the 2021 version of Appendix A, the Agency summarizes additional approaches for achieving surface lethality of pathogens that establishments can use.

In the 2017 and 2021 versions of Appendix A and in the *FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments*, FSIS identified the two primary goals of relative humidity in the cooking environment. The first goal is to reduce surface evaporation and the energy or heat that evaporation removes during heating. The second goal is to keep the product surface (and any pathogens) moister and prevent unwanted concentration of solutes as a result of drying.

As water is removed from a product because of surface evaporation, remaining solutes become more concentrated. As moisture evaporates from the surface, and the concentration of solutes increases, the water activity is reduced. Consequently, this leads to microbial heat tolerance, especially for *Salmonella*. In response to comments, FSIS has referenced additional articles that establishments can use to support their processes.

Although outbreaks have not occurred recently from *Salmonella* in RTE products, several occurred in the late 1970s and early 1980s, prior to the implementation of FSIS's cooking recommendations. Following a series of salmonellosis outbreaks in beef in 1977, USDA published an emergency rule prescribing a minimum temperature of 145°F for cooked beef and roast beef. In response to comments from industry as well as research by Goodfellow and Brown (1978), USDA expanded the temperature and time regulations to allow for more combinations validated to achieve a 7-log reduction in *Salmonella.*[11] At that time, the Agency also expanded the regulation to cooked corned beef based on Agency testing data and findings suggesting the potential for undercooking (47 FR 31856). Following these changes, several additional salmonellosis outbreaks were linked to the consumption of roast beef produced by four separate establishments in the northeastern United States. Epidemiologic investigations revealed that inadequate cooking times and

[11] Goodfellow, S. J. and W. L. Brown. 1978. Fate of Salmonella Inoculated into Beef for Cooking. Journal of Food Protection. 41:598-605.

temperatures were not the major contributing factors, and research at the time identified relative humidity as an important parameter during cooking. Outbreaks may have occurred because establishments were not adequately accounting for or applying humidity. Because of these outbreaks and the scientific research demonstrating that *Salmonella* may become tolerant to heat if low humidity is used,[12,13,14,15] the guidance continues to recommend that establishments apply humidity during the cooking process.

Comment: Six commenters, including a food technology consultant, academics, and establishments, questioned the older research used to develop Appendix A times/temperatures. Three commenters indicated research by Blankenship (1978)[16] and Goodfellow and Brown (1978) should not be used as support for requiring humidity. The commenters argued that the paper identified surviving *Salmonella* on the surface and hypothesized that this was due to heat tolerance from drying but did not test the humidity options FSIS uses. One commenter stated that there is a lack of current research data supporting the need for 90%

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[12] Goodfellow, S. J. and W. L. Brown. 1978. Fate of Salmonella Inoculated into Beef for Cooking. Journal of Food Protection. 41:598-605.

[13] Carlson, T.R., Marks, B.P., Booren, A.M., Ryster, E.T., and A. Orta-Ramirez. 2005. Effect of Water Activity on Thermal Inactivation of Salmonella in Ground Turkey. Journal of Food Science: 70(7): 363-366.

[14] Goepfert, J. M., I. K. Iskander and C.H. Amundson. 1970. Relation of the heat resistance of salmonellae to the water activity of the environment. Appl. Microbiol. 19(3):429-33.

[15] Gruzdev, N., Pinto, R., and S. Sela. 2011. Effect of desiccation on tolerance of *Salmonella enterica* to multiple stresses. App Environ Microbiology 77 (5):1667.

[16] Blankenship, L.C., 1978. Survival of a *Salmonella typhimurium* experimental contaminant during cooking of beef roasts. *Applied Environ Microbiol*, 35(6):1160-1165.

relative humidity. The commenter also indicated 90% relative humidity is excessive, is not supported scientifically for *Salmonella* lethality, and cited an article by Mann and Brashears (2007)[17] that supported less humidity.

Response: New research regularly continues to support the underlying concepts found in the research studies used to develop the recommendations in Appendix A. FSIS agrees that the research by Blankenship and by Goodfellow and Brown hypothesized that *Salmonella* on the surface of the product became more heat tolerant than those in the interior of the product. However, their research demonstrated that adding steam to the cooking process resulted in no survival of *Salmonella* on the surface of the product, demonstrating the effectiveness of moist cooking. Newer research supports that dehydration of *Salmonella* induces tolerance to stressors, including dry heat. In addition, research by Boles et al. (2004)[18] demonstrated that sealing the oven (closing dampers) for one hour at the beginning of the cooking process was more effective than opening the dampers. FSIS is not aware of other newer research supporting the relative humidity options; however, newer research has been performed that supports the cooking times and temperatures in Appendix A. Therefore, FSIS continues to cite the older articles

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[17] Mann, J.E. and Brashears, M.M. 2007. Contribution of Humidity to the Lethality of Surface-Attached Heat-Resistant Salmonella during the Thermal Processing of Cooked Ready-to-Eat Roast Beef. Journal of Food Protection (70): 3: 762-765.

[18] Boles, Neary, and Clawson. 2004. New intervention and validation for the control of pathogens in the processing of jerky. Report available at: https://www.fsis.usda.gov/sites/default/files/media_file/2021-08/C-11_New_Technology_FY2004_Final_Report.pdf.

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that were used as a basis for these recommendations and is continuing to seek additional research to add to the relative humidity options.

Specifically, Goodfellow and Brown's research showed greater survival of *Salmonella* inoculated on the surface of dry-roasted beef rounds than those in the interior. Research conducted by the Agricultural Research Service (ARS) and published by Blankenship in 1978 and 1980[19] substantiated this finding. In response to several outbreaks and research findings, FSIS issued an interim final rule in 1982 and finalized it in 1983 to address the handling, processing, cooling times and temperatures, and storage requirements necessary to ensure the wholesomeness of cooked roast beef. When the rule was finalized, FSIS added two options to the regulations for maintaining relative humidity that did not need to achieve 90% relative humidity for those products cooked to an internal temperature of 145° F or above. These options were to seal the oven or continuously introduce steam for 50% of the cooking time or one hour, whichever was longer. Although these exact options were not tested in the literature, FSIS used the research conducted by Goodfellow and Brown and Blankenship, along with expert opinion, to develop options that were practical and could be implemented by small and very small establishments. These

[19] Blankenship, L.C., Davis, C.E., and G.J. Magner. 1980. Cooking methods for elimination of Salmonella typhimurium experimental surface contaminant from rare dry-roasted beef roasts. Journal of Food Science. 45(2): 270-273.

options were designed to have a safety margin to ensure their effectiveness when applied to a wide variety of processes.

Newer research by McMinn et al. (2018) supports the time-temperature parameters in Appendix A to achieve sufficient reductions of *Salmonella.*[20] The research by McMinn et al. (2018) was conducted with product cooked in vacuum sealed bags, supporting the importance of cooking in a high moisture environment (that is 90% relative humidity). However, FSIS agrees 90% relative humidity is not needed in all cases. As stated previously, FSIS has provided additional relative humidity options for products cooked to an internal temperature of 145° F or above to include sealing the oven or introducing steam for 50% of the cooking time or one hour, whichever is longer. Research by Boles et al. (2004) supports the use of a sealed oven for maintaining relative humidity and other research does continue to support the importance of moisture during cooking. For example, research cited by commenters in Mann and Brashears (2007) supports the need for at least 30% relative humidity during cooking. This is consistent with the minimum amount of relative humidity the Agency believes is present when establishments seal the oven or introduce steam, based on FSIS's knowledge of establishments' processes, suggesting that these practical recommendations result in adequate relative humidity.

[20] McMinn, R.P., King, A.M., Milkowski, A.L., Hanson, R., Glass, K., and J.J. Sindelar. 2018. Processed Meat Thermal Processing Food Safety Generating D-Values for Salmonella, Listeria monocytogenes, and Escherichia coli. Meat and Muscle Biology. 2(1): 168-179.

The Agency is also not aware of any establishments that have had *Salmonella*-positives or been associated with a salmonellosis outbreak when following FSIS's temperature, time, and relative humidity guidance. Therefore, FSIS has updated the guidance to include a discussion of the research by Mann and Brashears (2007). The discussion outlines how the article supports the need for at least 30% relative humidity during cooking of roast beef, an amount the Agency believes is maintained when the oven is sealed, or steam is introduced suggesting these practical recommendations result in adequate humidity.

Comment: A food technology consultant and an academic referenced scientific support for cooking recommendations other than those recommended in Appendix A. Specifically, the commenters referenced a study by Sindelar et al. (2016)[21] supporting a wet-bulb time-temperature combination that may be a suitable replacement for the relative humidity recommendations during smokehouse processing.

Response: FSIS agrees with the commenters that the research conducted by Sindelar et al. (2016) contains scientifically-based thermal processing parameters to ensure sufficient reductions of *Salmonella* and other pathogens of concern during cooking. For this reason, this reference was included in the revised guideline as a journal article that may be used as alternative support. FSIS also generally agrees with the concept

[21] Sindelar, J.J., Glass, K., and B. Hanson. 2016. Investigating the Development of Thermal Processing Tools to Improve the Safety of Ready-to-Eat Meat and Poultry products. NAMIF Final Report.

of a surface lethality step or surface lethality treatment that relies on wet-bulb temperature to demonstrate how lethality is being achieved on the surface. However, FSIS does not consider the research sufficient to support applying a single wet-bulb temperature as a replacement for the current relative humidity options because of the limited treatments studied.

The research conducted by Sindelar (2016) provides scientific support for alternative processes including use of a wet-bulb temperature target. However, the researchers only evaluated reduction achieved for limited products under limited conditions. Therefore, establishments may choose to use this research as scientific support for their process, provided the critical operational parameters are met and the parameters chosen were ones that were tested in the laboratory to ensure sufficient reductions of *Salmonella* based on the establishment's desired target. Critical operational parameters identified in the research include the product type, thermal process schedule (dry-bulb temperature, wet-bulb temperature, and time at each stage), and final internal product temperature and time.

As stated above, FSIS is not replacing the time-temperature recommendations in Appendix A with those identified in the Sindelar research. FSIS's recommendations allow for temperatures ranging from 130 to 160°F for meat and 136 to 165°F for poultry and apply to all types of products and thermal processing schedules, provided a relative humidity option can be met. Because the research conducted by Sindelar only applies to

certain products and processes, it cannot be used by all establishments. In addition, the researchers were not able to achieve a 5-log reduction of *Salmonella* in chicken tenders even at the highest internal temperature tested of 175°F with a wet-bulb of 160°F. FSIS's relative humidity options in Appendix A applies to all meat and poultry products covered by the FSIS guidance. For these reasons, FSIS has added references to Sindelar's research to the guideline but has not used it to replace Appendix A humidity options.

Comment: One food technology consultant stated that the options for products cooked in less than one hour are too restrictive and that a low relative humidity process may be more lethal if it has a higher wet-bulb, citing research by Buege et al. (2006).[22] The commenter offered an alternative recommendation: Products cooked in less than one hour in a high temperature impingement or spiral oven must use a wet-bulb temperature of 160°F or higher for the entire process.

Response: FSIS agrees that there may be other approaches for demonstrating that surface lethality is achieved for products that are cooked for less than one hour. However, the Agency does not believe that there is enough data at this time to identify one target wet-bulb temperature, due to the wide variety of products and processes that are addressed in Appendix

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[22] Buege, D.R., G. Searls, and S.C. Ingham. 2006. Lethality of commercial whole-muscle beef jerky manufacturing processes against *Salmonella* serovars and *Escherichia coli* O157:H7. *Journal of Food Protection*. 69: 2091-2099.

A. The Agency also does not believe there is enough research at this time to apply FSIS' recommendations that rely on less than 90% relative humidity (that is sealing the oven or continuously introducing steam) to products that are cooked for less than one hour). The Agency is seeking more research related to this issue and will consider additional information as it becomes available.

The relative humidity recommendations were originally intended to be options for cooking large mass products such as cooked beef (i.e., brisket), roast beef, and cooked corned beef. Cooking time for such large mass products typically exceeds one hour, so FSIS's relative humidity recommendations were intended to be applied for at least one hour or more. However, in response to a series of outbreaks associated with beef jerky, including a 2003 outbreak from *Salmonella Kiambu*, FSIS added its recommendation to apply 90% relative humidity throughout cooking for processes when the cooking time is one hour or less in the 2007 *Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments* (updated in 2014)as well as the revised Appendix A. FSIS added this recommendation because one potential cause of the 2003 *Salmonella* Kiambu outbreak in jerky was the very slow drying process under low humidity conditions (1% Relative Humidity - 82°C dry-bulb, 30°C wet-bulb), which allowed *Salmonella* organisms to dehydrate during drying and become tolerant to heat.

FSIS recognizes that over time, many journal articles have been published increasing the scientific understanding of the critical role of certain parameters during jerky processing, including relative humidity. FSIS also recognizes that many of these articles, including that by Buege et al. (2006), support the use of less than 90% relative humidity, and the Agency does not object to establishments using these articles as scientific support, provided the critical operational parameters match the actual process being used. FSIS has included several articles establishments may use as scientific support for less than 90% humidity in the revised guideline. FSIS did not add the specific recommendation for use of wet-bulb to measure the temperature of products cooked for less than one hour in a high temperature impingement or spiral oven because, as explained earlier, FSIS does not believe there is enough information at this time to make a general recommendation that a single wet-bulb temperature can be used in addition to or in place of its relative humidity options.

Comment: A food technology consultant stated that the citations used by the Agency did not establish the premise that low humidity cooking of meats increases concentrations of salt and sugars and will lead to increased heat tolerance of pathogens. The commenter also contended that the Goepfert research cited by FSIS is of limited use to the meat industry because it was conducted with sugar-water solutions for the candy industry. The commenter recommended FSIS replace the

citation with papers by Buege et al. (2006), Boles et al. (2004), and Sindelar et al. (2016).

Response: FSIS agrees that these additional research citations support the importance of relative humidity and has added them to the revised guidance. In addition to these references, the increase in heat tolerance of microorganisms as water activity is reduced is well established in the literature.[23,24,25,26] While FSIS referenced work by Geopfert that was performed with sugar solutions, the same findings have been found for meat and poultry products. For example, Carlson et al. (2005) found that thermal inactivation of *Salmonella* decreased 64% when decreasing meat water activity from 0.99 to 0.95.

Comment: One establishment included a scientific paper by Carotenuto and Dell'Isola (1995),[27] stating that the calibration of equipment for relative humidity is poor.

Response: Accurate measurement is critical to ensuring that safe products are produced under the critical operational parameters of an establishment's HACCP system. Calibration also is important in maintaining accuracy over time. Often the owner's manual for humidity recorders recommends calibration on

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[23] Carlson, T.R., Marks, B.P., Booren, A.M., Ryster, E.T., and A. Orta-Ramirez. 2005. Effect of Water Activity on Thermal Inactivation of Salmonella in Ground Turkey. Journal of Food Science: 70(7): 363-366.
[24] Goepfert, J. M., I. K. Iskander and C.H. Amundson. 1970. Relation of the heat resistance of salmonellae to the water activity of the environment. Appl. Microbiol. 19(3):429-33.
[25] Blankenship, L. C. 1978. Survival of a Salmonella typhimurium experimental contaminant during cooking of beef roasts. Appl. Environ. Microbiol. 35:1160.
[26] Gruzdev, N., Pinto, R., and S. Sela. 2011. Effect of desiccation on tolerance of *Salmonella enterica* to multiple stresses. App Environ Microbiology 77 (5):1667.
[27] Carotenuto, A. and Dell'Isola, M. 1995. An Experimental Verification of Saturated Salt Solution-Based Humidity Fixed Points. International Journal of Thermophysics: 17(6): 1423-1439.

an annual basis, and FSIS recommends that establishments should follow the manual's instructions for calibration. Frequent calibration is the only way to know the humidity sensor is accurate. Concerns about lack of calibration have contributed to process deviations and recalls in the past. Frequent calibration and following equipment manufacturer instructions should address any concerns about inadequate calibration of equipment for relative humidity.

Appendix B Comments

Stabilization Performance Standards and Recommendations

Comment: Two industry groups contended that parts of the guideline were inconsistent, because the Agency stated in some sections that "no growth" of *Clostridium botulinum* is acceptable, while other sections state that "net growth ≤ 0.30" is acceptable. The commenters requested that this aspect of the guideline be clarified.

Response: The performance standard requirement is that there can be no multiplication of toxigenic microorganisms, such as *Clostridium botulinum* (9 CFR 318.17(2), 9 CFR 318.23(b)(3)(ii)(c), 9 CFR 381.150(a)(2), 9 CFR 318.23(C)(1), and 9 CFR 381.150(b)). However, FSIS realizes that existing predictive models, such as the ARS *C. botulinum* in beef broth model, do not predict no (zero) growth. As a practical way to evaluate cooling deviations, the Agency has regarded a predicted growth of no more than 0.3 logs (an approximate doubling, or one

generation) as an indication that there has been no growth. FSIS has clarified this in the guidance.

Cooling Options

Option 1

Comment: Thirteen comments from producers, industry groups, a consultant, and an academic stated that validation options for partially-cooked products have unnecessarily been narrowed in Option 1. One commenter expressed concern with the recommendation that the come-up-time be limited to one hour or less, as the come-up-time is longer for partially-cooked smoked sausages. Two commenters asked for clarification for what constitutes "small diameter" for the purposes of following Option 1 and asked for the definition of "come-up-time."

Response: Option 1 was always intended to be the only option for partially-cooked products, but this was not clear in the 1999 version. Therefore, the Agency made this clarification in the 2021 version. When Option 1 was developed, it was primarily for partially-cooked products, such as patties and poultry breakfast strips, which have a short come-up-time of one-hour or less. As establishments used the option for other types of partially-cooked products, the Agency determined that additional clarification was needed. In the 2021 version, the Agency has clarified that the come-up-time should be limited to temperatures between 50 to 130°F, to better define the recommendation. FSIS has also removed the mention of "small diameter," since that is not a critical operational parameter

that effects growth of spore-formers. In addition, FSIS has added an option that allows up to three hours come-up-time between 50 to 130°F for products that contain at least 150 ppm nitrite and at least two percent salt. This addition provides more time for partially-cooked smoked sausages. This option was designed using industry input provided through askFSIS. The Agency believes that this option will provide support for many partially-cooked smoked sausage processes. Finally, the Agency has provided additional information about research by Taormina and Bartholomew (2005)[28] that supports a longer cooling time for partially-cooked smoked bacon.

Option 2

Comment: A producer and two industry groups requested that FSIS clarify why the recommendation in Option 2 to cool from 120 to 80°F in one hour or less does not have to be monitored as part of a critical limit. The commenters cited a publicly posted askFSIS Knowledge Article ("Public Q&A"), that is no longer on FSIS's website, as support for this request. Comments from two large producers, a university, a small producer, and a food safety consultant stated that the recommendation to cool products from 120 to 80°F in one hour or less is too restrictive, too hard to meet for large-diameter products, and would require new equipment for the product to cool fast enough.

[28] Taormina, P.J., and Bartholomew, G.W. 2005. Validation of Bacon Processing Conditions to Verify Control of *Clostridium perfringens* and *Staphylococcus aureus*. Journal of Food Protection. 68(9): 1831-1839.

Response: FSIS incorporated the language that had been in the askFSIS Knowledge Article ("Public Q&A") into the guideline. The language had been in a note in the 2017 version. To make the information clearer, FSIS has moved the text in front of the table along with other text that explains how to use FSIS Cooling Options. The language states, "Establishments are not required to demonstrate that every lot of product is chilled between 120°F and 80°F within one hour, if data has been gathered during initial validation and as part of ongoing verification to support the critical operational parameters can be met." This language makes clear that establishments do not have to monitor these temperatures as a critical limit. FSIS recognizes that cooling large products from 120 to 80°F in one hour or less can be challenging.

FSIS has added four new options to the 2021 revision to allow for more time cooling from 120 to 80°F. Two of the four cooling options consider the pH levels of products to allow even more time between 120 to 80°F. These options are all supported by two pathogen modeling programs validated for estimating the growth of *Clostridium perfringens*: 1) the ComBase *Perfringens* Predictor and the Smith-Schaffner Model; and 2) the ARS *C. botulinum* cooling model. FSIS has also identified a scientific gap for establishments producing large mass non-intact products greater than 4.5 inches in size or greater than 8 pounds that are unable to cool the products between 120 to 80°F in one hour or less. For these products, establishments can continue to

follow the critical operational parameters FSIS has incorporated from the older guidance into the 2021 versions (cooling occurs from 120 to 55˚F in 6 hours or less and chilling is continuous to 40˚F) until additional research is complete.

Comment: A large producer questioned the use of the article by Ohye and Scott (1957)[29] as support for Option 2, because type E *C. botulinum*, which is a psychotroph and prefers low temperatures for growth, is not a microorganism of concern in meat; and is not a surrogate for *C. perfringens*. The producer also questioned whether the research supported the guidance because it was not conducted on meat.

Response: Option 2 of FSIS Appendix B originated from former regulatory requirements promulgated in the 1983 Final Rule, "Production Requirements for Cooked Beef, Roast Beef, and Cooked Corned Beef" (48 FR 24314, June 1, 1983). At that time, the primary hazard of concern identified by the Agency was *C. botulinum*. For this reason, research by Ohye and Scott (1957) was used as the scientific basis of the original recommendation to cool product from 120 to 55˚F in six hours. However, when Appendix B was developed in 1999, the Agency became more aware of the importance of also considering *C. perfringens* growth. Using available research at the time and expert opinion, FSIS added the recommendation that establishments consider the cooling time between 120 to 80˚F, since *C. perfringens* grows faster than C. botulinum. The 1999 guidance was vague in terms

[29] Ohye, D.F. and Scott, W.J. 1957. Studies in the physiology of *Clostridium botulinum* type E. Aust. L. Biol. Sci. 10:85–94.

of a recommended timeframe, so FSIS added a more specific time-frame recommendation to the 2017 revision. The recommendation in the 2017 version of Appendix B has been carried over into the 2021 version and confirmed using the following up-to-date pathogen modeling programs: the ComBase *Perfringens* Predictor and the Smith-Schaffner Model to confirm predicted C. *Perfringens* outgrowth; and the ARS *C. botulinum* cooling model to confirm predicted C. *botulinum* outgrowth. FSIS has added these additional modeling references to the 2021 version.

Comment: A small producer recommended that the first part of Option 2 (cooling from 120 to 80°F in one hour or less) be based on surface temperature instead of the internal temperature of the product. Additionally, another small establishment requested that the recommendation under Option 4 to cool a cured product's internal temperature from 120 to 80°F in two hours or less be applied to surface temperature. The commenters argued that these recommendations would be consistent with the original recommendation in FSIS Directive 7110.3 (cancelled by FSIS Directive 7111.1) for slow cooling for some cured products (now Option 4), which allowed for monitoring of the surface temperature for the first stage of cooling (cooling from 120 to 80°F in two hours or less).

Response: FSIS agrees that for intact products, it is possible to monitor the surface temperature of a product to demonstrate that the critical operational parameters of Appendix B are met. It would not be appropriate to use this approach for

non-intact products, since pathogens may be internalized and it is important to control the internal temperature, as well as the surface temperature. In response to comments, FSIS has removed the recommendation to monitor the time between 120 to 80°F from Option 4. The original recommendation in FSIS Directive 7110.3 cancelled by FSIS Directive 7111.1) contained an option to control the product's surface temperature so that it would not stay between 120 to 80°F for more than two hours or to cause "a continuous drop in product temperature." However, FSIS has determined that the original recommendation was made based on controlling *S. aureus* growth, assuming *S. aureus* presence is due to post-processing contamination and the potential for growth at the surface. After further review, FSIS does not recommend that establishments consider *S. aureus* as a hazard during cooling, provided they maintain sanitary conditions after cooking. Therefore, as stated above, FSIS is removing the recommendation that product be cooled from 120 to 80°F in two hours. Establishments may continue to follow this option if the product is continuously cooled, without the need to demonstrate any timeframe for cooling between 120 to 80°F. FSIS expects that establishments previously following the recommendation from FSIS Directive 7110.3 (cancelled by FSIS Directive 7111.1) to control the product's surface temperature should be able to meet this part of the recommendation instead.

Option 3

Comment: An individual provided an article by Taormina and Bartholomew (2005) and stated that the article provided support for Option 3 to be used for not-ready-to-eat products.

Response: The research by Taormina and Bartholomew (2005) provides validated parameters for cooking and cooling partially heat-treated bacon. However, the research does not provide sufficient support for using Option 3 for all not-ready-to-eat partially heat-treated products. This is because the Taormina research included other critical operational parameters that may have limited growth of *S. aureus* and *C. perfringens,* such as smoke, which are not currently part of FSIS's Option 3. Establishments are not required to use FSIS guidance as scientific support. The article by Taormina and Bartholomew (2005) may be used to support the cooking and cooling of partially heat-treated bacon, provided the establishment follows the critical operational parameters or maintains support to justify any differences in parameters. Specifically, the Taormina and Bartholomew research supported that bacon smoked with liquid smoke could be heated to 120°F with a six-hour heating come-up-time and safely cooled from 120 to 80°F in five hours and 80 to 45°F in 10 hours (15 hours total cooling time), without presenting a food safety hazard from either *C. perfringens* or *S. aureus*. Other critical operational parameters of this study include the following product composition factors: ≥ 1.6% salt concentration and ≥ 2.9% brine concentration. In addition, the brine injected into the bacon contained 0.5%

sodium phosphate, 547 ppm sodium erythorbate, and 120 ppm sodium nitrite (based on email correspondence with Dr. Taormina). Although the research was performed with liquid smoke, Dr. Taormina stated that the study also represented natural smoking because the phenolic fraction of smoked bacon derived from liquid smoke is similar to that of traditionally smoked bacon. Therefore, at this time, as indicated in Table 15, Time and Temperature Parameters Reported in the Literature for Stabilization Processes of the guidance, establishments may follow the validated cooling parameters from Taormina and Bartholomew's research for bacon that is naturally smoked. FSIS added a reference to this research to the guidance.

In addition to including this reference, the Agency has also clarified that establishments producing products that have been fully cooked but that they have reclassified into a NRTE HACCP category and labeled accordingly, may follow Option 3. FSIS believes this clarification may allow for the use of this option by establishments that may have previously interpreted the recommendation that the option applied to fully cooked products to mean that it could not be applied to fully cooked products that are labeled as NRTE.

Use of natural sources of nitrite and ascorbate

Comment: A food safety specialist, an industry group, a large producer, and a small producer stated there is continued confusion over use of natural sources of nitrite. Three industry groups, a small producer and an individual consumer recommended

that FSIS clarify, in Appendix B, that both purified and natural sources of sodium erythorbate or ascorbate (e.g., cherry powder) are acceptable to use within Option 3. They also recommended that FSIS clarify that any natural source containing at least 100 ppm of in-going nitrite may be used to replace celery powder. FSIS also received several questions through askFSIS asking if establishments can use natural sources of nitrite along with synthetic sources of ascorbate or erythorbate.

Response: After the 2017 version of the guideline published, the Agency issued three Knowledge Articles ("Public Q&As") (Part 1 of 3: Use of Celery Powder and Other Natural Sources of Nitrite as Curing Agents, Antimicrobials or Flavorings; Part 2 of 3: Revised Appendix B: Stabilization Option 3 for Products Containing Natural Sources of Nitrite and Natural Sources of Ascorbate or Ascorbic Acid, Part 3 of 3: Formulating Products Containing Natural Sources of Nitrite and Natural Sources of Ascorbate When Using Revised Appendix B: Stabilization Option 3) intended to provide clarification around the use of natural sources of nitrite and ascorbate, including labeling of products that contain these ingredients, and this information has been incorporated into the 2021 version. As part of these updates, FSIS revised FSIS Directive 7120.1 "Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products" to include any combination of a natural source of nitrite and a natural source of ascorbate, provided they are used following the minimum and maximum amounts listed in the

Directive. In the Knowledge Articles ("Public Q&As", Directive 7120.1, and the updated guidance, FSIS states that it is not appropriate to use natural sources of nitrite with purified or synthetic sources of erythorbate, as 9 CFR 424.21(c) requires that curing accelerators be used with curing agents.

Comment: FSIS received many questions through askFSIS from establishments as to whether using a natural source of nitrite makes a product "cured." FSIS has also received questions asking whether establishments can select the "cured" option, when using the ComBase *Perfringens* Predictor, if natural sources of nitrite and ascorbate are used as antimicrobials.

Response: Adding natural sources of nitrite and ascorbate does not make a product "cured." However, if the ingredients are used at the minimum levels recommended to be considered antimicrobials, establishments may be able to follow the cooling recommendations in FSIS's Option 3, originally designed for "cured" products, and may treat products as "cured" for pathogen modeling purposes (*i.e.*, by selecting the "cured meat" option) as explained in the revised Appendix B. Cultured celery powder and other natural sources of nitrite are approved for use as antimicrobials and flavorings. Neither celery powder (whether in a form containing pre-converted nitrite or when used with a nitrate-reducing bacterial culture) nor other natural sources of nitrite are approved for use in 9 CFR 424.21(c) as curing agents. As with natural sources of nitrite, natural sources of ascorbate (e.g., cherry powder) are approved for use as

antimicrobials, but not approved as cure accelerators. Ingredients approved for use as curing agents and cure accelerators are listed in 9 CFR 424.21(c).

Comment: Two small producers, an individual consumer, a large producer, and an industry group contended that Letters of Guarantee (LOGs) provided by their suppliers are sufficient to support the amount of nitrite and ascorbate added from natural sources as necessary to control for *C. botulinum* and *C. perfringens* and that a Certificate of Analysis (COA) for celery powder should not be needed.

Response: FSIS agrees it is possible for establishments to support that they have adequately addressed *C. botulinum* and *C. perfringens* using natural sources of nitrite and ascorbate with a LOG, provided it supports the amount or concentration of nitrite and ascorbate in each lot. Establishments must be able to support the concentrations of nitrite from natural sources in their products (9 CFR 417.5(a)(1)) when using them as antimicrobials, but they do not necessarily need to have a COA. Establishments should be aware that the concentration of nitrite and ascorbate or ascorbic acid from natural sources may vary depending on the source.

As stated in the revised Appendix B, FSIS recommends that establishments use natural sources of nitrite containing pre-converted nitrite, because the quantity of nitrite in the sources is known. When using pre-converted nitrite, establishments may need to request information from their

supplier regarding the nitrite level in each lot of product (e.g., through a COA), or they may be able to rely on formulation information from their supplier if the concentration is standardized from lot to lot. If the concentration of nitrite from natural sources is not standardized with each lot and a COA is used, establishments should calculate the amount of the natural source needed to achieve the appropriate nitrite concentration from each lot, as it varies.

Pathogen modeling

Comment: An individual stated that FSIS does not recognize ARS predictive models and recommended using models that are not from ARS. The commenter also recommended that research be sponsored to support models.

Response: ARS is the research arm of the U.S. Department of Agriculture. Not all of ARS' models have been validated. A validated cooling model is a predictive microbial model whose predictions have been found to agree with or be more conservative than actual observed results. For establishments to rely on pathogen models alone to support decisions in hazard analysis and product disposition, FSIS recommends the models be validated for the particular food of interest. For this reason, FSIS supports the use of the validated ARS models. FSIS does not support the use of models that have not been validated as sole support for decisions in hazard analysis and product disposition because the predictions of the model have not been found to agree with or be more conservative than actual results. If a

model has not been validated for a particular food of interest, then establishments need to provide additional supporting documentation to support the results from the model (e.g., sampling data or comparison with other model results) meet the requirements of 9 CFR 417.5(a)(1). Those models that have not been validated remain on the ARS website because they provide useful information to researchers such as initial estimates of growth or death of bacteria. FSIS has identified the ARS models that have been validated, such as the *C. perfringens* in the cooked uncured beef model, the *C. perfringens* in cooked uncured pork model, and the *C. perfringens* in cooked uncured chicken model. FSIS recognizes these validated models for use in supporting decisions in the hazard analysis and product disposition. FSIS has identified one ARS model, the *C. perfringens* in beef broth model, that could not be validated and typically under-predicted the growth of *C. perfringens*. Since the model could not be validated and was being used by establishments as sole support, it has been removed from the ARS website. FSIS continues to work with ARS to further research that supports model development and has listed a research priority on its website to "develop or refine cooking and cooling models."

Appendix B Baseline

Comment: A food safety consultant stated that cooked ready-to-eat meat and poultry products are not high-risk foods for *C. perfringens* illness. The commenter argued that the procedures

used by industry to chill cooked-products and the time-temperatures that ensure *C. perfringens* is controlled have been adequate. The commenter further mentioned that subsequent handling and preparation in homes, foodservice, and institutions have led to *C. perfringens* illness.

Response: FSIS agrees that most outbreaks associated with *C. perfringens* have resulted from the handling of food served in restaurants, homes for the elderly, or at large gatherings because the products are held at room temperature for too long or cooled in large batches, increasing the time it takes for the entire batch of product to cool. Outbreaks from *C. perfringens* associated with commercially produced meat and poultry products in the U.S. rarely occur likely because of good controls in the commercial setting that have been implemented in response to FSIS's requirements and guidance. As explained above, FSIS updated Appendix B because the Agency determined some of the old guidance recommendations were vague, putting establishments at risk of producing unsafe product and at risk for recalls. Additionally, some elements of the guidance were misunderstood or overlooked, resulting in FSIS guidance being applied in ways that increased food safety risks to consumers and potential business risks of recalls.

Comment: A food safety consultant commented that the 2005 *C. perfringens* Risk Assessment[30] indicated that data from

[30] See: https://www.fsis.usda.gov/node/2011.

Greenberg *et al.*, (1966)[31] could not be reliably used for quantitative modeling. The commenter, a co-author on the Greenberg *et al.*, (1996) article, stated that there was a typographical error in the paper on page 789 under "Sample Preparation," stating that the meat suspensions were pasteurized at 60°C for 15 minutes. According to the commenter, the temperature and time actually used throughout the survey was 60°C for 50 minutes. The commenter provided documentation to support this statement was an error.

Response: FSIS appreciates the commenter sharing this information. Because the 2005 *C. perfringens* Risk Assessment was performed in response to comments received on a 2001 proposed rule that FSIS did not finalize (66 FR 12589, February 27, 2001), this comment is not relevant to this guidance. FSIS did not use the risk assessment to update the guidance. FSIS is not addressing comments on the risk assessment because it is outside the scope of the guidance.

Comment: The same food safety consultant also commented that the baseline studies FSIS used for its 1998 *Lethality and Stabilization Performance Standards for Certain Meat and Poultry Products: Technical Paper* were not designed for estimating the risk of *C. perfringens* illness. The commenter stated that in 1998, FSIS over-estimated the number of surviving spores in meat and poultry products after cooking to arrive at a worst case of

[31] See: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1058416/pdf/applmicro00363-0093.pdf.

10^4 CFU/g of spores and did not consider the combined inhibitory effect of salt, nitrite, or other newer ingredients that are commonly used for pathogen control. The commenter also stated that this led to very conservative time-temperatures being recommended for cooling in the 1999 version of Appendix B (i.e., no greater than a 1-log increase in *C. perfringens* as required by 9 CFR 817.17(a)(2), 318.23(b)(3)(ii)(c), and 381.150(a)(2)). The commenter further argued that FSIS does not have credible data on the number of *C. perfringens* spores in raw meat or poultry and that the requirement that limits growth of *C. perfringens* to no greater than a 1-log increase during cooling is not valid. The commenter also stated that Kalinowski et al. (2003) questioned the need for the performance requirement of no more than 1-log growth of *C. perfringens* and suggested that a more appropriate upper limit for growth would be "no greater than a 2-log increase or no greater than 500/g at the time of shipment." Additionally, the commenter argued that the 2017 revision of Appendix B continues to be based on the same assumptions and estimates developed in 1998 and that there is a great need for new data on the concentration of *C. perfringens* spores in commercial blends of meat and poultry before cooking or after cooling.

Response: FSIS relied on levels reported in Agency baseline studies and surveys of *C. perfringens* performance standards in the *Lethality and Stabilization Performance Standards for Certain Meat and Poultry Products: Technical Paper*. However,

Agency cooling requirements in the former 9 CFR 318.17(h)(5) and (10) and the cooling recommendations in Directive 7110.3 issued in 1988 to industry (cancelled by FSIS Directive 7111.1) had the effect of limiting *C. perfringens* growth to 1-log even before the 1999 regulation was promulgated. FSIS assumed that the baseline studies and surveys either would substantiate the regulatory performance standard of 1-log or would indicate a need to revise the standard. FSIS assumed that reported *C. perfringens* levels in raw product from the baselines were confirmed, rather than just presumptive, and thus validated the proposed growth limitation (no more than 1-log growth). Therefore, the Agency may have overestimated worst-case levels.

For this reason, FSIS has studied additional data to determine more precisely the pre- and post-processing *C. perfringens* levels in RTE products. The Agency tested ground beef samples for *C. perfringens* and found two out of 593 samples collected positive, with one colony at the detection limit of 3 cfu/gram[32]. Also, a survey by industry researchers indicates that, while *C. perfringens* levels in finished product occasionally exceed 100-140 cfu/gram, levels higher than 500-1000 cfu/gram are rare, even after cooling deviations[33].

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[32] Eblen, D., Cook, V., and Levine, P. (2004). Prevalence and levels of *Clostridium perfringens* spores in raw ground beef from federally inspected establishments. Abstract submitted to the International Association for Food Protection, 2004 — 91st Annual Meeting, August 8-11, 2004.

[33] Kalinowski, R.M.; Tompkin, R.B.; Bodnaruk, P.W.; Pruett, W.P. 2003. Impact of cooking, cooling, and subsequent refrigeration on the growth or survival of *Clostridium perfringens* in cooked meat and poultry products. Journal of Food Protection 66. Pp. 1227-1232.

In addition, Taormina et al. (2003) reported that that the percent of positive for spores was 5.3% and 16.7% for cured ground/emulsified meat product mixtures and uncured ground/emulsified meat product mixtures, respectively. The average and maximum spore levels were 1.56 log CFU/g and 2.00 log CFU/g, respectively, for cured ground/emulsified meat product mixtures. The average and maximum spore levels were 1.75 log CFU/g and 2.11 log CFU/g, respectively, for uncured ground/emulsified meat product mixtures.

Notably, FSIS also has reviewed data from a large pork processing establishment in the Midwest showing that the *C. perfringens* spore counts were close to 1000 CFU/gram in raw sausage batter used to produce cooked sausages. In fact, 19 out of the 57 samples collected by the company resulted in *C. perfringens* spore counts ranging from 100 CFU/g to 760 CFU/g (2.88 log CFU/g) for the raw sausage batter[34].

FSIS continually assesses the state of scientific information and overall based on this analysis considers its recommendations to be based on the most up-to-date information. FSIS requests data from industry related to spore levels in raw formulated products. The Agency is also planning to conduct a market basket survey to assess levels of *C. perfringens* vegetative cells and spores in large mass ready-to-eat (RTE) meat and poultry products at retail. Although this study will

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[34] Taormina, P.J., Bartholomew, G.W., Dorsa, W.J. 2003. Incidence of Clostridium perfringens in Commercially Produced Cured Raw Meat Product Mixtures and Behavior in Cooked Products during Chilling and Refrigerated Storage. Journal of Food Protection: January 2003, Vol. 66, No. 1, pp. 72-81.

not determine the *C. perfringens* counts in all RTE meat and poultry products, it is focusing on large mass, non-intact RTE products because industry feedback has indicated that establishments cannot meet current cooling requirements for these products. FSIS plans to use the results of the study to determine the potential public health issues associated with these products and to assess whether changes to its policies are needed.

Lastly, at the time the 1998 FSIS Technical Report (Lethality and Stabilization Performance Standards for Certain Meat and Poultry Products: Technical Paper) was made available, FSIS determined 1-log growth of *C. perfringens* would provide an acceptable level of protection when considering worst-case levels of 4-logs CFU/g and building in a 1-log safety margin to ensure under worst-case levels would be below that which can cause human illness (i.e., 6-logs CFU/gram or higher). FSIS agrees that the worst-case of 4-logs CFU/g of spores used in the Technical Paper may have been over-estimated because of the methodological flaws of the baseline, discussed above. However, also discussed above, FSIS has reviewed newer data such as that from a large pork processing establishment in the Midwest showing that the *C. perfringens* spore counts were close to 3-logs CFU/g). Therefore, the Agency now considers 3-logs CFU/g *C. perfringens* in product a worst-case estimate. In addition, in 2010, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) recommended building in a 2-log

margin of safety to performance standards as opposed to the 1-log used in the Technical Paper[35]. Therefore, FSIS still considers allowing up to 1-log of *C. perfringens* in product to be an acceptable level of protection when considering worst-case spore counts of 3-log and a 2-log safety margin.

FSIS acknowledges the Technical Paper did not consider the effect of salt and nitrite on the germination of *C. perfringens* spores. However, FSIS cooling options do allow for slower cooling times when at least 100 ppm nitrite and at least 250 ppm erythorbate/ascorbate are added. By following FSIS recommendations, establishments would meet regulatory performance standards. Based on industry feedback, FSIS understands that establishments have historically been able to meet the time-temperature recommendations for cured ready-to-eat products. Finally, FSIS agrees that there is a need for data related to spore levels in raw formulated products and again asks industry to provide any available data.

Other Appendix B Issues

Comment: A large producer stated that the lower temperature limit for growth of *C. perfringens* is 53.6°F, according to Solberg and Elkind (1970),[36] while FSIS guidance states it is 43°F. The commenter also supported this statement with a

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[35] National Advisory Committee on Microbiological Criteria for Foods. 2010. Parameters for Determining Inoculated Pack/Challenge Study Protocol. J. Food Prot. 73:140-20.

[36] Solberg, M., and Elkind, B. 1970. Effect of processing and storage conditions on the microflora of *Clostridium perfringens*-inoculated frankfurters. Journal of Food Science. 35: 1267-1269.

reference to research by Kalinowski et al. (2003) that demonstrated cold storage reduces *C. perfringens*.[37]

Response: FSIS disagrees that the research by Solberg & Elkind (1970) supports a lower temperature limit of 53.6°F for the growth for *C. perfringens*. Solberg and Elkind (1970) found that *C. perfringens* vegetative cells in frankfurters increased by 3-logs in 5 days when held at 53.6°F, supporting that growth can occur at this temperature. The research found it was not until product was held at 50°F that growth was restricted. FSIS does recognize that there is a range of growth limits of *C. perfringens* reported in the literature, depending on experimental conditions, such as strain(s) used, nutrient availability, pH, and growth medium (Labbe, 1989)[38]. However, FSIS has reviewed the literature and determined that the most up-to-date research supports a minimum temperature of 50°F to limit growth, as opposed to 43°F that was included in the 2017 guideline. Therefore, FSIS has updated the lower growth limit temperature to 50°F in the revision. This value is consistent with the research by Solberg and Elkind (1970). FSIS also recognizes the growth rate of *C. perfringens* decreases and slows down below 55°F, but growth is not completely limited.

Regarding cold storage reducing *C. perfringens*, FSIS is aware of the research by Kalinowski et al., (2003). However, the

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[37] Kalinowski, R.M., Tompkin, R.B., Bodnaruk, P.W., and Pruett, P.W. 2003. Impact of Cooking, Cooling, and Subsequent Refrigeration on the Growth or Survival of *Clostridium perfringens* in Cooked Meat and Poultry Products. Journal of Food Protection. 66(7): 1227-1232.

[38] Labbe, R. "*Clostridium perfringens*". Foodborne Bacterial Pathogens. Ed. Michael P. Doyle. New York: Marcel Dekker, Inc. 1989. 796 pages.

reduction discussed in the research may be highly variable, product specific, and depend upon unstable or changing effects due to temperature and time.

Comment: A food safety consultant mentioned that FSIS had not established science-based upper and lower temperature limits for pathogen growth and consistently incorporated the values into their cooling options. The commenter noted that the minimum temperature at which growth of *C. perfringens* has been reported to multiply is 53.6°F (ICMSF, 1996). Yet, the guidance from FSIS is to chill to 55°F, 45°F, or 40°F. The commenter also stated that the minimum temperature for growth of the proteolytic strains of *C. botulinum* associated with meat in the USA is 50°F (ICMSF, 1996). The commenter stated that the lower critical limit for cooling should be 53.6°F (54°F) or 50°F.

Response: FSIS cooling options in the guidance are focused on ensuring cooling time to limit the optimum growth rate for *C. perfringens* and *C. botulinum* (i.e., between 130 or 120 to 80°F). As previously explained, FSIS has reviewed the literature and determined that the most up-to-date research supports a minimum growth limit of 50°F. This value is consistent with the research by Solberg and Elkind (1970). FSIS also recognizes the growth rate of *C. perfringens* decreases and slows down below 55°F, but growth is not completely limited. Therefore, the guidance recommends products continue to cool to 40°F to ensure the growth of other pathogens, such as *Listeria monocytogenes,* is limited because FSIS guidance is intended to be comprehensive.

Comment: A small producer requested that FSIS clarify why using spore counts alone in cooked products is not appropriate, given how the guidance suggests using spore counts in raw products to support the option allowing 2-log growth of *C. perfringens*.

Response: Although measuring *C. perfringens* spore counts is considered an appropriate method to quantify the initial levels of the *C. perfringens* inoculum, the final measure of bacterial load should include a measure of both spore levels and vegetative cells. FSIS considers it important for public health to measure the vegetative cells in addition to the spore levels because during stabilization, *C. perfringens* spores can germinate and grow into vegetative cells. Once vegetative cells reach a critical level and the contaminated food is consumed, the cells produce enough toxin in the intestines to cause illness. For this reason, FSIS recommends measuring spore counts as part of baseline testing to determine whether the initial levels of *C. perfringens* are low and then measuring both spore counts and vegetative cells after cooking and cooling to understand the public health risk of a product.

Comment: A food safety consultant commented that, on page five of the 2017 version, the mention of the European experience with *C. botulinum* in home-prepared ham raises concerns. The commenter stated that there is a long history in Europe of human cases of botulism being caused by psychrotrophic strains of *C.*

botulinum in meat products. Such cases have not been documented in the U.S.

Response: There are six distinct Clostridia that produce botulinum toxin, two of which are associated with food: *C. botulinum* Group 1 (proteolytic) and *C. botulinum* Group II (non-proteolytic). Although non-proteolytic *C. botulinum* is typically associated with fish and marine products, there have been several recent outbreaks in Europe associated with non-proteolytic *C. botulinum* and home-prepared (salted) ham (Peck et al., 2015).[39] However, establishments do not need to address non-proteolytic *C. botulinum* during cooling as controls for proteolytic *C. botulinum* during cooling are sufficient to address non-proteolytic *C. botulinum*.

Additional Public Notification

FSIS will make copies of this **Federal Register** 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 *Constituent Update* is available on the FSIS website. Through the website, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to

[39] Peck, M., Devlieghere, F., and Membre, J. 2015. *Clostridium botulinum*: a recurrent emerging foodborne pathogen. Symposium conducted at the International Association of Food Protection: Portland, Oregon. July 26-29, 2015.

selected food safety news and information. This service is available at: https://www.fsis.usda.gov/subscribe. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

Congressional Review Act

Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has determined that this notice is not a "major rule," as defined by 5 U.S.C. 804(2).

USDA Non-Discrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

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Done at Washington, DC:

Paul Kiecker,

Administrator.

[FR Doc. 2021-26993 Filed: 12/13/2021 8:45 am; Publication Date: 12/14/2021]