Ministero della Salute

DIREZIONE GENERALE PER L'IGIENE E LA SICUREZZA DEGLI ALIMENTI E LA NUTRIZIONE
Ufficio 2

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Veneto, Marche, Toscana
Calabria, Piemonte
e Province Autonome di Trento e di Bolzano

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SEGGEN - Ufficio 3

Associazioni di categoria
(settore carne)

PEC

Oggetto: Esportazione di prodotti a base di carne suina negli U.S.A. – sorveglianza microrganismi Piano di Campionamento ufficiale per *Listeria monocytogenes* e Salmonella spp. - anno 2022

Con la presente si desidera ricordare agli Enti in indirizzo che anche per l'anno in corso è prevista l'esecuzione di un piano di campionamento conforme ai requisiti stabiliti nella circolare ministeriale DGISAN/2/37041/P del 21-10-2020.

Si trasmettono pertanto i criteri di campionamento (allegato1) e la tabella riassuntiva del piano di campioni previsti per la ricerca di L. monocytogenes e Salmonella da effettuare presso gli stabilimenti autorizzati ad esportare negli USA prodotti a base di carne suina (allegato 2).

Nel piano sono inseriti in alternativa 1 gli stabilimenti che producono per l'esportazione unicamente prodotti sottoposti ad alte pressioni, laddove tale trattamento è considerato un processo post letale su un prodotto che ha già raggiunto le 5 riduzioni logaritmiche per Listeria e Salmonella previste dalla normativa statunitense quali necessarie per definire un prodotto RTE.

Inoltre, per opportuna informazione, si trasmettono le linee guida aggiornate nel corso del 2021 da USDA-FSIS relativamente a:

- trattamenti termici funzionali al raggiungimento della fase di letalità riferita alla Salmonella o altri patogeni da applicare ai prodotti RTE (Allegato 3 - Appendix A);
- requisiti utili alla stabilizzazione di prodotti sia RTE che NRTE trattati termicamente al fine di prevenire o limitare la crescita di spore, la formazione di batteri e altri agenti patogeni. (Allegato 4 - Appendix B).

Si ricorda che il Piano di sorveglianza per *Listeria monocytogenes* e Salmonella spp. si articola in RTE PROD_RAND e RTE PROD_RISK (effettuati esclusivamente sui prodotti), cui si aggiunge il Piano di monitoraggio della contaminazione da *Listeria monocytogenes* in prodotti e ambienti di lavorazione (RLm) eseguito sia su prodotto che su superfici a contatto e non a contatto.

Al fine di raggiungere la prevista percentuale del 25% di stabilimenti da sottoporre ad RLm rispetto al totale della lista, nel corso del 2022 si provvederà ad effettuare il Piano RLm presso:

- tutti gli stabilimenti autorizzati nel corso del 2021;
- quelli campionati all'inizio del ciclo quadriennale del 2018
- parte di quelli il cui ciclo quadriennale è iniziato nel 2019.

Per quanto riguarda la gestione dei ceppi, l'inserimento dei dati sul sistema informativo SINVSA, le modalità di prelievo ed analisi si rimanda alla nota del Ministero DGISAN/2/37041/P del 21-10-2020 la cui applicazione è oggetto di valutazione da parte dell'Ufficio 2 DGISAN in ambito di ispezioni di monitoraggio sugli stabilimenti, nonché in tema di audit di settore sui sistemi regionali di certificazione verso Paesi Terzi.

Si pregano i Servizi veterinari regionali e gli II.ZZ.SS. in indirizzo di trasmettere la presente Nota, rispettivamente, ai Servizi Veterinari delle AA.SS.LL. competenti per territorio e alle proprie Sezioni periferiche interessate.

Ringraziando per la fattiva collaborazione si porgono distinti saluti.

IL DIRETTORE GENERALE
Massimo Casciello

Allegati

Allegato 1: Piano di Sorveglianza - Criteri di campionamento
Allegato 2: Piano di Sorveglianza - Distribuzione dei campionamenti
Allegato 3: Appendix A
Allegato 4: Appendix B

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(Allegato 1)

CRITERI DI CAMPIONAMENTO PER I PIANI DI SORVEGLIANZA UFFICIALI ANNO 2022

I Servizi veterinari delle AA.SS.LL. sono incaricati di eseguire i prelievi previsti dai Piani di sorveglianza ufficiali presso gli stabilimenti autorizzati alla produzione di alimenti RTE a base di carne da esportare in U.S.A. Per l'anno 2022 sono previsti 2 piani di campionamento nazionali.
Il **primo piano nazionale** denominato "Piano di Sorveglianza per la ricerca di *Listeria monocytogenes* e *Salmonella* spp. da prodotti (RTE PROD)" si articola in una parte denominata "RTE PROD_RISK" (risk-based, già RTE 001) e una "RTE PROD_RAND" (not risk-based, già ALLRTE).
La parte del piano "RTE PROD_RISK" (risk-based), si applica agli stabilimenti che rientrano nel campo di applicazione del 9 CFR 430, e prevede un numero di campioni annui diverso a seconda delle alternative previste. Si effettua sul prodotto a maggior rischio tra quelli RTE contemplati nel Regolamento 9 CFR 430 e lavorati nello stabilimento. La frequenza di campionamento tiene in considerazione i fattori di rischio quali: quantità e livello di rischio del prodotto esportato, fasi di lavorazione effettuate e casi di positività per *Listeria monocytogenes* riscontrati nello stabilimento.
Sono esclusi dal campionamento "RTE PROD_RISK" i prodotti che non rientrano nel campo di applicazione del Regolamento 9 CFR 430 (es. prodotti RTE non esposti all'ambiente dopo trattamento letale). Pertanto, gli stabilimenti che esportano verso gli U.S.A. o lavorano esclusivamente tali prodotti sono esentati da questo piano.
La seconda parte, denominata "RTE PROD_RAND" (not risk-based), prevede almeno 1 campione anno e si effettua in modo indifferenziato su tutti i prodotti RTE lavorati nello stabilimento ed esportabili in USA, indipendentemente dal fatto che siano esposti o meno all'ambiente post-letale. Tutti gli stabilimenti sono sottoposti a tale piano indipendentemente dal rischio. Nel corso dell'anno possono essere raccolti da 1 a 3 campioni per stabilimento produttivo.

Sono esclusi dai piani di campionamento "RTE PROD_RISK" e "RTE PROD_RAND" i prodotti microbiologicamente stabili (es. sughi pronti) e i prodotti NRTE: pertanto quegli stabilimenti che esportano verso gli U.S.A. o lavorano esclusivamente tali prodotti sono esentati dai suddetti piani di campionamento.
I piani di campionamento "RTE PROD_RISK" e "RTE PROD_RAND" prevedono il campionamento del solo prodotto nel quale sono ricercati contestualmente *Listeria monocytogenes* e *Salmonella spp.*
Per ogni impianto selezionato per i Piani "RTE PROD_RISK" e "RTE PROD_RAND" non sono previsti più di 1 campione al mese e pertanto in un impianto non saranno effettuati più di 12 campioni all'anno per la finalità di questi piani.
I lotti dei prodotti campionati, preferibilmente selezionati tra quelli idonei al mercato USA, dovranno essere trattenuti fino al rilascio del referto analitico.
Nel caso in cui in uno stabilimento sia previsto il campionamento di 1 solo prodotto anno, tale prelievo dovrà essere effettuato su prodotto esportabile verso gli USA.

Il **secondo piano nazionale**, denominato "Piano di monitoraggio della contaminazione da *Listeria monocytogenes* in prodotti e ambienti di lavorazione (RLm)", prevede invece il campionamento, nel

corso dello stesso intervento, di superfici a contatto (FCS), superfici non a contatto (NFCS) e prodotto che è stato lavorato su tali superfici, per la ricerca di *Listeria monocytogenes.*

Il Piano "RLm" ha l'obiettivo di valutare la capacità degli stabilimenti, che producono RTE esposti all'ambiente dopo un trattamento letale, di gestire il pericolo *Listeria monocytogenes.* Il Piano deve essere eseguito mediante il prelievo di campioni di un medesimo giorno, di superfici a contatto, non a contatto e prodotti nell'area post letale dell'impianto. Per gli impianti inseriti che applicano quale trattamento post - letale le Alte Pressioni (HPP) il campionamento del prodotto sarà effettuato su quello pronto per l'esportazione verso gli USA, ciò dopo trattamento. Si continuerà sottoponendo a campionamento RLm il 25% degli stabilimenti tra cui obbligatoriamente saranno compresi i nuovi impianti inseriti in lista nel corso dell'anno precedente. Per il dettaglio dei campionamenti si veda la tabella allegata. Resta inteso che da parte dell'ASL competente tale programma potrà essere ampliato se ritenuto necessario, ad esempio in caso di riscontri di positività in autocontrollo, previa segnalazione al Ministero della Salute. Per ogni stabilimento selezionato deve essere eseguito una campionamento in relazione alle dimensioni dell'impianto. In relazione ai criteri USDA-FSIS, la dimensione dello stabilimento viene considerata in base al personale impiegato nello stesso. Si considera pertanto uno stabilimento molto piccolo se ha da 1 a 10 operai in questo caso deve essere effettuata una unità di campionamento; se lo stabilimento invece è piccolo, ovvero ha da 11 a 499 operai le unità di campionamento da effettuare sono due.

Si definisce "Unità di campionamento" il prelievo di:

- 10 superfici a contatto;
- 5 superfici non a contatto;
- 5 prodotti.

I prodotti devono essere campionati solo dopo essere stati confezionati. Nel caso di prodotti affettati o in tranci i campioni devono essere inviati nella confezione originale al laboratorio di analisi, mentre per i prodotti disossati e/o interi si procederà al campionamento in loco.

Saranno prelevati 5 prodotti confezionati da uno stesso lotto distribuendo il campionamento in modo omogeneo su tutto il lotto (un pezzo ogni quinto del lotto). Allo stabilimento deve essere notificato in anticipo l'effettuazione dei campionamenti, al fine di avere le specifiche produzioni in atto per effettuare i campionamenti.

L'effettuazione del prelievi per il Piano "RLm" deve essere notificata all'impianto almeno una settimana prima dell'esecuzione.

I lotti dei prodotti campionati, preferibilmente selezionati tra quelli idonei al mercato USA, dovranno essere trattenuti fino al rilascio del referto analitico.

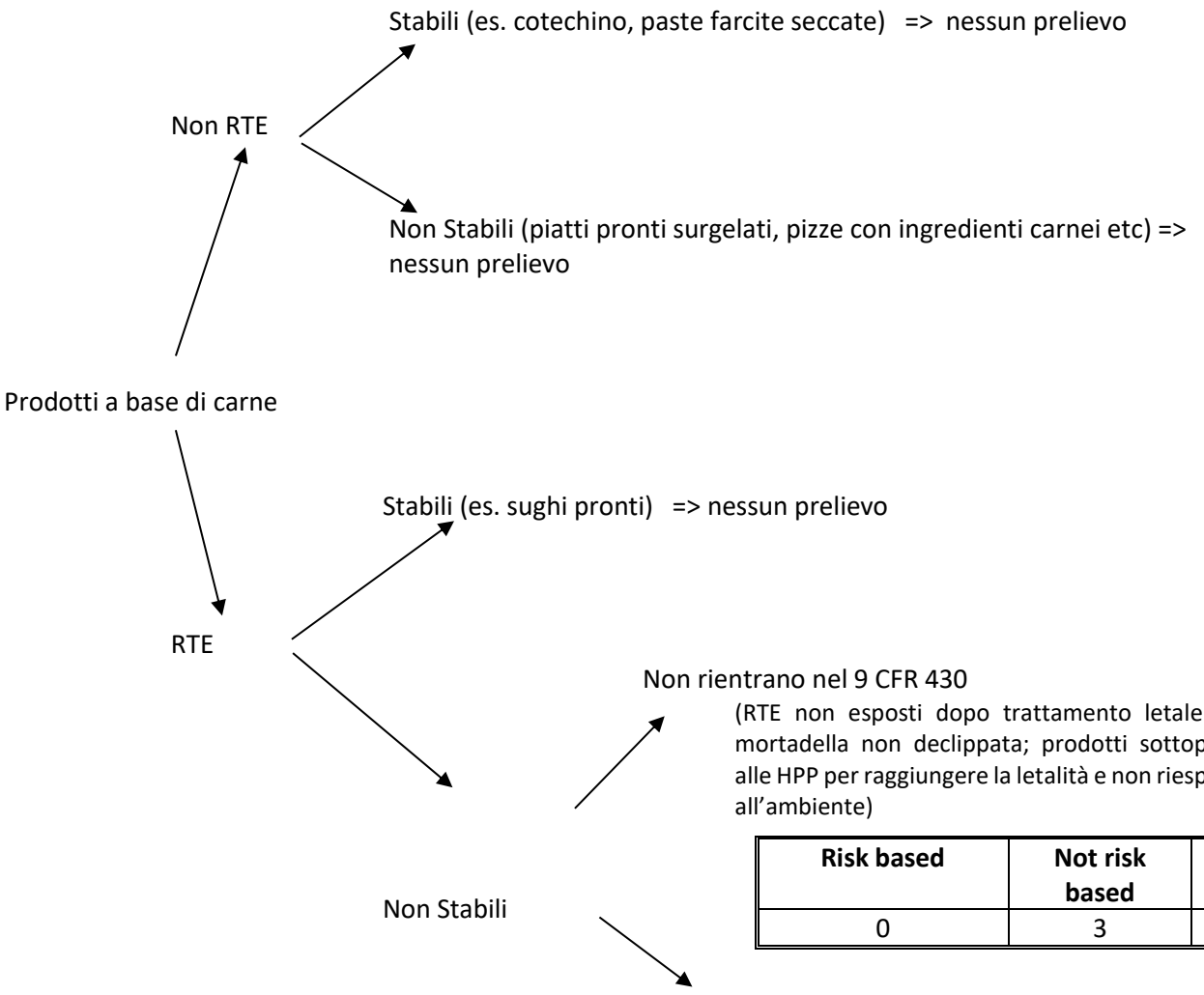
Si considerano adulterati e, quindi, non idonei al mercato statunitense:

- tutti i prodotti dello stesso lotto di un campione testato e risultato positivo per *Listeria monocytogenes*.
- i lotti di produzione che sono venuti a contatto con una superficie campionata e risultata positiva per *Listeria monocytogenes*.

Si considerano, inoltre, potenzialmente adulterati i prodotti che sono stati in ambienti (NCSF) dove è stato riscontrato un campione positivo per *Listeria monocytogenes*. In questo caso sarà cura del servizio veterinario valutare se vi sono condizioni per ritenere opportuno destinare i prodotti al mercato statunitense. (es. se la superficie ambientale contaminata e risultata positiva è una zona con condensa che può contaminare accidentalmente il prodotto, il prodotto non dovrà essere destinata al mercato USA).

Per quanto riguarda le superfici, la maggior parte dei campioni (70 % delle FCS) dovranno essere raccolti durante la lavorazione dei prodotti RTE che sono riesposti all'ambiente dopo il trattamento letale mentre, una minore parte (non più del restante 30% delle FCS) dovrà essere raccolta prima dell'inizio della lavorazione (dopo le sanificazioni preoperative).
Per quanto riguarda l'individuazione delle superfici non a contatto, si raccomanda di campionare sia quelle che potrebbero essere accidentalmente toccate dal personale che lavora prodotti RTE (es. corde/bottoni porte), sia le altre superfici non a contatto (es. pavimenti, canaline di scolo, muri, ventole, strutture sopraelevate). In questo caso i campioni potranno essere raccolti in qualsiasi momento della giornata.
In caso di positività di prodotti e/o superfici per *Listeria monocytogenes* l'azienda dovrà adottare le misure previste nella Nota Ministeriale DGISAN/2/37041/P del 21-10-2020.

Classificazione dei prodotti e numero annuo di campioni



Risk based	Not risk based	Tot
0	3	3

Alternative	Not risk based	Risk based	Tot
3 deli	3	9	12
3 not deli	1	6	7
2b	1	3	4
2a	1	3	4
1	1	1	2

FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) December, 2021

Document ID: FSIS-GD-2021-14

This guideline provides information on the Agency regulatory requirements associated with safe production of ready-to-eat (RTE) products with respect to the destruction of *Salmonella* and other pathogens. It applies to small and very small meat and poultry official establishments although all meat and poultry establishments may apply the recommendations in this guideline. It relates to 9 CFR 318.17(a)(1), 9 CFR 318.23, 381.150(a)(1), and 9 CFR 417.

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Preface

This is a revised version of the *FSIS Cooking Guideline for Meat and Poultry Products* (Revised Appendix A). It has been updated in response to comments received on the previous version and renamed. In addition, the guideline has been revised to include recommendations from previous versions and new updates based on up-to-date science. The guideline also includes changes to improve its readability.

This guideline represents FSIS's current thinking on these topics. Establishments that utilized previous versions of Appendix A as support should either:

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

The information in this guideline is provided to assist meat and poultry establishments in meeting the regulatory requirements. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to industry regarding existing requirements under the regulations. Under the regulations, meat and poultry establishments may choose to implement different procedures than those outlined in this guideline, but they would need to validate and support how those procedures are effective.

This guideline is focused on small and very small plants in support of the Small Business Administration's initiative to provide small businesses with compliance assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, all meat and poultry establishments may apply the recommendations in this guideline. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective Hazards Analysis and Critical Control Point (HACCP) systems. Although large plants can benefit from the information, focusing the guideline on the needs of small and very small establishments provides them with assistance that may be otherwise unavailable to them.

Purpose of this Guideline

This guideline contains information to assist meat and poultry establishments producing products that undergo cooking in complying with the HACCP regulatory requirements in 9 CFR 417. This guideline includes information on:

- Biological hazards during cooking.
- Regulatory requirements associated with the safe production of cooked ready-to-eat (RTE) products.
- Options establishments can use to achieve lethality of *Salmonella* and other pathogens.

- Processes that do not have validated research available (referred to as "scientific gaps") and options establishments can use until research is available.

- Resources for alternative support.

- Recommendations for evaluating cooking deviations.

Establishments can always seek guidance from State university extension service specialists and HACCP Coordinators on developing programs and plans not provided in this guideline to comply with HACCP regulatory requirements.

History of this Guideline and Reason for Reissuance

In the 1970s and 1980s, FSIS included prescriptive time, temperature, and humidity operating parameters in the regulations for cooked beef, roast beef, and cooked corned beef (42 FR 44217; 47 FR 31854; 48 FR 24314) in response to several outbreaks associated with these products and research performed to determine how to prepare them safely. When the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) final rule published in 1996, FSIS eliminated the prescriptive cooking regulations and replaced them with performance standards requiring a 6.5-Log reduction in *Salmonella* or alternative lethality for roast beef, cooked beef, and corned beef, minimum internal temperature and holding times for fully cooked patties that achieve a 5-Log reduction in *Salmonella*, and a 7-Log reduction in *Salmonella* or alternative lethality for poultry products (9 CFR 318.17(a)(1), 9 CFR 318.23, 9 CFR 381.150(a)(1); see General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18. FSIS converted these former regulations to "Safe Harbors" in an appendix to the final rule called Appendix A (64 FR 732). Establishments have been using FSIS's Appendix A, as published in 1999, as support for cooking processes for many years. The original requirements and subsequent guidance have been important to prevent human illness outbreaks and ensure the production of safe food. See General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18 for more information on the current regulatory requirements.

Over time, FSIS determined that some of its recommendations in the 1999 version of Appendix A were vague, putting establishments at risk of producing unsafe products. Additionally, some elements of the 1999 version of Appendix A were misunderstood or overlooked, resulting in FSIS guidance being applied in ways that increased food safety risks to consumers and potential risks to industry, including the risk of foodborne illness outbreaks. FSIS also determined establishments were broadly applying the recommendations for operating parameters in Appendix A beyond those meat and poultry products it was originally designed to support.

To provide the needed updates and clarifications, FSIS issued revisions of both its Cooking (Appendix A) and Stabilization (Appendix B) guidelines in 2017. The 2017 version of the guidelines took into account new and emerging technologies, processes, and science. FSIS has updated this guideline in response to comments received on the 2017 version and has included additional options for cooking support based on updated

science and technology. **The Agency is releasing this current 2021 version of the *FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A)* to replace all previous versions.**

Changes from the Previous Versions

This guideline dated December 14, 2021 is final. FSIS will update this guideline, as necessary, should new information become available.

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

For Appendix A, FSIS made changes to specify:

- The following products are not covered by the guideline (page 11): 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 (page 17).

- 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 (page 26) other than re-emphasizing that they apply to all products.

- Additional resources for selecting a relative humidity option when following FSIS's cooking guidance (page 28).

- The situations when relative humidity does not need to be addressed including by providing more information about situations considered to be direct heating (page 31) (*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 (on page 31)). 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 (page 33).

- More detailed information for evaluating product safety following a heating deviation (page 66). The revision also removes the recommendation for using the ComBase model for *Staphylococcus aureus* growth (which was not validated)

because of the development and validation of the Danish Meat Research Institute (DMRI) Staphtox model in 2018.

- Where gaps exist, recommendations from its older cooking guidance can be used until research is completed (see, Table 5. Scientific Gaps where Critical Operating Parameters From Older Guidance May be Used, page 43) 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 is included about a listeriosis outbreak associated with a cooked country-cured ham product and recommendations for establishments that cook a similar product once (page 90).

For Appendix A, FSIS removed:

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

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

In addition to these changes, the guidelines format was restructured to make it easier to use as described in the next section. This list of changes is not comprehensive, so

establishments should read the section titled FSIS Critical Operating Parameters for Cooking and other relevant sections as needed.

How to Effectively Use this Guideline

As explained above in the Changes from the Previous Versions, the guidelines format was restructured to make it easier to use. Specifically, the guideline is organized to include the following topics in the body of the guideline:

- Biological hazards during cooking.
- Regulatory requirements associated with the safe production of cooked ready-to-eat (RTE) products.
- Options establishments can use to achieve lethality of *Salmonella* and other pathogens.
- Processes that do not have validated research available (referred to as "scientific gaps") and options establishments can use until research is available.

Information included in the body of the guideline is intended as scientific support that can be used alone by establishments to meet Element 1 of validation (9 CFR 417.4(a)(1)) and to support decisions in the hazard analysis (9 CFR 417.5(a)(1)).

The following topics are included in attachments to the guideline:

- Resources for alternative support and
- Recommendations for evaluating cooking deviations.

Information provided in the attachments is not sufficient to use as sole support and additional documentation is needed. For example, Attachment A1. Customized Processes and Alternative Lethality Support (page 55), contains descriptions or brief summaries of available scientific articles. However, the summaries are not considered adequate support on their own because they do not contain the details of each study. For this reason, establishments must have the full copy of the article on-file as scientific support for their HACCP System. The summaries are provided to help establishments identify journal articles related to their process. Each establishment needs to determine if the operating parameters of a particular study match the establishment's process. Establishments are not limited to using the scientific articles listed and summarized as support. In addition, Attachment A2. Cooking Deviations (page 66), contains recommendations for evaluating product safety in the event of a deviation but this information is not considered adequate support on its own because establishments should perform predictive microbial modeling and may conduct sampling and testing in order to support product disposition. Other information included in attachments is intended to be supplementary.

Questions Regarding Topics in this Guideline

If after reading this guideline you still have questions, FSIS recommends searching the publicly posted Knowledge Articles ("Public Q&As") in the askFSIS database. If after searching the database, you still have questions, refer them to the Office of Policy and Program Development through askFSIS and select **HACCP Deviation & HACCP Validation** as the Inquiry Type or by telephone at 1-800-233-3935.

Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances.

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

Background

What is Lethality?

Lethality treatments are processes used by establishments to eliminate *Salmonella* and other pathogens in RTE products. Lethality treatments achieve a specific reduction in the number of *Salmonella* and other pathogens in the product (*i.e.,* an "X-Log_{10} colony forming units per gram[1] (CFU/g)" reduction). The combination of one or more lethality treatments must be sufficient to eliminate or adequately reduce *Salmonella* and other pathogens to undetectable levels and prevent the production of toxins or toxic metabolites in the RTE product (*e.g.,* from *Staphylococcus aureus*). Establishments may use a variety of different lethality processes, such as:

- Cooking the product (covered in this guideline).
- Fermentation.
- Drying.
- Salt-curing.
- Other processes that make the product safe for consumption.

Products and Processes Covered by this Guideline

This guideline addresses lethality of pathogens (*e.g., Salmonella*) in meat and poultry products[2] by heat treatment (cooking) including for products that are cooked to lethality but classified under a not-ready-to-eat HACCP plan.

NOTE: FSIS has provided additional information about the safe production of meat and poultry jerky products in

KEY DEFINITIONS

A ready-to-eat (RTE) product is defined as a meat or poultry product that is in a form that is edible by the end consumer without additional preparation to achieve food safety and that may receive additional preparation for palatability, aesthetic, or culinary purposes (9 CFR 430.1).

Lethality is the process (or combination of processes) that ensure a specific, reduction in the number of *Salmonella* and other pathogens in the product (*i.e.,* an "x-Log" reduction). Lethality processes eliminate or adequately reduce *Salmonella* and other pathogens and prevent the formation of their toxins or toxic metabolites, facilitating the production of a safe RTE food product.

[1] In the rest of this document, Log_{10} colony forming units per gram (Log_{10} CFU/g) will be annotated simply as "Log." All notations of "Log" should be read as in the unit Log_{10} CFU/g unless other information is provided.

[2] Throughout this document references to "meat and poultry products" may be considered inclusive of meat by-products, meat food products, and poultry food products as defined in 9 CFR 301.2 and 9 CFR 381.1, unless otherwise stated (*e.g.,* Products and Processes Not Covered by This Guidance).

the *FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments*. The information for jerky production remains in a separate guideline because of the complexities of the process, including drying procedures, and to help address questions from small and very small processing establishments.

Products and Processes Not Covered by this Guideline

The recommendations in this guideline do not apply to the following specific products:

Fish of the Order Siluriformes (e.g., catfish)

FSIS cooking guidance was not validated for fish of the order Siluriformes. Therefore, this guidance should not be used for fish.

Fish establishments may use the cooking guidance in Table A-3 of The Food and Drug Administration's (FDA's) *Fish and Fishery Products Hazards and Control Guidance* as support for the cooking step of fish products. The time-temperature recommendations are designed to achieve a 6-Log reduction in *Listeria monocytogenes* (*Lm)*.

Pork Rind Pellets

Establishments may cook pork skins in pork fat or oil for several hours rendering the fat and reducing the skin into pellets. This intermediate product is then further processed by frying to produce a finished product such as pork rinds, cracklins (cracklings), or chicharrones. FSIS cooking guidance does not apply to the cooking or rendering of pork skins into a pellet. Establishments may use the cooking requirements in 9 CFR 94.8(b)(4) as support for cooking pork skins into a pellet. Although these are Animal Plant and Health Inspection Service (APHIS) requirements for imported pork skins from countries where foot-and-mouth disease, African swine fever, classical swine fever, or swine vesicular disease exist, these cooking requirements ensure at least a 6.5-Log reduction of *Salmonella (*Juneja, *et al.,* 2001a; Murphy *et al.,* 2003; Murphy *et al.,* 2004).

NOTE: FSIS cooking guidance may be used for cooking of pork skins for products other than pork rind pellets (*e.g.,* for use in pickled products) and for frying of pork rind pellets into popped pork skins. Guidance for monitoring the cooking critical limit for these products can be found in the Key Question on page 21.

Rendered Lard and Tallow

FSIS cooking guidance does not apply to the rendering of animal fats, such as lard and tallow, which, due to the high fat content, generally need to reach higher temperatures and longer dwell[3] times to achieve the same reductions in *Salmonella* (Ramirez-Hernandez *et al.*, 2018). However, based on the D values (time at a constant temperature necessary to destroy 90% or 1-Log of the target organism) reported by Ramirez-Hernandez *et al.* (2018), the cooking requirements for rendering in 9 CFR 315.1(a) are adequate to ensure an animal fat rendering process achieves at least 6.5-

[3] "Dwell time" refers to the time a product is held at a specific temperature. Other commonly used terms such as "hold time" or "rest time" may be considered synonymous for the purpose of this guideline.

Log reductions of *Salmonella.* Therefore establishments may use 9 CFR 315.1 as support for a lard or rendering process, provided the critical operational parameters (≥ 170°F for ≥ 30 minutes) are met throughout the product.

Dried Products Processed Under Dry Conditions

FSIS cooking guidance does not support lethality for a process that relies on drying alone (*e.g.,* biltong), nor does this guidance support a process where the drying step comes before a cooking step that does not apply humidity or does not apply humidity during cooking at sufficient levels to rehydrate the product surface (*e.g.,* biltong or country-cured ham that is cooked in an unsealed oven after drying). This guidance also does not support lethality for a dried product cooked under moist conditions several times after drying (*e.g.,* country-cured ham that is cooked in a sealed oven several times after the hams have been salt-cured and dried).

Such dried products are typically considered intermediate moisture foods (*i.e.,* those foods that do not require refrigeration to control pathogens). The water activity range of foods considered intermediate moisture varies in the literature. For example, FDA classifies intermediate moisture foods as those with a water activity between 0.60 and 0.85 (FDA, 2018). However, some meat and poultry products may have a water activity > 0.85 and still be considered "intermediate moisture" because of other factors such as pH and salt concentration (Leistner, 1987). For example, country-cured ham has an average water activity of 0.88 but is considered shelf-stable due to the combination of water activity, high salt, and nitrite (Mikel and Newman, 2003; Reynolds *et al.*, 2001).

Establishments that apply these types of processes must identify other support for their HACCP System (9 CFR 417.5(a)(1) and 9 CFR 417.4(a)(1)).

NOTE: This guidance includes critical operating parameters for cooking products which are dried, then cooked **under moist conditions**. Scientific Gaps Identified by FSIS describes critical operating parameters (page 47) and Attachment A6. Cooking Country-Cured Hams includes additional tips, specific to country-cured hams (page 90).

Partially Heat-Treated NRTE Products

This guideline does not cover partially heat-treated products that are not ready-to-eat (NRTE) and did not reach a validated lethality time-temperature combination (for example: partially heat-treated bacon and hams). These products are addressed in the *FSIS Stabilization Guideline for Meat and Poultry Products* because cumulative growth of *Clostridium perfringens* and *Clostridium botulinum* are hazards of concern over the course of partial cooking and cooling processes.

KEY DEFINITIONS

Stabilization is the process of preventing or limiting the growth of spore-forming bacteria capable of producing toxins either in the product or in the human intestine after consumption. Stabilization processes may include cooling, hot-holding, or meeting and maintaining a certain pH or water activity level and other processes, such as drying and fermentation/ acidification that render the product shelf-stable or safe at room temperatures.

NOTE: As noted under the Products and Processes Covered by this Guideline, this guideline may be used for products that are cooked to lethality but classified under a Not RTE (NRTE) HACCP plan. For such products, please refer to the product reclassification guidance in the *Listeria Guideline*, Attachment 1.2 on pages 22-23 and Appendix 1.2 on pages 28-29 for guidance related to labeling, HACCP categorization, and intended use.

RTE Multi-hurdle Products

This guidance does not address the safe production of products that rely on multiple hurdles to achieve lethality and shelf-stability (*e.g.,* fermented and dried sausage). However, some regulatory information associated with such products is included in General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18.

NOTE: Stabilization requirements and recommendations for cooling meat and poultry products after heat treatment are described in the *FSIS Stabilization Guideline for Meat and Poultry Products*.

Biological Hazards of Concern During Cooking

The following section is designed to complement *FSIS's Meat and Poultry Hazards and Control Guide* and to further assist establishments in conducting a hazard analysis for cooked meat and poultry products as required by 9 CFR 417.2(a)(1) and for supporting decisions in their hazard analysis as required by 9 CFR 417.5(a)(1).

The following hazard is present in raw products whose outgrowth during the heating come-up time should be controlled:

- *Staphylococcus aureus* (*S. aureus*)

The following are hazards present in raw products that the lethality treatment should be designed to destroy:

- *Salmonella*
- Shiga toxin-producing *Escherichia E. coli* (STEC) (in beef)
- *Campylobacter* (in poultry)
- *Lm*
- *Trichinae spiralis* and *Toxoplasma gondii* (in pork, especially feral or non-confinement raised swine)

NOTE: Although all of these hazards are a concern, *Salmonella* is considered an indicator of lethality because the thermal destruction of *Salmonella* in cooked products would indicate the destruction of most other pathogens (64 FR 732).

More details about *S. aureus* and *Salmonella* (an indicator of lethality) can be found on the following page.

S. aureus

S. aureus is a bacterial pathogen that causes nausea, vomiting, and abdominal cramping with or without diarrhea. The Centers for Disease Control and Prevention (CDC) estimates over 240,000 illnesses annually in the U.S. are attributed to *S. aureus* (Scallan *et al.,* 2011). *S. aureus* causes illness when the bacteria grows to high levels in food and one or more heat-stable enterotoxins are produced (Kadariya *et al.,* 2014). Various types of foods serve as the optimum vehicle for *S. aureus.* The pathogen has been identified in meat products, such as fermented salami and brine-injected hams. In the 1980s, *S. aureus* enterotoxin outbreaks were frequently attributed to hams. Continued outbreaks at hotels, restaurants and institutions as documented in the National Outbreak Reporting System (NORS)[4] highlight that *S. aureus* is still a concern in hams particularly when prepared in these settings. For example, between 2013 to 2018, at least six *S. aureus* enterotoxin outbreaks at hotels, restaurants and institutions were reported in NORS in which ham was the suspected food vehicle. *S. aureus* can contaminate raw meat and poultry from the animal hide, skin, or tissue during slaughter. After slaughter and cooking, RTE meat or poultry products can be contaminated with *S. aureus* from handling by individuals carrying the organism. This pathogen is the main food safety concern during long heating come-up-times (CUT) (that is the amount of time product temperature is between 50 to 130°F while heating). *S. aureus* can be present on the raw meat or poultry and grow to high enough levels to produce a toxin in the food. Growth occurs from 45 to 118°F, but effectively begins at 60˚F, especially in raw meats where the growth of other bacteria is inhibited by nitrite or salt. The critical level for human illness is 5-Log or higher which allows enterotoxin production (Kadariya *et al.,* 2014). The toxin is not destroyed by the critical operating parameters described in this cooking guideline.

FSIS recommends limiting the growth of *S. aureus* during processing to 2-Log or less. Normal levels of *S. aureus* in raw meat are usually 2-Log (Doyle and Buchanan, 2013; IFT, 2003; Waldroup, 1996). Limiting growth to 2-Log or less allows for a margin of safety before *S. aureus* would produce toxins. Conditions that allow 3-Log growth are considered a public health concern because they would result in a total of 5-Log *S. aureus* in the product which is considered the minimum critical level for human illness (Kadariya *et al.,* 2014).

To limit *S. aureus* growth, some establishments formulate products with antimicrobials such as phosphate or lactate. But the most common practice is to limit the amount of time products spend in the temperature range where *S. aureus* grows the fastest (i.e., 50 to 130°F). This guideline identifies CUT as a critical operating parameter to ensure lethality by cooking when applying the time-temperature tables (see FSIS Critical Operating Parameters for Cooking on page 23). FSIS is aware that establishments preparing some products (*e.g.,* ham or beef brisket) may not be able to follow FSIS's *Come-Up-Time Option* 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 (page 48). This gap supports the use of any of FSIS's applicable time-temperature combinations (pages 35, 37, 38) and relative humidity,

[4] https://www.cdc.gov/nors/index.html

without considering CUT as a critical operating parameter until research can be complete.

Salmonella

Salmonella is a bacterial pathogen that causes diarrhea and fever. Infection with *Salmonella* may result in arthritis (Ajene *et al.,* 2013). The CDC reports that nontyphoidal *Salmonella* species (spp.) is one of the leading causes of foodborne illness, with an estimated 1 million cases of foodborne *Salmonella* infection annually in the U.S (Scallan *et al.,* 2011). *Salmonella* spp. infections are the second leading cause of foodborne illness in the United States. Meat and poultry outbreaks are frequently associated with *Salmonella spp.*

Salmonella occurs naturally in raw animal products; however, *Salmonella* should not be found in RTE meat and poultry products because these products have undergone a lethality treatment. Also, RTE products are intended to be consumed without further preparation for safety (*i.e.,* cooking), and if pathogens are present, their consumption may cause illness. FSIS considers all RTE meat and poultry products that are contaminated with *Salmonella,* as well as *Listeria monocytogenes* and STEC, to be adulterated under the Federal Meat Inspection Act and Poultry Products Inspection Act (21 U.S.C. 601(m)(1)) and 453(g)(1)). Any detectable *Salmonella* or other pathogens of concern adulterates RTE products (64 FR 732).

Salmonella as an Indicator of Lethality

Meat and poultry products may be contaminated with *Salmonella* during the slaughter and dressing process and by cross-contamination in the processing environment when insanitary conditions are present. For cooked products, FSIS recommends that establishments use *Salmonella* as an indicator of lethality because the thermal destruction of *Salmonella* in cooked products would indicate the destruction of most other pathogens (64 FR 732). If the establishment's scientific support demonstrates that the lethality treatment achieves sufficient reduction in *Salmonella*, it does not need to provide additional support that adequate reduction of other pathogens such as STEC, *Campylobacter*, *Lm*, *Trichinae spiralis* or *Toxoplasma gondii* is achieved. As stated in the *FSIS Compliance Guideline HACCP Systems Validation*, establishments should not use pathogens other than *Salmonella* as indicators of lethality for cooked products unless the alternate pathogen displays similar or higher resistance to the lethality processes.

NOTE: While *Salmonella* is considered an indicator of lethality for validation purposes, in the event of a deviation where the establishment missed its time-temperature parameters or applied insufficient relative humidity, FSIS recommends testing for other pathogens of concern (e.g., *E. coli* O157:H7 and *Lm*) because the absence of *Salmonella* does not

KEY DEFINITIONS

Critical operating parameters are those parameters of an intervention that must be met for the intervention to operate effectively and as intended. Such parameters include but are not limited to time, temperature, water activity, concentration, relative humidity, and type of equipment (to the extent that the use of different equipment would result in an inability to achieve the critical parameters of the study).

assure the absence of other pathogens since the establishment was unable to follow the critical operational parameters in its scientific support. In addition, depending on the type of deviation, other pathogens may also be of concern (e.g., *C. perfringens* and *C. botulinum*). For more information see Attachment A2. Cooking Deviations, page 66.

How to Control Salmonella

Establishments must ensure the target Log reduction of *Salmonella* and other vegetative pathogens is achieved throughout the product. To ensure vegetative pathogens, including *Salmonella*, are killed on the interior of the product, the endpoint time-temperature combination the product achieves is a critical operating parameter. Most often, the target temperatures used during cooking reported in scientific support documents and this guideline are the internal temperatures that the product should reach. FSIS has found that some establishments use the recommendations established for internal product temperature to set critical limits for the oven temperature. However, setting the oven temperature to the temperature identified in the FSIS time-temperature tables is not appropriate because doing so does not ensure that the product will reach the same target internal temperature.

In addition to the product temperature, the amount of time the product is held at this temperature (also known as the dwell time) is also critical to ensuring that adequate lethality is achieved. If the product is held at the target temperature for less time than specified in the time-temperature tables in this guideline, then adequate lethality may not be achieved.

To ensure a process achieves the target Log reductions of *Salmonella* on the surface of the product, moisture during cooking is a critical factor. Moisture (*e.g.*, relative humidity) around a product during cooking promotes lethality on the product surface in two ways:

- Moist cooking reduces surface evaporation from the product during heating (evaporative cooling). Producing products under conditions of high moisture early in the cooking process reduces evaporative cooling allowing product surfaces to reach higher temperatures resulting in a greater reduction in microorganisms; and

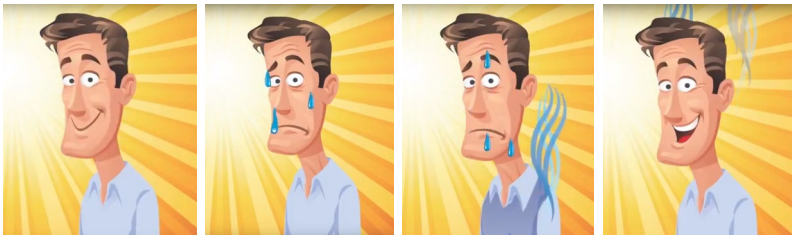
- Moist cooking keeps the product surface (and any pathogens) wet which prevents product drying. Product drying reduces the water activity and concentrates solutes (*e.g.,* sugar and salt). Research has demonstrated that bacteria can become more heat tolerant as their moisture levels decrease, and increased concentrations of solutes, especially salt, increase the heat resistance of bacteria (Buege *et al.,* (2006), Boles *et al.,* (2004), and Sindelar *et al.,* (2016)). Therefore, drying of the product surface before pathogens are destroyed will increase pathogen heat resistance and allow the pathogens to survive the heating process.

By incorporating moisture (*e.g.,* relative humidity) to minimize evaporation and the loss of surface moisture from the product, the D values (time at a constant temperature necessary to destroy 90% or 1-Log of the target organism) that are the basis for the

time-temperature combinations, will remain valid (Goepfert, 1970; Goodfellow and Brown, 1978). If evaporation, drying, or an increase in solute concentration is likely to occur, the times and temperatures in scientific studies and supporting documentation are not likely to be sufficient to provide the required lethality.

How does Moisture Ensure Bacteria on the Surface are Killed During Cooking?

During cooking, achieving a high oven temperature and internal product temperature alone are not enough to ensure the final product is free of harmful bacteria. Establishments need to make sure that cooking is done in a moist environment to ensure lethality. When relative humidity is low, oven air is dry, and a process called evaporative cooling increases, which is something we do not want. **Evaporative cooling** is the same thing that allows humans to keep cool by sweating. When you get too hot, you produce sweat, and when that sweat evaporates, it cools you down. Evaporation equals cooling.



When you get too hot… …you produce sweat. When that sweat evaporates… …it cools you down.

Evaporation = Cooling

Just like on a person's skin, evaporative cooling cools down the surface of meat and poultry during cooking. Although the oven is hot, because the surface of the product is cooling down, that moisture evaporation can actually prevent the surface of the product from becoming hot enough to kill off harmful bacteria. We can reduce evaporative cooling by keeping the humidity in the oven high. That way the moisture in the product does not evaporate as quickly, keeping the meat's surface moist and hot and resulting in an adequate bacterial kill. Why does this work?

Desert

Dry Heat = Cooling Down

VS.

Tropical

More Humidity = Less Cooling

Imagine that you are in New Mexico or Nevada where it is really hot, but dry. If you're outside, you're more likely to sweat and that sweat will cool you down, so you don't feel as hot. Now imagine you're in Florida where it is not only really hot, but also humid. If you're outside where it is humid, your skin's surface will stay sweaty and hot, your sweat will not evaporate, and you will not cool down. Since the air is already saturated, or full of moisture (humid), there is less evaporation from your body and, therefore, less cooling. The way humidity keeps you hot in Florida is the same way moisture keeps meat and poultry products hot, too.

General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking

Addressing Lethality in the HACCP System

FSIS has established performance standards in the regulations for specific ready-to-eat (RTE) products. The performance standards for specific products set required levels of *Salmonella* lethality during cooking as follows:

- **Cooked poultry products** must be processed to achieve at least a 7-Log reduction of *Salmonella* or an alternative lethality per 381.150(a)(1).
- **Roast, cooked, and corned beef** must be processed to achieve at least a 6.5-Log reduction of *Salmonella* or an alternative lethality (*e.g.,* at least a 5-Log reduction)) per 9 CFR 318.17.
- **Cooked uncured meat patties** must be processed to meet or exceed the time-temperature combinations listed in 9 CFR 318.23, which will achieve a 5-Log reduction of *Salmonella* (and other pathogens including STEC).

For products that are not subject to a performance standard, FSIS recommends the following pathogen Log reductions (*i.e.,* targets) be achieved in order to support decisions in the hazard analysis (9 CFR 417.5(a)(1)):

- For **cooked meat products**, FSIS recommends that establishments achieve a target 6.5-Log or 5-Log reduction of *Salmonella* in their process. To use a target 5-Log reduction, establishments should provide additional support for the safety of their process (see Supporting an Alternative Lethality Target (e.g., 5-Log) page 57).
- For **shelf-stable meat products**, FSIS recommends that establishments achieve a target 5-Log reduction of *Salmonella* (see How is Alternative 5-Log Lethality Related to Risk of Foodborne Illness? page 57).

KEY DEFINITIONS

Performance standards described in this guideline are quantifiable pathogen reduction levels or growth limit requirements **set by FSIS** for lethality and stabilization of certain meat and poultry products.

A **Log reduction** is a 90% reduction of a pathogen. For example, a 2-log reduction is a 99% reduction of a pathogen and a 3-log reduction is a 99.9% reduction of a pathogen in a product.

Targets are quantifiable pathogen reduction levels or growth limits **set by the establishment** to produce safe products in the absence of regulatory performance standards.

An **alternative lethality** is a treatment that achieves a different (often lower) Log reduction than what is prescribed in the regulations for certain products, but still achieves an equivalent probability that no viable *Salmonella* cells remain in the finished product, nor other pathogens and their toxins or toxic metabolites. An alternative lethality prevents adulteration and must be demonstrated to be achieved throughout the product (9 CFR 318.17(a)(1)).

An establishment should identify the performance standard or specific Log reduction target its process is designed to achieve in its HACCP plan or supporting documentation. If it does not, and FSIS cannot determine the pathogen reduction level the process achieves, FSIS may determine the establishment lacks support for its decisions related to *Salmonella* control (9 CFR 417.5(a)(1)). In addition, according to 9 CFR 417.2(c)(3), establishments must design their critical limits for Critical Control Points (CCPs) to meet all applicable performance standards and targets.

NOTE: If an establishment uses the time-temperature tables provided in this guideline or cooks beef patties according to 9 CFR 318.23, it does not need to indicate the specific Log reduction that its process achieves. It would be sufficient for the establishment to indicate that it uses time-temperature combinations from one of these documents as these regulations were designed to achieve a 5-log reduction in *Salmonella* and other pathogens including STEC.

Establishments are also required to validate that their HACCP system works as intended to address these hazards (9 CFR 417.4(a)). For more information on validation see the *HACCP Systems Validation Guideline*.

Key Question

Question: When a RTE meat food product is a mixture of meat and poultry such that the product has a meat legend, and the establishment is following this cooking guideline, does the RTE meat food product need to comply with the regulatory requirement found in 9 CFR 381.150(a)(1)?

Question: If a RTE meat food product has any amount of poultry in it, does it automatically have to meet the poultry Log reduction in the FSIS Time-Temperature Tables?

Answer: Yes to both questions.

RTE meat or poultry food products consisting of any combination of meat and poultry must meet the poultry lethality performance standard in 9 CFR 381.150(a)(1). Under the published final rule "Performance Standards for the Production of Certain Meat and Poultry Products," cooked product with any amount of poultry needs to meet the lethality requirements for the production of fully cooked poultry products (9 CFR 381.150(a)(1)) which stipulate a 7-Log *Salmonella* reduction or an alternative lethality that achieves an equivalent probability that no viable Salmonella organisms remain in the finished product. This provision is based on the FSIS national microbiological "baseline" survey of raw whole and ground meat and poultry products, which found higher levels of *Salmonella* in poultry than in meat (USDA 1994, 1996a-f). Consequently, FSIS established a higher lethality performance standard for RTE poultry products than for meat (based on highest "worst case" levels).

Alternative Lethality

An **alternative lethality** is a treatment that achieves a different (often lower) Log reduction than what is prescribed in the regulations but still achieves an equivalent probability that no viable *Salmonella* cells remain in the finished product, as well as ensures the reduction of other pathogens and their toxins or toxic metabolites (e.g., from *S. aureus*) necessary to prevent adulteration. Establishments may use alternative lethality treatments to meet the performance standards (9 CFR 318.17(a)(1) and 9 CFR 381.150(a)(1)). When using an alternative lethality treatment (*e.g.,* at least a 5-Log reduction of *Salmonella*), the establishment must validate its HACCP system to ensure that no viable *Salmonella* organisms (that is no organisms capable of causing human illness) remain in the finished product. Risk assessments have demonstrated that achieving a 5-Log reduction of *Salmonella* (instead of a 6.5-Log reduction) in cooked meat and poultry products that are not shelf stable is less protective of public health (Refer to text box: How is Alternative 5-Log Lethality Related to Risk of Foodborne Illness? page 57). Therefore, to use these lower targets, the establishment must provide additional support for its process as described in Attachment A1. Customized Processes and Alternative Lethality Support: Supporting an Alternative Lethality Target (e.g., 5-Log) on page 55. In contrast, risk assessments have shown that for shelf-stable meat and poultry products, a 5-Log reduction of S*almonella* (instead of a 6.5-Log or 7-Log reduction) is sufficient. Therefore, no additional support is needed to use a 5-Log reduction process in these shelf-stable products (9 CFR 417.5(a)(1) and 9 CFR 417.4(a)(1)).

Monitoring, Calibration, and Recordkeeping

The establishment's cooking procedures should be designed to ensure all products in a batch or lot achieve lethality, and the monitoring procedures should be designed to detect a deviation when it occurs. To achieve these goals, establishments should carefully consider the selection of the critical limit, as well as the design of their monitoring procedures. Lessons learned from several recalls attributed, in part, to insufficient monitoring procedures are shared on page 22.

Selection of the critical limit

Establishments producing cooked meat and poultry products should have sufficient monitoring equipment, including recording devices, to assure that the time, temperature, and relative humidity operating parameters of their processes are being met. With any monitoring equipment, the establishment should take the normal variation of the monitoring equipment into account when designing the critical limits. For example, if a minimum internal temperature of 165°F is necessary to destroy pathogens in a product and the thermometer has an accuracy of ± 1°F (plus or minus one degree), then the critical limit should be set no lower than 166°F. The written reasoning and equipment specification materials should be kept as part of the establishment's supporting documentation for its HACCP plan and the selection of its critical limit (9 CFR 417.5(a)(2)). All supporting documents and data from the recording devices must be made available to FSIS employees upon request (9 CFR 417.5).

Selection of the monitoring procedures

Establishments are required to maintain documents supporting the selection of monitoring procedures and associated monitoring frequencies (9 CFR 417.5(a)(2)). It is important that establishments take into account variation within the cooking process when developing monitoring procedures to ensure the procedures they develop can identify any deviations.

In addition, to accurately measure the internal temperature of the meat or poultry product, an establishment should understand the factors that can affect this temperature. These factors include cold spots in the oven, as well as variations in oven temperature during different seasons. Establishments should be aware that updated smokehouses that contain alternating or rotating dampers that result in varying breakpoints throughout the oven do reduce the temperature difference throughout the oven, but they do not eliminate it. Although monitoring the internal product temperature is strongly encouraged, an establishment can use the oven or smokehouse temperature in place of the product temperature, provided that the establishment has a consistent product and process and has sufficient data on file correlating the oven temperature selected with the internal product temperature in the scientific support.

A disadvantage with monitoring oven temperature alone is that it may make supporting product disposition after a cooking deviation more difficult. In many cases, FSIS recommends using predictive microbial modeling programs to evaluate potential hazards (see Attachment A2. Cooking Deviations on page 66). Microbial modeling programs use product temperature to predict pathogen growth and potential Log outgrowth or reductions achieved. Without product temperature records, the establishment would need other support (*e.g.,* product testing) to determine product disposition.

Key Question:

Question: How does an establishment develop a monitoring procedure for measuring endpoint temperature in meat or poultry products that are fried crispy such that a probe cannot be inserted into the product to measure internal temperature (*e.g.,* popped pork skins, and bacon slices, pieces, or bits) because the product is too thin or hard or because the thin product cools as soon as the product exits the cooking medium?

Answer: Depending on the product type, there are different recommendations. For example, for a product such as bacon slices, it may be possible to cut a slice twice as thick as normal so that the probe can be inserted. If this thicker piece reaches the lethality temperature, the thinner pieces should as well. This procedure is also recommended for jerky. It is not recommended to fold a piece of product over the thermometer, as this has been found to result in inaccurate temperatures (Buege *et al.*, 2006). For small products, such as bacon pieces or bits, it may be possible to pile the pieces or bits around the thermometer for measurement. If none of these procedures can be used, establishments may use other quantifiable measures such as a color scale value that is correlated to crispiness or the number of pieces that pass as "fried until crispy in all parts" based on a visual assessment as the critical limit for lethality for these products due to the physical challenges in monitoring the internal temperature, and the lack of outbreaks associated with them.

Lessons Learned from Undercooked Product Recalls

In 2016 and 2017, there were five recalls associated with under-cooked RTE poultry products (RC-106-2016, RC-110-2016, RC-115-2016, RC-017-2017, and RC-037-2017). For each of these recalls, FSIS determined that even though the establishments had documentation showing the critical limit (either 160°F or 165°F) was met, there were still pieces that may have entered commerce undercooked, indicating a loss of process control and insufficient monitoring procedures to identify a process deviation.

Investigations revealed a variety of concerns related to monitoring procedures, including taking temperatures from products not in the coldest spot, taking multiple product temperatures, and averaging the results of multiple temperature measurements as opposed to recording the lowest temperature.

Investigations also revealed a variety of contributing factors for inadequate cooking including:

- Raw product was partially frozen.
- Belt speed was increased.
- Shorter dwell time and lower oven temperature than normal were used.
- Product was stacked during sous vide cooking, preventing full immersion of the bags into the liquid cooking medium.
- Higher than normal product load overwhelmed the oven.

Each of these practices may have led to uneven or inadequate cooking. These findings also highlight the importance of maintaining process control of critical operating factors, such as oven temperature, product load, and belt-speed that affect the final product temperature, dwell time, and relative humidity. The establishment is required to validate that the entire HACCP system is operating as intended and to verify that it is producing a safe and wholesome product on an ongoing basis.

Complete failure to document critical limit monitoring has also contributed to the recall of cooked poultry products in the past due to a processing defect (RC-009-2017). Such a failure highlights the importance of accurate records documenting the implementation of the critical operating parameters to support the production of safe products.

Corrective Actions under HACCP Cooking Deviations

Cooking deviations occur when an establishment fails to meet its cooking CCP critical limit or cooking humidity option. Common causes for cooking deviations include product overlap, power failures, or breakdown of cooking equipment. The HACCP regulations require establishments to take corrective actions in response to these deviations, regardless of whether the cooking process is addressed through a CCP or prerequisite program. Corrective actions include ensuring no product that is injurious to health or otherwise adulterated because of the deviation enters commerce and supporting product disposition decisions (9 CFR 417.3(a) and (b)).

When cooking is addressed through a CCP, establishments are required to determine the cause of all cooking deviations, no matter how small (9 CFR 417.3(a)(1)), and ensure measures are established to prevent recurrence (9 CFR 417.3(a)(3)). Continual or repetitive process deviations from the critical limit demonstrate that the establishment is unable to control its process.

When cooking is addressed through a prerequisite program, establishments are required to reassess their HACCP system to determine whether the newly identified deviation or unforeseen hazard should be addressed and incorporated into the HACCP plan (9 CFR 417.3(b)(4)). Also, an establishment may not be able to continue to support the decision in its hazard analysis that pathogens are not reasonably likely to occur, if it has continual or repetitive deviations from its cooking prerequisite program (9 CFR 417.5(a)(1)). For more information on evaluating product disposition after a cooking deviation see Corrective Actions to Perform When a Cooking Deviation Occurs (page 66).

FSIS Critical Operating Parameters for Cooking

(Time-Temperature Tables)

Establishments that cook products to achieve lethality by applying the time-temperature combinations from this guideline need to consider the critical operating parameters that may affect pathogen Log reductions, specifically:

- Come-up-time (CUT),
- Relative Humidity, and
- Endpoint Time-Temperature.

Additionally, establishments cooking poultry products need to consider product species composition and fat content if applying FSIS cooking lethality guidance in the tables on pages 37 and 38. The FSIS Cooked Poultry Rolls Options (page 39) apply to all poultry products regardless of poultry species or fat content. For information about why product species should be considered when applying cooking lethality guidance on pages 37 and 38 and not when applying the FSIS Cooked Poultry Rolls Options see page 36.

Come-Up-Time (CUT)

When applying one of the time-temperature tables from this guideline, an establishment must also consider the heating CUT to be a critical operating parameter unless the establishment can provide a science-based rationale why heating CUT does not need to be addressed. For example, products that are fermented and then cooked to lethality may control *S. aureus* outgrowth by lowering the pH following the degree-hour concept as recommended in the American Meat Institute's *Good Manufacturing Practices for Fermented Dry & Semi-Dry Fermented Sausage Products* and therefore would not address CUT.

FSIS has developed a CUT Option that establishments may use to support its process control of *S. aureus* growth, specifically ≤ 2-Log that also prevents enterotoxin formation:

Come-Up-Time Option: Total time product temperature is between 50 and 130°F is 6 hours or less.

NOTE: This CUT Option is only for products that were cooked to lethality (including those cooked to lethality but classified as NRTE under a heat treated, not fully cooked, not shelf-stable HACCP plan). Please refer to the *FSIS Stabilization Guideline for Meat and Poultry Products* for the Agency's recommendations regarding CUT in partially cooked products that do not receive a full lethality. Please also refer to the product reclassification guidance in the *Listeria Guideline*, Attachment 1.2 on pages 22-23 and Appendix 1.2 on pages 28-29.

FSIS is aware that establishments preparing some products (*e.g.,* ham or beef brisket) may not be able to follow FSIS's *Come-Up-Time Option* above 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 (page 48). Additionally, alternative support for certain long CUT processes have been included in Attachment A1. Customized Processes and Alternative Lethality Support (page 55).

Temperatures referred to in FSIS's *Come-Up-Time Option* above, are internal temperatures. However, establishments may monitor surface temperatures during CUT, if the establishment provides support the product is intact and processed so pathogens have not been introduced below the product surface. Non-intact product temperatures should be taken internally at the center of the product (see Key Definitions panel to the right for an explanation of intact and non-intact products). Establishments should also take temperatures at the center of the product for products such as deboned and rolled hams where a portion of the product is rolled or folded over and pathogens may be internalized.

NOTE: FSIS time-temp tables list internal endpoint temperatures during cooking. It is not supportable to use surface temperature to address endpoint temperature. FSIS is only making this recommendation for its CUT option.

KEY DEFINITIONS

Come-up-time refers to the amount of time product temperature is between 50-130°F while heating.

Intact refers to products where the interior remains protected from pathogens migrating below the exterior/outside (such as beef brisket or a picnic shoulder that is not injected or vacuum tumbled).

Non-Intact refers to products where pathogens may have been introduced below the surface. Examples include products that have been mechanically tenderized (including those that have been injected with marinade or solution) or vacuum tumbled.

Key Question

Question: An establishment cooks a brisket to full lethality but realizes the smoke coloring is too light and wants to recook it to deepen the color. Can the establishment apply a new 6 hour CUT for the second cook?

Answer: Yes. Once a product achieves a lethal time-temperature combination, the allowed CUT is reset for the next cook. If the establishment chooses to recook the product, it may apply a new 6 hour CUT limit (page 23). However, if the product did not achieve a lethal time-temperature combination during the first cooking process, the CUT does not start over. The establishment should support the total time product temperature is between 50 and 130°F is 6 hours or less. Please review Attachment A2. Cooking Deviations subsection Missed Time-Temperature Parameter (page 67) for additional information.

Relative Humidity

FSIS time-temperature tables use relative humidity as a critical operating parameter to ensure moist cooking and adequate surface lethality. An establishment that uses the FSIS time-temperature tables to support its cooking process must address humidity, unless it meets one of the criteria listed in Situations when Humidity is Not Needed (page 31) or provides additional support for why humidity would not be needed in its process to ensure lethality on the product surface. FSIS has included specific relative humidity options for use with the time-temperature tables (page 26). Additional resources for determining which relative humidity option to adopt are included in Relative Humidity Resources (page 28).

NOTE: FSIS is aware that some establishments may not be able to use FSIS's humidity options because of the nature of the cooking process. Examples include products cooked for short times at high temperatures (*e.g.,* for meat balls or chicken tenders) or other processes that do not allow the use of humidity (*e.g.,* barbecue products cooked under dry heat including those cooked in smokehouses or open pits). Please refer to Scientific Gaps Identified by FSIS (page 41).

Selection of the proper relative humidity option depends on the endpoint time-temperature. Products cooked to endpoint time-temperatures of at least 145°F plus the dwell time, may apply any of the relative humidity options in Table 1. Critical Operating Parameters for FSIS Humidity Options.

KEY DEFINITIONS

Maintaining humidity means keeping the humidity at the same level throughout the cooking process. If the humidity drops during the cooking process, the establishment will need to provide additional support for the safety of the product

A **sealed oven** is generally defined as one in which the smokehouse doors and oven dampers are closed to prevent moisture loss.

The **cooking time** includes the time the product is placed in the heated oven (including surface preparation and color setting) until the product reaches the desired lethality time-temperature combination (also referred to as the "lethality treatment").

However, products cooked to an endpoint less than 145°F, should select Option 3 or 4 in Table 1. Critical Operating Parameters for FSIS Humidity Options depending on total cooking time.

NOTE: To be most effective, humidity needs to be applied during the lethality treatment, before drying. Using this guideline to support lethality processes in which the **drying step comes before the moist cooking step** (*e.g.,* country-cured ham) creates a vulnerability in the establishment's HACCP system. Establishments using this guideline for these processes should read Attachment A6. Cooking Country-Cured Hams (page 90) for recommendations to reduce this vulnerability, such as measuring water activity after cooking to verify it increases and the product surface was rehydrated during cooking.

To ensure that adequate humidity is attained, the establishment should monitor the humidity throughout the lethality treatment. The process should be monitored using wet and dry bulb thermometers (used to determine relative humidity) or a humidity sensor. FSIS recommends that establishments monitor relative humidity for every lot or batch of product produced.

Table 1. Critical Operating Parameters for FSIS Humidity Options

	CRITICAL OPERATING PARAMETERS		
	Relative Humidity	Endpoint Temperature	Cooking Time
OPTION 1:	The relative humidity of the oven is maintained by **continuously introducing steam** for **50 percent** of the cooking time, or 1 hour, whichever is longer.	≥145°F + dwell time	≥1 hour
OPTION 2:	The relative humidity of the oven is maintained by a **sealed oven** for at least **50 percent** of the total cooking time, or 1 hour, whichever is longer.	≥145°F + dwell time	≥1 hour
OPTION 3:	The relative humidity of the oven is maintained at **90 percent** or above for at least **25 percent** of the total cooking time, or 1 hour, whichever is longer.	**Any**	≥1 hour
OPTION 4:	The relative humidity of the oven is maintained at **90 percent** for the **entire cooking time.**	**Any**	**Any**

Key Question

Question: To follow the sealed oven or steam injection options, must establishments achieve a specific relative humidity?

Answer: No. Establishments do not need to achieve a specific relative humidity level in the oven if they are following the steam injection or sealed oven options in this guideline as their scientific support. Based on expert opinion, the *2014 FSIS Jerky Guideline* recommended that establishments producing jerky that monitor relative humidity try to achieve a wet bulb temperature of at least 125-130°F for 1 hour or more along with a corresponding dry bulb temperature needed to achieve at least 27-32% relative humidity or more. However, the *Jerky Guideline* also noted, achieving a wet bulb temperature of at least 125-130°F and at least 27-32% relative humidity for 1 hour or more is not adequate on its own to support that the process is being implemented consistently with FSIS Humidity Options. Rather, establishments should ensure that all critical operating parameters described in this guidance are met. Relative Humidity Resources (page 28 contains specific guidance for how to implement Option 1 steam injection and Option 2 sealed oven in a validated HACCP system. In addition, establishments should not apply the wet-bulb and relative humidity recommendations in the *Jerky Guideline* to other products without additional support.

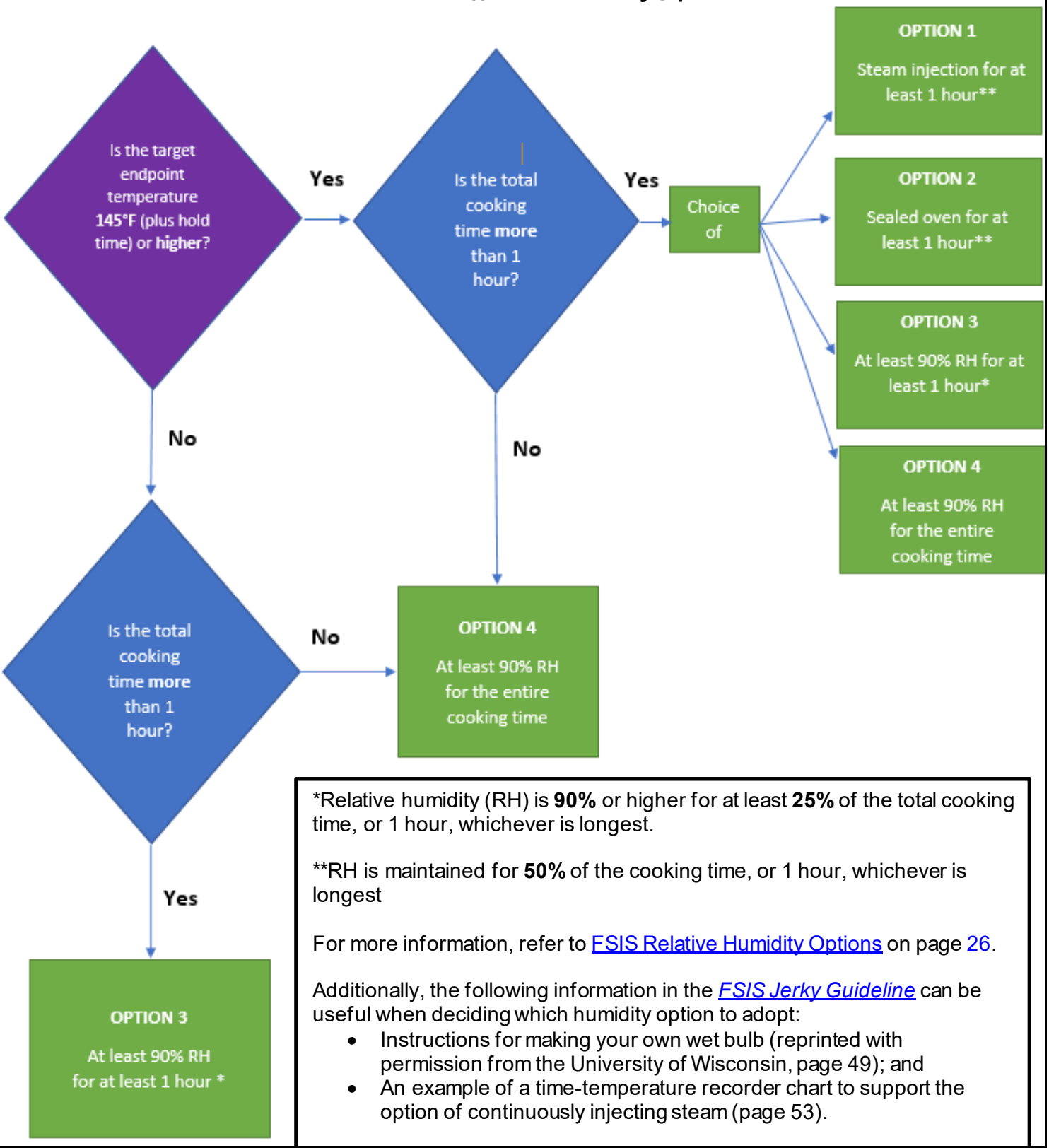
Current Support for FSIS Relative Humidity Options

Although the research cited as the basis of FSIS guidance dates as far back as 1978, newer research by McMinn *et al.,* (2018) supports that the time-temperature parameters in FSIS's cooking guidance achieves sufficient reductions of *Salmonella.* This 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. While newer research has not been conducted to validate the sealed oven and steam injection relative humidity options, research does continue to support the importance of moisture during cooking. For example, Mann and Brashears (2007), support the need for at least 30% relative humidity during cooking of roast beef. Based on FSIS knowledge of establishments' processes through its verification activities, the Agency believes when the oven is sealed, or steam is introduced, at least 30% relative humidity is maintained, suggesting that these practical recommendations result in adequate relative humidity. The Agency is also not aware of any establishments that have had *Salmonella* positives or been associated with a salmonellosis outbreak when following FSIS temperature, time, and relative humidity guidance while using effective monitoring procedures.

Relative Humidity Resources

The following flow chart contains specific guidance for how to choose a humidity option and the resources on the next two pages are designed to help establishments implement Option 1 steam injection and Option 2 sealed oven in a validated HACCP system.

Flow Chart to Choose a Humidity Option



*Relative humidity (RH) is **90%** or higher for at least **25%** of the total cooking time, or 1 hour, whichever is longest.

RH is maintained for **50% of the cooking time, or 1 hour, whichever is longest

For more information, refer to FSIS Relative Humidity Options on page 26.

Additionally, the following information in the *FSIS Jerky Guideline* can be useful when deciding which humidity option to adopt:

- Instructions for making your own wet bulb (reprinted with permission from the University of Wisconsin, page 49); and
- An example of a time-temperature recorder chart to support the option of continuously injecting steam (page 53).

Specific Guidance for Using the "Sealed Oven" Option

To support the use of the **sealed oven option** for addressing relative humidity, FSIS recommends establishments follow all 4 steps below:

1) **Maintain documentation that supports that the product achieves an internal product temperature equal to or greater than 145°F (plus the required dwell time) from the FSIS time-temperature tables.** Such documentation could include:
   a. Records of internal product temperature and time held at that temperature, (if applicable); or
   b. Records of the oven or smokehouse temperature in place of internal product temperature provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the internal product temperature in the scientific support;

2) **Maintain documentation that supports that the oven dampers are closed for at least one hour or 50% of the cooking time, whichever is longer.** Such documentation could include:
   a. Records from a computerized system that document the time at which the oven dampers were open and were closed; or
   b. Records, made manually, of the times at which the oven dampers were open and closed;
   c. Records demonstrating that the relative humidity level in the oven is maintained for at least one hour or 50% of the cooking time, whichever is longer (*e.g.,* by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement) with correlation data supporting a relationship between the relative humidity level in the oven and the time at which the oven dampers were open and closed;

3) **Maintain documentation that supports that when the oven dampers are closed, humidity is maintained in the ovens.** Such documentation could include:
   a. Records demonstrating the relative humidity level in the ovens is maintained (*e.g.,* by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), or
   b. Data gathered during the initial validation period along with ongoing verification that demonstrate that the relative humidity in the oven is maintained while the dampers are closed; and

4) **Perform routine checks to ensure the oven dampers are properly working along with a maintenance program that includes periodic monitoring to ensure oven seals are intact and functional, and that when the oven dampers are closed, a tight seal is obtained.**
   A tight seal is one that prevents a significant loss of humidity. FSIS acknowledges that a small amount of smoke or vapors might be seen escaping the smokehouse even when a tight seal is obtained. FSIS also recommends establishments consider whether there are other openings, particularly in older smokehouses, such as drain valves or air intake valves that need to be closed to ensure that a seal is obtained. Finally, some older ovens may have a stack or other opening that cannot be closed. For those establishments with older ovens that cannot be completely closed, the sealed oven method should not be used. However, the establishment may choose to close the parts of the oven it can, then add moisture in the system either by continuously introducing steam, or by using another validated method.

Specific Guidance for Using the "Continuously Introducing Steam" Option

To support the use of the **continuously introducing steam option** for addressing relative humidity, FSIS recommends establishments follow all 3 steps below:

1) **Maintain documentation that supports that the product achieves an internal product temperature equal to or greater than 145°F (plus the required dwell time) from the FSIS time-temperature tables.** Such documentation could include:
   a. Records of internal product temperature and time held at that temperature, (if applicable); or
   b. Records of the oven or smokehouse temperature in place of internal product temperature provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the internal product temperature in the scientific support;

2) **Maintain documentation that supports that steam is continuously introduced for at least one hour or 50% of the cooking time, whichever is longer.** Such documentation could include:
   a. Records from a computerized system that contains the time at which the steam is turned on and off; o r
   b. Records, made manually, of the times at which the steam is turned on and off; or
   c. Records demonstrating the relative humidity level in the oven is maintained for at least one hour or 50% of the cooking time, whichever is longer (*e.g.,* by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), along with correlation data supporting a relationship between the relative humidity level in the oven and the time steam is turned on or a letter from the manufacturer stating that when the relative humidity is rising, it is because of live steam injection; and

3) **Maintain documentation that supports that when steam is injected, humidity is maintained in the ovens.** Such documentation could include:
   a. Records demonstrating the relative humidity level in the ovens is maintained (*e.g.,* by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), or
   b. Data gathered during the initial validation period along with ongoing verification which demonstrates that the relative humidity in the oven is maintained while steam is being injected.

NOTE: The "continuously introducing steam" option refers to the use of live steam. This option may also apply to establishments that spray water onto hot heating elements, which creates steam that in turn produces humidity in the smokehouse. "Continuous" does not mean that the steam is injected for at least one hour during one stage. Rather, steam could be injected during specific stages or time intervals during the lethality (cooking) treatment as long as the total amount of time the steam is introduced adds up to at least one hour or 50% of the cooking time, whichever is longer. Furthermore, the establishment may turn the steam on and off throughout the cooking time when the target humidity is reached.

Establishments that use processes that match one of these situations do not need to monitor relative humidity as a critical operating parameter in their cooking procedure.

Situations when Humidity is Not Needed

FSIS recognizes two situations when humidity does not need to be addressed to ensure adequate lethality:

1. When moisture is inherently maintained; or
2. When product is cooked using direct heat.

Relative humidity does not need to be addressed when moisture is inherently maintained around the product. Examples of these types of processes include, but are not limited to:

- Completely immersing the meat or poultry product in a liquid cooking medium throughout the entire cooking process;
  - *E.g.,* unbagged, in water
- Cooking the product in a sealed, moisture impermeable bag (*e.g.,* cook-in-bag meat or poultry);
  - Cook-in-bag products may be eligible to be labeled as "pasteurized" (see Attachment A3. When can Products be Labeled as Pasteurized? page 81).
- Cooking product in a casing that holds moisture (*e.g.,* natural casings, cellulose casings, collagen casings, fibrous casings and plastic casings (sometimes called "synthetic" casings)).
  - See the question box on page 33 for information on cooking using natural casings.
- Heating meat or poultry products that weigh 10 pounds or more in an oven maintained at 250°F (121°C) or higher throughout a process achieving one of the time-temperature combinations in this guideline.

NOTE: Humidity is not needed for products that weigh 10 pounds or more in an oven maintained at 250°F (121°C) or higher because they have a low surface to mass ratio (Goodfellow and Brown, 1978). Therefore, the surface dries out slower than smaller products and *Salmonella* is less likely to become heat tolerant.

KEY DEFINITIONS

During **convective heating** the food product is indirectly heated by the movement of hot air. This type of heating is typical for solid foods cooked in a smoke house oven.

Conductive Heating: Heat is transferred directly into the food product by physical contact with the heating medium (*e.g.,* heating product in a skillet).

Radiant Heating: Heat is transferred directly into the food product by radiant energy without the movement of air or physical contact between the source and the food. Two common examples: are (1) broiling where food is exposed to direct, intense radiant heat or (2) certain types of rotisserie ovens where a flame emits radiant energy to heat food.

Forms of radiant energy also include gamma rays, electron beams, and x-rays.

Relative humidity also does not need to be addressed for processes that apply direct heat via conduction or radiant heating. Unlike convective heating, which uses moving hot air or steam to heat the product (*e.g.,* smoke house ovens, spiral ovens, impingement ovens), direct heating (*e.g.,* conductive heating, radiant heating) puts the product in direct contact with the heating medium. Direct heat ensures the product surface quickly reaches lethality temperatures before bacteria can develop heat tolerance due to the product's surface quickly drying out.

How is indirect heating identified?

Moving air or steam is a sign of convective (indirect) heating. Ovens that use moving air to heat the product **need to address relative humidity** to ensure sufficient Log reductions for pathogens are achieved.

Examples of direct heat include:

- Grill.
- Broil (exposure to direct, intense radiant heat).
- Heating coil,
- Flame.
- Certain rotisserie ovens that cook the meat or poultry over the heat source resulting in a product with a grilled quality.

NOTE: Direct heat cooking is rarely used in conjunction with rotisserie cooking. Indirect heat cooking is most often used because it allows the meat or poultry to cook slowly and evenly, which is the primary purpose for using a rotisserie for cooking. For indirect heat cooking, the rotisserie is positioned in front of or next to the heat source and it is the heated air that cooks the product (convection cooking).

Cooking meat patties per 9 CFR 318.23 does not include humidity considerations because these products were assumed to be cooked with direct heat such as a grill, heating coil, or flame. Meat patties cooked per 9 CFR 318.23 do not need to address relative humidity. For the definition of a patty see 9 CFR 318.23.

NOTE: Products cooked using microwave cooking methods that are not designed to control relative humidity is considered a Scientific Gap because these common cooking processes can't achieve the relative humidity options included in this guideline; however, there is a lack of research to support alternative parameters. For the critical operating parameters in this guideline that can be used for these processes, if using FSIS guidance as scientific support, see Table 5. Scientific Gaps where Critical Operating Parameters From Older Guidance May be Used page 44.

Do Products Cooked in Natural Casings Made from Animal Gastrointestinal Tracts Need to Address Relative Humidity?

No, establishments using FSIS cooking guidance as support **do not need to address relative humidity** for products that are **cooked** in a natural casing, including products that are cooked and then dried.[1]

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, depending on how they are used, the permeability of natural casings may be reduced. Most cooking processes likely reduce the permeability of natural casings early in the process so that humidity around the product is inherently maintained throughout the remainder of cooking and does not have to be added or monitored. According to Sebranek, (2010), establishments will apply smoke early in the process while the 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. Proteins in natural casings begin denaturing at 126°F (Tornberg, 2005). However, most drying processes use lower temperatures and address relative humidity to maintain casing permeability so that moisture can evaporate from the product during drying.

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 operating 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. For this reason, FSIS has posted a research study on its website to "Determine if natural casings maintain sufficient moisture to ensure product lethality using Appendix A time and temperature tables." Without this additional research, the Log reduction of *Salmonella* is less certain if meat products in natural casings are cooked using one of the time-temperature parameters in this FSIS cooking guidance without following one of the humidity options. So, while FSIS has indicated establishments using FSIS cooking guidance as support do not need to address relative humidity for products that are cooked in a natural casing, if an establishment uses one of the time-temperature parameters in FSIS cooking guidance without addressing relative humidity has a positive *Salmonella* test result through FSIS or its own testing, it should, as part of corrective actions, provide evidence that lack of relative humidity was not the cause. In addition, if research is completed and data becomes available that indicates relative humidity needs to be addressed when products are cooked in a natural casing, FSIS may change its recommendation.

[1]**NOTE:** As described in the Products and Processes Not Covered by This Guidance, this guideline is not appropriate support for lethality of a process that relies on drying alone or to support a process where the drying step comes before a cooking step that does not apply humidity or does not apply humidity during cooking at sufficient levels to rehydrate the product surface during the cooking step under dry conditions.

Key Question

Question: When an establishment decides to use a FSIS time-temperature table (*i.e.,* the 5-Log Meat Table, 6.5-Log Meat Table, or the 7.0-Log Poultry Time-Temperature Tables) from this guideline as its scientific support for its cooking/lethality step, can the establishment use the entire table as its critical limit in its HACCP plan?

Answer: Yes, the establishment can use the entire table to comply with 9 CFR 417.2(c)(3). The establishment needs to make a sound determination and support its decision in selecting and monitoring the time-temperature parameter(s) it uses for its production (9 CFR 417.5(a)(2)). In addition, establishments must collect in-plant data for at least one product from each HACCP category demonstrating the implementation of the critical operational parameters of the scientific support (9 CFR 417.4(a)(1)). At a minimum, the establishment will need to demonstrate that it is able to consistently meet a specific time-temperature from the table identified during the initial validation period to support the cooking/lethality process is validated (9 CFR 417.4(a)(1)).

Endpoint Time-Temperature

FSIS time-temperature tables in this guideline (Meat Table, the 5-Log Table, and the Poultry Time-Temperature Tables) list internal product temperatures and the corresponding dwell times needed to achieve specific Log reductions of *Salmonella*. These tables may be used as scientific support to ensure that the process meets regulatory requirements (see General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18).

NOTE: To apply an alternative lethality and use Table 6. Time-Temperature Combinations for Meat Products to Achieve a 5-Log Reduction (page 59), an establishment must provide additional documentation showing that the product meets the performance standard (if applicable) and that potentially hazardous pathogens have been controlled (see Attachment A1. Customized Processes and Alternative Lethality Support subsection: Supporting an Alternative Lethality Target (e.g., 5-Log) on page 57). The support should demonstrate the incoming load of *Salmonella* is lower than FSIS estimated based on its baseline studies, and therefore, a lower reduction from cooking would result in no viable *Salmonella* in the finished product.

Table 2. Time-Temperature Combinations for Meat Products to Achieve Lethality

Temperatures stated are the minimum internal temperatures that must be met in all parts of the meat product for the total dwell time listed.[5] An establishment must ensure both time and temperature parameters are met to use this table to support its process achieves the Log reduction target. **Relative humidity**[6] and heating **come-up-time (CUT)**[7] are also **critical operating parameters** when using this table. (See pages 37 and 38 for poultry endpoint time-temperature tables).

Degrees Fahrenheit	*Degrees Centigrade*	*6.5-log $_{10}$ Lethality*	*7-log $_{10}$ Lethality*
130	54.4	112 min.	121 min.
131	55.0	89 min.	97 min.
132	55.6	71 min.	77 min.
133	56.1	56 min.	62 min.
134	56.7	45 min.	47 min.
135	57.2	36 min.	37 min.
136	57.8	28 min.	32 min.
137	58.4	23 min.	24 min.
138	58.9	18 min.	19 min.
139	59.5	15 min.	15 min.
140	60.0	12 min.	12 min.
141	60.6	9 min.	10 min.
142	61.1	8 min.	8 min.
143	61.7	6 min.	6 min.
144	62.2	5 min.	5 min.
145	62.8	4 min.	4 min.
146	63.3	169 sec.	182 sec.
147	63.9	134 sec.	144 sec.
148	64.4	107 sec.	115 sec.
149	65.0	85 sec.	91 sec.
150	65.6	67 sec.	72 sec.
151	66.1	54 sec.	58 sec.
152	66.7	43 sec.	46 sec.
153	67.2	34 sec.	37 sec.
154	67.8	27 sec.	29 sec.
155	68.3	22 sec.	23 sec
156	68.9	17 sec.	19 sec.
157	69.4	14 sec.	15 sec.
158	70.0	0 sec.**	0 sec.**
159	70.6	0 sec.**	0 sec.**
160	71.1	0 sec.**	0 sec.**

[5] The required Log reductions are achieved instantly (0 seconds) when the internal temperature of a cooked meat product reaches 158°F or above.

[6] Time-Temperatures ≥ 145°F (in blue square) are eligible for FSIS Relative Humidity Options 1 and 2. All time-temperatures may apply FSIS Relative Humidity Options 3 and 4 (page 26).

[7] FSIS recommends limiting the total time product temperature is between 50 and 130°F to 6 hours or less (see page 23).

Additional Critical Operating Parameters for Poultry Products

The following are additional critical operational parameters that should be considered when cooking poultry products using FSIS newer guidance in the poultry time-temperature tables.

Note: The older poultry recommendations for Cooked Poultry Rolls on page 39 apply regardless of species or fat because these were not considered critical operating parameters at the time the recommendation was developed. FSIS is not aware of any outbreaks or food safety incidents as a result of applying these recommendations to products of varying species or fat level.

Product Species

Generally, FSIS accepts that research for an intervention's effectiveness on one species of poultry (*i.e.,* chickens, turkeys, ducks, geese, ratites, and squabs) can be applied to another species of poultry without additional support (FSIS Directive 5000.6, *Performance of the Hazard Analysis Verification Task*). However, research by Juneja *et al.* (2001a) demonstrated that in cooking processes, *Salmonella* heat tolerance depends on the poultry species. Therefore, when FSIS developed its time-temperature tables for poultry it developed two unique poultry time-temperature tables: one for chicken (page 37), another for turkey (page 38).

When making poultry products containing **poultry species other than chicken or turkey**, or products made with a **mixture of poultry species**, FSIS recommends selecting an endpoint temperature, then using the longest dwell time recommended for the product fat content and endpoint temperature in either the chicken or turkey table. Comparing the tables and using the longest recommended dwell time ensures the HACCP system is designed to address the worst-case scenario for *Salmonella* survival in the product. Products that are a **mixture of poultry and meat** must achieve a 7-Log reduction of *Salmonella* (see Key Question on page 19).

Fat Content

In the presence of fats, the heat tolerance of some microorganisms generally increases (Jay *et al.,* 2000). This is sometimes referred to as fat protection and is presumed to increase heat tolerance by affecting cell moisture. Juneja *et al.,* (2001b) showed that higher fat levels in beef result in increased heat resistance of *Salmonella*, which is in agreement with publications regarding other food borne pathogens (Line *et al.,* 1991; Ahmed *et al.,* 1995). The Poultry Time-Temperature Tables (pages 37 and 38) provide establishments with time-temperature combinations that can be used to cook chicken and turkey products with different fat levels.

Table 3. Time-Temperature Combinations for Chicken Products to Achieve Lethality

Times for given temperatures and fat levels that are needed to obtain a 7-Log reduction of *Salmonella* in chicken products.[8] As described on page 23, **relative humidity**[9] and heating **come-up-time (CUT)**[10] are **critical operating parameters** when using this table.

Degrees Fahrenheit	Degrees Centigrade	1% fat	2% fat	3% fat	4% fat	5% fat	6% fat	7% fat	8% fat	9% fat	10% fat	11% fat	12% fat
136	57.8	63.3 min	64.5 min	65.7 min	67 min	68.4 min	69.9 min	71.4 min	73 min	74.8 min	76.7 min	78.9 min	81.4 min
137	58.3	50.1 min	51 min	52.1 min	53.2 min	54.3 min	55.5 min	56.8 min	58.2 min	59.7 min	61.4 min	63.3 min	65.5 min
138	58.9	39.7 min	40.5 min	41.3 min	42.2 min	43.2 min	44.2 min	45.3 min	46.4 min	47.7 min	49.2 min	50.9 min	52.9 min
139	59.4	31.6 min	32.2 min	32.9 min	33.6 min	34.4 min	35.2 min	36.2 min	37.2 min	38.3 min	39.6 min	41.1 min	43 min
140	60.0	25.2 min	25.7 min	26.2 min	26.8 min	27.5 min	28.2 min	29 min	29.8 min	30.8 min	32 min	33.4 min	35 min
141	60.6	20.1 min	20.5 min	21 min	21.5 min	22 min	22.6 min	23.2 min	24 min	24.9 min	25.9 min	27.1 min	28.7 min
142	61.1	16.1 min	16.4 min	16.8 min	17.2 min	17.6 min	18.1 min	18.7 min	19.4 min	20.1 min	21 min	22.1 min	23.5 min
143	61.7	13 min	13.2 min	13.5 min	13.8 min	14.2 min	14.6 min	15.1 min	15.6 min	16.3 min	17.1 min	18.1 min	19.3 min
144	62.2	10.4 min	10.6 min	10.8 min	11.1 min	11.4 min	11.8 min	12.2 min	12.6 min	13.2 min	13.9 min	14.8 min	15.9 min
145	62.8	8.4 min	8.6 min	8.7 min	8.9 min	9.2 min	9.5 min	9.8 min	10.2 min	10.7 min	11.3 min	12.1 min	13 min
146	63.3	6.8 min	6.9 min	7 min	7.2 min	7.4 min	7.6 min	7.9 min	8.2 min	8.6 min	9.1 min	9.8 min	10.6 min
147	63.9	5.5 min	5.5 min	5.6 min	5.7 min	5.9 min	6.1 min	6.3 min	6.6 min	6.9 min	7.4 min	7.9 min	8.6 min
148	64.4	4.4 min	4.4 min	4.5 min	4.5 min	4.7 min	4.8 min	5 min	5.2 min	5.5 min	5.8 min	6.3 min	6.8 min
149	65.0	3.5 min	3.5 min	3.5 min	3.6 min	3.6 min	3.8 min	3.9 min	4.1 min	4.3 min	4.6 min	4.9 min	5.4 min
150	65.6	2.7 min	2.7 min	2.7 min	2.7 min	2.8 min	2.9 min	3 min	3.1 min	3.3 min	3.5 min	3.8 min	4.2 min
151	66.1	2.1 min	2 min	2 min	2.1 min	2.1 min	2.1 min	2.2 min	2.3 min	2.5 min	2.6 min	2.9 min	3.1 min
152	66.7	1.5 min	1.5 min	1.5 min	1.6 min	1.6 min	1.6 min	1.7 min	1.7 min	1.8 min	1.9 min	2.1 min	2.3 min
153	67.2	1.2 min	1.2 min	1.2 min	1.2 min	1.3 min	1.3 min	1.3 min	1.3 min	1.4 min	1.4 min	1.4 min	1.6 min
154	67.8	55.9 sec	56.9 sec	58 sec	59.1 sec	1 min	1 min	1 min	1.1 min	1.1 min	1.1 min	1.1 min	1.1 min
155	68.3	44.2 sec	45 sec	45.9 sec	46.8 sec	47.7 sec	48.6 sec	49.5 sec	50.4 sec	51.4 sec	52.4 sec	53.4 sec	54.4 sec
156	68.9	35 sec	35.6 sec	36.3 sec	37 sec	37.7 sec	38.4 sec	39.2 sec	39.9 sec	40.7 sec	41.4 sec	42.2 sec	43 sec
157	69.4	27.7 sec	28.2 sec	28.7 sec	29.3 sec	29.8 sec	30.4 sec	31 sec	31.6 sec	32.2 sec	32.8 sec	33.4 sec	34 sec
158	70.0	21.9 sec	22.3 sec	22.7 sec	23.2 sec	23.6 sec	24 sec	24.5 sec	25 sec	25.4 sec	25.9 sec	26.4 sec	26.9 sec
159	70.6	17.3 sec	17.6 sec	18 sec	18.3 sec	18.7 sec	19 sec	19.4 sec	19.8 sec	20.1 sec	20.5 sec	20.9 sec	21.3 sec
160	71.1	13.7 sec	14 sec	14.2 sec	14.5 sec	14.8 sec	15 sec	15.3 sec	15.6 sec	15.9 sec	16.2 sec	16.5 sec	16.9 sec
161	71.7	10.8 sec	11 sec	11.2 sec	11.5 sec	11.7 sec	11.9 sec	12.1 sec	12.4 sec	12.6 sec	12.8 sec	13.1 sec	13.3 sec
162	72.2	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	9.6 sec	9.8 sec	10 sec	10.2 sec	10.3 sec	10.5 sec
163	72.8	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**
164	73.3	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**
165	73.9	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**

[8] A 7-Log reduction of *Salmonella* is achieved instantly at internal temperatures in which the holding time is 0 seconds (0 sec.).

[9] Time-Temperatures ≥ 145°°F (in blue square) are eligible for FSIS Relative Humidity Options 1 and 2. All time-temperatures may apply FSIS Relative Humidity Options 3 and 4 (page 26).

[10] FSIS recommends limiting the total time product temperature is between 50 and 130°F to 6 hours or less (see page 23).

Table 4. Time-Temperature Combinations for Turkey Products to Achieve Lethality

Times for given temperatures and fat levels that are needed to obtain a 7-Log reduction of *Salmonella* in turkey products.[11] As described on page 23, **relative humidity**[12] and heating **come-up-time (CUT)**[13] are **critical operating parameters** when using this table.

Degrees Fahrenheit	Degrees Centigrade	1% fat	2% fat	3% fat	4% fat	5% fat	6% fat	7% fat	8% fat	9% fat	10% fat	11% fat	12% fat
136	57.8	64 min	64.3 min	64.6 min	64.9 min	65.3 min	65.8 min	66.3 min	66.9 min	67.6 min	68.4 min	69.5 min	70.8 min
137	58.3	51.9 min	52.2 min	52.4 min	52.8 min	53.2 min	53.6 min	54.1 min	54.7 min	55.3 min	56.2 min	57.2 min	58.5 min
138	58.9	42.2 min	42.5 min	42.7 min	43 min	43.4 min	43.8 min	44.2 min	44.8 min	45.4 min	46.2 min	47.2 min	48.5 min
139	59.4	34.4 min	34.6 min	34.9 min	35.1 min	35.4 min	35.8 min	36.2 min	36.7 min	37.3 min	38.1 min	39.1 min	40.4 min
140	60.0	28.1 min	28.3 min	28.5 min	28.7 min	29 min	29.3 min	29.7 min	30.2 min	30.8 min	31.5 min	32.5 min	33.7 min
141	60.6	23 min	23.2 min	23.3 min	23.5 min	23.8 min	24.1 min	24.4 min	24.9 min	25.5 min	26.2 min	27.1 min	28.2 min
142	61.1	18.9 min	19 min	19.1 min	19.3 min	19.5 min	19.8 min	20.1 min	20.5 min	21.1 min	21.7 min	22.6 min	23.7 min
143	61.7	15.5 min	15.6 min	15.7 min	15.9 min	16.1 min	16.3 min	16.6 min	17 min	17.4 min	18 min	18.8 min	19.8 min
144	62.2	12.8 min	12.8 min	12.9 min	13 min	13.2 min	13.4 min	13.7 min	14 min	14.4 min	15 min	15.7 min	16.6 min
145	62.8	10.5 min	10.6 min	10.6 min	10.7 min	10.8 min	11 min	11.3 min	11.5 min	11.9min	12.4 min	13 min	13.8 min
146	63.3	8.7 min	8.7 min	8.7 min	8.8 min	8.9 min	9 min	9.2 min	9.5 min	9.8 min	10.2 min	10.8 min	11.5 min
147	63.9	7.1 min	7.1 min	7.1 min	7.2 min	7.3 min	7.4 min	7.5 min	7.7 min	8 min	8.4 min	8.8 min	9.4 min
148	64.4	5.8 min	5.8 min	5.8 min	5.8 min	5.9 min	6 min	6.1 min	6.3 min	6.5 min	6.8 min	7.2 min	7.7 min
149	65.0	4.7 min	4.7 min	4.7 min	4.7 min	4.7 min	4.8 min	4.9 min	5 min	5.2 min	5.4 min	5.8 min	6.2 min
150	65.6	3.8 min	3.7 min	3.7 min	3.7 min	3.7 min	3.8 min	3.9 min	4 min	4.1 min	4.3 min	4.5 min	4.9 min
151	66.1	3 min	2.9 min	2.9 min	2.9 min	2.9 min	2.9 min	3 min	3.1 min	3.2 min	3.3 min	3.5 min	3.8 min
152	66.7	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.4 min	2.5 min	2.7 min	2.8 min
153	67.2	1.8 min	1.8 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	2.1 min
154	67.8	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.6 min	1.6 min	1.6 min
155	68.3	1.2 min	1.2 min	1.2 min	1.2 min	1.2 min	1.2 min	1.2 min	1.3 min	1.3 min	1.3 min	1.3 min	1.3 min
156	68.9	59 sec	59.3 sec	59.5 sec	59.8 sec	1 min	1 min	1 min	1 min	1 min	1 min	1 min	1 min
157	69.4	47.9 sec	48.1 sec	48.3 sec	48.5 sec	48.8 sec	49 sec	49.2 sec	49.5 sec	49.7 sec	49.9 sec	50.2 sec	50.4 sec
158	70.0	38.8 sec	39 sec	39.2 sec	39.4 sec	39.6 sec	39.8 sec	40 sec	40.1 sec	40.3 sec	40.5 sec	40.7 sec	40.9 sec
159	70.6	31.5 sec	31.7 sec	31.8 sec	32 sec	32.1 sec	32.3 sec	32.4 sec	32.6 sec	32.7 sec	32.9 sec	33 sec	33.2 sec
160	71.1	25.6 sec	25.7 sec	25.8 sec	26 sec	26.1 sec	26.2 sec	26.3 sec	26.4 sec	26.6 sec	26.7 sec	26.8 sec	26.9 sec
161	71.7	20.8 sec	20.9 sec	21 sec	21.1 sec	21.2 sec	21.3 sec	21.4 sec	21.5 sec	21.6 sec	21.7 sec	21.8 sec	21.9 sec
162	72.2	16.9 sec	16.9 sec	17 sec	17.1 sec	17.2 sec	17.3 sec	17.3 sec	17.4 sec	17.5 sec	17.6 sec	17.7 sec	17.7 sec
163	72.8	13.7 sec	13.7 sec	13.8 sec	13.9 sec	13.9 sec	14 sec	14.1 sec	14.1 sec	14.2 sec	14.3 sec	14.3 sec	14.4 sec
164	73.3	11.1 sec	11.2 sec	11.2 sec	11.3 sec	11.3 sec	11.4 sec	11.4 sec	11.5 sec	11.5 sec	11.6 sec	11.6 sec	11.7 sec
165	73.9	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**	0 sec.**

[11] A 7-Log reduction of *Salmonella* is achieved instantly at internal temperatures in which the holding time is 0 seconds (0 sec.).

[12] Time-Temperatures ≥ 145°°F (in blue square) are eligible for FSIS Relative Humidity Options 1 and 2. All time-temperatures may apply FSIS Relative Humidity Options 3 and 4 (page 26).

[13] FSIS recommends limiting the total time product temperature is between 50 and 130°F to 6 hours or less (see page 23).

Key Question

Question: Can establishments that produce poultry products with higher than 12% fat use values for 12% fat in the Poultry Time-Temperature Tables?

Answer: Yes. The time-temperature combinations listed in the tables for poultry products with 12% fat can be used for products with higher percentages of fat and for products with unknown fat content. These time-temperature combinations will achieve sufficient lethality as long as adequate humidity (FSIS Relative Humidity Options page 26) is applied during the process.

Cooked Poultry Rolls Options

FSIS recommends establishments use the options in the Poultry Time-Temperature Tables (page 37 and 38) (which include dwell times at 160°F that vary based on fat content and species) because they have been validated with updated research to address species and fat content as critical operating parameters to ensure adequate Log reductions of *Salmonella.* However, FSIS is including the two older options below for cooking poultry rolls and other poultry products because they still may be used by some establishments. Applying the cooked poultry rolls options below 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. Regardless, 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 below to better assure safety.

The options below can be applied to any poultry product (not just cooked poultry rolls) regardless of fat content or poultry species. However, if FSIS collects a RTE sample that is positive for *Salmonella* or if the establishment is implicated in a food safety investigation related to *Salmonella* (i.e., is associated with reports of illness or outbreak), FSIS will review and determine the adequacy of the establishment's required 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 options.

To use a cooked poultry rolls option, the establishment **must address** all critical operating parameters for cooking identified in this guideline (other than species or fat), including relative humidity (page 26) and CUT (page 23).

1. **Cooked poultry rolls** and other cooked poultry products must reach an internal temperature of at least **160°F** (instantaneous) during the cooking process.

2. **Cured and smoked poultry rolls** and other cured and smoked poultry must reach an internal temperature of at least **155°F** (instantaneous) during the cooking process.

Resources for Customized and Alternative Support

FSIS recognizes that not all meat and poultry products can be cooked using the FSIS critical operating parameters (humidity, CUT and endpoint time-temperature) included in this guideline. To assist establishments in cooking their products, FSIS has identified additional resources which may provide scientific support for a specific process or part of a process. Attachment A1. Customized Processes and Alternative Lethality Support includes information on the following:

- **Alternative Lethality Target**: Under certain circumstances and with additional support, establishments may be able to use an alternative lethality target (e.g. 5-Log). See Attachment A1. Supporting an Alternative Lethality Target, page 57 of this guideline.
- **Journal Articles**: Establishments could identify a published journal article which shows a specific process meets the performance standard and use this as scientific support. See Attachment A1. Common Topics and Journal Articles Used for Alternative Support page 60 of this guideline.
- **Customized Cooking Schedule**: Establishments may design a customized cooking plan using validated microbial models. See Attachment A1. Predictive Microbial Modeling for Critical Operating Parameters, page 62 of this guideline.
- **Challenge Studies**: Establishments could conduct challenge studies to determine if their proposed process would meet the performance standard. See Attachment A1. Designing Challenge Studies for Cooking, page 63 of this guideline.

In addition to information for developing customized critical operating parameters, this guideline contains additional resources, listed below, to address common questions and issues establishments may have regarding cooking of meat and poultry products.

- **Pasteurized Label**: Establishments may be able to label their cooked meat or poultry product as "Pasteurized." See Attachment A3. When can Products be Labeled as Pasteurized?, page 81 of this guideline.
- **Common Sources of *Salmonella***: *Salmonella* contamination may occur on cooked products for a variety of reasons. For information on sources of *Salmonella* contamination and Best Practices to implement to address it, see Attachment A4. Sources of *Salmonella* Contamination in RTE Products and Best Practices to Address It page 82 of this guideline.
- **Ready-to-eat (RTE) Self-Assessment Tool**: FSIS has included a self-assessment tool that establishments can use to identify areas in their process where they could improve *Salmonella* control. See Attachment A5. RTE *Salmonella* Self-Assessment Tool page 87 of this guideline.

Scientific Gaps Identified by FSIS

FSIS has identified several common cooking processes that can't achieve the critical operating parameters included in this guideline. FSIS encourages establishments to conduct challenge studies when other support is not available (page 63). However, the Agency realizes it may not be cost effective for establishments to conduct individual challenge studies for commonly produced meat and poultry products. To address these common processes, which lack readily available scientific support, FSIS has identified and communicated scientific gaps and is working to facilitate filling these gaps. FSIS posted research priorities on its website to communicate clear research needs with USDA Agricultural Research Service (ARS) and academic researchers. As additional data becomes available, FSIS will update the recommendations for these scientific gaps with the latest available scientific support.

An establishment producing products **using processes that fall under an identified scientific gap** may use the critical operating parameters in this guideline as scientific support (see Table 5. Scientific Gaps where Critical Operating Parameters From Older Guidance May be Used page 43). Table 5 also describes specific vulnerabilities with using the gaps as scientific support and recommends steps to reduce the vulnerabilities. In addition to those specific vulnerabilities, FSIS has the following concerns with establishments continuing to process products using the critical operating parameters in Table 5:

- Use of these critical operating parameters represents a vulnerability because these processes have not been validated to address all hazards of concern. The original research used to develop these critical operating parameters was performed on only the few products covered by the performance standard to be included in the 1999 version of Appendix A [64 FR 732].

- If a process deviation occurs for a process that is included 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 ready-to-eat (RTE) sample that is positive for *Salmonella*, or the establishment is implicated in a food safety investigation related to *Salmonella* (i.e., is associated with reports of illness or outbreak), FSIS would verify, as part of the corrective actions (9 CFR 417.3), that the establishment can support inadequate lethality **was not** the root cause, if it wants to continue to use the older recommendation.

- As additional data becomes available, FSIS will change the recommendations for processes that fall under one of these scientific gaps.

NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Additionally, Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical operating parameters listed in Table 5.

*Scientific gaps are processes which have **not** been validated to achieve sufficient lethality and to address all potential hazards during cooking, but establishments may continue to use this guidance as support to allow additional time for research to be conducted and gaps filled.*

FSIS will update this guideline as more research becomes available and new options can be developed.

NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5).

Table 5. Scientific Gaps where Critical Operating Parameters From Older Guidance May be Used

Gap	Examples of Products	1999 Critical Operating Parameters	Vulnerability with Continuing to Follow 1999 Parameters
1. Products cooked for **short times at high temperatures** that cannot maintain 90% humidity per Option 4 and do not meet the Situations when Humidity is Not Needed (page 31). **Processes that meet this gap include those in which product is:** • Cooked for less than 1 hour, at dry bulb oven temperatures above 212°F. **NOTE:** Above 212°F the maximum relative humidity decreases as the temperature increases making it impossible to achieve 90% relative humidity in the oven regardless of the amount of moisture present.	Cooking meatballs or poultry tenders using impingement, spiral, and steam-injected inline ovens. **NOTE**: Jerky products are not included under this gap. There are many validated lethality processes available for jerky products.	Apply FSIS time-temperature tables (pages 35, 37, 38), addressing all critical operating parameters (page 23) except relative humidity. **NOTE**: Relative humidity does not need to be addressed for products cooked in completely immersed in water (page 31).	These parameters may allow the surface of the product to dry out during cooking. Lack of humidity can cause pathogens to develop heat tolerance and allow them to survive the heating process. In addition, shorter cooking processes allow for limited additional lethality during the heating come-up time (sometimes called cumulative or integrated lethality) which reduces the safety margin the process provides. To minimize these vulnerabilities, an establishment may choose to implement, validate, and monitor as part of the HACCP system, any of the following to ensure moist cooking and demonstrate surface lethality: ○ Wet-bulb temperature. ○ Dew point temperature. ○ Percent moisture by volume. ○ Increase dwell time or endpoint temperature. ○ Increase total cooking time to increase integrated lethality. **Or** perform a challenge study (page 63). **Or** conduct finished product testing for *Salmonella* as part of on-going verification.

NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5).

Gap	Examples of Products	1999 Critical Operating Parameters	Vulnerability with Continuing to Follow 1999 Parameters
2. Products cooked using **microwave cooking methods that are not designed** to control relative humidity. **Processes that meet this gap include those in which a meat or poultry product is cooked using a continuous or non-continuous microwave oven.**	Sliced bacon or bacon chips cooked using continuous microwave ovens.	Apply FSIS time-temperature tables (pages 35, 37, 38), addressing all critical operating parameters (page 23) except relative humidity.	These parameters may not ensure surface lethality. In addition, shorter cooking processes allow for limited additional lethality during the heating come-up time (sometimes called cumulative or integrated lethality) which reduces the safety margin the process provides. To minimize these vulnerabilities, an establishment may choose to implement, validate, and monitor, any of the following to ensure moist cooking and demonstrate surface lethality: ○ Increase dwell time or endpoint temperature. ○ Increase total cooking time to increase integrated lethality. **Or** perform a challenge study (page 63). **Or** conduct finished product testing for *Salmonella* as part of on-going verification. **NOTE:** There is an additional vulnerability with microwave cooking that the microwave energy may not result in lethality of pathogens on continuous belt surfaces (Taormina *et al.*, 2011).

NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5).

Gap	Examples of Products	1999 Critical Operating Parameters	Vulnerability with Continuing to Follow 1999 Parameters
3. Products cooked using **cooking methods that are not designed** to control relative humidity other than microwave ovens. **Processes that meet this gap include those where product is either:** • Cooked in ovens that are not designed to be sealed (*e.g.,* no dampers) and designed without a mechanism to introduce steam. **Or** • Barbecue products cooked under dry heat to meet labeling requirements (*e.g.,* 9 CFR 319.80; and 9 CFR 381.164). **NOTE**: This does not include smokehouses where the gaskets or dampers are broken or have been removed.	Rotisserie chicken Products such as pork butt or beef brisket cooked using restaurant or foodservice type convection ovens. Barbecue products cooked under dry heat including those cooked in smokehouses or open pits. **NOTE**: Jerky products are not included in this gap. There are many validated lethality processes available for jerky products.	Apply FSIS time-temperature tables (pages 35, 37, 38), addressing all critical operating parameters (page 23) except relative humidity. **NOTE**: Relative humidity does not need to be addressed for products 10 pounds or more cooked in an oven at 250°F or higher (page 31).	These parameters may allow the surface of the product to dry out during cooking. Lack of humidity can cause pathogens to develop heat tolerance and allow them to survive the heating process. To minimize this vulnerability, an establishment may choose to implement, validate, and monitor, any of the following to ensure moist cooking and demonstrate surface lethality: ○ Wet-bulb temperature. ○ Dew point temperature. ○ Percent moisture by volume. Depending on the process, pans of water may be added to increase moisture in the cooking chamber. **Or** perform a challenge study (page 63). **Or** conduct finished product testing for *Salmonella* as part of on-going verification.

NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5).

Gap	Examples of Products	1999 Critical Operating Parameters	Vulnerability with Continuing to Follow 1999 Parameters
4. Other processes **that may inherently maintain relative humidity** around the meat and poultry filling but cannot follow one of the relative humidity options. **Processes that meet this gap include those that involve:** • Use of an edible wrapping that fully encloses a raw meat or poultry filling before cooking. Example wrappings include: ○ dough, ○ leaves, and ○ edible rice paper. **NOTE**: Products **cooked** in a natural casing are not included in this gap, since FSIS includes natural casing in Situations when Humidity is Not Needed (page 31).	Baked pasties, empanadas, pot-stickers, and dumplings.	Apply FSIS time-temperature tables (pages 35, 37, 38), addressing all critical operating parameters (page 23) except relative humidity.	These parameters may allow the surface of the filling or wrapping to dry during cooking. Lack of humidity can cause pathogens to develop heat tolerance and allow them to survive cooking. To minimize this vulnerability, an establishment may choose to implement, validate, and monitor as part of the HACCP system, any of the following to ensure sufficient lethality on the outside and inside of the wrapped products: ○ Cook filling first. ○ Measure water activity of filling before and after cooking to support moisture is inherently maintained (water activity stays the same or increases after cooking). FSIS recommends establishments achieve the highest water activity possible during cooking. Values ≥ 0.96 have been shown to prevent pathogen heat tolerance, but this water activity may not be possible to achieve for all processes (Kieboom, *et al.* 2006). ○ Cook to a higher endpoint temperature than the FSIS time-temperature tables, to compensate for the low humidity conditions. **Or** perform a challenge study (page 63). **Or** conduct finished product testing for *Salmonella* as part of on-going verification.

NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5).

Gap	Examples of Products	1999 Critical Operating Parameters	Vulnerability with Continuing to Follow 1999 Parameters
5. Processes where the **drying** step comes **before cooking** under **moist conditions.** **Processes that meet this gap include those in which products are:** • Dried to reduce the water activity and then cooked using one of the following options that ensures high relative humidity ○ Option 1, or ○ Option 3, or ○ Option 4, or ○ Cook-in-bag, or ○ Immersion cooking. **NOTE**: This gap does NOT apply products cooked after drying without applying relative humidity (*e.g.,* cooking under dry conditions or direct heat), or to dried products cooked multiple times. It is not supportable for dried products to apply direct heat instead of addressing relative humidity, without additional support for surface lethality (page 31).	Country-cured hams that are cooked-in-bag one time. Soups that have a reduced water activity due to a high salt concentration but are a liquid medium. **NOTE**: Jerky products are not included in this gap. There are many validated lethality processes available for jerky products.	Apply: FSIS time-temperature tables (pages 35, 37, 38), addressing all critical operating parameters (page 23) and use **relative humidity:** ○ Option 1, or ○ Option 3, or ○ Option 4, or ○ Cook-in-bag, or ○ Immersion cooking. **NOTE:** FSIS does not consider a sealed oven (Option 2) to be adequate support that the surface of the product is rehydrated during cooking of reduced water activity products.	There is a **vulnerability** if pathogens develop heat tolerance during drying which could allow them to survive the cooking process. To minimize this vulnerability, an establishment may choose to implement, validate, and monitor as part of the HACCP system, any of the following to ensure sufficient moisture during cooking: ○ Take water activity measurements of the surface of the product before and after cooking to support the surface is rehydrated (water activity increases after cooking). ○ Achieve the highest water activity possible during cooking. Values ≥ 0.96 have been shown to prevent pathogen heat tolerance, but this water activity may not be possible to achieve for all processes (Kieboom, *et al.* 2006). **Or** perform a challenge study (page 63). **Or** conduct finished product testing for *Salmonella* and *Lm* as part of on-going verification. Additional recommendations are included in Attachment A6. Cooking Country-Cured Hams on page 90.

NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 5).

Gap	Examples of Products	1999 Critical Operating Parameters	Vulnerability with Continuing to Follow 1999 Parameters
6. Products with **long heating come-up-times (CUTs).** **This gap applies to processes that require a:** • Heating come-up-time longer than 6 hours (page 23). **NOTE**: See page 62 for references supporting longer CUTs for fully cooked products formulated with antimicrobials to inhibit *S. aureus* that are cooked to lethality.	Ham and beef brisket. **NOTE:** Dry-cured or immersion cured products produced under this Cooking Guideline Scientific Gap may also be produced under a *Stabilization Guideline* Scientific Gap if formulated without erythorbate or ascorbate.	Apply any of FSIS's applicable time-temperature combinations (pages 35, 37, 38) and **relative humidity**, without considering CUT as a critical operating parameter. **NOTE**: For intact products, establishment may be able to monitor the surface temperature to allow for longer CUTs, instead of addressing this gap (page 24).	A **vulnerability** exists in that *S. aureus* may grow to levels that result in the production of a heat-stable enterotoxin if CUTs are longer than 6 hours without the use of antimicrobials. To minimize this vulnerability, an establishment may choose to implement, validate, and monitor as part of the HACCP system, any of the following to ensure *S. aureus* outgrowth is limited: ○ Critical parameters from a published journal article that supports extending the come-up-time in products and processes. (page 62). ○ Reduce product diameter to reduce CUT. ○ Conduct predictive pathogen modeling for a particular product and process (page 55). ○ Limit CUT between 50 – 130°F and set a defined limit based on the shortest CUT possible for the establishment's specific process. ○ Apply smoke, which may inhibit *S. aureus* and *C. perfringens* growth. **Or** perform a challenge study (page 63). **Or** conduct finished product verification testing for *S. aureus* enterotoxins (page 77); or

References

Ahmed, M.N., Conner, D.E. and Huffman, D.L. 1995. Heat resistance of *Escherichia coli* O157:H7 in meat and poultry as affected by product composition. Journal of Food Science 60:606-610.

Ajene, A.N., Walker, C.L.F., Black, R.E. 2013. Enteric pathogens and reactive arthritis: a systematic review of *Campylobacter, Salmonella* and *Shigella*-associated reactive arthritis. Journal of Health, Population, and Nutrition. 31(3):299-307.

AMIF (American Meat Institute Foundation). 1997. Good Manufacturing Processes for Fermented Dry & Semi-Dry Sausage Products. https://meathaccp.wisc.edu/Model_Haccp_Plans/assets/GMP%20Dry%20Sausage.pdf. Accessed 27 April 2020.

Blankenship L.C. 1978. Survival of a *Salmonella typhimurium* experimental contaminant during cooking of beef roasts. Applied Environmental Microbiology. 35(6):1160-1165.

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.

Borowski, A. G., Ingham, S. C., Ingham, B. H. 2009. Lethality of home-style dehydrator processes against *Escherichia coli* O157: H7 and *Salmonella* serovars in the manufacture of ground-and-formed beef jerky and the potential for using a pathogen surrogate in process validation. Journal of Food Protection. 72(10): 2056-2064.

Buege, D.R., Searls, G., Ingham, S.C. 2006. Lethality of commercial whole-muscle beef jerky manufacturing processes against Salmonella serovars and *Escherichia coli* O157: H7. Journal of Food Protection. 69(9):2091-2099.

Center for Disease Control (CDC). 1971a. Staphylococcal gastroenteritis associated with salami: United States. Morbidity and Mortality. 20(28): 253-258. Accessed 21 April 2020. https://www.jstor.org/stable/44070511.

Center for Disease Control (CDC). 1971b. Gastroenteritis associated with Genoa salami: United States. Morbidity and Mortality. 20(29): 261-266 Accessed 21 April 2020. www.jstor.org/stable/44070520.

Center for Disease Control (CDC). 1975. Staphylococcal food poisoning associated with Italian dry Salami: California. Morbidity and Mortality. 24(44):374-379. Accessed 21 April 2020. www.jstor.org/stable/44074111.

Dierschke, S., Ingham, S.C., Ingham, B.H. 2010. Destruction of *Escherichia coli* O157: H7, *Salmonella*, *Listeria monocytogenes*, and *Staphylococcus aureus* achieved during

manufacture of whole-muscle beef jerky in home-style dehydrators. Journal of Food Protection. 73(11):2034-2042.

Doyle, M.P., Buchanan, R.L. (ed.). 2013. Food microbiology: fundamentals and frontiers—4th ed. Washington (DC): ASM Press.

FDA (Food and Drug Administration). 2018. Hazard analysis and risk-based preventative controls for human food: draft guidance for industry. Available at: https://www.fda.gov/media/99572/download. Accessed: 7th July 2020.

Freier, T.A. 2001. Use of the AMI Process Lethality Spreadsheet to validate the safety of cooking procedures. American Meat Science Association (AMSA) Proceedings of the 54th Reciprocal Meat Conference. pp. 52-53. Accessed 26 November 2019. https://meatscience.org/docs/default-source/publications-resources/rmc/2001/use-of-the-ami-process-lethality-spreadsheet-to-validate-the-safety-of-cooking-procedures.pdf?sfvrsn=115cbbb3_2.

Genigeorgis, C., Lindroth, S. 1984. The safety of Basturma, and Armenian-type dried beef with respect to *Salmonella*. Proceedings of the 30th European Meeting of Meat Research Workers, Bristol, United Kingdom. (30):217–224.

Goepfert J.M., Iskander I.K., Amundson C.H. 1970. Relation of the heat resistance of salmonellae to the water activity of the environment. Applied Environmental Microbiology. 19(3):429-433.

Goodfellow S.J., Brown W.L. 1978. Fate of *Salmonella* inoculated into beef for cooking. Journal of Food Protection. 41(8):598-605.

Gunvig, A., Andresen, M.S., Jacobsen, T., Borggaard, C. 2018. Staphtox predictor-A dynamic mathematical model to predict formation of *Staphylococcus* enterotoxin during heating and fermentation of meat products. International Journal of Food Microbiology. 285:81-91.

ICMSF (International Commission on Microbiological Specifications for Foods). 1996. Microorganisms in Foods 5: Characteristics of microbial pathogens. Springer Science & Business Media.

ICMSF (International Commission on Microbiological Specifications for Foods). 2002. Microorganisms in Foods 7: Microbiological Testing in Food Safety Management. Springer Science & Business Media.

IFT (Institute of Food Technologists) 2003. Current and Proposed Definitions of "Potentially Hazardous Foods". Comprehensive Reviews in Food Science and Food Safety. 2:17-20. doi:10.1111/j.1541-4337.2003.tb00047.x

Ingham, S.C., Ingham, B.H., Borneman, D., Jaussaud, E., Schoeller, E.L., Hoftiezer, N., Schwartzburg, L., Burnham, G.M., Norback, J.P. 2009a. Predicting pathogen growth during short-term temperature abuse of raw sausage. Journal of Food Protection. 72(1):75-84.

Ingham, S.C., Vang, S., Levey, B., Fahey, L., Norback, J.P., Fanslau, M.A., Senecal, A.G., Burnham, G.M., Ingham, B.H. 2009. Predicting behavior of *Staphylococcus aureus, Salmonella* Serovars, and *Escherichia coli* O157: H7 in pork products during single and repeated temperature abuse periods. Journal of Food Protection. 72(10):2114-2124.

Jay, J. M. 2000. Food Microbiology 6th Edition. Gaithersburg, Maryland (US).

Jofré, A., Garriga, M., Aymerich, T. 2008. Inhibition of *Salmonella* sp., *Listeria monocytogenes* and *Staphylococcus aureus* in cooked ham by combining antimicrobials, high hydrostatic pressure and refrigeration. Meat Science. 78(1-2):53-59.

Juneja, V.K., Eblen, B.S., Ransom, G.M. 2001a. Thermal inactivation of *Salmonella* spp. in chicken broth, beef, pork, turkey, and chicken: Determination of D-and Z-values. Journal of Food Science. 66(1):146-152.

Juneja, V.K., Eblen, B.S., Marks, H.M., 2001b. Modeling non-linear survival curves to calculate thermal inactivation of *Salmonella* in poultry of different fat levels. International Journal of Food Microbiology. 70(1-2):37-51.

Kadariya, J., Smith, T.C. and Thapaliya, D., 2014. Staphylococcus aureus and staphylococcal food-borne disease: an ongoing challenge in public health. BioMed Research International, (2014).

Kieboom, J., Kusumaningrum, H.D., Tempelaars, M.H., Hazeleger, W.C., Abee, T., Beumer, R.R. 2006. Survival, elongation, and elevated tolerance of *Salmonella enterica serovar Enteritidis* at reduced water activity. Journal of Food Protection. 69(11):2681-2686.

Leistner, L. 1987. Shelf-stable products and intermediate moisture foods based on meat products. In Rockland, L.B., Beuchat, L.R. (eds.), Water activity: Theory and applications to food. New York (NY): Marcel Dekker.

Line, J.E., Fain J.R., A.R., Moran, A.B., Martin, L.M., Lechowich, R.V., Carosella, J.M., Brown, W.L. 1991. Lethality of heat to *Escherichia coli* 0157: H7: D-value and z-value determinations in ground beef. Journal of Food Protection. 54(10):762-766.

Ma, L., Kornacki, J.L., Lin, C.M., Doyle, M.P. 2007. Development of thermal surrogate microorganisms in ground beef for in-plant critical control point validation studies. J. Food Prot. 70: 952-957.

Mann, J.E., 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.

Mbandi, E., Shelef, L.A. 2002. Enhanced antimicrobial effects of combination of lactate and diacetate on *Listeria monocytogenes* and *Salmonella* spp. in beef bologna. International Journal of Food Microbiology. 76(3):191-198.

McMinn, R.P., King, A.M., Milkowski, A.L., Hanson R., Glass K.A., Sindelar JJ. 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.

Mikel, W.M and Newman, M.C. 2003. Development of appropriate intervention methods to reduce the occurrence of pathogenic bacteria on country-cured hams. Available at: https://www.fsis.usda.gov/news-events/publications/listeria-interventions-country-hams. Accessed: 9th August 2021.

Murphy, R.Y., Duncan, L.K., Beard, B.L., Driscoll, K.H. 2003. D and z values of *Salmonella*, *Listeria innocua*, and *Listeria monocytogenes* in fully cooked poultry products. Journal of Food Science. 68(4):1443-1447.

Murphy R.Y., Osaili T., Duncan L.K., Marcy J.A. 2004. Thermal inactivation of *Salmonella* and *Listeria monocytogenes* in ground chicken thigh/leg meat and skin. Poultry science. 83(7):1218-25.

NACMCF (National Advisory Committee on Microbiological Criteria for Foods). 2006. Requisite scientific parameters for establishing the equivalence of alternative methods of pasteurization. Journal of Food Protection. 69(5):1190-1216.

NACMF (National Advisory Committee on Microbiological Criteria for Foods). 2010. Parameters for determining inoculated pack/challenge study protocols. Journal of Food Protection 73(1):140-202.

Porto-Fett, A.C., Call, J.E., Luchansky, J.B. 2008. Validation of a commercial process for inactivation of *Escherichia coli* O157: H7, *Salmonella Typhimurium*, and *Listeria monocytogenes* on the surface of whole muscle beef jerky. Journal of Food Protection. 71(5):918-926.

Ramirez-Hernandez, A., Inestroza, B., Parks, A., Brashears, M.M., Sanchez-Plata, M.X., Echeverry, A. 2018. Thermal inactivation of *Salmonella* in high-fat rendering meat products. Journal of Food Protection. 81(1):54-58.

Reynolds, A.E., Harrison, M.A., Rose-Morrow, R., Lyon, C.E. 2001. Validation of dry cured ham process for control of pathogens. Journal of Food Science. 66(9):1373-1379.

Scallan, E., Hoekstra, R.M., Angulo, F.J., Tauxe, R.V., Widdowson, M.A., Roy, S.L., Jones, J.L., and P.M. Griffin, P.M.. 2011. Foodborne illness acquired in the United States—major pathogens. Emerging Infectious Diseases. 17(1): 7-15.

Scott, J., Weddig, L. 1998. Principles of integrated time-temperature processing. In Proceedings of the Meat Industry Research Conference. (September).

Sebranek, J.G. 2010. Natural vs. artificial casings: Evaluating which is best for your product. *Meatingplace, In Print Online*. American Association of Meat Processors.

Sindelar, J.J., Glass, K., Hanson, R. 2016. Investigating the development of thermal processing tools to improve the safety of Ready-To-Eat meat and poultry products. Foundation for Meat and Poultry Research and Education Final Report. https://meatpoultryfoundation.org/research/investigating-development-thermal-processing-tools-improve-safety-ready-eat-meat-and-poultry Accessed 19 December 2018.

Taormina, P. J., Anthony, M., Bartholomew, G., Dorsa, W.J. 2011. Validation of lethality during an industrial microwave bacon cooking process. Prog. Intl. Assoc. Food Prot. 98th Annual Meeting, Jul 31st-Aug 3rd, Milwaukee, WI.

Tornberg, E. 2005. Effects of heat on meat proteins – Implications on structure and quality of meat products. Meat Science. 70: 493-508.

U.S. Department of Agriculture, Food Safety and Inspection Service. Risk Assessment of the Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products. 2007a. Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C.

U.S. Department of Agriculture, Food Safety and Inspection Service. 1994. Nationwide Beef Microbiological Baseline Data Collection Program: Steers and Heifers. Available at: https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/baseline-microbiology-data-reports. Accessed: 9th August 2021.

U.S. Department of Agriculture, Food Safety and Inspection Service. 1996a. Nationwide Beef Microbiological Baseline Data Collection Program: Cows and Bulls. Available at: https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/baseline-microbiology-data-reports. Accessed: 9th August 2021.

U.S. Department of Agriculture, Food Safety and Inspection Service. 1996b. Nationwide Broiler Chicken Microbiological Baseline Data Collection Program. Available at: https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/baseline-microbiology-data-reports. Accessed: 9th August 2021.

U.S. Department of Agriculture, Food Safety and Inspection Service. 1996c. Nationwide Federal Plant Raw Ground Beef Microbiological Survey. Available at: https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/baseline-microbiology-data-reports. Accessed: 9th August 2021.

U.S. Department of Agriculture, Food Safety and Inspection Service. 1996d. Nationwide Pork Microbiological Baseline Data Collection Program: Market Hogs. Available at: https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/baseline-microbiology-data-reports. Accessed: 9th August 2021.

U.S. Department of Agriculture, Food Safety and Inspection Service. 1996e. Nationwide Raw Ground Chicken Microbiological Survey. Available at: https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/baseline-microbiology-data-reports. Accessed: 9th August 2021.

U.S. Department of Agriculture, Food Safety and Inspection Service. 1996f. Nationwide Raw Ground Turkey Microbiological Survey. Available at: https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/baseline-microbiology-data-reports. Accessed: 9th August 2021.

U.S. Department of Agriculture, Food Safety and Inspection Service. 2020. Listeria monocytogenes illness outbreak associated with ready-to-eat, country-cured-ham 2017-2018: After-Action Review Report 2018-16. Available at: https://www.fsis.usda.gov/sites/default/files/media_file/2020-11/Listeria%20monocytogenes%20Illness%20Outbreak%20Associated%20with%20Ready-to-Eat%2C%20Country-Cured%20Ham%2C%202017%E2%80%932018.pdf. Accessed: 9th August 2021.

Veeramuthu, G.J., Price, J.F., Davis. price, C.E., David, A.M. Booren, A and D.M., Smith, D.M. 1998. Thermal inactivation of *Escherichia coli* O157: H7, *Salmonella senftenberg*, and enzymes with potential as time-temperature indicators in ground turkey thigh meat. Journal of Food Protection. 61(2): 171-175.

Waldroup, A. L. 1996. Contamination of raw poultry with pathogens. World's Poultry Science Journal. 52(1): 7-25.

Williams, M. S., Y. Cao, Y., Ebel, and E. D. Ebel. 2013. Sample size guidelines for fitting a lognormal probability distribution to censored most probable number data with a Markov chain Monte Carlo method. International Journal of Int. J. Food Microbiology. Micro. 165(2): 89-96.

Attachment A1. Customized Processes and Alternative Lethality Support

Following FSIS Critical Operating Parameters for Cooking (Time-Temperature Tables) (page 23) will yield product that meets the lethality performance standards and targets. However, some establishments may want to develop customized processing procedures to achieve lethality. Establishments or their process authorities may develop customized processes or an alternative lethality that meets the performance standards or targets by using information obtained from the literature or by comparing their processes with established processes. However, all processes must achieve a supported Log reduction of pathogens and prevent the production of toxins or toxic metabolites (*e.g., Staphylococcus aureus*) to meet HACCP requirements and produce safe food (General Considerations for Designing HACCP Systems to Achieve Lethality by Cooking, page 18). Regardless of the scientific support used, the establishment's actual process must match the critical operating parameters in the scientific support in order to achieve adequate lethality and meet validation requirements.

In addition to the recommendations provided in the *HACCP Systems Validation Guideline*, FSIS recommends that establishments and processing authorities address the following questions when evaluating how journal articles and other sources of alternative support may apply to a cooking process:

1. Does the scientific support (*e.g.,* book chapters, journal articles) demonstrate that sufficient lethality of *Salmonella* (or a supported surrogate) is achieved in the product?

    - Negative results obtained from finished product sampling alone (without inoculation) are not sufficient to demonstrate that the product meets the performance standards or targets because they do not support any particular reduction in pathogens is achieved by the process.

    - Studies should evaluate the survival of a mixture (cocktail) of *Salmonella*, including strains associated with human illness and strains isolated from meat and poultry products. Ideally, some of the strains selected should be those with known heat-tolerance properties.

2. Does the scientific support identify all critical operating parameters used to achieve lethality (*e.g.,* relative humidity)?

    - Many research studies designed to determine D-values of pathogens in different food matrices use enclosed systems that maintain moisture, such as sealed glass tubes, or impermeable bags immersed in hot water. These studies, as published in journal articles, may not specifically list controlling moisture during cooking as a critical operating parameter, but the methods used inherently maintain moisture in the system. To achieve

the same result as the study, an establishment would need to consider how its process will apply moisture to ensure lethality on the product surface during cooking (see page 16).

Acceptability of Challenge Study Results

There are different ways to evaluate the results of challenge studies and scientific literature, such as journal articles. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), in its 2010 article *"Parameters for Determining Inoculated Pack/Challenge Study Protocols"* recommends a statistical analysis be performed on results or, if not, a clear justification be provided.

Below are three acceptable ways to determine if the results of the research are sufficient to support an establishment's lethality process:

1. The mean (average) is ≥ performance standard or target log reduction.

2. Results for all replicates are ≥ performance standard or target.

3. The lower 95% confidence limit for the results from the study is ≥ performance standard or target.

    - What this means is the reduction is calculated based on the mean log reduction minus 1.94 times the standard deviation. The recommendation to subtract 1.94 times the standard deviation from the mean log reduction is based on a study with an n of 6 (*i.e.*, three replicates and two samples per replicate or two replicates and three samples per replicate).

The approaches are listed in order of increasing confidence the results support an acceptable lethality process. The first approach (using the mean or average result) provides the least confidence the lethality process will consistently achieve the performance standard or target because it does not take into account variation found in the results. The third approach (using the lower 95% confidence limit) provides the greatest confidence but is also the most conservative because it takes into account a confidence interval based on variation found during the study.

Supporting an Alternative Lethality Target (*e.g.*, 5-Log)

Establishments that use an alternative lethality (*e.g.,* FSIS 5-Log Table) need to consider a number of factors that were identified in the *Salmonella* risk assessment, specifically:

- Product categorization (shelf-stable or not shelf-stable).
- Pathogen load in raw materials.
- Storage and growth.
- Consumer reheating.

How is Alternative 5-Log Lethality Related to Risk of Foodborne Illness?

Historically, FSIS has recommended that establishments achieve at least a 6.5-Log reduction of *Salmonella* in cooked meat products (other than beef patties which require a 5-Log reduction). The previous recommendations were due to the Risk Assessment of the Impact of Lethality Standards on Salmonellosis from RTE Meat and Poultry Products, 2005 (*Salmonella* Risk Assessment), 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 regulations for cooked beef, corned beef, and roast beef in 9 CFR 318.17(a)(1) allow for the use of alternative lethality, provided it provides equivalent probability that no viable *Salmonella* cells remain in the finished product, as well as ensures the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration. FSIS is providing guidance to establishments regarding how to validate the alternative lethality option of achieving at least a 5-Log reduction of *Salmonella* in **cooked** meat products other than beef patties to ensure the lower reduction does not result in a greater risk of illness. For **shelf-stable** products, that primarily rely on means other than cooking to achieve lethality, the *Salmonella* Risk Assessment did not show a substantially higher risk of illness for product with a 5-Log reduction compared to a 6.5-Log reduction, so FSIS continues to recommend a 5-Log reduction of *Salmonella* for shelf-stable products. Therefore, establishments do not need to provide additional support for decisions in the hazard analysis (9 CFR 417.5(a)(1)) if they identify a 5-Log reduction of *Salmonella* as the lethality target for shelf-stable.

An establishment can use the following bulleted options to support an alternative lethality target. The alternative lethality target may be from alternative supporting documentation (Attachment A1. Customized Processes and Alternative Lethality Support page 55) or with the time-temperature combinations in Table 6. Time-Temperature Combinations for Meat Products to Achieve a 5-Log Reduction (page 59).

- Use source materials that have been tested or treated to reduce pathogens. The establishment can use a cooking process that achieves a 5-Log lethality of *Salmonella* if it uses source materials that have been tested or treated to reduce pathogens. The establishment should maintain support (*e.g.,* Letters of Guarantee (LOG), Certificates of Analysis (COA), or sampling information) for each lot demonstrating that the levels of *Salmonella* are low enough to be controlled by a process achieving 5-Log reduction with an appropriate safety margin (*e.g.,* 2-Log). For example, an establishment may provide a LOG indicating that a certain Log reduction (*e.g.,* 1.5-Log or 2-Log) is achieved in the source materials using a validated antimicrobial intervention.

- Conduct a *Salmonella* baseline study on the raw source material. The baseline study should be designed such that the establishment can demonstrate, with reasonable confidence, that less than 0.01% of the raw, formulated product contains concentrations > 10 CFU/gram of *Salmonella* before cooking. This is based on the premise that a 5-Log lethality step would reduce a *Salmonella* level of < 10 CFU/gram to < 1 CFU/ 100 grams and provide a 2-Log margin of safety (NACMCF, 2010).

Key Question

Question: Do establishments that want to use the 6.5-Log Time-Temperature Tables need to perform raw product testing or provide other support?

Answer: No. The times and temperatures listed in the tables for 6.5-Log or 7.0-Log reductions can be used without any additional support or testing. These time-temperature combinations will achieve sufficient lethality as long as adequate humidity (page 26) is applied during the process.

Challenges Supporting a 5-Log Alternative Lethality for Cooked Beef Products

FSIS recognizes that extensive baseline sampling and testing needed to apply a 5-Log lethality may be cost prohibitive for small and very small establishments. However, this document provides multiple options for meeting the performance standards for certain RTE products. As noted in the question box above, establishments do not need additional testing or support to apply the 6.5-Log Meat Table, or the 7.0-Log Poultry Time-Temperature Tables in their process.

Table 6. Time-Temperature Combinations for Meat Products to Achieve a 5-Log Reduction

Temperatures stated are the minimum internal temperatures that must be met in all parts of the product for the total dwell time listed[14, 15]. An establishment must ensure both time and temperature parameters are met to use this table to support that its process achieves a 5-Log reduction of *Salmonella*. As described on page 23, **relative humidity**[16] and heating **come-up-time (CUT)**[17] are **critical operating parameters** when using this table.

Degrees Fahrenheit	Degrees Centigrade	Time for 5.0 log Reduction
130	54.4	86 min.
131	55	69 min.
132	55.6	55 min.
133	56.1	44 min.
134	56.7	35 min.
135	57.2	28 min.
136	57.8	22 min.
137	58.4	18 min.
138	58.9	14 min.
139	59.5	11 min.
140	60	9 min.
141	60.6	7 min.
142	61.1	6 min.
143	61.7	5 min.
144	62.2	4 min.
145	62.8	3 min.
146	63.3	130 sec.
147	63.9	103 sec.
148	64.4	82 sec.
149	65	65 sec.
150	65.6	52 sec.
151	66.1	41 sec.
152	66.7	33 sec.
153	67.2	26 sec.
154	67.8	21 sec.
155	68.3	17 sec.
156	68.9	14 sec.
157	69.4	11 sec.
158	70	0 sec.**
159	70.6	0 sec.**
160	71.1	0 sec.**

[14] A 5-Log reduction of *Salmonella* is achieved instantly (0 seconds) when the internal temperature of a cooked meat product reaches 158°F or above.
[15] When using this table for not shelf-stable products other than meat patties, establishments must provide additional support to show why a 5-Log reduction is sufficient to ensure pathogens are eliminated (Supporting an Alternative Lethality Target (e.g., 5-Log) page 50).
[16] Time-Temperatures ≥ 145°°F (in blue square) are eligible for FSIS Relative Humidity Options 1 and 2. All time-temperatures may apply to FSIS Relative Humidity Options 3 and 4 (page 26).
[17] FSIS recommends limiting the total time product temperature is between 50 and 130°F to 6 hours or less (see page 23).

Common Topics and Journal Articles Used for Alternative Support

Many journal articles have been published that have increased scientific understanding of the critical role of certain operating parameters during cooking including relative humidity. FSIS recognizes that many of these journal articles, including that by Buege et al., (2006), support the use of less than 90% relative humidity (FSIS Relative Humidity Option 4; page 26). Establishments may use these journal articles as scientific support as long as establishments ensure the published critical operating parameters match the critical operating parameters being used in the establishment's process. FSIS agrees that wet-bulb temperature is a good indicator of surface lethality during cooking but 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 place of the FSIS relative humidity options for all products. For more information see FSIS' wet-bulb video available at: https://youtu.be/as-c2bCsoHQ.

Other commonly used alternatives to relative humidity include dew point temperature and percent moisture by volume. Alternative measures are particularly valuable in products cooked at high dry bulb temperatures. However, at this time, there is no consensus or scientifically supported recommendation for how to use those parameters or a targeted value to reach for each parameter. Consequently, FSIS has posted an FSIS research priority on its website and is aware that researchers are actively investigating this issue (Scientific Gaps Identified by FSIS page 41).

Journal articles or reports establishments may consider using as scientific support, grouped by topic area, include:

- Validated cook schedules for making beef jerky by controlling dry bulb and wet bulb temperatures.
    - Buege, D.R., Searls, G., Ingham, S.C. 2006. Lethality of commercial whole-muscle beef jerky manufacturing processes against Salmonella serovars and *Escherichia coli* O157: H7. Journal of Food Protection. 69(9):2091-2099.
    - Porto-Fett, A.C., Call, J.E., Luchansky, J.B. 2008. Validation of a commercial process for inactivation of *Escherichia coli* O157: H7, *Salmonella Typhimurium*, and *Listeria monocytogenes* on the surface of whole muscle beef jerky. Journal of Food Protection. 71(5):918-926.
    - Borowski, A. G., Ingham, S. C., Ingham, B. H. 2009. Lethality of home-style dehydrator processes against *Escherichia coli* O157: H7 and *Salmonella* serovars in the manufacture of ground-and-formed beef jerky and the potential for using a pathogen surrogate in process validation. Journal of Food Protection. 72(10): 2056-2064.
    - Dierschke, S., Ingham, S.C., Ingham, B.H. 2010. Destruction of *Escherichia coli* O157: H7, *Salmonella*, *Listeria monocytogenes*, and *Staphylococcus aureus* achieved during manufacture of whole-muscle beef jerky in home-style dehydrators. Journal of Food Protection. 73(11):2034-2042.

- Validated cook schedules for making turkey jerky by controlling dry bulb and wet bulb temperatures.
    - Porto-Fett, A.C.S., Call, J.E., Hwang, C.A., Juneja, V., Ingham, S., Ingham, B., Luchansky, J.B. 2009. Validation of commercial processes for inactivation of *Escherichia coli* O157: H7, *Salmonella Typhimurium*, *and Listeria monocytogenes* on the surface of whole-muscle turkey jerky. Poultry Science, 88(6):1275-1281.

- Use of high temperature, short time cooking procedures and monitoring a wet bulb temperature target. The research provides scientific support for alternative processes including use of a wet-bulb temperature target.
    - Sindelar, J.J., Glass, K., Hanson, R. 2016. Investigating the development of thermal processing tools to improve the safety of Ready-To-Eat meat and poultry products. Foundation for Meat and Poultry Research and Education Final Report. https://meatpoultryfoundation.org/research/investigating-development-thermal-processing-tools-improve-safety-ready-eat-meat-and-poultry Accessed 19 December 2018.

      NOTE: Establishments may use this final report as scientific support until a peer-reviewed journal article is published.

Why do some journal articles support using different critical operating parameters for cooking than those recommended by FSIS?

FSIS guidance is designed to ensure lethality for a large number of meat and poultry products across broad product categories. Research on specific processes and product types may support adequate lethality can be achieved using different critical operating parameters for certain products (*e.g.,* shorter dwell time or lower endpoint temperature), but research is not always available to support using those parameters across the many product categories and product types that this guidance covers. Establishments may choose to follow journal articles or other peer-reviewed scientific data instead of FSIS guidance, provided the same critical operating parameters are met (*e.g.,* product type, dry-bulb temperature, wet-bulb temperature, internal product temperature, and intrinsic factors) and the process achieves sufficient reductions for *Salmonella* based on the establishment's desired target.

CUT Option

FSIS's CUT option (page 23) was developed to support a wide variety of products. It is designed to use product characteristics that would allow the most *S. aureus* growth (worst-case scenario). Using worst-case conditions ensures that the option prevents *S. aureus* from being a hazard in all products. Establishments may be able to identify

journal articles with longer CUT for products with specific characteristics that inhibit pathogen growth (*e.g.,* formulated with antimicrobials like sodium lactate).

Example:

- This following journal article provides critical limits for the brine injection and the thermal process that control *S. aureus* growth and enterotoxin production during a 14-hour CUT.
    - Ingham, S.C., Losinski, J.A., Dropp, B.K., Vivio, L.L., Buege, D.R. 2004. Evaluation of *Staphylococcus aureus* growth potential in ham during a slow-cooking process: use of predictions derived from the US Department of Agriculture Pathogen Modeling Program 6.1 predictive model and an inoculation study. Journal of food protection, 67(7):1512-1516. https://meathaccp.wisc.edu/validation/heat_treatment.html.

- This following journal article provides critical operating parameters for hams formulated with phosphate and cooked to lethality while applying a long CUT.
    - Sindelar, J., Glass, K., Hanson, R., Sebranek, J.G., Cordray, J., Dickson, J.S. 2019. Validation for lethality processes for products with slow CUT: Bacon and bone-in-ham. Food Control. 104:147-151.

NOTE: Although Sindelar *et al*. (2019) contains information on the growth of pathogens during the heating CUT for partially heat-treated bacon, the article is not adequate sole support for controlling the growth of *C. perfringens* and *C. botulinum*. Please review the *FSIS Stabilization Guideline for Meat and Poultry Products* for additional details.

Predictive Microbial Modeling to Support CUT

Alternatively, establishments may use predictive microbiology modeling to develop custom critical operating parameters. Predictive food microbiology uses models (*i.e.,* mathematical equations) to describe the growth, survival, or inactivation of microbes in food systems from knowledge of the intrinsic and extrinsic factors of the food over time. There are many free predictive microbial models available to establishments either online or through a download. Please refer to Predictive Microbial Modeling (page 72) for FSIS recommendations on using predictive microbial models to evaluate *S. aureus* growth during heating CUT deviations. These same recommendations can be applied when validating a custom CUT for a HACCP system.

Designing Challenge Studies for Cooking

One of the most definitive tools at the disposal of an establishment or processing authority for validating a process is the challenge study.

As stated in the *HACCP Systems Validation Guideline*, establishments may perform challenge (or inoculated pack) studies to provide scientific support for their processes. These studies are performed in a laboratory or pilot plant by a processing authority or expert. The documentation on file should specify the level of pathogen reduction, elimination, or growth control; describe the process, including all critical operating parameters affecting the reduction or elimination of the pathogen of concern; and give the source of the documentation. Such studies are often not published in peer-reviewed journal articles but should contain the same level of detail as is provided for peer-reviewed studies.

Challenge studies should be designed and conducted to accurately simulate the commercial process. Challenge studies should be undertaken by individuals who have a thorough knowledge of laboratory methods used in *Salmonella* research. Challenge studies should be based on a sound statistical design (*i.e.,* a statistical design that ensures confidence in the data) and should also employ positive and negative controls. The statistical design should include the number of samples collected at each time interval and the number of study replicates needed to ensure the validity of the study. There are quantitative methods for assessing the statistical quality of a study (*e.g.,* power analysis). As per the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), the minimum number of samples to be analyzed initially and at each time interval during processing or storage should be at least two. However, NACMCF highly recommends analysis of three or more samples at each time interval. According to NACMCF, challenge studies should include replicates. Replicates should be independent trials using different lots of product and inoculum to account for variations in product, process, inoculum, and other factors. When the number of samples analyzed at each time interval is only two, NACMCF suggests it is better for the study to be repeated (replicated) more than two times. In studies with three or more samples tested at each time interval, two replicates are usually adequate. A cocktail of various serotypes of *Salmonella* should be used in an inoculated pack study to demonstrate that the lethality performance standard or target is met. At least five strains of the pathogen should be used in the inoculum. Relatively heat tolerant pathogenic strains should be included in the cocktail to develop a worst case. The serotypes/strains selected should be among those that have been historically implicated in an appreciable number of outbreaks.

FSIS does not require establishments to validate that their process achieves a specific reduction of STEC or *Lm* in cooked product if they achieve sufficient reductions of *Salmonella* because FSIS considers *Salmonella* an indicator of lethality for cooked products. Without further scientific support, establishments should not use pathogens other than *Salmonella* as indicators of lethality. For example, establishments should not

use reductions in *Lm* to support similar reductions in *Salmonella* without support that *Lm* is at least equally as heat tolerant as *Salmonella* under the conditions being studied.

If an establishment chooses to conduct a challenge study in a testing laboratory, the study should use at least five strains of *Salmonella*, including strains associated with human illness and strains isolated from meat and poultry products. Ideally, some of the *Salmonella* strains selected should be those with known heat-tolerance properties. FSIS recommends that establishments and their laboratories include a justification for the strains chosen (*e.g.*, associated with human illness or isolated from meat or poultry products) in the challenge study report.

Key Question

Question: Should a Challenge Study use *S.* Senftenberg 775W?

Answer: Not necessarily. FSIS would not require that. The *FSIS Jerky Guideline* states, "*One good* [strain] *choice, for example, might be* Salmonella enterica *serovar Senftenberg strain 775W, which displays heat resistance properties (Ng et al., 1969).* Salmonella enterica *serovar Senftenberg occurs in the top 10 serotypes seen in FSIS testing for both cow/bull carcass testing and ground beef, as well as in turkeys (carcass and ground) (FSIS testing data, 2012), so it would also be an appropriate choice for what might be seen in these products being tested."* However, additional studies have determined that *Salmonella* Senftenberg has much higher heat tolerance than other pathogens (McMinn, *et al.*, 2018; Veeramuthu, *et al.*, 1998). In addition, more recent data does not continue to identify it in the top 10 serotypes seen in FSIS testing.

In addition, the inoculum level should be at least 2-Log greater than the Log reduction to be demonstrated. FSIS recommends that establishments use *Salmonella* as an indicator of lethality (Goodfellow and Brown, 1978; Line *et al.,* 1991) or an appropriate surrogate of *Salmonella* that has similar heat and drying-tolerance properties. For example, *Enterococcus faecium* has been validated as a suitable surrogate for *Salmonella* during cooking of ground beef (Ma *et al.*, 2007). FSIS considers all *Salmonella* serotypes to be pathogens of public health concern. At a minimum, a study for a microbiological food safety hazard should identify:

- The hazard (including the specific strains studied).
- The expected level of hazard reduction or prevention to be achieved.
- The processing steps that will achieve the specified reduction.
- All critical operating parameters or conditions (*e.g.,* time, temperature, and humidity) necessary to achieve the reduction.
- Procedures to monitor the critical operating parameters or conditions.
- The critical ingredients (*e.g.,* concentration of salt, sugar, and cure).
- The critical product characteristics (*e.g.,* pH, water activity, moisture level, and fat content).

NOTE: For more information on conducting challenge studies, please review the article, *"Parameters for Determining Inoculated Pack/Challenge Study Protocols,"*

published by the NACMCF in the Journal of Food Protection in 2010. For more information on the use of positive and negative controls in challenge studies as well as general guidance on how to select a microbiological testing laboratory please review FSIS' *Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory*.

Attachment A2. Cooking Deviations

Corrective Actions to Perform When a Cooking Deviation Occurs

Cooking deviations occur when an establishment fails to meet its cooking CCP critical limit for endpoint time-temperature, cooking humidity option, or heating come-up time option. Common causes for cooking deviations include product overlap, power failures, or breakdown of cooking equipment. Establishments are required to take corrective actions, as required by the HACCP regulations, regardless of whether the cooking process is addressed through a CCP or prerequisite program. This includes ensuring no product that is injurious to health or otherwise adulterated because of the deviation enters commerce (9 CFR 417.3(a) or (b)).

- **When cooking is addressed through a CCP,** establishments are required to determine the cause of all cooking deviations, no matter how small (9 CFR 417.3(a)(1)), and ensure measures are established to prevent recurrence (9 CFR 417.3(a)(3)). If the cause of each small cooking deviation is not traced and corrected when first noticed, the problem will likely recur and become more frequent and more severe. The establishment should consider an occasional small process deviation to be an opportunity to find and correct a process control problem. Large process deviations or continual small ones always constitute unacceptable risk. Also, continual or repetitive process deviations from the critical limit demonstrate that the establishment is unable to control its process and that its corrective actions are not preventing recurrence as intended.

- **When cooking is addressed through a prerequisite program** and a deviation occurs, establishments are required to reassess their HACCP system to determine whether the newly identified deviation or unforeseen hazard should be addressed and incorporated into the HACCP plan (9 CFR 417.3(b)(4)). Also, an establishment may not be able to continue to support the decision in its hazard analysis that pathogens are not reasonably likely to occur, if it has continual or repetitive deviations from its cooking prerequisite program (9 CFR 417.5(a)(1)).

To assist establishments in determining and supporting product disposition as required 9 CFR 417.3(a) or (b), FSIS is including information regarding potential pathogens of concern during different types of cooking deviations and recommendations for using pathogen modeling and sampling. Establishments should carefully evaluate each deviation as each situation is unique and needs to be evaluated individually. Ultimately, the establishment should rely on the expertise of a processing authority to determine the severity of cooking deviations and subsequent appropriate disposition of the product in question. Knowledge of the specific product and factors that would favor or inhibit the growth of various bacterial pathogens is essential to determine product safety. As stated in the *HACCP Systems Validation Guideline*, the advice of processing authorities should include reference to established scientific principles as well as reference to peer-reviewed scientific data.

Pathogens of Concern During Cooking Deviations

Cooking deviations can allow pathogens that are controlled under normal cooking procedures to become a hazard, depending on the type of cooking deviation (described below) that occurs. Specific pathogens of concern may include:

- *Salmonella,* STEC (in beef products), and *Lm,* which could grow as vegetative cells to levels that overwhelm the Log reductions achieved by cooking.
- *S. aureus,* if allowed to grow to high levels, may produce heat-stable enterotoxins in the food.
- *Bacillus cereus* (*B. cereus*) (in rare cases), if allowed to grow to high levels in the food, may produce a heat-stable emetic toxin in the food or enterotoxins in the small intestine.
- *Clostridium perfringens* (*C. perfringens*) and *Clostridium botulinum* (*C. botulinum*) spore-forming pathogens that can germinate and grow in product held at higher temperatures (*e.g.,* > 80°F).

Again, it is important someone knowledgeable such as a processing authority evaluates each deviation to determine the pathogens of concern.

Three Common Types of Cooking Deviations

When cooking products to lethality, deviations may occur due to three main reasons:

1. The establishment fails to meet a time--temperature parameter in its lethality CCP for meat or poultry products.

2. The establishment fails to maintain sufficient humidity during the cooking step.

3. Slow heating CUT allows product to remain at temperatures that allow pathogen growth (*e.g.*, product remains at temperatures 50°F to 130°F for more than 6 hours; see FSIS Critical Operating Parameters for Cooking Come-Up-Time (CUT), page 23).

Specific recommendations for evaluating each type of cooking deviation, including the pathogens of concern, are provided below. Alternatively, the establishment can provide additional support for the safety of the product (*e.g.,* a journal article, or support from a processing authority). These are general recommendations; the specific responses will vary based on the unique factors of each deviation.

Type 1. Missed Endpoint Time-Temperature

When evaluating product disposition after the process fails to meet an endpoint time or temperature parameter, the first step is to assess whether the process met a different time-temperature combination in the reference table. In some cases, the process may not have achieved an instantaneous lethality temperature (*e.g.,* 158°F for meat) identified in the CCP but may have achieved the dwell time needed for a lower

temperature in the same table (*e.g.,* 154°F for 27 seconds) when considering the total time product temperature was at or above the lower temperature.

Did the process meet a **different validated** time-temperature combination?

- If yes, then product is safe to release.

- If no, then FSIS recommends contacting a processing authority who may help you identify proper D and z values to calculate **integrated process lethality** considering the product come-up -time and come-down-time. One common tool for calculating integrated lethality is the AMI Process Lethality Determination Spreadsheet. If properly conducted, the AMI lethality spreadsheet is a sound scientific approach for determining the overall lethality of a cooking process (Scott and Wedding, 1998). The D-values at the reference temperature for the three main pathogens of concern (*Salmonella* spp. *E. coli* O157:H7, and *Lm*) are generally conservative values and should be valid for most cooked meat ready-to-eat (RTE) processes provided that the product is moist when cooked (high relative humidity). However, if the product is not moist when cooked and the product surface is allowed to dry out during the lethality step, the D-values referenced in the AMI lethality spreadsheet are not valid.

  NOTE: There are many complexities involved in identifying appropriate D and z values needed as inputs for calculating integrated pathogen lethality. FSIS advises establishments to work with a processing authority or someone knowledgeable in thermal death-time values, to ensure they select appropriate values and are properly using the lethality calculator.

- Establishments may consider **recooking** the product, but only if all critical operating parameters (including relative humidity and CUT time) were met during the initial heating and during recook.

  - If the relative humidity option in the scientific support was not applied, the establishment should also follow recommendations for evaluating a Type 2 Deviation: Insufficient Humidity During Cooking described on page 69, or

  - If the CUT parameter was not met, the establishment should also follow recommendations for evaluating a Type 3 Deviation: Long Heating CUT described on page 70, and contact a **processing authority** for assistance.

    NOTE: Cooking deviations that combine a missed time-temperature parameter with a long CUT are complex situations which may require considering *C. perfringens* and *C. botulinum* as described in the *Stabilization Guideline*, in addition to the other pathogens of concern.

- If establishments cannot **recook** the product, they should consider the following alternative actions:

    - Provide **alternative support** (page 55) (*e.g.,* information from a processing authority that includes scientific citations that product is safe to release);

    - **Sample and test the product** (see Product Testing recommendations for Type 1 deviations, page 77); or

    - **Destroy the product** (renderer or landfill).

Type 2. Insufficient Humidity During Cooking

As described on page 16, some bacteria can become more heat tolerant when they are exposed to moderate levels of heat, drying, and other factors. Bacteria can then survive at higher temperatures than they normally would. Below are general recommendations for an establishment to consider when evaluating products after a Type 2 cooking deviation resulting from insufficient humidity (*i.e.,* the relative humidity option in the scientific support was not followed) during cooking.

- Consider **sampling and testing** product for *Salmonella*, *Lm*, and *E. coli* O157:H7 (if a beef product), using a statistically based sampling program as described in Product Testing on page 77.

- If **recooking**, apply a **higher time-temperature** combination validated to achieve lethality in a product with similar intrinsic factors (*e.g.,* water activity).

    - It would not be appropriate to recook the product following FSIS Relative Humidity Options (page 26) without additional support that recooking conditions adequately rehydrate the product surface (see Attachment A6. Cooking Country-Cured Hams, page 90).

    - Under these circumstances, FSIS would need to verify that such scientific support is adequate in the context of the specific product, process, and situation. Examples of acceptable support may include support that:

        - Demonstrates that a validated wet bulb temperature target has been met to ensure lethality. To show that the surface has been rehydrated, the wet bulb target should be higher than the product surface temperature.

        - Includes water activity testing: A water activity increase after recooking (compared to water activity before recooking), may indicate that the surface has been rehydrated.

NOTE: FSIS is not aware of any research validating recooking procedures for products that may have heat tolerant *Salmonella* because of a lack of relative humidity during the initial cook. However, FSIS plans to update these recommendations as more research becomes available.

Type 3. Long Heating CUT

If the total time between 50 and 130°F is longer than hours 6, recooking alone may not be sufficient to ensure the safety of the product. That is because during the extended CUT toxigenic pathogens could grow rapidly (*e.g., S. aureus*), allowing enterotoxins to form. Some enterotoxins are extremely heat-stable and are not inactivated by normal cooking temperatures. Therefore, it is not always possible to recook the product alone to ensure its safety. The establishment should continue to recook the product to address vegetative pathogens (*e.g.,* STEC, *Lm*, and *Salmonella*). It should also provide additional support that heat-stable enterotoxins do not present a hazard in the product after the recooking step.

As noted in Type 1. Missed Endpoint Time-Temperature, cooking deviations that **combine** a missed time-temperature parameter with a long CUT are complex situations that may require considering *C. perfringens* and *C. botulinum* as described in the *Stabilization Guideline*, in addition to the other pathogens of concern. The establishment may want to contact a processing authority for assistance.

To determine product disposition after a long heating CUT deviation, the establishment should:

1. Address growth of vegetative pathogens that do not produce toxins, AND
2. Address the potential enterotoxin formation as described below.

If either hazard is not controlled to safe levels, then product should be destroyed. Further guidance on these two recommendations is provided below:

1. **Address growth of vegetative pathogens:** (*e.g.,* STEC, *Lm*, and *Salmonella*).

    - FSIS recommends that establishments use microbial modeling (page 72) and other information (*e.g.,* scientific journal articles, book chapters, and processing authorities) to estimate growth of *E. coli*, *Lm*, and *Salmonella.*

        - If modeling estimates the growth of vegetative pathogens to be **1-Log or less**, provided the predictive microbial modeling program is validated, modeling is adequate to show that the process prevented vegetative pathogen outgrowth and the establishment can address the potential for enterotoxin formation (see 2 on the next page).

        - If modeling estimates **more than 1-Log growth** of any vegetative pathogen, establishments should **recook product** OR **sample and**

test for vegetative pathogens to determine the safety of the product (see Type 3 deviation recommendations in Product Testing, page 77).

- Many establishments avoid the cost of sampling and testing by recooking the product or consulting a processing authority to identify alternative support that vegetative pathogens are addressed.

- **If product is recooked**, it should be done to a higher time and temperature that has been shown to achieve enough additional Log reductions to address the amount of vegetative cell growth the model predicted. Using a recook procedure that achieves the correct additional Log reduction is important to ensure increased pathogen load will not overwhelm the Log reductions achieved during the recook procedure (see page 72). For example, if predictive microbial modeling showed a 2.5-Log and 3.0-Log increase for *Salmonella* and *E. coli* O157:H7, respectively, in a roast beef product, the recook step should be adjusted so that the cooking time-temperature combination can achieve at least a 9.5-Log reduction of *Salmonella* instead of a 6.5-Log reduction. The AMI Process Lethality Determination Spreadsheet discussed on page 68 may be used to support the cooking time-temperature combination can achieve sufficient Log reductions.

2. **Address potential enterotoxin formation:** (*e.g., S. aureus)* by demonstrating that toxigenic pathogens **did not** grow to levels of public health concern or **produce enterotoxin**.

    - FSIS recommends that establishments use microbial modeling (page 72) and other information (*e.g.,* scientific journal articles, book chapters, and processing authorities) to provide additional information to determine product safety.

        - If predictive microbial modeling estimates a **< 3-Log growth of *S. aureus***, modeling is adequate to show that the process prevented enterotoxin formation provided the predictive microbial modeling program is validated. **If growth of vegetative pathogens is also addressed the product can be released**.
          NOTE: Due to the rapid growth of *S. aureus* in meat and poultry products, modeling for *B. cereus* (which grows slower) is not needed when *S. aureus* growth is controlled (< 3-Log).
        - If microbial modeling estimates a **≥ 3-Log growth of *S. aureus***, then product should be **tested** for *S. aureus* **enterotoxins** A, B, C,

D, and E using a statistically representative sampling procedure. If the product contains non-meat ingredients previously associated with *B. cereus* associated illnesses (*e.g.,* rice, or pasta) and microbial modeling estimates > 3-Log growth of *S. aureus*, then establishments may also want to consider testing for *B. cereus* emetic toxin (Product Testing page 77).

NOTE: As stated previously, **conditions that allow for 3-Log or higher growth of *S. aureus* are a public health concern** (ICMSF, 1996). Furthermore, this level of growth (*i.e.,* 3-Log) for *S. aureus* is consistent with the pass/fail criteria developed by the Institute of Food Technologists (IFT) for the FDA to control for this food safety hazard (IFT, 2003).

*To support safe release of the product, **both** the vegetative pathogens **and** enterotoxin formation must be addressed with supporting documentation. If either hazard is not controlled to safe levels, then product should be **destroyed**.*

Predictive Microbial Modeling

Establishments may use predictive microbial modeling to estimate the relative growth of bacteria during a long heating CUT deviation (Type 3). As explained above for Type 3 heating deviations, modeling results can be used to support various product disposition options including release, recooking, sampling and testing, or destruction provided the model used has been validated. Predictive microbial modeling tools may be used to evaluate product disposition in the event of other types of deviations (*e.g.,* for Type 1 deviations establishments may use the AMI Process Lethality Determination Spreadsheet). However, this section is focused on evaluating product disposition during Type 3 heating deviations due to their complexity.

When performing predictive microbial modeling, it is important that establishments:

1. Use validated models (see examples below):
    - It is not appropriate to rely solely on one model unless the model has been validated for the particular food of interest. A validated cooking model is a model whose predictions have been found to agree with or are more conservative than actual observed results. If a model has not been validated for a particular food of interest, the establishment should provide additional supporting documentation to support the results from the model (*e.g.,* sampling data or comparison with other model results).
2. Enter accurate product formulation information:

- FSIS recommends entering the raw product formulation values for Type 3 Deviations: Long CUT, since the high moisture values at the start of cooking will support faster pathogen growth and therefore represents the worst-case scenario. If using finished product values, establishments should provide reasoning for how that represents the product matrix during CUT.

3. Enter accurate time and temperature information in the model:

   - When entering time and temperatures into the model, the establishment should include all parts of the process, including cooking and recooking CUTs after a Type 1 or 3 cooking deviation. If the establishment does not include all parts of the process, it may underestimate pathogen growth.

   - When determining the temperature, the establishment should take into account both the temperature at the coldest internal area (center) of the product and at the surface of the product.

   - It is important to obtain an internal time and temperature profile of the product, and a wet bulb time and temperature profile of product since wet bulb can be used to describe the product's surface temperature. If an establishment does not have wet bulb temperature data, it can conduct predictive microbial modeling using the internal time-temperature profile of the product, provided that sufficient humidity was used during cooking. However, the establishment should take into account that the product surface temperature will be higher than the center of the product under high relative humidity conditions.

   - For cases with large time gaps between known temperature observations, establishments may consider interpolating to estimate additional time-temperature data points between known observations assuming linear heating. However, if the product temperature dwells or holds between 90 and 120°F (the optimal growth range of *S. aureus*) for an extended period of time, excess *S. aureus* growth could result in a potential hazard in the product being uncontrolled. The establishment should consider the likely accuracy of the predicted growth when making a product disposition determination using linear interpolation.

   - Assume **no *S. aureus* growth above 120°F.**

     NOTE: FSIS has included the time that product remains from 120 to 130°F in the heating CUT option (page 23) to reduce the risk *B. cereus* (a spore-former) could germinate and then grow at these higher temperatures, potentially producing a heat-stable emetic toxin.

4. Address model limitations in a conservative manner:

    - If product characteristics or other conditions are outside the range of the model, accuracy is not guaranteed. Establishments should support how the model results represent the product or the worst-case scenario for the hazard in the product or should compare the results to several other pathogen models and should make decisions based off the model that shows the worst-case scenario (i.e., for *S. aureus* that is the model that estimates the most outgrowth).

NOTE: This guidance contains recommendations for addressing certain limitations in two recommended models at the time the guidance was written. Neither modeling program is controlled by USDA-FSIS and may change. FSIS will update its modeling recommendations in future revisions to be consistent with any changes made to the modeling programs.

Recommended Models

- **Therm 2.0 model** (S. *aureus*, *Salmonella*, and *E. coli* O157:H7).
  The University of Wisconsin Therm 2.0 model is designed to allow processors to input the product's time-temperature profile and it has been validated for estimating the growth of S. *aureus*, *Salmonella*, and *E. coli* O157:H7.

  The three input variables and their ranges for entering into the growth model are provided below (Ingham *et al.,* 2009):

    - **Input variables and ranges:**
        - Temperature profile: 50°F to 110°F (10ºC to 43.33ºC)
        - Date/time: the model allows for entry of calendar date and time
        - Meats:
            - **In meat and poultry products containing salt** (≤ 2.5%), establishments should use the Therm 2.0 model for **Bratwurst** for predicting pathogen growth. This model should be used because it was designed to take into account the bacterial pathogen's behavior in pork sausage and related products that contain higher fat levels, sodium chloride, and spices. For example, adding salt to product will inhibit the competing microorganisms, but allow for greater growth of salt tolerant *S. aureus*; the Therm 2.0 model will predict this. Because the Therm 2.0 model for Bratwurst was developed with data from a pork product, establishments should compare the results with another model, such as the DMRI Staphtox Predictor when evaluating deviations involving poultry products.

- **In meat and poultry products without any added salt**, establishments should use the Therm 2.0 model for **Beef, Pork, or Poultry** based on the product type (Ingham *et al.,* 2009).

- **Overcoming model temperature limitations**: (maximum 110°F)

  - The Therm 2.0 model **does not automatically interpolate** (estimate a linear change) between time-temperature data points entered by the user. Therefore, FSIS recommends establishments enter temperature observations for at least every 30 minutes, or at the lowest time interval available.

  - For temperatures >110°F, substitute 110°F for any temperature above 110°F up to 120°F. *S. aureus* grows fastest at 110°F. The growth rate slows as temperatures increase from 110 to 120°F. Modeling using 110°F for temperatures observed from 110 to 120°F will slightly overestimate the growth of *S. aureus*.

  - For temperatures between 120 and 130°F assume no growth of *S. aureus* (leave this out of the model).

- **DMRI Staphtox Predictor (Version 1.0)** (*S. aureus*)
  The Danish Meat Research Institute's (DMRI) Staphtox predictor (Version 1.0) may also be used to predict the growth of *S. aureus* in meat and poultry products, with added salt (*i.e.,* 1.8% to 4.2%). This model has been validated and was specifically designed to predict the growth of *S. aureus* in different meat product processes based on product composition and changes in temperature.

  The six input variables and their ranges for entering product composition information into the growth model are provided below (Gunvig *et al.,* 2018):

  - **Input variables and ranges:**
    - Temperature profile: 32°F to 105.6°F (0ºC to 40.9ºC)
    - pH: 4.4 – 6.1
    - % sodium chloride (NaCl) in product (based on the total weight of the product formulation): 1.8 – 4.2%.

      NOTE: The model converts % sodium chloride (NaCl) into the % water-phase salt.

    - % potassium chloride (KCl) in product (based on the total weight of the product formulation): 0.0 – 4.2%
    - Sodium nitrite added to product: 0 – 150 ppm
    - % water in final product (as determined through laboratory analysis): 62 – 78%

- **Worst Case Scenario**: FSIS recommends using the values listed below as model inputs for any products where the values are unknown. These values represent a worst-case scenario for the growth of *S. aureus* based on product composition:

    - pH: 6.1
    - % NaCl in product: 1.8%
    - % KCl in product: 0.0
    - Sodium nitrite added to product: 0 ppm
    - % water in final product: 78% (highest allowed in model)
    - Initial level *S. aureus*: 100 CFU/g

- **Overcoming model temperature limitations:** (maximum 105.6°F)

    - For temperatures > 105.6°F (40.9°C), substitute 105.6°F for any temperature above 105.6°F (40.9°C), up to 120°F (48.9°C). The fastest growth in this model is at 105.6°F. As described above, *S. aureus* continues growing at higher temperatures, but the growth rate slows as temperature increases up to 120°F (48.9°C). For modeling, use 105.6°F for temperatures observed from 105.8°F (41°C) up to 120°F (48.9°C), which will slightly overestimate the growth of *S. aureus* (fail-safe).

    - For temperatures between 120°F (48.9°C) and 130°F (54.4°C) assume no growth of *S. aureus* (leave out of the model).

NOTE: Establishments may use the ComBase *S. aureus* model as support. However, this model has not been validated and establishments should follow the recommendation for using models that are not validated (*i.e.,* compare the results of several models and make decisions using the worst-case results) as described above.

Product Testing

As described in the cooking deviation and the microbial modeling recommendations (pages 67-72), if the establishment is unable to support the product disposition through predictive microbial modeling or some other means, the establishment can test a statistically-based number of samples of the product to support its safety. Table 7 identifies the hazards to be tested for according to the type of cooking deviation that took place. These are general recommendations; it is important that someone knowledgeable such as a processing authority evaluate each deviation to determine the appropriate sampling and testing plan.

Table 7. FSIS Recommendations for Product Sampling and Testing After Each Type of Cooking Deviation to Determine Product Disposition

Type of Heating Deviation*	Vegetative Pathogens			Heat-stable Enterotoxins
	Salmonella	*Lm*	*E. coli* O157:H7 **	*S. aureus* Enterotoxins A, B, C, D, and E
1 - Missed Time-Temperature	X	X	X	
2 - Insufficient Humidity	X	X	X	
3 - Long CUT				X
Multiple Types in Combination (*i.e.,* missed time-temperature AND long CUT)	Contact a **processing authority** for assistance evaluating product disposition in a complex deviation which combined multiple types of heating deviation. May need to consider *C. perfringens* and *C. botulinum* in addition to the hazards listed in this table.			

*Cooking deviation Types 1-3 are described on page 66.
***E. coli* O157:H7 testing recommended only for products containing beef. Establishments may also choose to test for other STEC; however, testing for *E. coli* O157:H7 alone is sufficient.

Sampling in Response to a Cooking Deviation

- The establishment should test a statistically representative number of samples per lot depending on the bacterial pathogen. FSIS recommends testing at least 10-15 products per lot as outlined by the two-class sampling plan (Case 11 and Case 13, respectively) per the International Commission on Microbiological Specifications for Foods (ICMSF, 2002).

- If the product contains non-meat ingredients previously associated with *B. cereus* associated illnesses (*e.g.,* rice, or pasta) and microbial modeling estimates >3-Log growth of *S. aureus*, then establishments may also want to consider testing for *B. cereus* emetic toxin.

NOTE: FSIS does not recommend all products to be tested for *B. cereus* emetic toxin due to the low incidence of *B. cereus* in raw meat and poultry. If you are uncertain if the formulation of product affected by a cooking deviation may need to address *B. cereus* emetic toxin as a potential hazard, please contact askFSIS (page 9).

Key Question

Question: Can samples be composited for lab testing?

Answer: It depends on what the sample is being tested for:

- **Enterotoxins? No.** FSIS does not recommend compositing samples to be tested for enterotoxins. Combining multiple samples for a single test (*i.e.,* compositing) could prevent the test from detecting enterotoxins in the product.

- **Vegetative pathogens? Yes.** However, the number of samples that can be combined depends on the pathogen. Additionally, establishments should ensure the lab method has been validated for the larger test portion.

    - *Salmonella* and *E. coli* O157:H7: FSIS recommends compositing up to 3 samples (total 75g) for a total of 5 analyses although establishments may also be able to support compositing up to 15 – 25-g samples (total 375 grams). The establishment would collect 15 samples from different pieces of product. The lab would combine the 25g sample from each of 3 different pieces, to make a 75g composited sample for analysis. The lab analyzes 5 composited samples. When compositing, establishments should ensure the method has been validated for the larger test portion. FSIS has validated a 325g test portion size for its analysis of RTE product samples collected under the RTEPROD program (see the *FSIS' Microbiology Laboratory Guideline Salmonella* Chapter).

    - *Lm:* FSIS recommends compositing up to 5 samples (total 125g) and 3 lab tests total. The establishment would collect 15 samples from different pieces of product. The lab would combine the 25g test sample from each of 5 different pieces, to make a 125g composited sample for analysis. The lab analyzes 3 composited samples. When compositing, establishments should ensure the method has been validated for the larger test portion. FSIS has validated a 25g and 125g test portion size for its analysis of RTE product samples collected under the RTEPROD and R*Lm* programs, respectively (see the *FSIS' Microbiology Laboratory Guideline Listeria monocytogenes* Chapter).

Disposition after Testing Results:

To support the safe release of the product, **every hazard** associated with the type of heating deviation identified (see Table 7) must be controlled for the safe release of product. If any single hazard is not controlled, then product should be **destroyed** (renderer or landfill).

- **Enterotoxins:**
  - If the product tests negative for enterotoxins, product can be **released,** unless insanitary (or other) conditions exist that could adulterate the product (*e.g.,* vegetative pathogens).
  - If any enterotoxin is found, the lot is adulterated, and product should be **destroyed** (renderer or landfill).)

- **Vegetative Pathogens:**
  - If the product tests negative for vegetative pathogens, product can be **released**, unless insanitary (or other) conditions exist that could adulterate the product (*e.g.,* enterotoxins).

    NOTE: It would be inappropriate to test for live *S. aureus* instead of enterotoxin because it is possible for *S. aureus* to produce enterotoxins prior to the death of the bacteria (*e.g.,* during cooking). The food product would still cause illness even though no vegetative bacteria were found.

  - If any vegetative pathogens are found, the lot is adulterated. Product may be:
    - **Recooked** per Type 1 or Type 2 recommendations (pages 67-69); or
    - **Destroyed** (rendered or denatured per 9 CFR 314.3(a), 9 CFR 325.11(a), 9 CFR 325.13(a)(1) through 325.13(a)(7), or 9 CFR 381.95 and sent to a landfill).

Common Mistakes made by Establishments when Evaluating Heating Deviations—and the Recommended Solutions

1) The establishment did not input an accurate internal time-temperature profile into the model. The establishment should be using a data logger or collecting time and temperature data at regular intervals during cooking. The establishment should take into account all parts of the process and temperatures at both the center and surface of the product (Monitoring Endpoint Temperature page 21 and Monitoring Surface Temperature page 24).

2) In Type 1 or 3 deviations with a missed time-temperature parameter, the establishment failed to take into consideration the amount of bacterial growth that could occur during the cooking come-up-time when the cooking cycle was restarted. To address this issue, the establishment should consider both the original come-up-time, the initial cooling, and second come-up-time when the cooking is restarted as part of its modeling.

3) The establishment did not address whether additional growth of *Salmonella*, *E. coli* O157:H7 and *Lm* could have occurred during the Type 1 heating deviation and whether heat tolerance could have developed. To address this issue, when recooking the product, the establishment should increase endpoint time-temperature and apply sufficient humidity (FSIS Relative Humidity Options page 26).

4) The establishment failed to address the amount of growth of *S. aureus* and other bacterial pathogens that could occur on the product's surface. Measuring the temperature both at the product center and at the surface (wet bulb) temperature would address this issue.

5) The establishment failed to take into account the initial levels of *S. aureus* commonly found in raw meat and poultry. Levels of pathogens in raw product are approximately 2-Log. Increases of 3-Log or more could result in conditions where enterotoxin could be formed. Establishments should limit *S. aureus* growth to 2-Log or less, to support safe release of product based on microbial modeling. See Biological Hazards of Concern During Cooking subsection: *Staphylococcus aureus* (page 14) for more information.

Attachment A3. When can Products be Labeled as Pasteurized?

FSIS defines pasteurization as any process, treatment, or combination thereof, that eliminates or reduces the number of pathogenic microorganisms to achieve at least a 5-Log reduction of either *Salmonella* or *Lm,* on or in ready-to-eat (RTE) meat or poultry products in the **final finished package**.

With adequate validation, pasteurization processes **may include** alternative technologies other than traditional cooking (*e.g.,* high pressure processing (HPP)). FSIS considers products **with a raw appearance** that have been treated with a lethality process that renders the product RTE, and that are not post-lethality exposed (*e.g.,* "steak tartare" subjected to a HPP treatment) as pasteurized.

For the product to be labeled "pasteurized," the treatment needs to:

1) Be applied in the final package (product is not post-lethality exposed);
2) Be sufficient to eliminate the number of pathogenic microorganisms to make the product safe for human consumption (so there are no detectable pathogens; RTE), and
3) Be effective for at least as long as the product shelf life.

Irradiation is not a pasteurization process. Although the effect is similar to pasteurization, FSIS considers ionizing radiation a food additive under 9 CFR 424.22.

Establishments may label products as "pasteurized." However, the term "pasteurized" is a **special statement and claim** that needs to be submitted to the Agency for label approval under 9 CFR 412.1(c)(3). The request for label approval needs to include supporting documentation providing evidence that the process achieves a 5-Log reduction of *Salmonella* or *Lm*. For more information see the *FSIS Compliance Guidance for Label Approval*.

Attachment A4. Sources of *Salmonella* Contamination in RTE Products and Best Practices to Address It

Although the *Salmonella* percent positive found in ready-to-eat (RTE) products is low, the presence of *Salmonella* in RTE products may indicate a serious processing and public health problem. Common sources of *Salmonella* in RTE products include:

- Under processing.
- Cross-contamination.
  - Product contact surfaces that are contaminated with *Salmonella*; or,
  - Raw product contact with RTE product.
- Ingredients added to the product or the sauce after the cooking step.
- Improper handling by establishment employees.
- Insect or animal vectors.

Each common source of *Salmonella* contamination on RTE products and best practices to prevent the hazard are discussed in detail below.

Under-Processing

Under-processing occurs when the lethality treatment is not adequate to eliminate the pathogens of concern. For heat-treated product, under-processing may result from inadequate cooking or the development of bacterial heat tolerance due to drying of the product's surface before completion of the lethality step because of inadequate humidity (see FSIS Critical Operating Parameters for Cooking (Time-Temperature Tables) page 23).

Cross-Contamination

Cross-contamination of product can occur from situations such as the following:

- Using the same equipment (*e.g.,* slicers) for both raw and cooked products without complete cleaning and sanitizing of the equipment (as should be addressed in the establishment's Sanitation Standard Operating Procedure (SOP)) after raw production and prior to RTE production.
  - In a for-cause Food Safety Assessment (FSA) in response to a *Salmonella* positive in a RTE head cheese product, FSIS identified equipment used to grind both raw and cooked ingredients for head cheese was not cleaned and sanitized between use for raw and cooked meat potentially resulting in *Salmonella* cross-contamination.

- Placing cooked product on the same surface (*e.g.,* cutting table) as raw product without complete cleaning and sanitizing of the surface before reuse.

- Using the same utensils or containers (*e.g.,* scoops or buckets) for both raw and cooked product.
    - In two FSAs, popped pork skins were most likely contaminated with *Salmonella* when the same buckets and tongs were used for handling both raw and RTE product.

- Condensation or aerosolization in the processing environment.

Best Practices to Prevent Cross-Contamination

Under the HACCP regulations, establishments are required to prevent contamination of product with pathogens after the lethality step. Establishments are required to maintain sanitation in the RTE area to ensure that food contact surfaces are free of contamination from pathogens such as *Lm* and *Salmonella*. Best practices include:

- Completely separating the processing areas by time or space (*e.g.,* scheduling raw and RTE processing on different days).

- Installing separate air ventilation systems that are designed to prevent or minimize condensation and other potential air contaminants. If separate ventilation systems are not feasible, ensure that airflow is directed from the RTE areas to the raw areas.

- Using separate equipment for RTE and raw processing. If this is not possible, schedule use of equipment first for RTE processing and then for raw processing.

- Restricting travel of personnel from the non-RTE area to the RTE area during processing.

- Establishing proper sanitation procedures for equipment that is moved from a non-processing area to an RTE processing area to prevent product contamination from the equipment during operation.

- Avoiding passing raw product through RTE areas and passing RTE product through raw production areas.

- Not allowing RTE product in coolers to come into contact with raw products or surfaces that may be contaminated.

- Discarding products that touch environmental surfaces (*e.g.,* product that has fallen on the floor) if the product cannot be properly reconditioned to ensure that any possible contamination is eliminated.

- During cleaning and sanitizing, following proper sanitation procedures to ensure that no food residue is left on the equipment.

- When adding ingredients to a second container, avoiding any contact between the ingredient container and the interior of the second container.

Ingredients Added After the Lethality Treatment

Salmonella contamination may occur from the addition of uncooked vegetables (*e.g.,* tomatoes and onions), fresh herbs, eggs, spices (that may or may not have been treated to eliminate *Salmonella*), or other ingredients (*e.g.,* nuts, hydrolyzed vegetable protein (HVP)) to processed meat and poultry products after the primary lethality treatment. Sauce that has not undergone a lethality treatment may also be a source of contamination of the finished product, even if the pH is low. The safety of all ingredients added to the product after the lethality step should be considered, even if they are normally considered RTE. In some cases, FSAs determined the addition of seasonings or other ingredients after the cooking step resulted in the contamination of RTE product with *Salmonella*. Failure to identify all steps in a process, including the addition of contaminated ingredients and sauces, can result in an inadequate food safety system.

Outbreaks related to ingredients added after lethality treatment

An outbreak and several recalls of meat and poultry products that were prepared using *Salmonella*-contaminated ingredients exemplify the need to ensure the safety of all ingredients added to the product after the lethality treatment. Examples include a 2010 outbreak-related recall of salami products coated with contaminated pepper (RC-006-2010) and recalls involving products containing HVP that was the subject of an FDA recall (*i.e.,* bacon base, RC-015-2010; beef tornados, RC-016-2010, and beef taquitos and chicken quesadillas, RC-017-2010). RC-055-2010 may have been due to contaminated sauce added to the product after the lethality step. There have also been two recalls of meat and poultry salads containing *Salmonella* contaminated tomatoes recalled by the supplier (RC-033-2011 and RC-79-2011), and Caesar salad containing contaminated cilantro that was the subject of an FDA recall (RC-059-2012). In 2018, there were 12 recalls due to potential vegetable contamination with *Salmonella* and *Lm* that were triggered by an FDA investigation and subsequent recall from the same supplier (RC-092-2018, RC-093-2018, RC-094-2018, RC-095-2018, RC-096-2018, RC-097-2018, RC-098-2018, RC-099-2018, RC-100-2018, RC-101-2018, RC-102-2018, and RC-103-2018).

Requirements and Best Practices to Prevent Hazards from Ingredients Added Post-Lethality

Establishments are required to:

- Ensure all ingredients and other articles used in the preparation of any meat or poultry product are clean, sound, healthful, wholesome and otherwise such as will not result in the product being adulterated (9 CFR 318.6 and 9 CFR 424.21).

- Consider any potential food safety hazards at the step in the process where the non-meat ingredient is 'received' into the food safety system (9 CFR 417.2(a)(1)) and document any controls it needs to support its decisions (9 CFR 417.5(a)(1)) about those hazards.

    - Establishments may choose to use COAs that include negative test results for each lot of the non-meat ingredient as support or may test each lot of non-meat ingredients upon receipt; however, establishments have flexibility and do not have to only rely on testing.

    - Alternatively, establishments may maintain 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).

    - In most cases, a LOG alone would not be sufficient to support the safety of non-meat ingredients added to a product unless they indicate how each lot of ingredients is processed, tested, treated, or otherwise processed to ensure its safety as described in the bullet above.

    - A LOG can be used to support the safety of pre-packaged ingredients (*e.g.,* ketchup or mustard) that have not been associated with previous outbreaks or recalls.

NOTE: Many frozen vegetables are considered NRTE by the producing facility. FSIS recommends establishments that do not receive a COA or LOG as described in the bullets above, treat all frozen vegetables as NRTE and address potential hazards from this ingredient (*e.g.,* by testing each lot of non-meat ingredients upon receipt or applying a validated lethality treatment). Additionally, any vegetables labeled with cooking instructions are to be treated as NRTE.

- Developing procedures to ensure that spices or other source materials are maintained under sanitary conditions and are not contaminated by the introduction of pathogens during repeated opening of the container and removal of the ingredient for use in multiple production lots.

- Taking steps to ensure sauce used for RTE products is also not contaminated by exposure to unclean surfaces, untreated ingredients, or contact with raw products.

Food Handlers

There is a high incidence of salmonellosis in the US. Additionally, some people can be asymptomatic carriers that spread *Salmonella* without appearing ill. Establishment employees that are asymptomatic carriers may be a source of *Salmonella* in RTE products.

Best Practices to Prevent Hazards from Food Handlers

Food handlers, employees, and supervisors at food preparation facilities should:

- Stay home from work when having symptoms of vomiting or diarrhea and wait to resume work until at least 24 hours have passed since the vomiting and diarrhea symptoms ended.
- Wash hands upon resuming duties after breaks and before putting on gloves.
- Wear separate or color-coded frocks in RTE areas of the establishment and control employee traffic between raw and RTE production areas.
- Train employees in proper hygiene practices, and regularly monitor those practices, and retrain employees at least annually.
- Develop and maintain procedures to ensure that sanitizer concentrations in footbaths are monitored and maintained adequately.

Animals

Animals (*e.g.,* birds and rodents) and insects may also contaminate food products with *Salmonella*. It is possible for animal fecal contamination within and outside the establishment to be introduced into the RTE production area.

Best Practices to Prevent Hazards from Animals

- Maintaining an effective pest control program to maintain sanitary conditions and ensure that product is not adulterated (9 CFR 416.2(a)). Rats, mice, birds, and insects are sources of pathogen contamination.
- Product and ingredients should always be protected from contamination and adulteration during processing, handling, and storage (9 CFR 416.14).

Attachment A5. RTE *Salmonella* Self-Assessment Tool

FSIS recommends that establishments use this tool to determine whether they have adopted the appropriate procedures to control *Salmonella,* or whether they should adopt new procedures. If establishments find that they are not meeting the recommendations in this guideline, FSIS recommends they consider changing practices to better control *Salmonella* in the product.

The questions are related to evaluating the following:

- Hazard Analysis/HACCP Plan
- Ingredients
- Corrective Actions in Response to *Salmonella* Positives

Hazard Analysis/HACCP Plan	YES	NO	N/A
1. Have you considered whether *Salmonella* is a hazard reasonably likely to occur (RLTO) in your Hazard Analysis?	□	□	□
2. If you determined that *Salmonella* was RLTO, did you establish CCPs to control or prevent it?	□	□	□
3. If you established CCPs, do you have sufficient supporting documentation to support the effectiveness of the measures you are taking?	□	□	□
4. If you produce roast, cooked, or corned beef, does your process achieve at least a 6.5-Log or other supportable (*e.g.,* 5-Log) reduction of *Salmonella*?	□	□	□
5. If you produce cooked uncured meat patties, does your process achieve at least a 5-Log reduction of *Salmonella*?	□	□	□
6. If you produce cooked poultry, does your process achieve at least a 7-Log reduction of *Salmonella*?	□	□	□
7. If you produce other cooked RTE meat products, does your process achieve at least a 6.5-Log or other supportable (*e.g.,* 5-Log) reduction of *Salmonella* in the product?	□	□	□
8. If you are using an alternative lethality Log reduction target (*e.g.,* 5-Log reduction) do you have additional support such as COA, LOG, combined interventions, or baseline testing?	□	□	□
9. As part of your critical limits, have you identified the target or performance standard that your	□	□	□

process is designed to achieve (9 CFR 417.2(c)(3))?			
10. If you produce cooked products and use a time-temperature table, are you applying humidity during the cooking process?	□	□	□
11. If "no" to the question above, do you have support for why relative humidity is not a critical operating parameter?	□	□	□
12. If "no" to the question above, are you applying a scientific gap for lack of relative humidity? Which one? (fill in here) _____	□	□	□
13. If you produce cooked products and use a FSIS time-temperature table, have you limited product heating come-up-time (50 to 130°F) to 6 hours or less?	□	□	□
14. If "no" to the question above, do you have alternative support for applying a long come-up-time?	□	□	□
15. If "no" to the question above, are you applying a scientific gap for long come-up-time?	□	□	□

Ingredients	**YES**	**NO**	**N/A**
16. Do you add ingredients to the product after the lethality treatment? (if "no," move to the next section)	□	□	□
17. Do you maintain COAs, LOGs, or other information (*e.g.,* sampling data) to support the safety of the ingredients?	□	□	□
18. If you use LOGs, do they indicate how each lot of ingredients is processed, tested, or otherwise treated to ensure its safety?	□	□	□
19. Are the ingredients that you add to the product included in your flow chart or hazard analysis?	□	□	□
20. If you use pre-packaged ingredients that are included in the final package with the finished product do you have LOGs or other information to support their safety?	□	□	□

Corrective Actions in Response to *Salmonella* Positives	YES	NO	N/A
21. Has a RTE product sample tested positive for *Salmonella* from FSIS or establishment testing? (If "no" the assessment is complete).	☐	☐	☐
22. If you control *Salmonella* in your HACCP plan, did you take corrective actions according to 9 CFR 417.3(a)? (If you prevent *Salmonella* through a Sanitation SOP or other prerequisite program, skip to #26).	☐	☐	☐
23. Did you take steps to identify and eliminate the cause of the deviation, according to 9 CFR 417.3(a)(1)?	☐	☐	☐
24. If the cause of the positive result is under-processing, did you immediately review your processing system and bring the process back into compliance?	☐	☐	☐
25. If the cause of the positive result is lack of support for your lethality process, did you change your process or provide additional support for the safety of the process, in light of the positive result?	☐	☐	☐
26. If you prevent *Salmonella* through a Sanitation SOP or another prerequisite program, did you take corrective actions according to 9 CFR 417.3(b)?	☐	☐	☐
27. As part of your corrective actions, did you reassess your HACCP plan according to 9 CFR 417.3(b)(4)?	☐	☐	☐
28. As a result of your reassessment, did you address the pathogen in a CCP or make substantive changes to your prerequisite program?	☐	☐	☐

Attachment A6. Cooking Country-Cured Hams

In October 2018, an establishment recalled cooked country-cured ham product that was associated with a listeriosis outbreak (Recall 084-2018; CDC: Outbreak of Listeria Infections Linked to Deli Ham). FSIS's investigation at the establishment found that the country-cured hams were cooked in a sealed bag **multiple times.** Before being cooked multiple times, the ham was salt-cured and dried, thus reducing its water activity. Additionally, after an initial cooking step in a sealed bag, the ham was removed, drained of its juices, and placed into a second bag; during this process, the ham may have been cross-contaminated from the processing environment. Additionally, the draining of juices may have resulted in drier conditions during cooking. The establishment used FSIS cooking guidance (Appendix A) as scientific support that cooking achieved lethality of pathogens, including *Lm*. However, as discussed on page 12, Appendix A guidance was not intended for lower water activity products cooked under dry conditions or for dried products cooked multiple times. Hence the process may not have been lethal to *Lm* (USDA/FSIS, 2020). Establishments that apply these types of processes must identify other support for their HACCP System (9 CFR 417.5(a)(1) and 9 CFR 417.4(a)(1)).

During the outbreak investigation, FSIS also discovered that several establishments cook country-cured hams **once** under moist conditions using FSIS cooking guidance as support. FSIS cooking guidance was also not intended for lower water activity products cooked even under moist conditions; however, FSIS is not aware of any imminent food safety issues with this practice. Therefore, page 47 (Table 5), includes critical operating parameters that may be applied to cook dried products like country cured hams if they are cooked **once** under moist conditions to rehydrate the surface. While cooking under moist conditions should rehydrate the surface, there is no research validating this process so it is considered a scientific gap. As with other scientific gaps, there is a vulnerability because FSIS's lethality guidance is not designed for processes where the drying step comes before the moist cooking step. This is because cooking under low moisture conditions results in product with a lower water activity. These conditions lead to pathogens, such as *Lm,* becoming more heat-tolerant and the organism could survive the cooking process. To minimize this vulnerability, FSIS recommends:

If the product is cooked **once:**

- Establishments should gather support such as water activity measurements after drying (before cooking), then again after cooking to demonstrate that the water activity increased, and product surface was rehydrated during cooking. This recommendation applies even if the product is cooked-in bag, because the water activity may not be high enough to ensure that pathogens are killed on the product without addition of moisture.

- Establishments should achieve the highest water activity possible during cooking. Values ≥ 0.96 have been shown to prevent bacterial heat tolerance

(Kieboom, *et al.* 2006), but this water activity may not be possible for all processes to achieve.

- Establishments conduct finished product testing for *Salmonella* and *Lm* as part of on-going verification.

Establishments should also ensure that the cooking bag is completely sealed, so that moisture is contained in the bag and the product is not exposed to the environment or contaminants. Cooking bags may be compromised during steps such as molding or shaping. The establishment should have a process to verify the package integrity, and if leaks are observed, the establishment should reprocess/recook the product, using a supported process.

https://www.fsis.usda.gov/contact-us/askfsis

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FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B) December, 2021

Document ID: FSIS-GD-2021-13

This guideline provides information on the Agency regulatory requirements associated with safe production of heat-treated ready-to-eat (RTE) and not-ready-to-eat (NRTE) meat and poultry products with respect to preventing or limiting the growth of spore-forming bacteria and other pathogens. It applies to small and very small meat and poultry official establishments although all meat and poultry establishments may apply the recommendations in this guideline. It relates to 9 CFR 318.17(a)(2), 9 CFR 318.23(c)(1), 9 CFR 381.150(a)(2), 9 CFR 381.150(b), and 9 CFR 417.

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

Table of Contents

Preface

This is a revised version of the *FSIS Stabilization Guideline for Meat and Poultry Products* (Revised Appendix B). It has been updated in response to comments received on the previous version and renamed. In addition, the guideline has been revised to include recommendations from previous versions and new updates based on up-to-date science. The guideline also includes changes to improve its readability.

This guideline represents FSIS's current thinking on these topics and should be considered usable as of its issuance. Establishments that used previous versions of Appendix B as support should either:

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

The information in this guideline is provided to assist meat and poultry establishments in meeting the regulatory requirements. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to industry regarding existing requirements under the regulations. Under the regulations, meat and poultry establishments may choose to implement different procedures than those outlined in this guideline, but they would need to validate and support how those procedures are effective.

This guideline is focused on small and very small plants in support of the Small Business Administration's initiative to provide small businesses with compliance assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, all meat and poultry establishments may apply the recommendations in this guideline. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective Hazards Analysis and Critical Control Point (HACCP) systems. Although large plants can benefit from the information, focusing the guideline on the needs of small and very small establishments provides them with assistance that may be otherwise unavailable to them.

Purpose of this Guideline

This guideline contains information to assist meat and poultry establishments producing products that undergo cooking in complying with the HACCP regulatory requirements in 9 CFR 417. This guideline includes information on:

- Biological hazards during stabilization.
- Regulatory requirements associated with the safe production of stabilized heat-treated and partially heat-treated products.
- Options establishments can use to prevent the growth of *C. perfringens* and other pathogens.

- Processes that do not have validated research available (Scientific Gaps), and options establishments can use until research is available.
- Recommendations for evaluating cooling deviations.
- Resources for alternative support.

Establishments can always seek guidance from State university extension service specialists and HACCP Coordinators on developing programs and plans not provided in this guideline to comply with HACCP regulatory requirements.

History of this Guideline and Reason for Reissuance

In the 1980s, FSIS included prescriptive time and temperature cooling parameters in the regulations for cooked beef, roast beef, and cooked corned beef in response to several outbreaks associated with these products and research performed to determine how to prepare them safely (47 FR 31854; 48 FR 24314). When the Pathogen Reduction/ Hazard Analysis and Critical Control Points (PR/HACCP) final rule published in 1996 and included performance standards for the production of certain meat and poultry products, FSIS eliminated the prescriptive cooling regulations (to allow no growth of *C. botulinum* and no more than 1 log multiplication of *C. perfringens*; 9 CFR 318.17(a)(2), 9 CFR 318.23(c)(1), and 9 CFR 381.150(a)(2)). FSIS converted these former regulations to optional "Safe Harbors" in an appendix to the final rule called "Appendix B" (64 FR 732). Establishments have been using FSIS's Appendix B, as published in 1999, as support for cooling processes for many years. The original requirements and subsequent guidance have been important to prevent human illness outbreaks and ensure the production of safe food.

Over time, FSIS determined that some of its recommendations in the 1999 version of Appendix B were vague, putting establishments at risk of producing unsafe products. Additionally, some elements of the 1999 version of Appendix B guidance were misunderstood or overlooked, resulting in FSIS guidance being applied in ways that increased food safety risks to consumers and potential risks to industry, including the risk of recalls. FSIS also determined establishments were broadly applying the recommendations for operating parameters in Appendix B beyond those meat and poultry products it was originally designed to support.

To provide the needed updates and clarifications, FSIS issued revisions of both its Cooking (revised Appendix A) and Stabilization (revised Appendix B) guidelines in 2017. The 2017 versions of the guidelines took into account new and emerging technologies, processes, and science. FSIS also expanded the information included in Appendix B beyond cooling to include other methods of stabilization. FSIS has updated this guideline in response to comments received on the 2017 version and has included additional options for cooling and hot-holding stabilization support based on updated science and technology. **The Agency is releasing this current 2021 version of the *Stabilization Guideline for Meat and Poultry Products (Revised Appendix B)* to replace all previous versions.**

Changes from the Previous Versions

This guideline dated December 14, 2021 is final. FSIS will update this guideline as necessary should new information become available.

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

For Appendix B, FSIS made changes to specify:

- Cooling options for both RTE and NRTE products that are cooked to lethality are included in Table 1 and incorporate the previous options, 1, 2, 3 and 4 as options 1.1, 1.2, 1.3 and 1.4.
- Cooling options for partially cooked products are included in a separate table (Table 2) and include former Option 1 as Option 2.1.
- Tables 1 and 2 list the critical operating parameters for each option.
- One additional option for partially cooked products, Option 2.2.
- That cooling in stage 1 of option 1.2 from 120 to 80 °F should occur in ≤ 1 hour.
- That the heating come-up-time (CUT) in Option 2.1 for partially cooked products should be limited to ≤ 1 hour between 50 and 130°F. FSIS extended the CUT up to 3 hours in Option 2.2 for partially cooked products, if the product meets the critical operating parameters for concentrations of salt, nitrite, and a cure accelerator sufficient for purpose.
- New options 1.5 – 1.8 that provide additional cooling time during the first stage of cooling.
- That to use Option 1.3, establishments should incorporate at least 250 ppm sodium erythorbate or ascorbate, along with at least 100 ppm ingoing sodium nitrite (either from a purified or natural source such as celery powder).
- That natural sources of nitrite and ascorbate should not be mixed with purified or synthetic sources.
- FSIS removed the recommendation to cool from 120 to 80 ºF 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' Predictive Microbial Modeling Support for 1-Log Cooling Options (page 50).

- 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 (page 80) 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 (See Scientific Gaps as indicated in Table 3 (page 29)), 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 can't follow the options in Table 2.

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

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

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

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

For Appendix B, FSIS removed:

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

In addition to these changes, the guidelines format was restructured to make it easier to use as described in the next section.

How to Effectively Use this Guideline

As explained above in the Changes from the Previous Versions, the guidelines format was restructured to make it easier to use. Specifically, the guideline is organized to include the following topics in the body of the guideline:

- Biological hazards during stabilization.
- Regulatory requirements associated with the safe production of stabilized heat treated and partially heat-treated products.
- Options establishments can use to prevent the growth of *C. perfringens* and other pathogens.
- Processes that do not have validated research available (Scientific Gaps), and options establishments can use until research is available.
- Recommendations for evaluating cooling deviations.
- Resources for alternative support.

Information included in the body of the guideline is intended as scientific support that can be used alone by establishments to meet Element 1 of validation (9 CFR 417.4(a)(1)) and to support decisions in the hazard analysis (9 CFR 417.5(a)(1)).

The following topics are included in Attachments to the guideline:

- Resources for alternative support.
- Recommendations for evaluating cooking deviations.

Information provided in the attachments is not sufficient to use as sole support and additional documentation is needed. For example, this guideline contains attachments with summaries of scientific articles. However, the summaries are not considered adequate support on their own because they do not contain the details of each study. For this reason, establishments must have the full copy of the article on-file as scientific support for their HACCP System. The summaries are provided to help establishments identify journal articles related to their process. Each establishment needs to determine if the operating parameters of a particular study match the establishment's process. Establishments are not limited to using the scientific articles listed and summarized as support. In addition, the guideline contains recommendations for evaluating product safety in the event of a deviation. This information is not considered adequate support on its own because establishments should perform predictive microbial modeling and may conduct sampling and testing to support product disposition. Other information included in attachments is intended to be supplementary.

Questions Regarding Topics in this Guideline

If after reading this guideline you still have questions, FSIS recommends searching the publicly posted Knowledge Articles ("Public Q&As") in the askFSIS database. If after searching the database, you still have questions, refer them to the Office of Policy and Program Development through askFSIS and select **HACCP Deviation & HACCP Validation** as the Inquiry Type or by telephone at 1-800-233-3935.

Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances.

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

Background

What is Stabilization?

Stabilization is the process of preventing or limiting the growth of spore-forming bacteria capable of producing toxins either in the product or in the human intestine after consumption (See Attachment B1. Characteristics of *Clostridial* pathogens page 41 for more information about spore-forming bacteria). Establishments may use a variety of different stabilization processes, such as:

- Cooling.
- Hot-holding (e.g., hot-holding of soups prior to hot-fill packaging).
- Meeting and maintaining certain pH, % brine (salt) concentration in the product, or water activity levels.

Stabilization is an important food safety control of the growth of pathogens in food products.

Products and Processes Covered by this Guideline

This guideline addresses stabilization of meat and poultry products after a full or partial heat treatment is applied.

Establishments may use FSIS Cooling Options in Table 1 for products that do not contain nitrite and erythorbate or ascorbate (i.e., Options 1.1., 1.2. 1.5-1.8), including for cooling of rice, pasta and bean products (see FSIS Support for Application of Options 1.1, 1.2, 1.5-1.8 to Rice, Pasta, and Beans page 61).

Products Not Covered by this Guideline

Fish of the order Siluriformes (e.g., catfish) are considered meat under the FMIA. However, fish of the order Siluriformes and fish products are not covered by this Stabilization Guideline because the options in the

KEY DEFINITIONS

Stabilization is the process of preventing or limiting the growth of spore-forming bacteria capable of producing toxins either in the product before consumption or in the human intestine after consumption. Establishments may use a variety of different stabilization processes, such as cooling, hot-holding, and meeting and maintaining certain pH or water activity levels.

Bacterial spores are dormant cells that can survive environmental conditions that would normally kill bacteria. These conditions include high temperature, high UV irradiation, desiccation, chemical damage, and enzymatic destruction. The extraordinary resistance to such stresses makes spores of particular importance because they are not readily killed by many antimicrobial treatments, including traditional cooking.

guideline have only been validated for livestock products.

Establishments may use *FDA's Fish and Fishery Products Hazards and Controls Guidance* or Section 3-501.14 Cooling of the 2017 FDA Food Code as support for cooling of fish of the order Siluriformes. Cooling guidance found in the FDA Food Code is discussed further in Attachment B6. Other Published Processing Guidelines for Cooling page 77.

For more information on FSIS' regulatory requirements related to fish of the order Siluriformes see *FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products*.

Biological Hazards of Concern During Stabilization

The following section is designed to complement *FSIS' Meat and Poultry Hazards and Control Guide* and to further assist establishments in conducting a hazard analysis for heat-treated meat and poultry products as required by 9 CFR 417.2(a)(1) and for supporting decisions in the hazard analysis as required by 9 CFR 417.5(a)(1).

The primary hazards of concern during cooling and hot holding are:

- *C. perfringens* and
- *C. botulinum*.

Clostridia are Gram-positive, rod-shaped, spore-forming bacteria that can occur as either vegetative cells (active cells that can grow, multiply and produce toxin) or spores (dormant cells that are resistant to heat and other extreme conditions). Vegetative cells can produce spores and spores can germinate back into vegetative cells. *Clostridia* (both vegetative cells and spores) are usually found in soil and water. These are anaerobic organisms; in other words, they can grow without oxygen. ***Clostridia* do not grow well in the presence of normal amounts of oxygen; however, they do not need a complete lack of oxygen to grow well**. This is an important consideration for establishments as they assess hazards, design processes, and assess supporting documentation to prevent *Clostridia* growth and spore formation because it would not be appropriate to assume that *Clostridia* are not a hazard of concern just because oxygen is present. Even products that are exposed to oxygen may support *Clostridia* growth.

Meat and poultry products may become contaminated with *Clostridia* during the slaughter and dressing process and by cross-contamination in the processing environment when insanitary conditions are present. Added ingredients, such as spices and herbs can contribute to the amount of *Clostridia* spores in raw formulated cooked/heat-treated meat and poultry products. For example, in one survey, *C. perfringens* spores were isolated from 80% of 54 different spices and herbs (Juneja and Sofos, 2010).

Why Clostridia Spores Survive Cooking

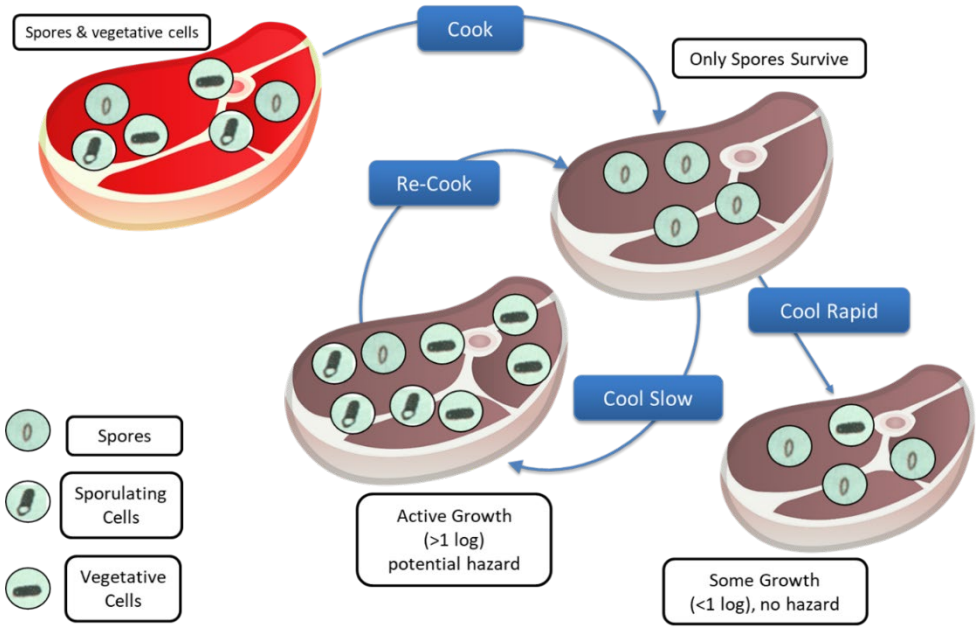
As explained above, raw meat and poultry products may become contaminated with *Clostridia* spores and vegetative cells. Heating meat and poultry products to full lethality (cooking) is generally sufficient to destroy vegetative cells; however, under these same conditions, spores may survive cooking and multiply during cooling when the conditions favor their growth (Figure 1). The destruction of vegetative cells (from *Clostridia* as well as bacteria such as *Salmonella*, Shiga toxin-producing *Escherichia coli* (STEC), and indigenous microflora) during heat treatment leaves little competition for the spore-forming pathogens to grow during cooling. Anaerobic, non-refrigerated conditions facilitate multiplication and growth of spore-forming pathogens. If cooling is rapid, growth can be limited to safe levels. However, if cooling is slow, excessive growth may occur. Similarly, situations where meat and poultry products cooked without reaching full lethality and then cooled could create an ideal environment for growth of *C. perfringens* and *C. botulinum*. This is because cumulative growth can occur over the course of the partial heating and cooling steps. Cooking by the consumer, retailer, or other end user may not eliminate these bacteria or the toxins that form in meat and poultry products especially if they grow to high levels. Therefore, it is important that an establishment producing meat and poultry products control bacterial growth in the products, to the extent possible, before they reach the end user or consumer.

C. perfringens and _C. botulinum_ form spores that can survive cooking.

Spores can germinate and grow during cooling.

Cooling products quickly, will limit pathogen growth and keep food safe.

Figure 1. Schematic depicting how spores can form, germinate, and grow in meat and poultry products after heat is applied.



General Considerations for Designing HACCP Systems to Control the Growth of *Clostridia*

Stabilization in the HACCP System

FSIS has established performance standards in the regulations for the stabilization of specific heat-treated products as listed in Attachment B2. FSIS Stabilization Performance Standards or Targets for *Clostridia* Growth (page 47). These performance standards establish permissible levels of growth of spore-forming bacteria allowed during stabilization.

- RTE cooked beef, RTE roast beef, RTE cooked corned beef must be stabilized to allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 318.17(a)(2).
- RTE uncured beef patties must be stabilized to allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 318.23(c)(1).
- RTE cooked poultry must be stabilized to allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 381.150(a)(2).
- NRTE partially cooked and char-marked meat patties and partially cooked poultry breakfast strips must be stabilized to allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 318.23(c)(1) and 9 CFR 381.150(b).

For products that are not subject to a performance standard, FSIS recommends the following pathogen Log reductions (i.e., targets) be achieved in order to support decisions in the hazard analysis (9 CFR 417.5(a)(1)):

- For other NRTE, heat-treated meat and poultry products, FSIS recommends establishments allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens*.

KEY DEFINITIONS

Performance standards described in this guideline are quantifiable pathogen growth limit requirements set by FSIS for the stabilization of certain meat and poultry products.

Targets described in this guideline are quantifiable pathogen growth limits set by the establishment to produce safe products in the absence of regulatory performance standards.

Critical operating parameters are those parameters of an intervention that must be met for the intervention to operate effectively and as intended. Such parameters may include but are not limited to time, temperature, water activity, concentration, relative humidity, and type of equipment (to the extent that the use of different equipment would result in an inability to achieve the critical operating parameters of the study).

An establishment should identify the performance standard (for products subject to the standard) or specific Log growth target (for other heat-treated products) its process is designed to achieve as part of its HACCP plan or supporting documentation to meet record-keeping requirements (9 CFR 417.5(a)(1)). In addition, according to 9 CFR 417.2(c)(3), establishments must design their critical limits for the critical control points (CCPs) to meet all applicable performance standards or targets.

NOTE: If an establishment uses the stabilization options from this guideline, it does not need to indicate the specific Log growth that its process achieves in its HACCP plan or supporting documentation. It would be sufficient for the establishment to indicate that it uses the critical operating parameters from this guidance document.

CCPs versus Prerequisite Programs

Establishments have flexibility regarding how they address critical operating parameters in their HACCP systems.

- If a critical operating parameter is addressed as part of a CCP, the establishment is required to list the critical limits (9 CFR 417.2(c)(3)), and support the monitoring procedures, and frequencies chosen for monitoring each CCP to ensure compliance with the critical limits (9 CFR 417.2(c)(4) and 9 CFR 417.5(a)(2)). Establishments are required to calibrate process-monitoring instruments as part of ongoing verification activities (9 CFR 417.4(a)(2)). Furthermore, establishments are required to support their verification procedures and frequencies of those procedures per (9 CFR 417.5(a)(2)).

- If a critical operating parameter is addressed in a prerequisite program, and the establishment determines that the implementation of that program results in potential hazards being not reasonably likely to occur, then it must have supporting documentation for the decisions made in the hazard analysis (9 CFR 417.5(a)(1)).

If the establishment does not include the critical operating parameters in its HACCP plan or one or more prerequisite programs and has no documentation to show why they are not needed in its processes, FSIS will likely find that the establishment is not meeting the recordkeeping requirements of (9 CFR 417.5(a)(1)).

Validation, Monitoring, Calibration, and Recordkeeping

It is important the establishment's cooling procedures are designed to ensure all products limit the growth of spore forming pathogens and for the monitoring procedures to be designed to detect a deviation when it occurs. To achieve this, establishments should carefully consider the selection of the critical limit as well as the design of their monitoring procedures.

Establishments are required to validate that their HACCP system works as intended to address these hazards (9 CFR 417.4(a)). For more information on validation see the, *FSIS Compliance Guideline HACCP Systems Validation*. To understand the situations

when both RTE and NRTE products would be considered adulterated due to *Clostridia* outgrowth under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA), refer to Attachment B2., subsections: What is the public health concern of *C. perfringens* and *C. botulinum* in RTE Products? (page 48) and What is the public health concern of *C. perfringens* and *C. botulinum* in NRTE Products (page 49).

Below are specific considerations for monitoring the critical operational parameters of product temperature.

- While cooling is a continuous process, FSIS recommends that establishments monitor temperature in two distinct temperature intervals, called stages, to better document pathogen control. This does not mean that cooling starts and stops at each of these stages. However, monitoring is performed at two different points. The first stage of cooling corresponds to the optimal growth temperatures for pathogens of concern (see Appendix B1. Subsection: Product Characteristics that Affect Clostridia Growth, page 42). Reducing time that the product spends in the first stage of cooling provides greater pathogen control. The second stage of cooling takes the product temperature down to the point where pathogens cannot grow, so it needs to be monitored as well.

KEY QUESTION

Question: Are establishments *required* to use this Stabilization Guideline as support for cooling meat and poultry products?

Answer: No. Establishments are **NOT required** to use this guideline as scientific support for cooling and stabilization processes. Establishments may choose to adopt different procedures than those provided in the guideline; however, they would need to support that those procedures are effective to meet validation requirements and support decisions in their hazard analysis (9 CFR 417.4(a)(1) and 9 CFR 417.5(a)(1)). A few resources that may be used as alternative support for cooling processes have been included in this guideline, see Customized Processes and Alternative Support (page 26). (pag26).

- FSIS recommends establishments measure the temperature of the product throughout cooling. If the scientific support in their validated system identifies multiple stages of cooling, establishments must ensure product is chilled to meet the time limit for each stage. During initial validation, establishments should initially gather sufficient time-temperature data to understand the rate of temperature change in each stage of cooling. For example, the establishment should determine whether the product cools down quickly at first and then takes longer as the process continues, or if it cools at the same rate throughout the entire process. The rate of temperature change throughout cooling can have a significant impact on the amount of growth of *C. perfringens* and *C. botulinum*. Even if two processes take the same total amount of time to chill product when the product starts at the same temperature, if the cooling rate is different, then

the amount of pathogen growth can vary significantly. FSIS recommends establishments gather time-temperature data in 15- to 30-minute increments when the product temperature is between 130°F and 80°F. The time-temperature data should be in 30- to 60-minute increments when the product temperature is between 80°F and final temperature (40°F or 45°F depending upon the option used).

  - This is particularly important for FSIS Option 1.2, since *C. perfringens* grows fastest at temperatures between 120 and 80°F. However, establishments are not required to demonstrate that every lot of the product is chilled from 120 to 80°F in one hour or less, if data is gathered during initial validation and as part of ongoing verification to support a reduced monitoring frequency (see *FSIS HACCP Systems Validation Guideline*).

  - If establishments choose not to measure each stage of cooling, they should recognize that a deviation may affect additional product and pathogen modeling may not be an available option to determine product disposition.

- In addition, as part of the initial validation, FSIS recommends that the establishment use worst-case scenarios to ensure that the product will meet the critical operating parameters on an ongoing basis. Conditions affecting consistent cooling include:
  - Size, shape, and weight of product;
  - Stacking/storage in the cooler and the amount of product in the cooler;
    - For example, a relatively empty cooler might not cool at the same rate as an overfilled cooler.
  - Air velocity and initial temperature of the cooler/freezer; and
  - Product composition (*e.g.,* fat level and moisture content).

Worst-case scenarios should take into account all of these factors (*i.e.,* largest size or weight product, fullest cooler, highest initial cooler temperature, etc.). For more information on factors that affect product cooling rate, see Attachment B4. Steps an Establishment Can Take to Cool Products More Rapidly (page 63).

Establishments producing stabilized meat and poultry products are required to have sufficient monitoring equipment, including recording devices, to assure that the critical operating parameters of the stabilization processes—including time, temperature, and pre-cooling conditions—are being met (9 CFR 417.5(a)(2)). The establishment should take the normal variation of the monitoring equipment into account when designing the critical limits. For example, if a minimum internal temperature of 140°F is necessary to control pathogen growth while hot-holding a product and the thermometer has an accuracy of ± 2°F, the critical limit should be set no lower than 142°F. The written reasoning and equipment specification materials are required to be kept as part of the establishment's supporting documentation (9 CFR 417.5(a)(2)).

In addition, establishments are required to maintain documents supporting the selection of monitoring procedures and associated frequencies (9 CFR 417.5(a)(2)). It is important that establishments take into account variation within the cooling process

when developing monitoring procedures to ensure they are sufficient to identify any deviations. Ultimately, the establishment should ensure that the whole HACCP system is operating as intended to produce a safe and wholesome product.

Product Characteristics and Processes to Control Clostridia Growth

Several factors affect the growth of *C. perfringens* and *C. botulinum* during stabilization. These include the:

- Product time-temperature profile.
- pH.
- % brine concentration in product.
- Type and concentration of phosphates (wt/wt basis).
- Water activity (a_w).
- Type and concentration of organic acid salts (e.g., lactate/diacetates and others).
- Ingoing sodium nitrite and erythorbate or ascorbate concentrations.

For more information on these factors—including the use of natural sources of nitrite and ascorbate—which effect *Clostridia* species growth see Attachment B1. Characteristics of *Clostridial* Pathogens (page 41). Much of the scientific support establishments can use to validate their process will include one or more of these factors. For more information on scientific support see FSIS Options for Stabilization (page 21) or Customized Processes and Alternative Support (page 27) of this guideline.

FSIS Critical Operating Parameters for Stabilization (Revised Appendix B)

Establishments have many options for the types of scientific support documentation that can be used to demonstrate that their stabilization process results in acceptable levels of *Clostridia* growth. Product characteristics (e.g. pH) and specific cooling schedules (e.g. Appendix B cooling options) are commonly used as critical limits. Product sampling results may not be used as scientific support for a stabilization process, because these results do not provide information regarding the level of growth allowed by the process.

NOTE: FSIS is aware that several common processes cannot achieve the critical operating parameters in this guideline and scientific research is not readily available to support several common processes. For information on these processes/resultant products see Scientific Gaps Identified by FSIS (page 27) of this guideline.

Product Characteristics as Critical Limits

If heat-treated meat and poultry products are produced in a manner such that the final product has a certain specific characteristic or characteristics, then the growth of *Clostridia* is inherently inhibited; see Attachment B1. Characteristics of *Clostridial* Pathogens page 41 of this guideline. Establishments may use any one of the specific characteristics listed below as a sole critical limit to demonstrate *Clostridia* outgrowth is controlled provided, the characteristic is achieved *before* cooling:

- **pH**: pH of 4.6 or less; or
- **Brine Concentration in Product**:10% or more; or
- **Water activity (a_w)**: A water activity of 0.93 or less.

KEY DEFINITIONS

Brine Concentration is a measure of the amount of salt in the water phase of the product. Brine concentration can't be determined by the formulation; it is a value calculated from the total salt content and total water content values obtained by a lab analysis.

$$\%\ Brine = \frac{(Total\ Salt)}{(Total\ Salt + Total\ Water)} * 100$$

Refer to FSIS Processing Inspectors' Calculations Handbook Chapter 14 for more information.

To use any of the above characteristics as a critical limit, it is very important that the product achieves the target value quickly, throughout the entire product, and *before* cooling. Establishments that use a marinade or other solution to lower the pH of their product should be aware that it can take time for the product to equilibrate (balance) to the pH of the solution. If a product takes too long to equilibrate, significant growth of *C. perfringens* and *C. botulinum* can occur (see Chitterlings Example below).

Importance of Achieving target pH or water activity before cooling: Chitterlings Example

FSIS verification activities have identified a trend in establishment sampling results that show high levels of *C. perfringens* (2 to 4-Log CFU/g) in chitterlings that establishments try to stabilize using low pH brine. FSIS analyses uncovered a recurring incorrect assumption by establishments that the pH of the chitterlings is reduced to ≤ 4.6 as soon as the brine is added to the hot chitterlings, when it actually may take several hours for the pH to be reduced, during which time the product is cooling and outgrowth of *C. perfringens* is occurring. As stated above, products should achieve a pH ≤ 4.6 *before* cooling to achieve food safety control. These findings are important because the levels of *C. perfringens* found through testing indicate growth may occur at a level of public health concern when FSIS's critical operating parameters are not followed.

Establishments that use pH or a_w as critical operating parameters for stabilization, may still need to cool their product in a timely manner (i.e., continuously) depending on the final pH or a_w. Products that use low pH for stabilization should ensure the product has equilibrated prior to cooling. If the product cannot be equilibrated prior to cooling, then the product should be cooled using different scientific support such as one of the cooling options in this guideline.

Establishments that choose to stabilize through reduced water activity after a cooking lethality treatment should ensure that product temperature remains at 140°F or higher until water activity decreases below the growth limit of *Clostridium perfringens* and *Clostridium botulinum* (< 0.93) to prevent outgrowth as discussed. Establishment may be able to monitor oven temperatures in lieu of product temperature as discussed in the *2020 Cooking Guideline*.

Product stabilized by one of these characteristics should be cooled continuously because the products could become contaminated with *Listeria monocytogenes* (*Lm*) or *Staphylococcus* (*S. aureus*) during cooling, and these pathogens may be able to grow in the product depending on the final pH or a_w. For example, while *C. perfringens* and *C. botulinum* cannot grow in products with an a_w < 0.93, *S. aureus* can grow in products stored aerobically with an a_w as low as 0.86 (ICMSF, 1996). If FSIS collects a RTE sample that is positive for *Lm* during cooling, FSIS will verify whether the establishment has identified and eliminated the root cause of the incident as part of corrective actions (9 CFR 417.3(b)) and that the establishment can still support its cooling procedure.

FSIS Hot-Holding Options

Hot-holding is the process of holding meat and poultry products that have been cooked to full lethality at hot temperatures (typically above 130°F) prior to distribution. Often, products such as meals or meat pies are held at hot temperatures and then shipped hot to customers (either consumers or to retailers, such as convenience stores) for immediate consumption. Soups may also be hot-held prior to hot-filling into the final packaging. FSIS is including in this guideline recommendations for hot-holding that were previously found in FSIS Directive 7110.3 *Time/Temperature Guidelines for Cooling Heated Products,* which has been cancelled.

Hot-holding Temperatures

Uncured cooked products should be held for:

- Up to 4 hours if kept above 130°F, or
- An extended period if kept above 140°F.

If product drops below 130°F for over 30 minutes, the processor should:

- Continuously cool it to meet the critical operating parameters of the chosen support document,
- immediately reheat it to 160°F, or
- Discard it.

NOTE: Establishments should choose a hot holding critical operating temperature above 140°F unless they have established consistent temperature control over every portion of the product. Thus, establishments should maintain product above 140°F when in transit, in the absence of container temperature monitoring, and in similar cases where control procedures are not established and monitored. Establishments should also have ongoing communication with the retailer to support that the product is being hot-held appropriately.

Intermediate Holding Temperatures

Occasionally, some establishments will need to hold product at an intermediate temperature (< 60°F) prior to completion of cooling. When this occurs, FSIS recommends:

Products are heated above 155°F, then promptly cooled from 130°F to 60°F within 2 hours. These products may be held for up to 4 hours, if they are:

- Kept below 60°F during the 4 hours,
- Protected from post-cooking contamination, and
- At the end of the 4-hour holding period, are cooled to 40°F within 2 hours.

FSIS Cooling Options

Tables 1 and 2 summarize all of the FSIS cooling options that limit the growth of *C. perfringens* to ≤ 1.0-Log_{10} colony forming units per gram[1] (CFU/g) and allow for no multiplication of *C. botulinum*. These options are intended for products that are cooled in a continuous manner and do not apply to processes where cooling starts and stops multiple times or processes where the product is cooked to a full lethality, cooled, and then partially heat-treated and cooled again. For processes with multiple heating steps, FSIS recommends establishments use microbial modeling to design custom cooling schedules as described in Attachment B5. Predictive Microbial Modeling (page 64).

Gray boxes in Tables 1 and 2 are parameters that changed from the 1999 version of Appendix B or are new. The food safety significance of these changes is explained on page 28 of this guideline. FSIS considers the cooling options in Tables 1 and 2 to be validated process schedules.[2] Establishments that struggle to meet any of the cooling options in Tables 1 and 2 may find Attachment B2. Stabilization Requirements for Specific Meat and Poultry Products (page 47) useful. Other establishments may use processes that FSIS has identified as a Scientific Gap (page 27). Further information about using FSIS's Cooling Tables is included below.

Importance of Pathogen Modeling for Multiple Cooling Steps: Tamales Example

Many establishments produce a meat or poultry product that involves multiple heating and cooling steps. One example is an establishment that will cook meat to lethality and then cool the meat product. During that first cooling, C. perfringens may grow up to 1-Log.The establishment will then reheat the meat product, such as a tamale filling. The tamale with the filling will be heated and then cooled. Spore-forming pathogens, already at 1-Log of growth from the first cooling will then have the opportunity to grow during non-lethal reheating and the 2nd cooling. This could result in sufficient growth to create a public health concern. Establishments that choose to reheat a meat or poultry product may be able to design the process so that the cumulative growth from all of the heating and cooling steps is less than 1-Log. In order to design a process with multiple heating and cooling steps, FSIS recommends the establishment use predictive microbial models. For more information on how to perform predictive microbial modeling for multiple cooling steps see the Section titled Using Predictive Microbial Models to Assess Growth of Clostridia when a Process Incorporates Multiple Heat Treatments page 69 of this guideline.

[1] In the rest of this document, Log_{10} colony forming units per gram (Log_{10} CFU/g) will be annotated simply as "Log." All notations of "Log" should be read as in the unit Log_{10} CFU/g unless other information is provided.

[2] The scientific research and data used to develop each option is included in Attachment B3. FSIS' Predictive Microbial Modeling Support for 1-Log Cooling Options, page 68.

To Use FSIS Cooling Tables 1 and 2:

First, choose the applicable table.

Table 1 should be used if the product is cooked to full lethality (RTE or NRTE).

- Cooked to full lethality refers to achieving lethality following validated critical operating parameters such as those in the *FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A)*. FSIS recognizes that products may continue to be cooked for longer dwell times or to higher temperatures for quality reasons. To apply Table 1, the establishment must support that its products meet all critical operating parameters from their chosen scientific support for cooking to lethality. For example, if the supporting document is the *FSIS Cooking Guideline*, the cooking process must address relative humidity and come-up-time (CUT), in addition to internal endpoint time-temperature.

- Products that receive a lethality treatment that achieves sufficient Log reduction of *Salmonella* may be classified as RTE or NRTE as long as they are not defined by a standard of identity as a RTE product. For more information on product reclassification see Attachment 1.2 on pages 22-23 and Appendix 1.2 on pages 28-29 of the 2014 *FSIS Compliance Guideline: Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products*.

Table 2 should be used if the product does not receive a full lethality treatment (NRTE).

- Many products may be heated during processing to temperatures that do not achieve full lethality. These products are also referred to as partially heat-treated. Examples include smoked breakfast sausages, smoked pork bellies, and par-fried breaded patties or nuggets (cooked enough to set the breading).

- Table 2 includes heating CUT as a critical operating parameter to control the cumulative outgrowth of *C. perfringens* and *C. botulinum* during the entire process, since any pathogen growth during heating will not be eliminated due to the lack of a full lethality time-temperature (See Why *Clostridia* Spores Survive Cooking page 12).

Second, choose the option that matches the process, and follow all critical operating parameters.

- To use the FSIS Cooling Options as support for decisions in the hazard analysis, establishments must follow all critical operating parameters in the chosen option. If an establishment does not follow all critical operating parameters of an option, it should provide support for why that option should still limit growth of *C. perfringens* to ≤ 1.0-log and allow for no multiplication of *C. botulinum.*

- Temperatures referred to in Tables 1 and 2 are internal product temperatures. However, establishments may provide support for monitoring surface temperatures of **intact** products (such as beef brisket or a picnic shoulder that is not injected or vacuum tumbled). The internal temperature of product that is deboned and rolled or **non-intact** should be taken at the coldest point of the product interior (See Key Definitions to the right for an explanation of intact vs. non-intact).

- Monitoring for cooling is performed at two different points. The first stage of cooling is the most important for stabilizing the product, as it is the optimal growth temperature for pathogens of concern. If an establishment can shorten the time it takes to complete the first stage of cooling, the establishment may add the remaining time to the second stage of cooling. However, the total cooling time would remain the same as the original option.

For helpful tips on how to cool products faster, refer to Attachment B4. Steps an Establishment Can Take to Cool Products More Rapidly (page 63).

In the event that a process deviates from FSIS's Cooling Options, the establishment may use its monitoring records to perform predictive microbial modeling to develop support for product disposition. For more information see Attachment B5. Predictive Modeling, subsection Corrective Actions to Perform When a Cooling Deviation Occurs, page 71.

KEY DEFINITIONS

Intact refers to products where the interior remains protected from pathogens migrating below the exterior/outside.

Non-Intact refers to products where pathogens may have been introduced below the surface. Examples include products that have been mechanically tenderized or vacuum tumbled.

Come-up-time (CUT) refers to the amount of time product temperature is between 50-130°F while heating.

Table 1. FSIS Cooling Options for Products Cooked to Full Lethality[3,4,5]

Option	Critical Operating Parameters			
	Pre-Cooling Conditions	1st stage of cooling (temperature reduction/time)	2nd stage part of cooling (temperature reduction/time)	Total cooling time
Option 1.1		130 to 80°F ≤ 1.5 hours	80 to 40°F ≤ 5 hours	≤ 6.5 hours
Option 1.2	Chilling must begin within 90 minutes after the cooking cycle is complete	**120 to 80°F ≤ 1 hour**	80 to 55°F ≤ 5 hours; Continuous chilling until 40°F	≤ 6 hours Plus time to reach 40°F
Option 1.3	≥ 100 ppm sodium nitrite[6] + **≥ 250 ppm sodium ascorbate or erythorbate**	130 to 80°F ≤ 5 hours	80 to 45°F ≤ 10 hours	≤ 15 hours
Option 1.4	**≥ 40 ppm sodium nitrite[7] and ≥ 6% brine concentration OR $a_w \leq 0.92$**	**120 to 40°F ≤ 20 hours; Continuous temperature drop**	**NA**	**≤ 20 hours**
Option 1.5		**130 to 80°F ≤ 2 hours**	**80 to 40°F ≤ 5 hours**	**≤ 7 hours**
Option 1.6		**126 to 80°F ≤ 1.75 hours**	**80 to 55°F ≤ 4.75 hours; chilling until 40°°F**	**≤ 6.5 hours**
Option 1.7	**pH ≤ 6.0**	**126 to 80°F ≤ 2.25 hours**	**80 to 55°F ≤ 3.75 hours; Continuous chilling until 40°F**	**≤ 6 hours**
Option 1.8	**pH ≤ 5.8**	**126 to 80°F ≤ 2.75 hours**	**80 to 55°F ≤ 3.25 hours; Continuous chilling until 40°F**	**≤ 6 hours**

[3] To apply this table, the establishment must support that products meet all critical operating parameters identified in their chosen scientific support documentation for cooking to lethality.
[4] Options and operating parameters that changed since 1999 Appendix B are bolded and shaded grey.
[5] FSIS's Scientific Support and references used to develop these options can be found in (Attachment B3. FSIS' Predictive Microbial Modeling Support for 1-Log Cooling Options, page 68).
[6] Nitrite and erythorbate/ascorbate may be added using natural or synthetic sources (page 45).
[7] This option does not require a cure accelerator due to the high brine concentration inhibiting spore outgrowth. Nitrite is optional if the product has a $a_w \leq 0.92$.

Table 2. FSIS Cooling Options for Products that Do NOT Receive a Full Lethality[8,9]

Option	Critical Operating Parameters			
	Pre-Cooling Conditions	**1st stage of cooling**	**2nd stage of cooling**	**Total cooling time**
Option 2.1	**CUT between 50- 130°F ≤ 1 hour**	130 to 80°F ≤ 1.5 hours	80 to 40°F ≤ 5 hours	≤ 6.5 hours
Option 2.2	**CUT between 50-130°F ≤ 3 hours; and ≥ 2% salt; and ≥ 150 ppm sodium nitrite[10] and cure accelerator or natural source of ascorbate (sufficient for purpose)**	**130 to 80°F ≤ 1.5 hours**	**80 to 40°F ≤ 5 hours**	**≤ 6.5 hours**

[8] Options and operating parameters that changed since 1999 Appendix B are bolded and shaded grey.
[9] FSIS' Scientific Support and references used to develop these options can be found in (Attachment B3. FSIS' Predictive Microbial Modeling Support for 1-Log Cooling Options, page 68).
[10] Nitrite and erythorbate/ascorbate may be added using natural or synthetic sources (page 45).

Food Safety Significance of Changes

Why do partially cooked products have fewer options for cooling (only those in Table 2)?

In general, for partially cooked meat and poultry products, the cooling options are more limited because without a validated lethality step, cumulative growth of *C. perfringens* and *C. botulinum* can occur over the course of the partial cooking or heating and cooling steps. Cumulative growth allows for more vegetative cells in the finished product and having a vegetative high cell count increases illness risk.

To limit cumulative growth, FSIS recommends a heating CUT for partially cooked products. CUT as used in this guideline refers to the time the product temperature is between 50 and 130°F during heating, because this is the primary range of concern for pathogen growth. While CUT is important for fully cooked products, the CUT is not addressed in stabilization options for fully cooked products cooked to full lethality, because all vegetative cells of *C. perfringens* and *C. botulinum* are destroyed by the cooking process. Note that on page 24 of the FSIS Cooking Guideline, FSIS has recommended CUTs for fully cooked products cooked to full lethality to ensure *S. aureus* growth is controlled.

Why did FSIS change Option 1.2 to include a first-stage of cooling (120 to 80 °F in ≤ 1 hour)?

When Appendix B was developed as a safe harbor to the stabilization performance standards, FSIS added the note that "if product remains between 120 to 80°F more than one hour, compliance with the performance standard is less certain." However, validated pathogen modeling and research from 2018 supports that cooling between 120 to 80°F for 3-4 hours can result in 2 to 3-Log growth of *C. perfringens* (Smith, *et al.*, 2018), which would definitely exceed the performance standard or target. One outbreak occurred from a RTE large diameter turkey loaf product that can take several hours to cool between 120 to 80°F. FSIS has included options in Table 1 that extend the time during 120 to 80°F as much as possible when considering other intrinsic product characteristics, such as pH.

Why does Option 1.3 include the recommendation to add at least 250 ppm erythorbate or ascorbate, in addition to the original recommendation to add at least 100 ppm nitrite?

Research from 2015 found that erythorbate or ascorbate is needed in addition to sodium nitrite to control the growth of *C. perfringens* to safe levels.

Why does Option 1.4 no longer apply to products formulated with ≥ 120 ppm of sodium nitrite or its equivalent and a brine concentration of 3.5% or more?

Currently available validated pathogen modeling programs have indicated these parameters may result in > 2.0-log *C. perfringens* growth.

Why does Option 1.4 no longer have an option for the first stage of cooling to cool from 120 to 80°F in 2 hours or less?

FSIS determined that these parameters were based on *S. aureus* growth on the surface of the product which is not the hazard this Option is designed to address. Instead, establishments should demonstrate a continuous drop in temperature without the need to demonstrate any particular time-frame is met between 120 to 80°F.

Customized Processes and Alternative Support

FSIS recognizes that not all products can be stabilized using the FSIS critical operating parameters included in this guideline. To assist establishments in stabilizing their products, FSIS has identified resources that could be used as scientific support. Resources in the attachments include information on the following:

- **Customized Cooling Schedule:** Establishments may design a customized cooling plan with multiple cooling and heating steps using validated pathogen models. See Attachment B5. Predictive Microbial Modeling page 64.
- **Processing Guidelines**: Other government agencies have published validated cooling guidelines that establishments could use as scientific support. See Attachment B6. Other Published Processing Guidelines for Cooling page 77.
- **Challenge Studies:** Establishments could conduct challenge studies to determine if their proposed process would meet the performance standard. See Attachment B7. Using Challenge Studies to Support Alternative Stabilization/Cooling Procedures page 78.
- **Journal Articles:** Establishments could identify a published journal article that shows a specific process meets the performance standard and use this as scientific support. See Attachment B8. Using Journal Articles to Support Alternative Stabilization/Cooling Procedures page 80.

Scientific Gaps Identified by FSIS

FSIS has identified several common stabilization processes that can't achieve the critical operating parameters included in this guideline. FSIS encourages establishments to conduct challenge studies when other support is not available (page 78). However, the Agency realizes it may not be cost effective for establishments to conduct individual challenge studies for commonly produced meat and poultry products. To address these common processes that lack readily available scientific support, FSIS has identified and communicated scientific gaps and is working to facilitate filling these gaps. FSIS posted research priorities on its website to communicate clear research needs with USDA Agricultural Research Service (ARS) and academic researchers. As additional data becomes available, FSIS will update the recommendations for these scientific gaps with the latest available scientific support.

An establishment producing products **using processes that fall under an identified scientific gap** may continue to use the critical operating parameters in this guideline as scientific support (see Table 3). Table 3 also describes specific vulnerabilities with using the gaps as scientific support and recommends steps to reduce the vulnerabilities. In addition to those specific vulnerabilities, FSIS has the following concerns with establishments continuing to process products using the critical operating parameters in Table 3:

- 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.

- As additional data becomes available, FSIS will change the recommendations for processes that fall under one of these scientific gaps.

NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Additionally, Products Not Covered by this Guideline would NOT be adequately supported by the critical operating parameters listed in Table 3.

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*Scientific gaps are processes which have **not** been validated to achieve stabilization and address all potential hazards during cooling, but establishments may continue to use this guidance as support for those processes to allow additional time for research. to be conducted.*

FSIS will update this guideline as more research becomes available and new options can be developed.

NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 3).

Table 3: Scientific Gaps where Critical Operating Parameters from Older Guidance May be Used

Scientific Gaps	Example Products	Critical Operating Parameters from Older Guidance	Vulnerability with Continuing to Follow Parameters from Older Guidance

1. Large mass non-intact products that cannot cool quickly enough to follow the new options in Table 1.
 	
Processes that meet this gap include all of the following:
• Cooked to full lethality.
• Non-intact.
• Large product size or weight
  ○ >4.5 inches or
  ○ >8 pounds.
	Non-intact turkey breast > 8 pounds or roast beef that is > 4.5 inches thick.	Chilling begins within 90 minutes after the cooking cycle is complete.
		
		Cooling occurs from 120 to 55°F in ≤ 6 hours.
		
		Continuous chilling until 40°F.
			These parameters do not take into account the amount of time product remains between 120 to 80°F. If products take more than 1 hour to cool between 120 to 80°F, excessive growth of *C. perfringens* and *C. botulinum* may occur, particularly if products are non-intact. In the event of a deviation, if product takes more than 1 hour to cool between 120 to 80°F, it is unlikely that pathogen modeling will support product safety, and sampling may be needed.
			
			To minimize this vulnerability, establishments may choose to validate any of the following:
			• If possible, limit the time between 120°F to 80°F to no more than 2.5 hours or between 80°F and 55°F for more than 3.5 hours (6 hours total cooling time) to limit *C. perfringens* growth to 2-log or less. If that is not possible, identify the shortest amount of time it is thermodynamically possible to go from 120 to 80°F, and monitor this point on a routine basis.
			• Conduct finished product testing for *C. perfringens* (see page 74).
			• Add antimicrobials.
			• Reduce product diameter or thickness.
			• Perform a challenge study or pathogen modeling for particular product.

NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 3).

Scientific Gaps	Example Products	Critical Operating Parameters from Older Guidance	Vulnerability with Continuing to Follow Parameters from Older Guidance
2. Partially heat-treated, smoked products, that contain nitrite and erythorbate/ascorbate and have long come-up and cooling times in Table 2. **Processes that meet this gap include *all of* the following:** • Partial heat treatment, Smoked. • Slower CUT (greater than 3 hours in Option 2.2). • Formulated with at least 100 ppm nitrite or nitrate (synthetic or natural). • Formulated with at least 250 ppm 250ppm erythorbate or ascorbate (synthetic or natural).	Hams containing nitrite and erythorbate or ascorbate.	Apply Option 1.3 to this partially heat-treated product* specifically: 130 to 80°F in ≤ 5 hours and 80 to 40°F in ≤ 10 hours, with 15 hours total cooling time. ***NOTE:** No CUT parameter.	These parameters may allow excessive cumulative growth of *C. perfringens* during heating and cooling if CUT is not addressed, although smoke, nitrite, and erythorbate/ascorbate may help limit growth. To minimize this vulnerability, establishments may choose to validate any of the following: • Cook the product to lethality, which would allow a CUT of up to 6 hours between 50-130°F per FSIS Cooking Guideline. This product may then apply Option 1.3 without being in a Scientific Gap for Stabilization. • Perform a challenge study or pathogen modeling for a particular product. ***NOTE:** Products cooked to full lethality which exceed a CUT of 6 hours between 50-130°F may meet the conditions for a Cooking Guideline Scientific Gap. **Note:** While this gap may be applied to bacon there is research that supports some common partially heat-treated bacon processes.

NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 3).

Scientific Gaps	Example Products	Critical Operating Parameters from Older Guidance	Vulnerability with Continuing to Follow Parameters from Older Guidance
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. **Processes that meet this gap include *all of* the following:** • Lethal time and temperature combination but relative humidity has not been addressed (therefore, product is not considered to achieve "full lethality")*. • Formulated with at least 100 ppm nitrite or nitrate (synthetic or natural). • Formulated with at least 250 ppm erythorbate or ascorbate (synthetic or natural). *Note: relative humidity does not need to be monitored when cooking meat or poultry products that are 10 pounds or more in an oven maintained at or above 250 °F (121 °C).	Bacon containing nitrite and erythorbate or ascorbate.	Apply Option 1.3 to this partially heat-treated product* specifically: 130 to 80°F in ≤ 5 hours and 80 to 40°F in ≤ 10 hours, with 15 hours total cooling time. ***NOTE:** No CUT parameter	These parameters may allow insufficient surface lethality of pathogens such as *Salmonella*. To minimize this vulnerability, establishments may choose to validate any of the following: • Cook the product to lethality, which would include using a humidity option. Apply Option 1.3 without being in a Scientific Gap for Stabilization. • Perform a challenge study or pathogen modeling for a particular product. ***NOTE:** Products cooked to full lethality which exceed a CUT of 6 hours between 50-130°F may meet the conditions for a Cooking Guideline Scientific Gap. **Note:** While this gap may be applied to bacon there is research that supports some common partially heat-treated bacon processes.

NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 3).

4. Immersion or dry-cured products that contain nitrate and/or nitrite and use of equilibration time instead of erythorbate or ascorbate but cannot meet cooling options without nitrite in Table 1 or Table 2. **Processes that meet this gap include *all of* the following:** • A heat treatment (full or partial). • Immersion or dry-cured. • Slower CUT (greater than 3 hours in Option 2.2). • Formulated with at least 100 ppm nitrite or nitrate (synthetic or natural). • Formulated without erythorbate or ascorbate (synthetic or natural). • Allow equilibration time for the cure reaction to occur (e.g., at least 2 to 3 days).	Immersion or dry-cured bacon and ham containing nitrite without erythorbate or ascorbate.	Apply Option 1.3 to product without erythorbate or ascorbate* specifically: 130 to 80°F in ≤ 5 hours and 80 to 40°F in ≤ 10 hours, with 15 hours total cooling time ***NOTE:** No CUT parameter for partially heat-treated products.	One vulnerability is the potential for excessive cumulative growth of *C. perfringens* during heating and cooling if CUT is not addressed. To minimize this vulnerability, establishments may choose to: • Cook the product to lethality, which would allow a CUT of up to 6 hours between 50-130°F per *FSIS Cooking Guideline*. NOTE: Ensuring adequate equilibration time is still critical (see second vulnerability). A second vulnerability is the minimum equilibration time needed to ensure nitrite conversion to produce antimicrobial activity without a cure accelerator is unknown. To minimize this vulnerability, establishments may choose to validate any of the following: • Equilibration time for salt and nitrite to penetrate throughout product and time to allow nitrite to convert to active form and limit growth or. • Perform a challenge study or pathogen modeling for a particular product. **NOTE:** Products cooked to full lethality which meet this Stabilization Guideline Scientific Gap may also meet the conditions for a Cooking Guideline Scientific Gap if CUT exceeds 6 hours.

NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 3).

Scientific Gaps	Example Products	Critical Operating Parameters from Older Guidance	Vulnerability with Continuing to Follow Parameters from Older Guidance
5. Products that contain nitrite and use equilibration time instead of erythorbate or ascorbate, but do not have a brine concentration ≥ 6% to meet Option 1.4. **Processes that meet this gap include <u>all of</u> the following:** • Any heat treatment, • Pumped with nitrite, • Formulated with at least 120 ppm nitrite or nitrate (synthetic or natural), • Formulated without erythorbate or ascorbate (synthetic or natural), • Brine concentration of 3.5% or more and • Allows equilibration time for the cure reaction to occur (e.g., at least 2 to 3 days).	Pumped ham containing nitrite without erythorbate or ascorbate.	Apply Option 1.4 to product* with ≥ 120 ppm nitrite and ≥ 3.5% brine concentration 120 to 40°F ≤ 20 hours; Continuous temperature drop ***NOTE:** No CUT parameter for partially heat-treated products	There is a vulnerability that there may be excessive cumulative growth of *C. perfringens* during heating and cooling if CUT is not addressed, although smoke and nitrite may help limit growth. To minimize this vulnerability, establishments may choose to validate any of the following: • Equilibration time for salt and nitrite to penetrate throughout product and time to allow nitrite to convert to active form; • Cook the product to lethality, which would allow a CUT of up to 6 hours between 50 to 130°F per FSIS Cooking Guideline; or. • Perform a challenge study or pathogen modeling for a particular product. **NOTE:** Products cooked to full lethality which meet this Stabilization Guideline Scientific Gap may also meet the conditions for a Cooking Guideline Scientific Gap.

NOTE: Scientific gaps only affect very specific products and processes. Process deviations and malfunctioning equipment are NOT scientific gaps. Products and Processes Not Covered by this Guideline would NOT be adequately supported by the critical parameters listed in scientific gaps (Table 3).

Scientific Gaps	Example Products	Critical Operating Parameters from Older Guidance	Vulnerability with Continuing to Follow Parameters from Older Guidance
6. Scalded offal that cannot cool quickly enough to follow the new options in Table 2. **Processes that meet this gap include <u>all of</u> the following:** • Edible offal which is partially heat-treated or scalded.	Scalded beef tripe or pork stomachs.	Product chilled to 45°F in ≤ 24 hours.	These parameters do not take into account the amount of time product remains between 120 to 80°F. If products take more than 1 hour to cool between 120 to 80°F, excessive growth of *C. perfringens* and *C. botulinum* may occur. In the event of a deviation, if product takes more than 1 hour to cool between 120 to 80°F, it is unlikely that pathogen modeling will support product safety, and sampling may be needed. To minimize this vulnerability, establishments may choose to validate any of the following: • If possible, limit the time between 120°F to 80°F to no more than 2.5 hours nor between 80°F and 55°F for more than 3.5 hours (6 hours total cooling time) to limit *C. perfringens* growth to 2-log or less. If that is not possible, identify the shortest amount of time it is thermodynamically possible to go from 120 to 80°F, and monitor this point on a routine basis. • Conduct finished product testing for *C. perfringens* (see page 74). • Add antimicrobials. • Perform a challenge study or pathogen modeling for a particular product. NOTE: Establishments may limit the time between 120°F to 80°F by increasing the amount of dry ice when packing the product, packing offal in smaller boxes, or not stacking as many boxes on a pallet which can impede airflow.

References

Akhtar, S., Paredes-Sabja, D., Sarker, M.R. 2008. Inhibitory effects of polyphosphates on *Clostridium perfringens* growth, sporulation and spore outgrowth. Food Microbiology. 25(6):802-808.

Blankenship, L.C., Craven, S.E., Leffler, R.G., Custer, C. 1988. Growth of *Clostridium perfringens* in cooked chili during cooling. Applied Environmental Microbiology. *54*(5):1104-1108.

CDC (Centers for Disease Control and Prevention).1963. Provisional information on selected notifiable diseases in the United States and on deaths in selected cities for week ended October 26, 1963. Morbidity and Mortality. 12(43):357-364. https://stacks.cdc.gov/view/cdc/476. Accessed 27 May 2020.

CDC (Centers for Disease Control and Prevention). 2007. Botulism associated with commercially canned chili sauce — Texas and Indiana, July 2007. Morbidity and Mortal Weekly Report, July 30, 2007. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm56d730a1.htm. Accessed 08 August 2015.

CDC (Centers for Disease Control and Prevention). 2000. Surveillance for foodborne-disease outbreaks — United States, 1993-1997. Morbidity and Mortality Weekly Report, 49(SS-1) CDC Surveillance Summaries, March 17, 2000. http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4901a1.htm. Accessed 08 August 2015.

Desmond, E. 2006. Reducing salt: A challenge for the meat industry. Meat Science. *74*(1):88-196.

FSQS (Food Quality and Safety Service). 1978. Final Report on Nitrites and Nitrosamines: Report to the Secretary of Agriculture by the Expert Panel on Nitrites and Nitrosamines. https://archive.org/stream/CAT89924771/CAT89924771_djvu.txt. Accessed 30 October 2019.

FDA (Food and Drug Administration). 2017. Food Code. Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2017. https://www.fda.gov/food/fda-food-code/food-code-2017. Accessed 9th August 2021.

Hauschild, A.H.W. 1989. *Clostridium botulinum*. Foodborne Bacterial Pathogens. 111-189.

Haneklaus, A.N., Harris, K.B., Marquez-Gonzalez, M., Lucia, L.M., Castillo, A., Hardin, M.D., Osburn, W.N., Savell, J.W. 2011. Alternative cooling procedures for large, intact meat products to achieve stabilization microbiological performance standards. Journal of Food Protection. 74(1):101-105.

ICMSF (International Commission on Microbiological Specifications for Foods). 1996. Chapter 5: *Clostridium botulinum* and Chapter 6: *Clostridium perfringens* in Microorganisms in Foods 5: Characteristics of Microbial Pathogens. (5). Springer Science & Business Media.

Jackson, A.L., Sullivan, G.A., Kulchaiyawat, C., Sebranek, J.G., Dickson, J.S. 2011a. Survival and growth of *Clostridium perfringens* in commercial no-nitrate-or-nitrite-added (natural and organic) frankfurters, hams, and bacon. Journal of Food Protection. 74(3):410-416.

Jackson, A.L., Kulchaiyawat, C., Sullivan, G.A., Sebranek, J.G., Dickson, J.S. 2011b. Use of natural ingredients to control growth of *Clostridium perfringens* in naturally cured frankfurters and hams. Journal of Food Protection. 74(3):417-424.

Johnson, K.M., Nelson, C.L., Busta, F.F. 1983. Influence of temperature on germination and growth of spores of emetic and diarrheal strains of *Bacillus cereus* in a broth medium and rice. Journal of Food Science. 48(1):286-287.

Juneja, V.K., Marmer, B.S., Miller, A.J. 1994. Growth of sporulation potential of *Clostridium perfringens* in aerobic and vacuum-packaged cooked beef. Journal of Food Protection 57(5):393-398.

Juneja, V.K., Marmer, B.S., and Miller, A.J. 1998. Thermal inactivation of *Clostridium perfringens* vegetative cells in ground beef and turkey as affected by sodium pyrophosphate. Food Microbiology. 15(3):281-287.

Juneja, V.K., Porto-Fett, A.C.S., Gartner, K., Tufft, L., Luchansky, J.B. 2010. Potential for growth of *Clostridium perfringens* from spores in pork scrapple during cooling. Foodborne Pathogens and Disease. 7(2):153-157.

Juneja, V.K., Snyder, O.P., Cygnarowicz-Provost, M. 1994. Influence of cooling rate on outgrowth of *Clostridium perfringens* spores in cooked ground beef. Journal of Food Protection. 57(12):1063-1067.

Juneja, V.K., Sofos, J.N. 2010. Pathogens and toxins in foods. ASM Press, Washington, D.C.

Juneja, V.K., Thippareddi, H. 2004a. Inhibitory effects of organic acid salts on growth of *Clostridium perfringens* from spore inocula during chilling of marinated ground turkey breast. International Journal of Food Microbiology. 93(2):155-163.

Juneja, V.K., Thippareddi, H. 2004b. Control of *Clostridium perfringens* in a model roast beef by salts of organic acids during chilling. Journal of Food Safety. 24(2):95-108.

Juneja, V.K., Thippareddi, H. Friedman, M.2006. Control of *Clostridium perfringens* in cooked ground beef by carvacrol, cinnamaldehyde, thymol, or oregano oil during chilling. Journal of Food Protection. 69(7):1546-1551.

Juneja, V.K., Bari, M.L., Inatsu, Y., Kawamoto, S. Friedman, M. 2007. Control of *Clostridium perfringens* spores by green tea leaf extracts during cooling of cooked ground beef, chicken, and pork. Journal of Food Protection. 70(6):1429-1433.

Juneja, V.K., Baker, D.A., Thippareddi, H., Snyder, O.P., Mohr, T.B. 2013. Growth potential of *Clostridium perfringens* from spores in acidified beef, pork, and poultry products during chilling. Journal of Food Protection. 76(1):65-71.

King, A.M., Glass, K.A., Milkowski, A.L. and Sindelar, J.J. 2015. Comparison of the effect of curing ingredients derived from purified and natural sources on inhibition of *Clostridium perfringens* outgrowth during cooling of deli-style turkey breast. Journal of Food Protection 78(8):1527-1535.

Labbe, R. 1989. Chapter 5: *C. perfringens* in: Kramer, J.M., Gilbert, R.J., Doyle, M.P. 1989. Foodborne Bacterial Pathogens. MP Doyle, Marcel Dekker, Inc., New York and Basel. 22-70.

Li, L., Valenzuela-Martinez, C., Redondo, M., Juneja, V.K., Burson, D.E., Thippareddi, H. 2012. Inhibition of *Clostridium perfringens* spore germination and outgrowth by lemon juice and vinegar product in reduced NaCl roast beef. Journal of Food Science. 77(11):M598-M603.

Lindström, M., Kiviniemi, K. and Korkeala, H. 2006. Hazard and control of group II (non-proteolytic) *Clostridium botulinum* in modern food processing. International Journal of Food Microbiology. 108(1):92-104.

Lund, B.M. and Peck, M.W. 2000. *Clostridium botulinum*. In Lund, B.M., Baird-Parker, T.C. and Gould, G.W. (Eds.). The Microbiological Safety and Quality of Food Ed. E 1057–1109. Gaithersburg: Aspen.

Mohr, T.B. Assessing the performance of *Clostridium perfringens* cooling models for cooked, cured meat and poultry products. Symposium conducted at the International Association of Food Protection: Salt Lake City, Utah. July 8 – 11, 2018. Slides available at: https://www.fsis.usda.gov/news-events/events-meetings/assessing-performance-clostridium-perfringens-cooling-models-cooked.

Mohr, T.B., Juneja, V.K., Thippareddi, H.H., Schaffner, D.W., Bronstein, P.A., Silverman, M., Cook, L.V. 2015. Assessing the performance of *Clostridium perfringens* cooling models for cooked, uncured meat and poultry products. Journal of Food Protection. 78(8):1512-1526.

Montville, T.J., Matthews, K.R. 2008. *Staphylococcus aureus* In: Montville, T.J., Matthews, K.T.(Ed). Food Microbiology: An Introduction, 2nd ed. Washington, DC: ASM Press. 189–201.

National Advisory Committee on Microbiological Criteria for Foods. 2010.Parameters for determining inoculated pack/challenge study protocols. Journal of Food Protection. 73(1):140.

Ohye, D.F., Scott, W.J. 1957. Studies in the physiology of *Clostridium botulinum* type E. Australian Journal of Biological Sciences. 10(1):85-94.

Peck, M., Devlieghere, F., Membre, J. 2015. *Clostridium botulinum*: A recurrent emerging foodborne pathogen. IAFP Symposium conducted at the International Association of Food Protection: Portland, Oregon. July 26-29, 2015. Slides available at: https://iafp.confex.com/iafp/2015/webprogram/Session2482.html.

Sindelar, J., Glass, K. 2015. Personal Communication. September 21, 2015.

Redondo-Solano, M., Valenzuela-Martinez, C., Cassada, D.A., Snow, D.D., Juneja, V.K., Burson, D.E., Thippareddi, H. 2013. Effect of meat ingredients (sodium nitrite and erythorbate) and processing (vacuum storage and packaging atmosphere) on germination and outgrowth of *Clostridium perfringens* spores in ham during abusive cooling. Food Microbiology. 35(2):108-115.

Roberts, T.A., Gibson, A.M., Robinson, A. 1981. Factors controlling the growth of *Clostridium botulinum* types A and B in pasteurized, cured meats: Part I. Growth in pork slurries prepared from 'low' pH meat (pH range 5.5–6.3). International Journal of Food Science & Technology. 16(3):239-266.

Roberts, T.A., Gibson, A.M., Robinson, A. 1981. Factors controlling the growth of *Clostridium botulinum* types A and B in pasteurized, cured meats: Part II. Growth in pork slurries prepared from 'high' pH meat (pH range 6.3–6.8) International Journal of Food Science & Technology. 16: 267-281.

Sabah, J.R., Thippareddi, H., Marsden, J.L., Fung, D.Y.C. 2003. Use of organic acids for the control of *Clostridium perfringens* in cooked vacuum-packaged restructured roast beef during an alternative cooling procedure. Journal of Food Protection. 66(8):408-1412.

Sabah, J.R., Juneja, V.K., Fung, D.Y.C. 2004. Effect of spices and organic acids on the growth of *Clostridium perfringens* during cooling of cooked ground beef. Journal of Food Protection. 67(9):1840-1847.

Sanchez-Plata, M.X., Amezquita, A., Blankenship, E., Burson, D.E., Juneja, V., Thippareddi, H., 2005. Predictive model for *Clostridium perfringens* growth in roast beef during cooling and inhibition of spore germination and outgrowth by organic acid salts. Journal of Food Protection. 68(12):2594-2605.

Scallan, E., Hoekstra, R.M., Angulo, F.J., Tauxe, R.V., Widdowson, M.A., Roy, S.L., Jones, J.L., Griffin, P.M. 2011. Foodborne illness acquired in the United States—major pathogens. Emerging Infectious Diseases.17(1)7. https://dx.doi.org/10.3201/eid1701.P11101. Accessed 26 September 2016.

Sindelar, J., Glass, K., Hanson, R., Sebranek, J.G., Cordray, J., Dickson, J.S. 2019. Validation of lethality processes for products with slow come up time: Bacon and bone-in ham. Food Control. 104:147-151.

Singh, A., Korasapati, N.R., Juneja, V.K., Thippareddi, H. 2010. Effect of phosphate and meat (pork) types on the germination and outgrowth of *Clostridium perfringens* spores during abusive chilling. Journal of Food Protection. 73(5):879-887.

Smith, A.M., Dunn, M.L., Jefferies, L.K., Egget, D.L., Steele, F.M. 2018. Inhibition of *Clostridium perfringens* growth during extended cooling of cooked uncured roast turkey and roast beef using a concentrated buffered vinegar product and a buffered vinegar product. Journal of Food Protection. 81(3):461-466.

Smith, S., Juneja, V., Schaffner, D.W. 2004. Influence of several methodological factors on the growth of *Clostridium perfringens* in cooling rate challenge studies. Journal of Food Protection. 67(6):1128-1132.

Solberg, M., Elkind, B. 1970. Effect of processing and storage conditions on the microflora of Clostridium perfringens-inoculated frankfurters. Journal of Food Science. 35(2):126-129.

Steele, F.M. and Wright, K.H. 2001. Cooling rate effect on outgrowth of *Clostridium perfringens* in cooked, ready-to-eat turkey breast roasts. Poultry Science, 80(6):813-816.

Tamplin, M.L., 2002. Growth of *Escherichia coli* O157: H7 in raw ground beef stored at 10 C and the influence of competitive bacterial flora, strain variation, and fat level. Journal of Food Protection. 65(10):1535-1540.

Taormina, P.J., 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.

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, 66(1):72-81.

Thompson, D.R., Willardsen, R.R., Busta, F.F., Allen, C.E. 1979. *Clostridium perfringens* population dynamics during constant and rising temperatures in beef. Journal of Food Science. 44(3):646-651.

USDA FSIS. (1992–1996). Nationwide Microbiological Baseline Data Collection Program. Available at: https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/baseline-microbiology-data-reports.

Velugoti, P.R., Bohra, L.K., Juneja, V.K., Thippareddi, H. 2007. Inhibition of germination and outgrowth of *Clostridium perfringens* spores by lactic acid salts during cooling of injected turkey. Journal of Food Protection. 70(4):923-929.

Velugoti, P.R., Rajagopal, L., Juneja, V.,Thippareddi, H. 2007. Use of calcium, potassium, and sodium lactates to control germination and outgrowth of *Clostridium perfringens* spores during chilling of injected pork. Food Microbiology. 24(7-8):687-694.

Vold, L., Holck, A., Wasteson, Y. Nissen, H. 2000. High levels of background flora inhibits growth of *Escherichia coli* O157: H7 in ground beef. International Journal of Food Microbiology. 56(2-3):219-225.

Walls, I., Scott, V.N. 1996. Validation of predictive mathematical models describing the growth of *Escherichia coli* O157: H7 in raw ground beef. Journal of Food Protection. 59(12):1331-1335.

Willardsen, R.R., Busta, F.F., Allen, C.E., Smith, L.B. 1978. Growth and survival of *Clostridium perfringens* during constantly rising temperatures. Journal of Food Science. 43: 470-475.

Williams, M.S., Cao, Y., Ebel, E.D. 2013. Sample size guidelines for fitting a lognormal probability distribution to censored most probable number data with a Markov chain Monte Carlo method. International journal of Food Microbiology. 165(2):89-96.

Zaika, L.L. 2003. Influence of NaCl content and cooling rate on outgrowth of *Clostridium perfringens* spores in cooked ham and beef. Journal of Food Protection. 66(9):1599-1603.

Attachment B1. Characteristics of *Clostridial* Pathogens

Public Health Risk in Meat and Poultry

Clostridia can be a problem in foods other than heat-treated meat and poultry products, such as improperly canned low acid foods (pH > 4.6), raw honey, and fermented, smoked, and salted seafood. Most illness outbreaks associated with *C. perfringens* are traced to food served in restaurants, homes for the elderly, or at buffet-style gatherings. In fact, *C. perfringens* is often referred to as the "food service germ," because outbreaks may occur if the products are held at room temperature for too long or they are cooled in large batches, allowing pathogens to grow. A limited number of *C. perfringens* illnesses are attributed to products produced under FSIS inspection. A 2005 FSIS risk assessment found that stabilization at processing plants accounted for 0.05% and 0.4% of predicted *C. perfringens* illnesses at 1-Log and 2-Log allowable growth, respectively. There have been a limited number of *C. perfringens* outbreaks associated with commercially produced meat and poultry products in the U.S. Specifically, one outbreak was associated with *C. perfringens* from a commercially produced RTE turkey loaf product (CDC, 2000; personal communication, R.F. Woron, N.Y. State Department of Health, August 2002).

C. perfringens

grows the fastest of the spore-forming pathogens.

It is a good indicator of food safety during stabilization.

C. perfringens and *C. botulinum* cause human illness in different ways. *C. perfringens* causes illness when people ingest a large infectious dose of 6-Log/gram or higher ($\geq 10^6$ CFU/g). These high levels of cells occur when the product remains at growth temperatures for too long, allowing the vegetative cells to grow. If a large enough dose of *C. perfringens* is ingested, vegetative cells may survive the environment in the stomach and briefly persist in the gut. These conditions cause this pathogen to form spores and **produce a toxin in the gut**. *C. perfringens* is estimated to cause 965,958 illnesses, including 438 hospitalizations and 26 deaths in the U.S each year (Scallan et al., 2011).

C. botulinum causes human illness when people ingest a **potentially deadly neurotoxin (botulin) that is produced in affected food**. After 12 to 36 hours following ingestion, botulin can cause muscle paralysis and suffocation with as little as 1 nanogram (ng) of toxin per kilogram (kg) of body weight. Botulin is considered one of the most toxic naturally occurring toxins. While human botulism cases are rare in the U.S., it is estimated that *C. botulinum* causes approximately 55 illnesses, including 42

hospitalizations and 9 deaths each year (Scallan et al., 2011). 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). Proteolytic *C. botulinum* is the most common group associated with illness from meat and poultry products in the United States. 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). Because of the potency of the neurotoxin that this pathogen produces, it is critically important to control *C. botulinum* in food products.

NOTE: *B. cereus* is a spore-forming bacterium that may also be a hazard of concern during severe deviations of cooling and hot-holding (*e.g.*, where pathogen modeling shows the potential for ≥ 3-Log *C. perfringens* growth). *B. cereus,* if allowed to grow to high levels (typically 5-Log CFU/g) can produce emetic and diarrheal toxins in the food. However, *B. cereus* is not discussed in further detail in this guideline because if *C. perfringens* and *C. botulinum* growth are adequately controlled or prevented using options discussed in this guideline, then *B. cereus* growth will be adequately addressed as well. For this reason, FSIS did not identify outgrowth of *B. cereus* as a hazard of concern at the cooling/stabilization step in the *FSIS Meat and Poultry Hazards and Control Guide*.

Product Characteristics that Affect Clostridia Growth

Below is a review of the critical operating parameters that are important for cooling heat-treated RTE and NRTE meat and poultry products.

Product time-temperature profile

An establishment's cooling schedule should take into account the amount of time a product takes to cool in certain temperature ranges associated with growth as follows:

- The optimum growth temperature for ***C. perfringens*** is 109.4 – 117°F (43 - 47°C), and the lower and upper growth limits are 50°F and 126°F (6°C and 54°C), respectively (Solberg and Elkind, 1970).
- The optimum temperature for growth for ***C. botulinum*** (proteolytic, which is the kind found in meat) is 95 – 104°F (35 - 40°C), and the lower and upper growth limits are between 50°F and 122°F (10.0°C and 50°°C), respectively (ICMSF, 1996).

In addition, establishments should also design their cooling process to match the time-temperature profile in their scientific support.

General Considerations for Designing HACCP Systems to Control the Growth of Clostridia contains additional recommendations for initial validation of cooling processes (page 13).

pH

The lower and upper pH growth limits for *C. perfringens* are 5.0 and 8.3, respectively. For *C. botulinum* (proteolytic, which is the kind found in meat), the lower and upper pH growth limits are 4.7 and 9, respectively (Hauschild, 1989; Labbe, 1989). As the pH decreases, the growth of *C. perfringens* and *C. botulinum* becomes slower.

Brine concentration in product

As the brine concentration increases (defined on page 18), the growth of *C. perfringens* and *C. botulinum* becomes slower. The minimum inhibitory brine concentration is 8% for *C. perfringens* (ICMSF, 1996) and 10% for *C. botulinum* (proteolytic) (Lund and Peck, 2000).

The type and concentration of phosphate (wt/wt basis)

A high phosphate concentration, 0.4-0.5 %, can have a limited effect on inhibiting the growth of *C. perfringens* in the product (Akhtar *et al*., 2008; Singh *et al*., 2010).

Water activity (a_w)

As the water activity decreases, growth of *C. perfringens* and *C. botulinum* slows. The water activity limit for growth and germination of both *C. perfringens* and *C. botulinum* is 0.93. (ICMSF, 1996). Therefore, a water activity less than 0.93 is required to control the growth and toxin formation of *Clostridia.*

The type and concentration of sodium lactate/diacetates

Many establishments are now adding sodium lactate/diacetate or other organic salts as an antimicrobial agent to RTE meat or poultry products to meet the requirements of Alternative 1 or Alternative 2, Choice 2 of the *Lm* regulations (9 CFR 430.1 and 9 CFR 430.4). Establishments should ensure that the sodium lactate/diacetate or organic acid salt used in their process matches the antimicrobial used in their scientific support and should also ensure or consider the following:

- That the scientific support is based on the specific trade name for the sodium lactate/diacetate or organic acid salt product used during product formulation;
- That the active component concentrations (%) of sodium lactate/diacetate or organic acid salt in the commercially formulated product used during product formulation is the same as that in the scientific support; and
- The concentration (wt/wt basis) of the sodium lactate/diacetate or organic acid salt in the product after formulation.

Several published research articles have shown lactate/diacetate products and other organic salts can significantly inhibit the growth of *C. perfringens* during cooling, and even extend the chilling times from 15 to 21 hours for cooked, uncured meat or poultry products. (See the research articles summarized in Attachment B8. Using Journal Articles to Support Alternative Stabilization or Cooling Procedures, Table 15. that include lactate/diacetate products; page 82).

Ingoing sodium nitrite/nitrate concentration and erythorbate or ascorbate

Sodium nitrite slows the growth of *C. perfringens* and inhibits the growth and toxin formation of *C. botulinum,* if it is used in combination with a cure accelerator, such as sodium erythorbate or ascorbate or a high salt concentration (King *et al.*, 2015). The amount of sodium nitrite and erythorbate or ascorbate needed will depend on the establishment's scientific support. Establishments should be aware that a minimum of 120 ppm ingoing nitrite should be added in all cured "Keep Refrigerated" products, unless the establishment can demonstrate that safety is assured by some other preservation process, such as thermal processing, pH, or moisture control. This 120 ppm recommendation is based on safety data reviewed when the bacon standard was developed (FSQS, 1978).

Natural Sources of Nitrite and Ascorbate

Research supports that naturally occurring sources of nitrite (*e.g.*, from celery powder) are functionally equivalent to pure sodium nitrite for inhibiting the growth of *C. perfringens* if a sufficient quantity of a natural source of ascorbate (*e.g.*, from cherry powder) is also used (King *et al.*, 2015). Similar research has not been performed on the growth of *C. botulinum*. However, FSIS has determined from expert opinion that nitrite from natural sources will likely also control the growth of *C. botulinum,* if sufficient quantities of nitrite and ascorbate are used (J. Sindelar, personal communication, 2015).

Synthetic versions of cure accelerators
may not be used with natural sources of nitrate or nitrite.

When using natural sources of nitrite, establishments must provide support that the level of nitrite and ascorbate used are effective to control the growth of *C. perfringens* and *C. botulinum*. Natural sources of nitrite are generally available in two forms:

- Vegetable juices and powders that contain sodium **nitrate**. The establishment should use these products in combination with a bacterial culture that reduces the **nitrate** to **nitrite** in the product. When using natural sources of sodium nitrate, the quantity of sodium nitrite present is not known because the conversion of nitrate to nitrite that occurs in the product as a result of the presence of a bacterial culture can occur at varying rates. Because the nitrate to nitrite conversion rate may vary from batch to batch, there is concern about obtaining a consistent conversion and thus the sodium nitrite level in the product (Jackson *et al.*, 2011b).

- Vegetable juices and powders in which the sodium nitrate has been **pre-converted** to sodium **nitrite** by the supplier so there is no need to add a bacterial

culture. Because the sodium nitrate has been pre-converted, the concentration of sodium nitrite in the natural source is known. However, the amount may still vary between lots of the natural source due to differences in the conversion rate.

Establishments should ensure the levels of sodium nitrite are safe and suitable according to FSIS Directive 7120.1, *"Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products"* and 9 CFR 424.21(c)). If establishments are using natural sources of sodium nitrite, FSIS recommends that, when possible, establishments use natural sources of sodium nitrite with known concentrations of nitrite. By knowing the concentration of nitrite, establishments can ensure they neither use too little nor too much in their formulation.

In order to use one of the cooling Options for products formulated with sufficient nitrite, establishments must support that they have added sufficient quantities of nitrite (*e.g.*, for Option 1.3 at least 100 ppm nitrite). (Note that mixing natural sources of nitrate/nitrite with synthetic versions of a cure accelerator would not be eligible for using option 1.3.) Establishments using nitrite may need to request this information from the supplier. Suppliers of sodium nitrite with known concentrations may supply this information as either:

- **Certificate of Analysis** (COA) for each lot that states the sodium nitrite in parts per million. An establishment would then need to calculate the quantity of nitrite to add to a given formulation in order to obtain the final ingoing concentration. See the *Processing Inspectors' Calculations Handbook* for example calculations on page 11; or

- **Standardized formulation directions** for the natural source of nitrite (*e.g.* in a Letter of Guarantee or LOG). Some suppliers standardize the concentration of nitrite from lot to lot. These suppliers may provide formulation directions to achieve a specific concentration of nitrite, *e.g.*, "Add 1 pound of [the blend] to 100 pounds of meat block." The establishment should maintain documentation of this final concentration achieved in the formulation.

Natural Sources of Nitrite and Ascorbate – Approvals and Labeling

Celery powder and other natural sources of nitrite are approved by FSIS and FDA for use as antimicrobials and flavorings but are not approved as curing agents. Cherry powder and other natural sources of ascorbate are also approved for use as antimicrobials and flavorings but are not approved as cure accelerators. Ingredients approved for use as curing agents and cure accelerators are listed in 9 CFR 424.21(c) and the *FSIS Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products*. According to 9 CFR 424.21(c) cure accelerators may only be used if the product contains an approved curing agent. Therefore, synthetic versions of cure accelerators may not be used with natural sources of nitrate or nitrite as these are not approved as curing agents.

Celery powder and other natural sources of nitrite are considered safe and suitable as antimicrobials, if used in combination with a natural source of ascorbate, such as cherry powder (See *FSIS Directive 7120.1, Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products*). Celery powder may be added to meat and poultry products as a flavoring in accordance with 9 CFR 317.2(f)(1)(i)(B) and 9 CFR 381.118(c)(2) along with other natural sources of nitrite, such as beet juice and sea salt. Because celery powder and other natural sources of nitrite are not currently approved for use in 9 CFR 424.21(c) as curing agents, products that are required to contain curing agents and cure accelerators as part of a standard of identity in 9 CFR 319 or 9 CFR 317.17(b), but instead are formulated with natural sources of nitrite and ascorbate, must be labeled as "uncured" under 9 CFR 319.2. Also, the label must contain the statement "no nitrates or nitrites added" (9 CFR 317.17) that is qualified by the statement "except for those naturally occurring in [name of natural source of nitrite such as celery powder]" as to not be considered misbranded due to false and misleading labeling under 9 CFR 317.8. For example, hot dogs and corned beef that contain celery powder instead of sodium or potassium nitrite, and cherry powder instead of ascorbate, must be labeled as "uncured" and contain the qualifying statement "except for those naturally occurring in celery powder." It would not be appropriate to label products with natural sources of nitrite with other terms such as "naturally cured" or "alternatively cured."

NOTE: Products formulated with natural sources of nitrate and ascorbate that contain an amount of salt sufficient to achieve a brine concentration of 10% or more are exempted from the "Uncured" and accompanying "no nitrates or nitrites added" statement and the qualifier labeling requirement per 9 CFR 317.17(c)(3).

Attachment B2. Stabilization Requirements for Specific Meat and Poultry Products

To ensure safety of heat-treated RTE meat and poultry products, FSIS has developed performance standards and recommended targets, for *C. perfringens* and *C. botulinum* growth in RTE and NRTE products. By designing their HACCP systems to meet these standards, establishments should be able to avoid producing adulterated product (See: What is the public health concern of *C. perfringens* and *C. botulinum* in RTE Products? (page 48)).

As described under the section titled Stabilization in the HACCP System (page 13) of this guideline, for each biological hazard identified, establishments must design their HACCP systems to meet applicable **performance standards** or **targets** for reduction or prevention. For stabilization, targets are used by the establishment to demonstrate that its processes prevent the outgrowth of *Clostridia* to acceptable levels and prevent any outgrowth of botulinum. Whether an establishment must meet a required performance standard or identify a target, depends on whether the meat or poultry products are RTE or NRTE, and whether the products are subject to a regulatory stabilization performance standard. Table 4 lists the regulatory performance standards for specific meat and poultry products and describes the recommended targets for other RTE meat and poultry products and other NRTE, heat-treated meat and poultry products.

Table 4. Stabilization performance standards and recommended targets for *Clostridia* growth

If an establishment produces:	Then its stabilization treatment must:
RTE cooked beef RTE roast beef RTE cooked corned beef	Allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 318.17(a)(2).
RTE uncured beef patties	Allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 318.23(c)(1).
RTE cooked poultry	Allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 381.150(a)(2).
Other RTE meat products	Consider the food safety hazards that are reasonably likely to occur in stabilization processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2). FSIS recommends that establishments set a target to allow no more than a 1-Log multiplication of *C. perfringens* within the product and no multiplication of *C. botulinum*.

If an establishment produces:	Then its stabilization treatment must:
NRTE partially cooked and char-marked meat patties, and partially cooked poultry breakfast strips	Allow no multiplication of toxigenic microorganisms such as *C. botulinum* and no more than 1-Log multiplication of *C. perfringens* to comply with 9 CFR 318.23(c)(1) and 9 CFR 381.150(b).
Other NRTE, heat-treated meat and poultry products	Consider the food safety hazards that are reasonably likely to occur in stabilization processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2). FSIS recommends that establishments set a target to allow no more than a 1-Log multiplication of *C. perfringens* within the product and no multiplication of *C. botulinum.*

NOTE: The recommendation that the stabilization of NRTE meat and poultry products should limit the growth of *C. perfringens* and *C. botulinum* to the same levels in RTE meat and poultry products is consistent with guidance for controls in any raw meat or poultry process. In both cases, the establishment needs to document in its hazard analysis the necessary controls that must be maintained to minimize microbial growth to a level such that customary cooking practices would be sufficient to make the product safe.

As described in 9 CFR 303.1(h), the Administrator may in specific classes of cases waive for limited periods any provisions of the regulations to permit experimentation so that new procedures, equipment, and/or processing techniques may be tested to facilitate definite improvements.

What is the public health concern of C. perfringens and C. botulinum in RTE Products?

Certain pathogens, including *Salmonella* and *Lm*, when present in a RTE meat or poultry product at any level, cause the product to be adulterated since consumption of the product would be "injurious to health" as per 21 U.S.C. 601(m)(1)) and 453(g)(1)). Other pathogens, such as *C. perfringens,* are only a public health concern when growth occurs at levels that could lead to toxin formation; this indicates the products were prepared, packed, or held under insanitary conditions as per 21 U.S.C. 601(m)(4) and 453(g)(4).

- For *C. perfringen*s, spore levels found in raw meat and poultry are usually 2-3-Log. These spores can survive cooking and germinate into vegetative cells during cooling (see page 12). If conditions during cooling allow for **3-Log growth or higher** of these vegetative cells, then there is a public health concern because this would result in total levels of > 5-Log. At 5-Log, a toxin could be produced in the gut and cause illness.

- For *C. botulinum*, conditions permitting spore germination and **any growth of vegetative cells** in the product are a public health concern because the toxin is

the most toxic natural substance known to humankind (Montville and Matthews, 2008). FSIS considers predictive modeling results with mean growth > 0.30-Log to be evidence of *C. botulinum* growth.

C. perfringens: **Some growth is acceptable before the product is considered adulterated.**

C. botulinum: **Any level of growth is a concern and makes the product adulterated.**

What is the public health concern of C. perfringens and C. botulinum in NRTE Products?

NRTE products that are contaminated with toxins such as the botulinum toxin are adulterated because cooking by consumers may not destroy the toxins, rendering the products injurious to health (21 U.S.C. 601(m)(1)) and 453(g)(1)).

In addition, if levels of growth occur that would be considered a public health concern (*i.e.*, ≥ 3-Log of *C. perfringens*; or > 0.30-Log of *C. botulinum*), the product would be adulterated. In this situation, products would also be adulterated because they were prepared, packed, or held under insanitary conditions (21 U.S.C. 601(m)(4) and 453(g)(4)).

NOTE: Examples of NRTE meat and poultry products include char-marked patties, partially cooked poultry breakfast strips, or products like hams or sausage that are cooked to a lethal time-temperature, but the establishment chooses to reclassify as NRTE.

Attachment B3. FSIS' Predictive Microbial Modeling Support for 1-Log Cooling Options

This section contains the supporting documentation FSIS used to develop its 1-Log cooling options. A summary of each option is provided with the original journal articles used to develop the option. Also included is the most current research and pathogen modeling to support each option. All pathogen modeling FSIS performed was based on linear cooling in each stage. Also, the modeling was based on the use of a worst-case scenario pH of 6.2 and a salt concentration of 1% (Mohr *et al.*, 2015). In addition to the modeling results, a figure showing the modeling output was also included for each option. This Appendix also includes FSIS Support for Application of Options 1.1, 1.2, 1.5-1.8 to Rice, Pasta, and Beans page 61.

FSIS' Support for Option 1.1.

Table 5. Summary of Option 1.1 (for products cooked to full lethality).

Option	Pre-Cooling Conditions	1st Stage of Cooling	2nd Stage of Cooling	Total Cooling Time
Option 1.1		130 to 80°F ≤ 1.5 hours	80 to 40°F ≤ 5 hours	≤ 6.5 hours

The original option was developed using research found in:

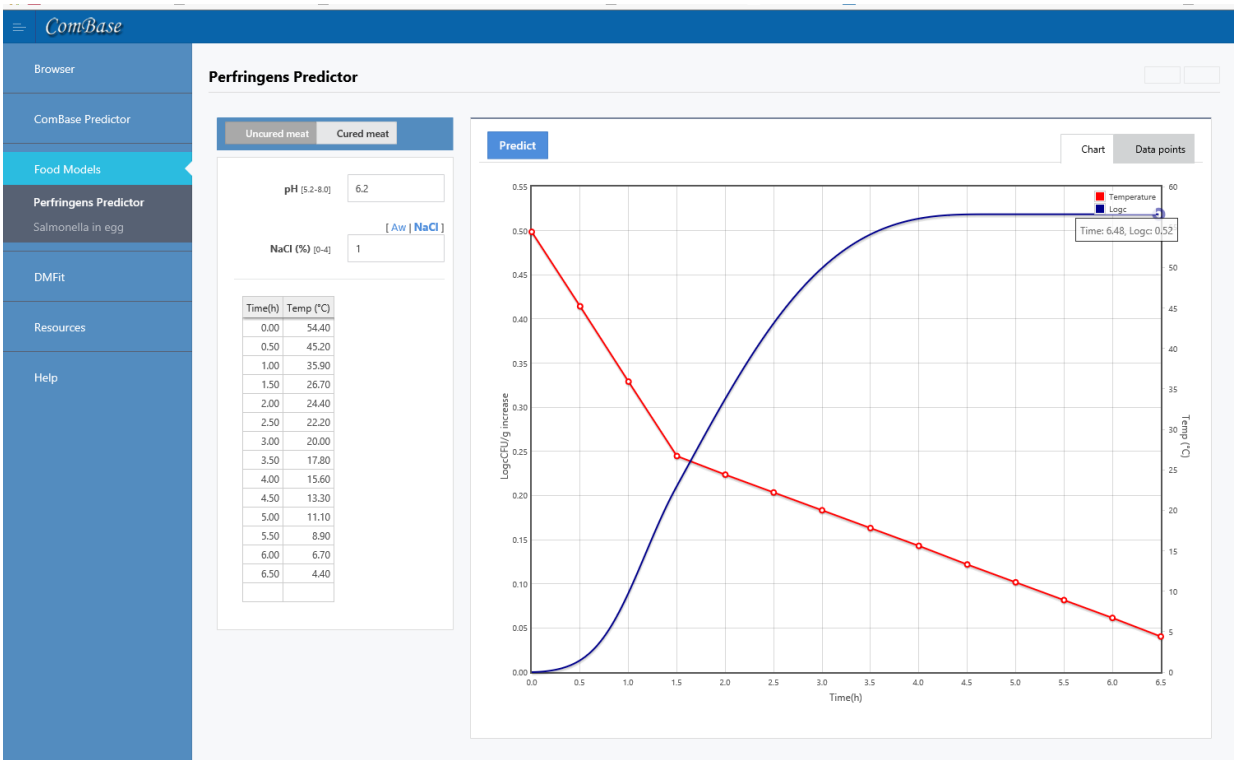
- Blankenship, L.C., Craven, S.E., Leffler, R.G., Custer, C. 1988. Growth of *Clostridium perfringens* in cooked chili during cooling. Applied Environmental Microbiology. *54*(5):1104-1108.

- Thompson, D.R., Willardsen, R.R., Busta, F.F., Allen, C.E. 1979. *Clostridium perfringens* population dynamics during constant and rising temperatures in beef. Journal of Food Science. 44(3):646-651.

Up-to-date validated modeling provided the following results for products cooked to full lethality:

- ComBase *Perfringens* Predictor Results = **0.52**-Log growth (see Figure 2 for modeling output.)

Figure 2. ComBase *Perfringens* Predictor Modeling Output for Option 1.1.



FSIS' Support for Option 1.2

Table 6. Summary of Option 1.2 (for products cooked to full lethality).

Option	Pre-Cooling Conditions	1st Stage of Cooling	2nd Stage of Cooling	Total Cooling Time
Option 1.2	Chilling will begin within 90 minutes after the cooking cycle is complete	120 to 80°F ≤ 1 hour	80 to 55°F ≤ 5 hours; Continuous chilling until 40°F	≤ 6 hours

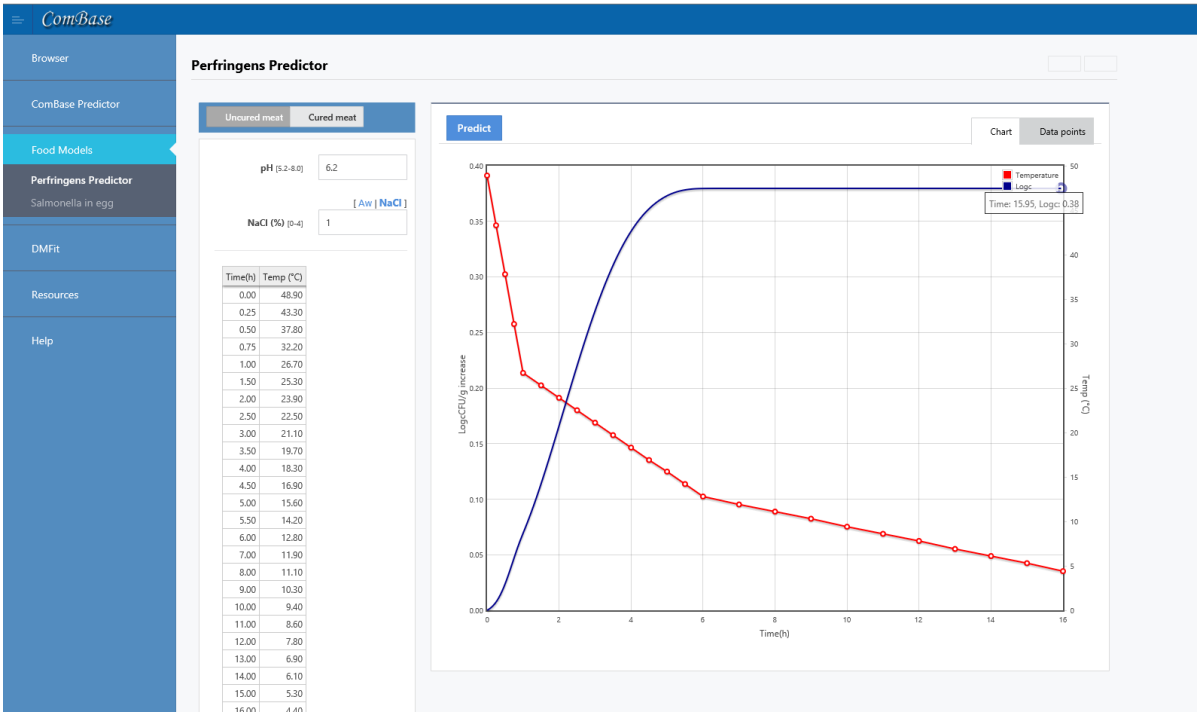
The original option was developed using research found in:

- Ohye, D.F., Scott, W.J. 1957. Studies in the physiology of *Clostridium botulinum* type E. Australian Journal of Biological Sciences. 10(1):85-94.

Up-to-date validated modeling provided the following results for products cooked to full lethality:

- ComBase *Perfringens* Predictor Results = **0.38**-Log growth (see Figure 3 for modeling output.))

Figure 3. ComBase *Perfringens* Predictor Modeling Output for Option 1.2.



FSIS' Support for Option 1.3

Table 7. Summary of Option 1.3 (for products cooked to full lethality).

Option	Pre-Cooling Conditions	1st Stage of Cooling	2nd Stage of Cooling	Total Cooling Time
Option 1.3	≥ 100 ppm sodium nitrite and ≥ 250 ppm sodium ascorbate or erythorbate	130 to 80°F ≤ 5 hours	80 to 45°F ≤ 10 hours	≤ 15 hours

The original option was developed using research found in:

- Roberts, T.A., Gibson, A.M., Robinson, A. 1981. Factors controlling the growth of *Clostridium botulinum* types A and B in pasteurized, cured meats: Part I. Growth in pork slurries prepared from 'low' pH meat (pH range 5.5–6.3). International Journal of Food Science & Technology. 16(3):239-266.

- Roberts, T.A., Gibson, A.M., Robinson, A. 1981. Factors controlling the growth of *Clostridium botulinum* types A and B in pasteurized, cured meats: Part II. Growth in pork slurries prepared from 'high' pH meat (pH range 6.3–6.8) International Journal of Food Science & Technology, 16: 267-281.

Up-to-date validated modeling provides the following results for products cooked to full lethality:

- Results of modeling using the ComBase *Perfringens* Predictor ranged from **3.92**-Log *C. perfringens* growth for a product with 1% salt to **2.8**-Log *C. perfringens* growth for a product with 2% salt concentration. Due to the high levels of predicted growth for *C. perfringens*, a figure of the modeling output has not been included in the guideline. FSIS decided, however, to still include the option itself in the guideline because the modeling is likely overestimating growth as follows:

    1. **The modeling was based on a worst-case salt scenario and cured products have higher salt concentrations.** The modeling was based on the use of a worst-case scenario pH of 6.2 and a salt concentration of 1%. However, many cured products have higher salt concentrations inherent to their formulation or as a result of processing (Desmond, 2006); and.

    2. **The modeling does not take into account the role of cure accelerators that have been found to increase the effectiveness of nitrite**. Research by King *et al.*, 2015 supports that products formulated with at least 100 ppm sodium nitrite and at least 250 ppm erythorbate or ascorbate that are cooled following FSIS Option 1.3 allow ≤ 1-Log *C. perfringens* growth. The research supports that other combinations of nitrite and erythorbate or ascorbate are effective at limiting the growth of *C. perfringens*. Although the research was performed with a poultry product, the authors indicated this was chosen as a worst-case scenario itself and that the results also apply to meat products (Personal Communication, 2017).

FSIS' Support for Option 1.4

Table 8. Summary of Option 1.4 (for products cooked to full lethality)

Option	Pre-Cooling Conditions	1st Stage of Cooling	2nd Stage of Cooling	Total Cooling Time
Option 1.4	≥ 40 ppm sodium nitrite and ≥ 6% brine concentration OR a_w ≤ 0.92	120 to 40°F ≤ 20 hours; Continuous temperature drop	Not Applicable	≤ 20 hours

The original option was developed using research found in:

- Roberts, T.A., Gibson, A.M., Robinson, A. 1981. Factors controlling the growth of *Clostridium botulinum* types A and B in pasteurized, cured meats: Part I. Growth

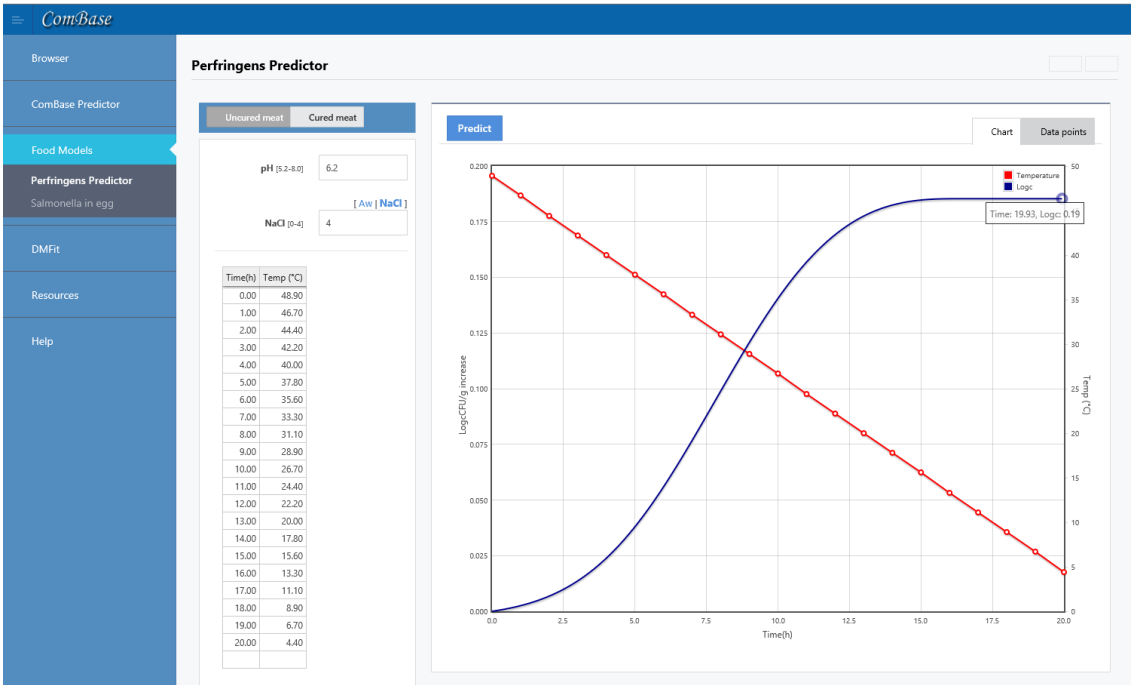
in pork slurries prepared from 'low' pH meat (pH range 5.5–6.3). International Journal of Food Science & Technology. 16(3):239-266.

- Roberts, T.A., Gibson, A.M., Robinson, A. 1981. Factors controlling the growth of *Clostridium botulinum* types A and B in pasteurized, cured meats: Part II. Growth in pork slurries prepared from 'high' pH meat (pH range 6.3–6.8) International Journal of Food Science & Technology, 16: 267-281.

Up-to-date validated modeling shows the following results for products cooked to full lethality, formulated with ≥ 40 ppm of sodium nitrite or its equivalent, and a brine concentration of 6% or more:

- ComBase *Perfringens* Predictor Results = **0.19**-Log growth (see Figure 4 for modeling output.))

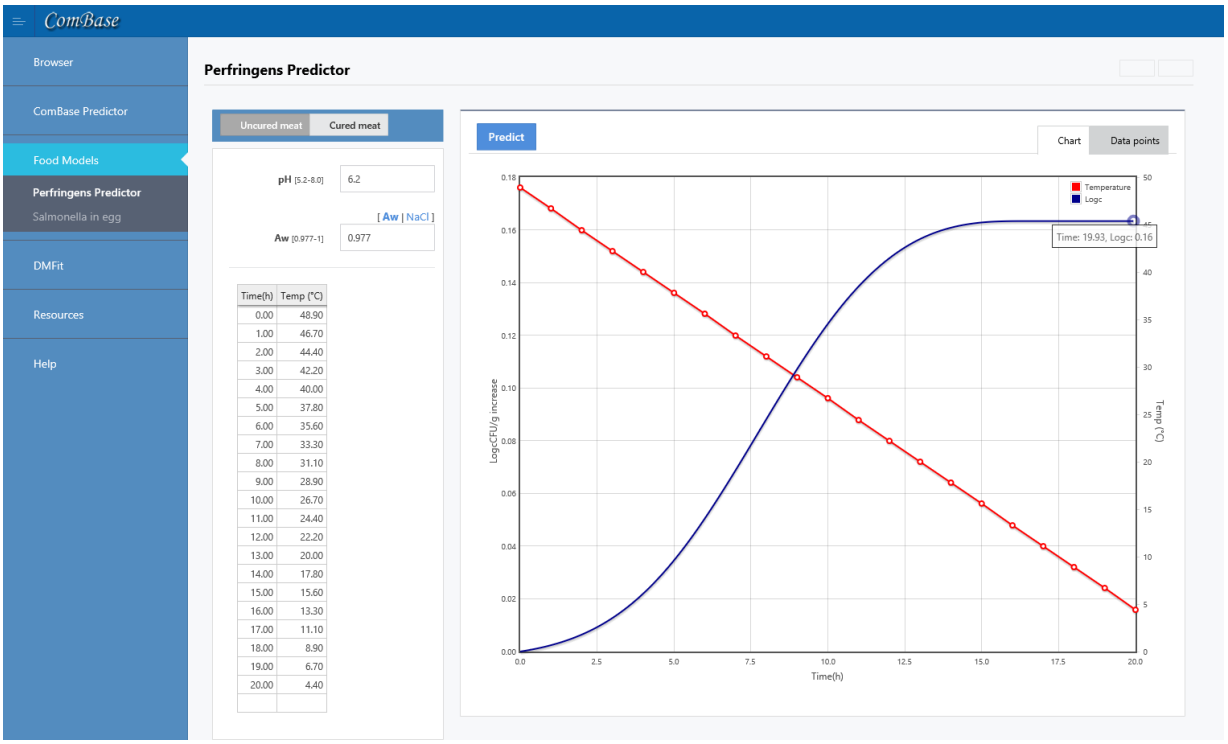
Figure 4. ComBase *Perfringens* Predictor Modeling Output for Option 1.4 (products formulated with ≥ 40 ppm of sodium nitrite or its equivalent and a brine concentration of 6% or more).



Up-to-date validated modeling provides the following results for products cooked to full lethality formulated with or without nitrite (such as salt cured product), and with a maximum water activity of 0.92:

- ComBase *Perfringens* Predictor Results = **0.16**-Log growth (see Figure 5 for modeling output).

Figure 5. ComBase *Perfringens* Predictor Modeling Output for Option 1.4 (products with a maximum water activity of 0.92).



FSIS' Support for Option 1.5

Table 9. Summary of Option 1.5 (for products cooked to full lethality).

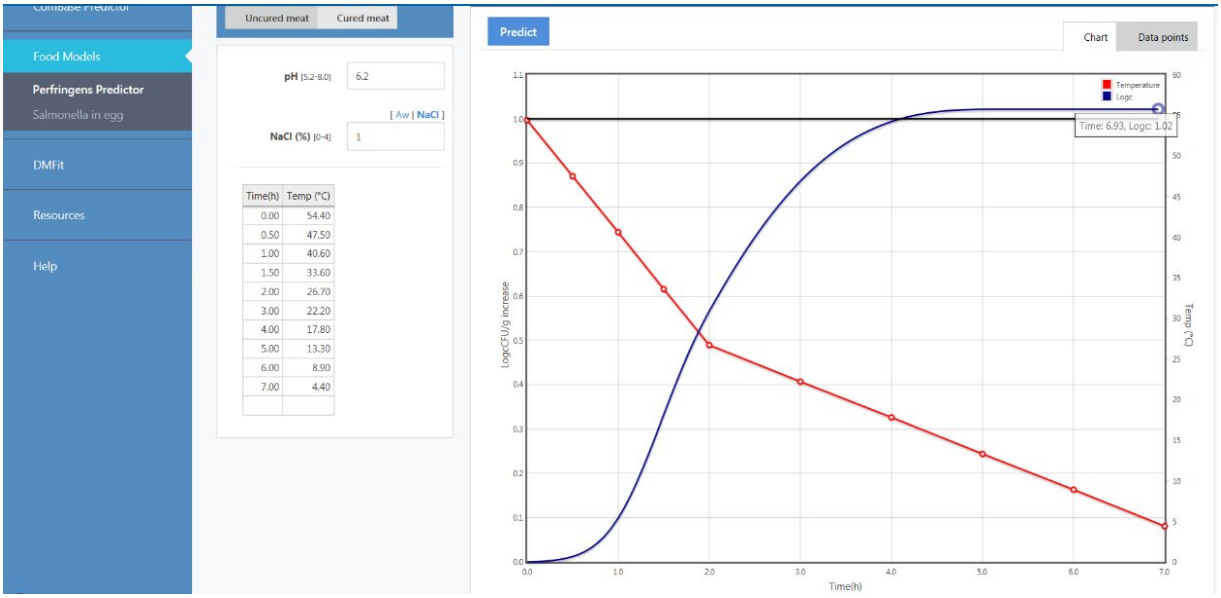
Option	Pre-Cooling Conditions	1st Stage of Cooling	2nd Stage of Cooling	Total Cooling Time
Option 1.5		130 to 80°F ≤ 2 hours	80 to 40°F ≤ 5 hours	≤ 7 hours

Option 1.5 is a modification of Option 1.1 that FSIS developed using validated modeling.

Up-to-date validated modeling provides the following results for products cooked to full lethality:

- ComBase *Perfringens* Predictor Results = **1.02**-Log growth (see Figure 6 for modeling output)

Figure 6. ComBase *Perfringens* Predictor Modeling Output for Option 1.5.



FSIS' Support for the Development of Option 1.6

Table 10. Summary of Option 1.6 (for products cooked to a fully lethality).

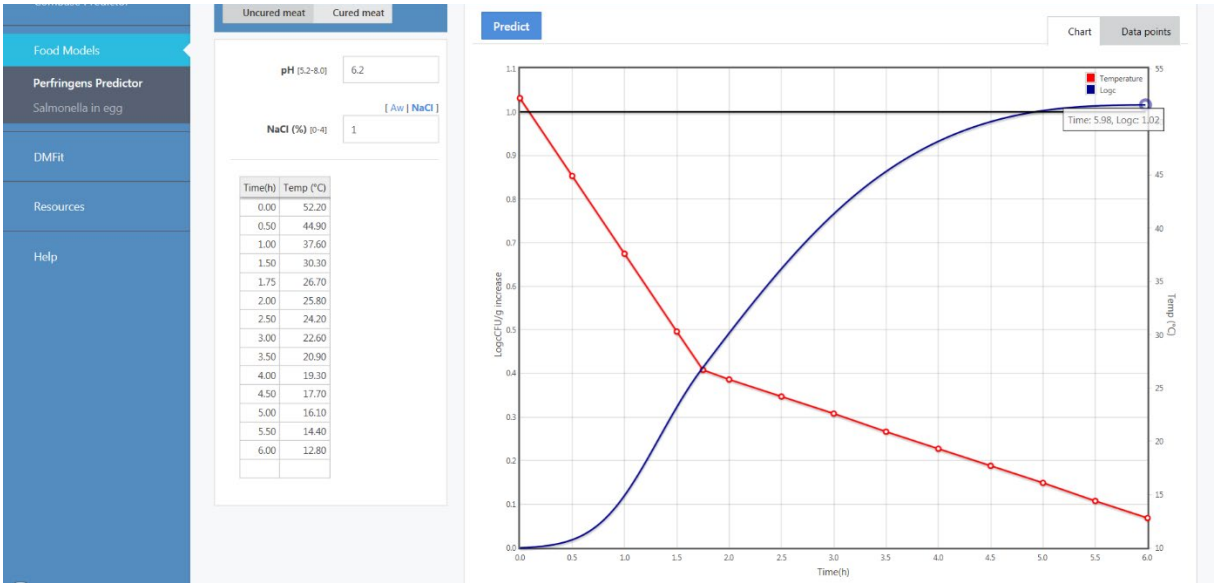
Option	Pre-Cooling Conditions	1st Stage of Cooling	2nd Stage of Cooling	Total Cooling Time
Option 1.6		126 to 80°F ≤ 1.75 hours	80 to 55°F ≤ 4.75 hours; Continuous chilling until 40°F	≤ 6.5 hours

Options 1.6 is a modification of Option 1.2 that was designed to extend the time during the 1st stage of cooling as long as possible using validated modeling.

Up-to-date validated modeling provides the following results for products cooked to full lethality:

- ComBase *Perfringens* Predictor Results = **1.02**-Log growth (see Figure 7 for modeling output).

Figure 7. ComBase *Perfringens* Predictor Modeling Output for Option 1.6.



FSIS' Support for Option 1.7

Table 11. **Summary of Option 1.7** (for products cooked to full lethality).

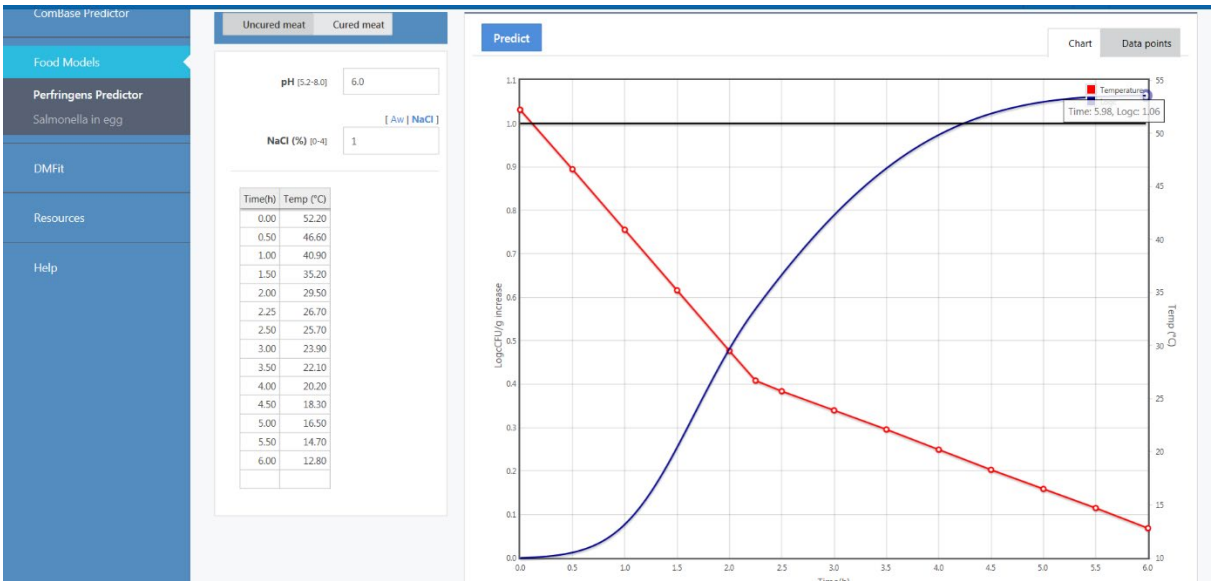
Option	Pre-Cooling Conditions	1st Stage of Cooling	2nd Stage of Cooling	Total Cooling Time
Option 1.7	pH≤ 6.0	126 to 80°F ≤ 2.25 hours	80 to 55°F ≤ 3.75 hours; Continuous chilling until 40°F	≤ 6 hours

Option 1.7 is a modification of Option 1.2 developed using validated modeling.

Up-to-date validated modeling provides the following results for products cooked to full lethality:

- ComBase *Perfringens* Predictor Results = **1.06**-Log growth (see Figure 8 for modeling output).

Figure 8. ComBase *Perfringens* Predictor Modeling Output for Option 1.7.



FSIS' Support for Option 1.8

Table 12. Summary of Option 1.8 (for products cooked to full lethality).

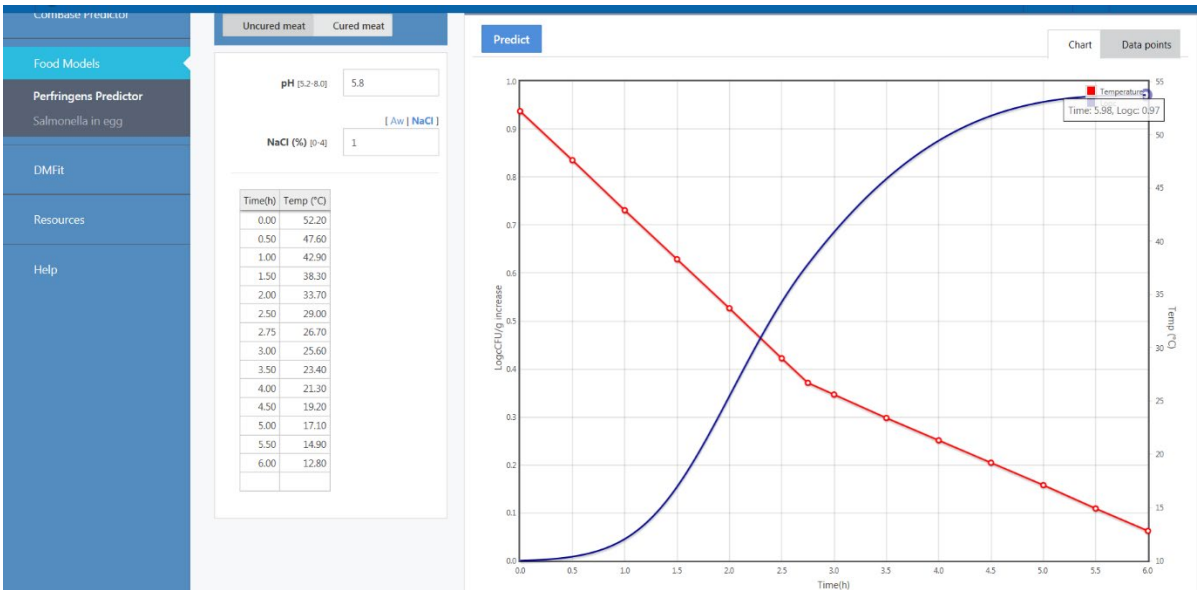
Option	Pre-Cooling Conditions	1st Stage of Cooling	2nd Stage of Cooling	Total Cooling Time
Option 1.8	pH≤ 5.8	126 to 80°F ≤ 2.75 hours	80 to 55°F ≤ 3.25 hours; Continuous chilling until 40°F	≤ 6 hours

Option 1.8 is a modification of Option 1.2 developed using validated modeling.

Up-to-date validated modeling provides the following results for products cooked to full lethality:

- ComBase *Perfringens* Predictor Results = **0.97**-Log growth (see Figure 9 for modeling output).

Figure 9. ComBase *Perfringens* Predictor Modeling Output for Option 1.8.



FSIS' Support for Option 2.1

Table 13. Summary of Option 2.1 (for products not cooked to full lethality).

Option	Pre-Cooling Conditions	1st Stage of Cooling	2nd Stage of Cooling	Total Cooling Time
Option 2.1	CUT between 50 - 130°F ≤ 1 hour	130 to 80°F ≤ 1.5 hours	80 to 40°F ≤ 5 hours	≤ 6.5 hours

Option 2.1 is a modification of Option 1.1 for products not cooked to full lethality. The original option (Option 1.1) was developed using research found in:

- Blankenship, L.C., Craven, S.C., Leffler, R.G., and Custer, C. 1988. Growth of *Clostridium perfringens* in Cooked Chili during Cooling. Appl. Environ. Microbiol. 54:1104-1108; and

- Thompson, D.R., Willardsen, R.R., Busta, F.F., Allen, C.E. 1979. *Clostridium perfringens* population dynamics during constant and rising temperatures in beef. Journal of Food Science. 44(3):646-651.

Option 2.1 was developed using validated modeling. To develop the critical operating parameter to limit the CUT between 50 to 130°F to one hour, FSIS used the Smith-Schaffer Model because this model allows input of data as the product temperature increases (during the heating CUT) and input of data as the product temperature decreases (during cooling). The application of the Smith-Schaffner Model with a one-hour CUT followed by the cooling process in Option 1.1 resulted in a **1.13-Log**

cumulative increase in *C. perfringens*. This is slightly above the regulatory requirement of no more than a 1-Log multiplication of *C. perfringens* for partially heat-treated products (9 CFR 318.23(c)(1) and 9 CFR 381.150(a)(2)). However, the modeling was performed based on a worst-case time-temperature profile assuming linear heating and cooling. Normally, meat and poultry products heat up and cool down exponentially. Linear modeling of the heating come up and cool down result in underestimating pathogen growth during the short heating come up period but overestimating pathogen growth during the longer cool down period, resulting in an overall overestimation of pathogen growth. Therefore, FSIS considers this modeling result fail-safe (that is a result that is not accurate in modeling terms but that errs on the side of the product being safe).

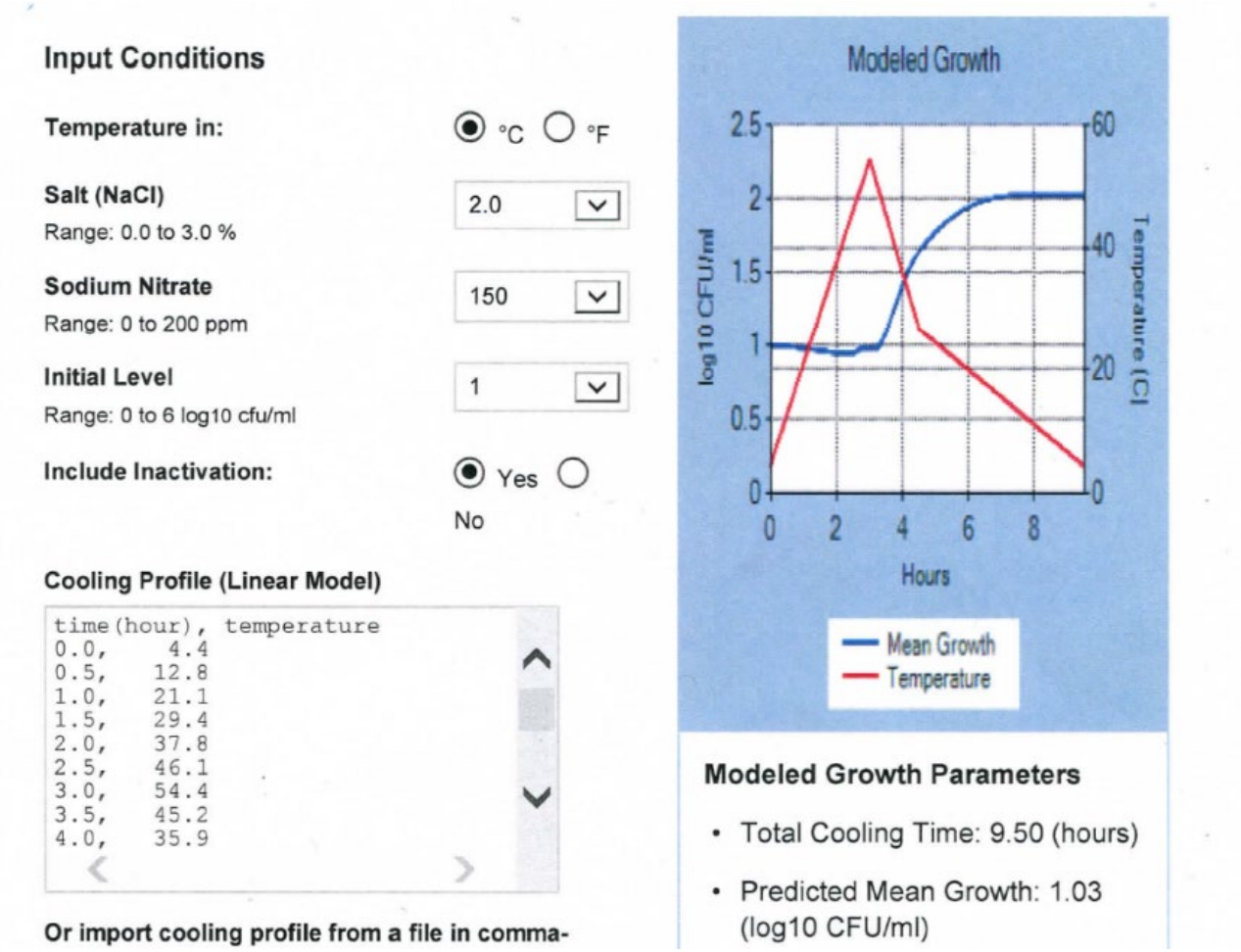
FSIS' Support for Option 2.2

Table 14. Summary of Option 2.2(for products not cooked to full lethality).

Option	Pre-Cooling Conditions	1st Stage of Cooling	2nd Stage of Cooling	Total Cooling Time
Option 2.2	CUT between 50 - 130°F ≤ 3 hours and ≥ 2% salt and ≥ 150 ppm sodium nitrite and cure accelerator or natural source of ascorbate (sufficient for purpose)	130 to 80°F ≤ 1.5 hours	80 to 40°F ≤ 5 hours	≤ 6.5 hours

Option 2.2 is also a modification of Option 1.1 for products not cooked to full lethality. Option 2.2 was also developed using validated modeling. This option was developed based on the use of the ARS PMP Online Cooling Model for Growth of *C. perfringens* in Cooked Beef supplemented with NaCl, Sodium nitrite, and Sodium pyrophosphate, which allows for input of the heating CUT, the cooling time, and NaCl (salt) and nitrite concentrations. The ARS cooling model estimates the growth of *C. perfringens* to be **1.03-Log** based on modeling in a conservative manner. The ARS cooling model is more conservative when compared against predictions from the validated ComBase *Perfringens* Predictor (see Figure 10 for modeling output).

Figure 10. ARS PMP Online Cooling Model for Growth of *C. perfringens* in Cooked Beef Supplemented with NaCl, Sodium nitrite, and Sodium pyrophosphate Modeling Output for Option 2.2.



FSIS Support for Application of Options 1.1, 1.2, 1.5-1.8 to Rice, Pasta, and Beans

As stated in the section titled Products and Processes Covered by this Guideline, page 10, establishments may use FSIS Cooling Options in Table 1 for products that do not contain nitrite and erythorbate or ascorbate (*i.e.,* Options 1.1, 1.2, 1.5-1.8) or for the cooling of rice, pasta and bean products. This recommendation is based on the scientific rationale that the time and temperature conditions that would generally limit the growth of *C. perfringens* to 1-Log or less would also effectively limit the growth of *Bacillus cereus* (*B. cereus is* a spore-former that is a greater hazard of concern than *C. perfringens* in rice, pasta, and bean products) and prevent multiplication of *C. botulinum*, since these pathogens generally grow more slowly than *C. perfringens*. For example, the shortest generation time (the time it takes to double in population) for *C. perfringens* under optimum growth temperatures (i.e., 43°C to 47°C) is approximately seven (7) minutes in ground beef (Willardson, *et a*l., 1978), whereas the shortest generation time for *B. cereus* ranged from 18 to 27 minutes in tryptic soy broth (TSB)

and rice under optimum growth temperatures (i.e., 35°C to 45°C) (Johnson, *et al.*, 1983). In addition, the cooling options in Table 1 for products that do not contain nitrite and erythorbate or ascorbate are similar to the FDA Food Code cooling recommendations which are designed to control the growth of all spore-forming bacterial pathogens including *B. cereus* in all cooked products (see Attachment B6. Other Published Processing Guidelines for Cooling, page 77).

Attachment B4. Steps an Establishment Can Take to Cool Products More Rapidly

Some establishments may have challenges meeting the cooling recommendations in this guideline, particularly for large mass products. For products that are close to meeting the time-temperature parameters for the cooling options in this guideline, establishments may benefit from critically examining their cooling process and system and making minor improvements such as:

- Making sure the cooling system is operating properly.
- Ensuring cooler door seals and gaskets are in good repair and properly seal when each door is closed.
- Pre-chilling the cooler before loading the product.
- Using a lower temperature setting in the cooler.
- Increasing airflow (*e.g.*, adding a fan) to speed cooling.
- Leaving more space between products to allow increased air circulation between products.
- Allowing space between product and the walls, floors, and ceiling to improve air circulation.
- Agitating or stirring liquid products while cooling.
- Cooling product before packaging, stacking, or palletizing because stacks of product can insulate those products in the middle and inhibit cooling. May also make smaller stacks of product because smaller pieces or smaller groups of products cool faster.
- Reducing the amount of product in each batch or lot placed in the cooler at one time to reduce the total heat load to be removed.
- Taking steps that would decrease the temperature of the product prior to placing it in the cooler to reduce the heat load on the cooling system. For example, apply a liquid cooling procedure (*e.g.*, cold brine shower, ice bath) or dry ice to rapidly cool the product prior to placing it in the cooler.
- Making minor production changes to reduce product size or diameter (*e.g.*, by cutting large roasts into smaller portions or using a smaller size casing for sausages), provided these changes do not impact product quality.

Attachment B5. Predictive Microbial Modeling and Corrective Actions Following a Deviation

This appendix on predictive modeling includes the following several sections:

Predictive food microbiology uses models (*i.e.*, mathematical equations) to describe the growth, survival, or inactivation of microbes in food systems based on knowledge of the **intrinsic** and **extrinsic** factors of the food over time. Establishments can use predictive microbial models to help guide the design of a customized cooling process for processes that can't meet the critical operating parameters recommended in this guideline. Predictive microbial models can also be used to support product safety in the event of a cooling deviation, potentially preventing the need to perform sampling. There are many free predictive microbial models available to establishments either online or through a download. Establishments should not rely on the results of a predictive model alone unless the model has been validated for the particular food of interest. Note that there are several validated predictive models available for assessing *C. perfringens* growth.

KEY DEFINITIONS

Intrinsic factors are those parameters inherent to a food that affect the growth of microorganisms. Examples of intrinsic factors include pH, moisture content, salt concentration, water activity, and nutrient content.

Extrinsic factors are those parameters that are external to the food that affect the growth of microorganisms. Examples of extrinsic factors include temperature of storage unit, time of storage, and relative humidity.

Recommendations when Conducting Predictive Microbial Modeling

FSIS recommends that the establishments abide by the following principles when choosing and using a predictive microbial model to assure they model useful scientific support.

1. Use a model that has been validated for the product of interest.
2. Conduct modeling using at least five time-temperature data points.
3. Conduct modeling based on the worst-case cooling time-temperature profile for the product of interest.
4. Input accurate pH and salt concentrations, if included in the model; and
5. Maintain the results of the modeling electronically or via a hardcopy file.

More detail on each of these principles is below:

1. **Use a model that has been validated for the product of interest.** Do not rely solely on a model unless the model has been validated for the particular food of

interest. A validated cooling model is a model in which predictions have been found to agree with or are more conservative than the actual observed results. If a model has not been validated for a particular food of interest, establishments need to provide additional documentation to support the results from the model (*e.g.*, sampling data or comparison with other model results).

- These four cooling models **have been validated** for assessing the growth of *C. perfringens* in cooked/heat-treated meat and poultry products:
  1. ComBase *Perfringens* Predictor Model
     a. uncured and cured meat, and
     b. poultry
  2. USDA ARS Predictive Microbiology Information Portal (PMP Online) models for:
     a. cooked, uncured beef, pork, and chicken;
     b. cured pork and beef; and
     c. cooked beef supplemented with NaCl, sodium nitrite, and sodium pyrophosphate;
  3. USDA ARS Pathogen Modeling Program (download version 7.0/8.0) models for:
     a. cooked, cured beef and chicken; and
  4. Smith-Schaffner Model—Version 3
     a. uncured meat and poultry products

- This cooling model **failed validation testing and is not recommended:** ARS *C. perfringens* in beef broth model. This model has been found to typically under-predict the growth of *C. perfringens* (Mohr *et al.*, 2015). Because the model failed to be validated, it has been removed from the ARS website although some establishments may have it downloaded on their computers.

- This cooling model **has not been validated, but may be used:** ARS *C. botulinum* in beef broth cooling model (Available through PMP Online or the downloaded version of the ARS Pathogen Modeling Program). Although this model has not been validated, it is the best tool available at this time. Therefore, FSIS does not object to the use of this model without additional support.

2. **Conduct modeling using at least five time-temperature data points.** At least five data points are needed to run certain cooling models and to get an accurate estimate. If less than five data points are available, establishments may be able to develop a cooling curve by interpolating additional points, assuming a linear decrease between known values. One common error is incorrectly inputting time points using the wrong units; hours instead or minutes or minutes instead of hours.

3. **Conduct modeling based on the worst-case cooling time-temperature profile for the product of interest.** To assess what the worst-case cooling scenario might be, the establishment should account for its actual cooling CCP or prerequisite program critical limits. For example, if the establishment's

customized cooling process schedule critical limits are to cool from 130°F to 80°F in 2 hours and between 80°F and 40°F in 5.5 hours, it should assume the worst-case (that is, a linear decrease) between these values in order to determine the growth of *C. perfringens*.

4. **Input accurate pH and salt concentrations, if included in the model.** Knowledge of intrinsic and extrinsic factors (*e.g.*, pH, a_w, temperature, salt concentration) used as inputs for the model is essential to have confidence in the results. Establishments should determine and use values for these parameters that represent the worst-case of possible processing conditions and have documentation to support the values used. If the establishment does not know the pH and salt concentrations, it should assume a worst-case pH of 6.2 and salt concentration of 1% unless no salt is added and then 0% should be used.

5. **Maintain modeling results on file.** Both the input and the output of the modeling results should be maintained as part of the supporting documentation for the life of the plan (9 CFR 417.5(a)(1)), along with support that the model has been validated (which could include this guideline).

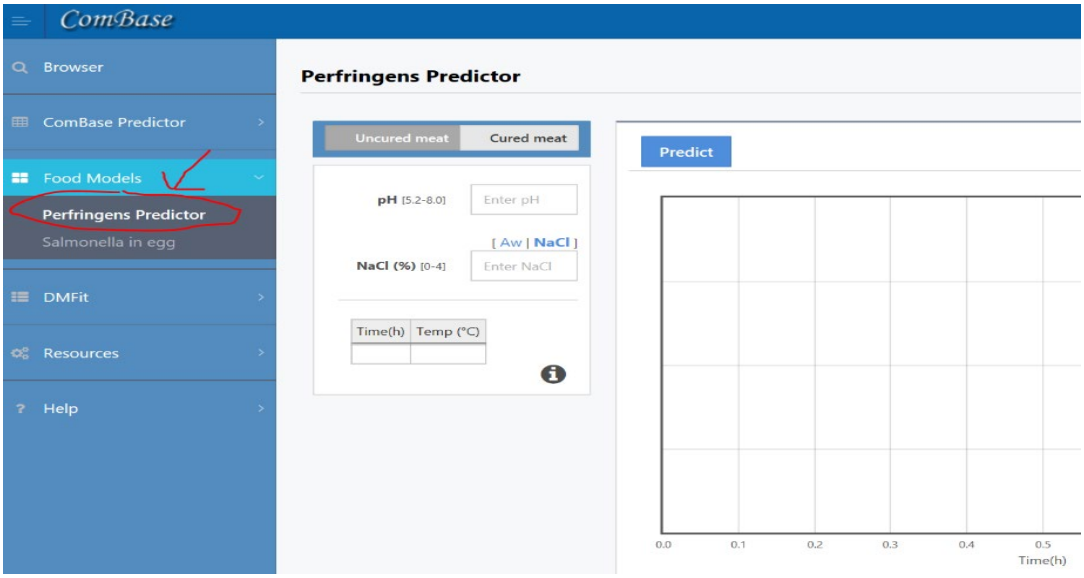
Validated Pathogen Models

As described above, establishments should not rely on the results of a model alone unless the model has been validated for the particular food of interest. This section describes, in more detail, the **sources for validated cooling models** currently available for assessing the growth of *C. perfringens* in cooked/heat-treated meat and poultry products, with information on their availability. Not all models cover a full range of growth parameters. Therefore, knowledge of the basis for the model and its limitations in different food systems is key to making supportable determinations and using a model properly.

ComBase *Perfringens* Predictor Model:

The ComBase website contains a number of predictive microbial models. One in particular, The ComBase *Perfringens* Predictor model (see Figure 11) available at *https://browser.combase.cc/Perfringens_Predictor.aspx* has been validated[11] for cooked, cured, and uncured meat and poultry products. Therefore, establishments may rely on the results from this model alone.

Figure 11. Screenshot of ComBase *Perfringens* Predictor.



Establishments should be aware that this model provides an **accurate** estimation of the growth of *C. perfringens* in cooked, cured, and uncured meat and poultry products. Furthermore, in addition to taking into account whether the products are cured or uncured, the ComBase *Perfringens* Predictor model takes into account the pH and salt concentration of the meat or poultry product, which the other cooling models do not. Establishments may select the "cured" option for products that contain at least 100 ppm of ingoing nitrite from a synthetic or natural source.

USDA ARS Predictive Microbiology Information Portal (PMIP or PMP Online):

The USDA ARS PMP Online, available at https://pmp.errc.ars.usda.gov/PMPOnline.aspx, contains a number of predictive microbial models (See Figure 12 for an example.).

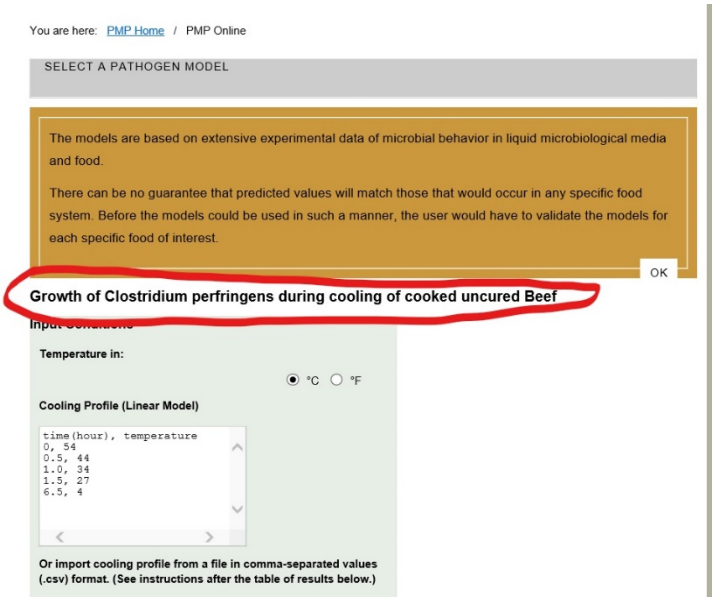
[11] A copy of the validation report is available from the Food Standard Agency, United Kingdom. The cooling model research has been published in the International Journal of Food Microbiology (Yvan Le Marc *et al.*, 2008).

The following three cooling models for uncured meat and poultry products on PMP Online have been validated (Mohr *et al.*, 2015).

- *C. perfringens* in cooked, uncured beef.
- *C. perfringens* in cooked, uncured pork.
- *C. perfringens* in cooked, uncured chicken.

Establishments may, therefore, rely on the results from these cooling models alone, without any additional supporting documentation.

Figure 12. Screenshot of ARS PMP Online.



In addition, the following models for cured meat and poultry products have been validated (Mohr, 2018):

- *C. perfringens* in cooked, cured beef.
- *C. perfringens* in cooked, cured pork.
- *C. perfringens* in cooked beef supplemented with NaCl, sodium nitrite, and sodium pyrophosphate.

Establishments may, therefore, also rely on the results from these cooling models alone.

Establishments should be aware that, in most cases, these cooling models will **over-estimate** the amount of growth of *C. perfringens* in a meat or poultry product involved in a cooling deviation or for a customized cooling schedule. In addition, establishments should not rely solely on the results of other models within the PMP Online because most of them have not been validated.

USDA ARS Pathogen Modeling Program (download version 7.0/8.0)

The USDA's ARS has a number of predictive microbial models that are available in its downloadable Pathogen Modeling Program. The downloadable version of the Pathogen Modeling Program can be found at: https://portal.errc.ars.usda.gov/PMP.aspx. The following cooling models are available within the downloadable Pathogen Modeling Program (both version 7.0 and 8.0):

- *C. perfringens* in cooked, cured beef.
- *C. perfringens* in cooked, cured chicken.

These cooling models have been validated (Mohr, 2018). Therefore, establishments may rely on the results from these cooling models alone.

Establishments should be aware that in most cases these cooling models will **over-estimate** the amount of growth of *C. perfringens* in a meat or poultry product involved in a cooling deviation or for a customized cooling schedule. In addition, establishments should not rely solely on the results of other models within the PMP Online since most of them have not been validated.

Smith-Schaffner Model—Version 3:

The Smith-Schaffner Model, Version 3, a Microsoft Excel-based model, is another cooling model that can be used for assessing the growth of *C. perfringens*. The Smith-Schaffner Model, Version 3, also meets the FSIS criteria for acceptable performance and "validation for food safety" (Mohr *et al.*, 2015). Therefore, establishments may rely on the results of this model alone.

This model has been validated for cooked, uncured meat and poultry products. It is a reliable model for assessing the severity of cooling deviations for cooked, uncured meat and poultry products with typical pH values and typical levels of salt and phosphate. It is also a useful model for evaluating deviations because it allows for input of data where the temperature decreases and then increases and decreases a second time. The Smith-Schaffner Model is no longer available on-line but establishments may request a copy through askFSIS.

Using Predictive Microbial Models to Assess Growth of Clostridia when a Process Incorporates Multiple Heat Treatments

As previously explained, FSIS guidance is designed for cooling processes where the product is cooked or heated once and then cooled. A full lethality treatment will destroy all vegetative cells of *Clostridia,* leaving only the spores to survive. It is the outgrowth of spores and the production of toxins or high levels of vegetative cells that are the concerns during stabilization. However, for some processes where the products are cooked, cooled, and then undergo a partial heat treatment followed by cooling, establishments should assess the cumulative growth of *Clostridia*.

Establishments should take the following into account when determining whether they need to assess the growth of *Clostridia* over multiple heating and cooling steps:

- If the process incorporates multiple full lethality treatments (*i.e.*, by achieving *FSIS Cooking Guideline* conditions), the establishment needs to assess the growth of *Clostridia* during the cooling step following each individual lethality treatment and does not need to assess the cumulative growth over the multiple steps; and

- If the process incorporates a full lethality treatment, and then is followed by a post-lethality heat treatment that does not achieve a full lethality and then re-stabilizes (cools) the product, the establishment should assess the cumulative growth of *C. perfringens* that occurs during the first cooling process, the growth

that occurs during the heating come-up, and the growth that occurs during the cooling come-down time of the subsequent post-lethality treatment or warming step. Common examples of processes that use post lethality heat treatments include double smoking, applying heat to the surface of a cooled RTE product after slicing, reheating a filling, or frying a tamale that contains cooked meat.

To assess the cumulative growth of *C. perfringens* in the process, as described in the second bullet above, establishments should perform predictive microbial modeling of certain heating and cooling steps in the process. More specifically, this modeling should include the first cooling step and the heating come-up and cooling come-down time of the subsequent post-lethality treatment or warming step using the same model. FSIS recommends that to perform the modeling, establishments collect time-temperature profiles for each of the aforementioned heating and cooling steps. Establishments that receive previously cooked product from a supplier and then apply a heat treatment should communicate with their supplier to obtain its worst-case cooling profile or its cooling critical limits/prerequisite program limits to determine the worst-case cooling profile (*e.g.*, by interpolating additional points for modeling by assuming a linear decrease between time-temperature limits).

Based on the worst-case time-temperature profiles, establishments can use one of the options below for modeling cooked meat and poultry products:

1. Use the ComBase *Perfringens* Predictor cooling model (found under Food Models on the ComBase website) and the ComBase *C. perfringens* Growth Model (found under Growth Models on the ComBase website) to assess the cumulative growth of *C. perfringens* during the entire time-temperature profile based upon a worst-case scenario approach. For this option, FSIS recommends that establishments:

    - Use the ComBase *Perfringens* Predictor to estimate the *C. perfringens* growth during the first cooling step and then add those results to the results obtained by performing the next step below.

    - Use the ComBase *C. perfringens* Growth Model to estimate the *C. perfringens* growth during the heating come-up and cooling come-down time of the subsequent post-lethality treatment or warming step.
        - Use a physiological state of 1 (no lag phase) to model in a conservative manner, given that many of these predictive microbial growth models are not fail-safe for predicting the lag phase (Tamplin, 2002; Vold, *et al.*, 2000; Walls and Scott, 1996).
        - Use a temperature of 59°F (15°C) for the product's time-temperature data points that are below 59°F (15°C) to overcome one of the shortcomings of using the ComBase *C. perfringens* growth model.

      NOTE: It is only appropriate to conduct separate models for each of the steps in the process (*e.g.*, modeling the first cooling step and then the second heating CUT and cooling step separately) if a physiological state of 1 is used to indicate no lag phase, when using the ComBase *C. perfringens* Growth Model. Otherwise, the modeling would assume *C. perfringens* undergoes a lag phase

each time the model is run, which would not be representative of the actual process.

2. Use the ComBase *C. perfringens* Growth Model to assess the cumulative growth of *C. perfringens* during the entire time-temperature profile based upon a worst-case scenario approach. For this option, FSIS recommends that establishments:

   - Use a physiological state of 1 to model, in a conservative manner, especially given that many of these predictive microbial growth models are not fail-safe for predicting the lag phase (Tamplin, 2002; Vold, *et al.*, 2000; Walls and Scott, 1996); and

   - Use a temperature of 59°F (15°C) for product's time-temperature data points that are below 59°F (15°C) to overcome one of the shortcomings of using the ComBase *C. perfringens* growth model.

3. Use the Smith-Schaffner Model to assess the cumulative growth *of C. perfringens* during the entire time-temperature profile based upon a worst-case scenario approach.

The modeling results should demonstrate that the entire process allows no more than the performance standard or the target the establishment identifies (*i.e.*, 1.0-Log total growth of *C. perfringens* and no multiplication of *C. botulinum*) in the finished product before shipment. When employing a post-lethality heat treatment, establishments should remember that *C. perfringens* will not grow at temperatures of 130°F or greater.

Establishments may also choose to conduct a challenge study to demonstrate that the entire process allows no more than the performance standard or the target the establishment identifies (*i.e.*, 1.0-Log total growth of *C. perfringens* and no multiplication of *C. botulinum*) in the finished product before shipment.

Corrective Actions to Perform When a Cooling Deviation Occurs

Cooling deviations occur when an establishment fails to meet its cooling CCP critical limit or cooling process schedule. Common causes for cooling deviations are exceeding the chilling capacity of the coolers, power failures, or breakdowns of refrigeration equipment. Establishments are required to take corrective actions, as per the HACCP regulations, regardless of whether the cooling process is addressed through a CCP or prerequisite program. In such situations, establishments must be able to ensure that no product that is injurious to health or otherwise adulterated because of the deviation enters commerce, and to support its product disposition decisions (9 CFR 417.3(a) and (b)).

NOTE: FSIS included the Corrective Actions to Perform When a Cooling Deviation Occurs within the Pathogen Modeling section because FSIS recommends pathogen modeling as the first step to evaluate product safety. FSIS does not recommend testing without modeling first.

When cooling is addressed through a CCP, establishments are required to determine the cause of all cooling deviations, no matter how small (9 CFR 417.3(a)(1)), and ensure measures are established to prevent recurrence (9 CFR 417.3(a)(3)). Ultimately, if the cause of each small cooling deviation is not traced and corrected when first noticed, the problem will likely recur and become more frequent and more severe. The establishment should consider an occasional small deviation to be an opportunity to find and correct a-problem. Large deviations or continual small ones always constitute unacceptable risk. Also, continual or repetitive deviations from the critical limit demonstrate that the establishment is unable to control its process and that corrective actions are not preventing problems as intended (9 CFR 417.4(b)).

When cooling is addressed through a prerequisite program and a deviation occurs, establishments are required to reassess their food safety system to determine whether the newly identified deviation or unforeseen hazard should be addressed and incorporated into the HACCP plan (9 CFR 417.3(b)(4)). Also, an establishment may not be able to continue to support the decision in its hazard analysis that spore-formers are not reasonably likely to occur, if it has continual or repetitive deviations from its cooling prerequisite program (9 CFR 417.5(a)(1)).

To determine the safety of the product affected by a cooling deviation, FSIS recommends that establishments first conduct modeling using validated cooling models. Depending on the results of the modeling, sampling may be recommended. As part of the support for product safety, FSIS recommends establishments write up an assessment of the deviation that addresses the specific hazards and includes:

- The predictive microbial model selected (including supporting documentation that the model has been validated).
- The data inputs to the model (and in the case of missing data, a rationale or support for data used).
- An assessment of the results generated by the model.
- A product disposition determination.

Using Pathogen Modeling to Assess a Cooling Deviation

FSIS recommends establishments use validated predictive microbial models to assess cooling deviations, such as the ComBase *Perfringens* Predictor model. General recommendations regarding cooling models can be found on page 64 of this guideline. Predictive microbial models (*i.e.*, cooling models) are an excellent tool to use in assessing the severity of a cooling deviation, provided the model has been validated for the specific product. In the case of a cooling deviation, establishments should input the time-temperature profile as documented through monitoring. If an establishment does not know the pH or salt concentration of the product that experienced the cooling deviation, it should assume a worst-case pH of 6.2 and a salt concentration of 1% (Mohr *et al.*, 2015).

Once establishments obtain modeling results, they should evaluate them to determine product disposition. The disposition of RTE and NRTE product resulting from cooling deviations and based on modeling and/or sampling should follow the criteria below:

- **Result 1**. There is no more than 1-Log growth of *C. perfringens* and no *C. botulinum* growth (mean net growth ≤ 0.30-Log)[12] then the process meets the stabilization performance standard or policy and the product may be:
    - Released into commerce.
- **Result 2**. There is more than a 1-Log growth of *C. perfringens*, no *C. botulinum* growth[13] (mean net growth ≤ 0.30-Log), less than 3.0-Log growth of *B. cereus*[14], and the establishment does not have support that spore levels in the product are low, then product may be:
    - Recooked,
    - Sampled and Tested (N ≥ 10), or

[12]If there is no more than 1-Log growth of *C. perfringens,* then multiplication of *C. botulinum* is unlikely based on FSIS's review of modeling that establishments conducted in response to deviations and FSIS' modeling performed to support its cooling recommendations. Therefore, establishments can support the products' safety using *C. perfringens* alone **without conducting modeling for *C. botulinum***.

[13]In the event of a cooling deviation for **cured** meat and poultry products, establishments can support the safety of affected product using modeling for *C. perfringens* alone **without conducting modeling for *C. botulinum*** because the presence of nitrite, salt, and a cure accelerator such as sodium erythorbate, should ensure that no multiplication of *C. botulinum* occurred during the deviation

[14]In general, establishments only need to assess *B. cereus* growth when modeling estimates *C. perfringens* growth is > 3.0-Log—because *C. perfringens* grows faster than *B. cereus*. Establishments can assess *B. cereus* growth using the ComBase Growth Model for *B. cereus* (found under ComBase Predictor Growth Models). Although this model has not been validated, it is the best tool available, so establishments may use it. Establishments should use a physiological state of 1 to model in a conservative manner, especially given that many of these predictive microbial growth models are not fail-safe for predicting the lag phase.

- Destroy the product (rendered or denatured per 9 CFR 314.3(a), 9 CFR 325.11(a), 9 CFR 325.13(a)(1) through 325.13(a)(7), or 9 CFR 381.95 and sent to a landfill).

- **Result 3**. There is greater than a 1.0-Log growth of *C. perfringens* and greater than a 0.30-Log increase of *C. botulinum*[15], then product must be:

  - Destroy the product (rendered or denatured per 9 CFR 314.3(a), 9 CFR 325.11(a), 9 CFR 325.13(a)(1) through 325.13(a)(7), or 9 CFR 381.95 and sent to a landfill).

Sampling after Pathogen Modeling

If an establishment has conducted modeling that showed Result 2 above, then the establishment may conduct sampling to assess the safety of the product involved in a deviation. FSIS recommends that establishments conduct modeling prior to any sampling, because it provides greater confidence for estimating levels of *C. perfringens* growth. Sampling is more limited because *C. perfringens* is generally not evenly distributed throughout the product. Therefore, depending on the results of the modeling, sampling may be an appropriate tool to provide information to the establishment to help support product disposition. Specifically, if modeling indicates there is more than a 1-Log growth of *C. perfringens* and no *C. botulinum* growth (mean net growth ≤ 0.3-Log), less than 3-Log growth of *B. cereus*, and the establishment does not have support that spore levels in the product are low, then product may be sampled to further support product safety. The following are FSIS recommendations for conducting this sampling and testing:

- At least 10 samples per affected lot should be taken at random. Samples should **NOT** be composited because the analysis is quantitative for each sample to determine product disposition.

- Samples should be refrigerated at 2-10°C (35-50°F) immediately after collection. Samples should be shipped to the laboratory under refrigerated (2-10°C) conditions overnight or for receipt within 24 hours at the laboratory. Upon laboratory receipt, samples should be inspected for condition and temperature and immediately refrigerated (2-10°C). The laboratory should promptly analyze samples to avoid loss of cell viability. The laboratory should not analyze samples more than 24 hours after receipt or that have been compromised during shipping.

- Testing should be performed to specifically assess for *C. perfringens* or gas forming anaerobes (GFAs).

[15] FSIS considers modeling results that demonstrate > 0.30-Log increase of *C. botulinum* to indicate multiplication. In general, predictive models FSIS recommends, such as the ARS *C. botulinum* in beef broth model, do not predict zero growth. As a practical way to evaluate cooling deviations, the Agency has regarded a predicted growth of no more than 0.3-Log (an approximate doubling, or one generation) as an indication that there has been no growth.

- If no sample exceeds 100 CFU/gram and no more than two samples equal 100 CFU/gram, then the lot can be released into commerce and sold as is. If no more than two samples exceed 100 CFU/gram and none exceeds 500 CFU/gram, then establishments should recook the lot of product. If more than two samples equal or exceed 100 CFU/gram or any exceed 500 CFU/gram, then the product should be destroyed.

Recooking after Pathogen Modeling

If an establishment has conducted modeling that showed Result 2 above, then the establishment also has the option to recook the product (without sampling and testing). FSIS recommends establishments conduct predictive microbial modeling for *C. botulinum* before recooking, because in the event the modeling shows greater than a 0.3-Log increase of *C. botulinum,* then recooking is not an appropriate method of product disposition.

A minimum recook temperature of 149°F with a holding time of at least two minutes, or a minimum instantaneous temperature of 169°F, is recommended when recooking product. This will address the hazard of *C. perfringens* vegetative cells because it will result in at least a 5.0-Log reduction.

FSIS recommends establishments recook only when:

- All product was either immediately refrigerated after the deviation or can be immediately recooked after the deviation.

- The recooking procedure can achieve a final internal product temperature of at least 149°F (65°C) for two (2) minutes or an instantaneous internal product temperature of 169°F. Subsequent to recooking, the product must again be cooled according to the establishment's support.

- When the product is to be reworked with another raw product, the recooking procedure for the combined product must achieve a minimum internal product temperature of 149°F (2 minutes holding time) to address the cooling deviation. The time-temperature for the combined product should be increased further, if necessary, to be in accord with any other requirement relative to microbiological safety for the intended final product. The reworked product must again be cooled to meet these same stabilization performance standards or targets.

FSIS recommends establishments recook product to a final internal product temperature of at least 149°F (65°C) for two (2) minutes or an instantaneous internal product temperature of 169°F, because *C. perfringens* is more heat tolerant once a product has been cooked. The time-temperature options in the *FSIS Cooking Guideline* meat table are based on thermal death time studies for *Salmonella* in **raw** ground beef. Therefore, the recommendations may not be sufficient to address *C. perfringens* in a cooked product. For example, Vijay *et al.*, 1998 showed that contaminated **cooked** beef should be re-heated to an internal temperature of 62.5°C (144.5°F) for at least 9.6 minutes and **cooked** turkey for at least 7.8 minutes to achieve at least a 6-Log

reduction of *C. perfringens*. However, the *FSIS Cooking Guideline* time-temperature table for meat products only has a dwell time of 5 minutes at 62.2°C (144°F). FSIS's recooking recommendations are based on D- and z-values reported in the published research (Vijay *et al.*, 1998). FSIS defined instantaneous temperature based on a dwell time of ≤ 10 seconds. Establishments may recook to other temperatures, provided they can support that the procedure would result in at least a 5.0-Log reduction of *C. perfringens* in a product that has been cooked. These values may not be suitable if the product to be recooked underwent a drying process after the original cooking step.

Attachment B6. Other Published Processing Guidelines for Cooling

FDA Time-Temperature Recommendations for Cooling

The Food and Drug Administration (FDA) Food Code is another type of support that establishments may use for cooling. Section 3-501.14 Cooling of the 2017 FDA Food Code recommends the following parameters for cooling products cooked to full lethality:

> (A) Cooked TIME/TEMPERATURE CONTROL FOR SAFETY FOOD shall be cooled:
>
> (1) Within 2 hours from 57ºC (135ºF) to 21ºC (70°F); and
>
> (2) Within a total of 6 hours from 57ºC (135ºF) to 5ºC (41°F) or less.

This option applies to:

1. Products cooked to full lethality (including intact or non-intact meat or poultry).

Establishments must keep the most up-to-date copy of the FDA Food Code on file as supporting documentation to use this cooling procedure.

CFIA Time-Temperature Recommendations for Cooling

An establishment may follow the cooling parameters from the Canadian Food Inspection Agency (CFIA) cooling procedure found in the CFIA's Cooling of Heat Processed Meat Products, because FSIS has verified this option results in ≤ 1 log growth of *C. perfringens* and no multiplication of *C. botulinum*.

During continuous cooling immediately after the heating cycle is completed:

> (A) The product's maximum internal temperature must not remain between 54°C (129.2°F) and 27°C (80.6°F) for more than two (2) hours, and
>
> (B) Not remain between 54°C (129.2°F) and 4°C (39.2°F) for more than 7 hours.

Attachment B7. Using Challenge Studies to Support Alternative Stabilization/Cooling Procedures

In cases where an establishment's process does not match available scientific support documents, such as this guideline or a published journal article, establishments may decide to conduct an inoculation challenge study to support that their process achieves adequate cooling and controls the growth of *Clostridia*. In a challenge study, the number of organisms before and after the application of the control measure are counted to determine the effect of the control measure. Challenge studies should be conducted by a microbiologist trained in performing challenge studies in a laboratory to avoid the possible spread of contamination in an establishment. The challenge study should be designed to match the establishment's time-temperature cooling profiles and intrinsic factors in the establishment's actual process in order to establish these as critical operating parameters.

It is also important for the challenge study to be conducted using the pathogen of interest and that the appropriate inoculation level be 1 to 3-Log CFU/g) to show limited Log growth of the target pathogens. *C. perfringens* can be used alone in an inoculated pack study to demonstrate that the cooling performance standard or target is met for both *C. perfringens* and *C. botulinum*. This is because conditions of time-temperature that would limit the growth of *C. perfringens* to 1-Log or less would also prevent multiplication of *C. botulinum*, which is much slower. A cocktail of various strains of *C. perfringens* spores is often used for this purpose. Relatively "fast" growing toxigenic strains of *C. perfringens* should be used to develop a worst-case scenario. However, the spore strains selected should also be heat-tolerant and among those that have been historically implicated in an appreciable number of outbreaks, especially in products similar to those being prepared by the establishment. In consultation with ARS, FSIS recommends establishments use a cocktail of the following three strains of *C. perfringens*: NCTC 8238 (Hobbs serotype 2), NCTC 8239 (Hobbs serotype 3) and NCTC 10240 (Hobbs serotype 13). The final measure of bacterial load in the product after cooling should include a measure of both spore levels and vegetative cells.

Challenge studies should contain an equivalent level of detail as peer-reviewed scientific literature and should use methodology equivalent to that used in peer-reviewed research. As stated in the *FSIS Validation Guideline*, page 8, challenge studies should be based on a sound statistical design (*i.e.*, a statistical design that ensures confidence in the data) and should employ positive and negative controls. The statistical design should include the number of samples collected at each time interval and the number of study replicates needed to ensure the validity of the study. There are quantitative methods for assessing the statistical quality of a study (*e.g.*, power analysis). As recommended by the National Advisory Committee on Microbiological Criteria of Foods (NACMCF), the minimum number of samples to be analyzed initially and at each time interval during processing or storage should be at least two; however, NACMCF recommends analysis of three or more samples. According to NACMCF, replicates should also be conducted. Replicates should be independent trials using different lots of product and inoculum to account for variations in product, process, inoculum, and other factors. When the number of samples analyzed at each time interval is only two, it is better for the study to be repeated (replicated) more than two

times. In studies with three or more samples tested at each time interval, two replicates are usually adequate. All the critical elements of the study discussed above need to be included to permit evaluation or confirmation of the results. For more information on conducting challenge studies please review the article, "*Parameters for Determining Inoculated Pack/Challenge Study Protocols*" published by the NACMCF in the Journal of Food Protection in 2010.

Attachment B8. Using Journal Articles to Support Alternative Stabilization or Cooling Procedures

Establishments may use published journal articles as scientific support for their process as they are a type of peer-reviewed scientific data discussed in the *FSIS Validation Guideline*. If an establishment chooses to use a journal article as scientific support, it should ensure that all critical operating parameters used in the study match those used in the actual process. Examples of critical operational parameters that should be compared include cooling time-temperature profile, amenable species of meat or poultry used in the product, pH, water activity, salt concentration, sodium nitrite concentration, and any added antimicrobial ingredients. Some of these critical operational parameters may become part of the critical limits of a CCP, may be incorporated into a prerequisite program or may be monitored at the set-up of the food safety system as part of initial validation. If one or more of the critical operating parameters are not addressed in the establishment's process or do not match the parameters used in the support, then the establishment should document a science-based justification for why the parameter does not need to be met or measured, or why it differs from the support. Additionally, an establishment should have knowledge of the products it produces, including knowledge of the pH, salt concentration, etc. even if these are not critical operating parameters in its scientific support because this information can be helpful in the event of a cooling deviation.

FSIS has compiled a summary table of journal articles that establishments may use as scientific support for their process in Table 15 (page 82). In response to common questions, FSIS has included in this table articles for the stabilization of partially heat-treated bacon and fully cooked scrapple (Table 15). FSIS has also provided recommendations for using published research on bacon heating CUT along with predictive microbial modeling to support stabilization of bacon processes (page 81). Table 15 is only to be used as a quick reference guide so an establishment can identify a similar product and process. This table is not valid support for a HACCP system. Rather, establishments should maintain a copy of any articles it uses for scientific support of their systems.

Alternative support for partially heat-treated bacon

FSIS is also aware of a study by Sindelar *et al.* (2019) evaluating *C. perfringens* growth during slow partial heat treatment of pork instead of smoked pork bellies. This article was not included in the summary table (Table 15) since it does not address *C. perfringens* growth during stabilization (cooling). However, establishments may consider using this article and predictive microbial modeling to support a custom cooling schedule for partially heat-treated bacon products with long CUT. To do this, the establishment would:

1. Follow the heating process schedule from the article (Sindelar *et al.,* 2019), address all critical operating parameters, and maintain a copy of the article on file.

2. Use predictive microbial modeling to develop a custom cooling schedule that limits the growth of *C perfringens* during cooling to 0.3-Log or less. To model the cooling, FSIS recommends using the ComBase *C. perfringens* Growth Model based upon a worst-case scenario approach. When performing modeling, FSIS recommends that establishments:

    - Use a physiological state of 1 (no lag phase) to model in a conservative manner, since Sindelar *et al.* (2019) showed the bacteria will be out of the lag phase as the product starts to cool;
    - Use a temperature of 59°F (15°C) for product's time-temperature data points that are below 59°F (15°C) to overcome one of the shortcomings of using the ComBase *C. perfringens* Growth Model.

3. Maintain a copy of the custom modeling support on file (see Attachment B5. Predictive Microbial Modeling, page 64).

4. Maintain a decision-making document or a copy of this guidance to explain how the two scientific documents may be combined to address cumulative *C. perfringens* growth
    - Specifically, the Sindelar *et al.* (2019) estimated that 0.7-Log *C. perfringens* growth during the heating CUT, plus ≤0.3-Log growth during the custom cooling schedule, will ensure that total *C. perfringens* growth during heating and cooling of the bacon is limited to 1.0-Log or less.

This Appendix is not considered adequate support on its own because it does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process. Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used.

Table 15. Time and Temperature Parameters Reported in the Literature for Stabilization Processes

Key:

≤1 = ≤1.0 log CFU/g *C. perfringens* growth

≤2 = > 1.0 log CFU/g but ≤ 2.0 log CFU/g *C. perfringens* growth

>2 = > 2.0 log CFU/g *C. perfringens* growth

Product	Critical Operational Parameters Provided	Experimental Conditions for Chilling/*C. perfringens* Growth			Reference
Roast Beef	➢ pH range 5.51-5.77 ➢ Salt (NaCl)[16] ➢ Potassium tetra pyrophosphate ➢ Ional=buffered sodium citrate ➢ Ional Plus=buffered sodium citrate supplemented with sodium diacetate ➢ Purasal=sodium lactate ➢ Optiform= sodium lactate supplemented with sodium diacetate ➢ Single rate exponential cooling	**54.4°C(130°F) to 7.2°C (45°F)**	**18 h**	**21 h**	**Juneja, V.K. and Thippareddi, H. 2004b.**
		Ional 0.75%	≤ 1	≤ 1	
		Ional 1%	≤ 1	≤ 1	
		Ional 1.3%	≤ 1	≤ 1	
		Ional Plus 0.75%	> 2	> 2	
		Ional Plus 1%	≤ 1	≤ 1	
		Ional Plus 1.3%	≤ 1	≤ 1	
		Purasal 1.5%	≤ 1	≤ 2	
		Purasal 3%	≤ 1	≤ 1	
		Purasal 4.8%	≤ 1	≤ 1	
		Optiform 1.5%	≤ 1	≤ 1	
		Optiform 3%	≤ 1	≤ 1	
		Optiform 4.8%	≤ 1	≤ 1	
Roast Beef	➢ pH 5.79 ➢ a_w 0.98 ➢ Salt ➢ Sodium pyro-and poly-phosphate blend ➢ MoStatin LV1 (buffered lemon juice and vinegar) ➢ Single rate exponential cool	**54.4°C (130°F) to 7.2°C (45°F)**	**6.5 h**	**9 h**	**Lin, L. 2012.**
		Beef (2.0% Salt)	≤ 1	≤ 1	
		Beef (1.5% Salt)	≤ 2	≤ 2	
		Beef (1.5%Salt + MoStatin)	≤ 1	≤ 1	

[16] The concentration of salt and other ingredients is not included in this attachment. For this reason, if an establishment chooses to use one of the articles provided in the attachment for scientific support, the establishment will need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operational parameters used in the study.

This Appendix is not considered adequate support on its own because it does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process. Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used.

Product	Critical Operational Parameters Provided	Experimental Conditions for Chilling/*C. perfringens* Growth					Reference
Roast Beef	➢ Salt ➢ Sodium citrate ➢ Sodium lactate ➢ Trisodium phosphate ➢ Exponential cooling	**54.4°C (130°F) to 4°C (39.2°F)**	**18 h**				**Sabah, J.R. *et al.*, 2003.**
		Sodium citrate (pH 5.6) at 2.0% (wt/wt)	≤ 1				
		Sodium citrate (pH 5.6) at 4.8% (wt/wt)	≤ 1				
		Sodium citrate (pH 5.0) at 2.0% (wt/wt)	≤ 1				
		Sodium citrate (pH 5.0) at 4.8% (wt/wt)	≤ 1				
		Sodium citrate (pH 4.4) at 2.0% (wt/wt)	≤ 1				
		Sodium citrate (pH 4.4) at 4.8% (wt/wt)	≤ 1				
		Sodium lactate (pH 7.3) at 2.0% (wt/wt)	≤ 1				
		Sodium lactate (pH 7.3) at 4.8% (wt/wt)	≤ 1				
	➢ Salt ➢ Sodium acetate ➢ Trisodium phosphate ➢ Exponential cooling	**54.4°C (130°F) to 4°C (39.2°F)**	**18 h**				
		Control	≤ 2				
		Sodium acetate (pH 9.0) at 0.25% (wt/wt)	≤ 2				
		Sodium diacetate (pH 4.5) at 0.25% (wt/wt)	≤ 1				
Roast Beef	➢ Salt ➢ Potassium tetrapyrophosphate ➢ Vacuum packaged	**54.44°C (130°F) to 7.2°C (45°F)**	**9 h**	**12 h**	**15 h**	**18 h**	**21 h**	**Sánchez-Plata, M. *et al.*, 2005.**
		Control	≤ 2	> 2	> 2	> 2	> 2	
Cooked Ground Beef	➢ Salt (NaCl) ➢ Sodium nitrite ➢ Sodium erythorbate ➢ Sodium phosphates ➢	**54.4°C (130°F) to 8.5°C (47.3°F)**	**15 h**	**18 h**	**21 h**			**Zaika, L. 2003.**
		NaCl 0.0%	> 2	> 2	> 2			
		NaCl 1%	> 2	> 2	> 2			
		NaCl 2%	≤ 1	≤ 1	≤ 1			
		NaCl 3%	≤ 1	≤ 1	≤ 1			
		NaCl 4%	≤ 1	≤ 1	≤ 1			

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Product	Critical Operational Parameters Provided	Experimental Conditions for Chilling/*C. perfringens* Growth				Reference
Cooked Ground Beef	➢ Salt ➢ Chili ➢ Sodium lactate ➢ Sodium citrate ➢ Garlic ➢ Herbs ➢ Curry ➢ Oregano ➢ Clove ➢ Sodium triphosphate ➢ Exponential cooling	**54.4°C (130°F) to 7.2°C (45°F)**	**15 h**	**18 h**	**21 h**	**Sabah, J.R., Juneja, V.K., and Fung, D.Y.C. 2004.**
		Control	> 2	> 2	> 2	
		Chili	≤ 2	> 2	> 2	
		Chili+Sodium Lactate	≤ 1	≤ 1	≤ 1	
		Chili+Sodium Citrate	≤ 1	≤ 2[17]	≤ 1	
		Garlic and Herbs	> 2	> 2	> 2	
		Garlic and Herbs+Sodium Lactate	≤ 1	≤ 2	≤ 2	
		Garlic and Herbs+Sodium Citrate	≤ 1	≤ 2[5]	≤ 1	
		Curry	> 2	> 2	> 2	
		Curry+Sodium Lactate	≤ 2	≤ 2	≤ 2	
		Curry+Sodium Citrate	≤ 1	≤ 1	≤ 1	
		Oregano	≤ 1	> 2	> 2	
		Oregano+Sodium Lactate	≤ 1	≤ 1	≤ 1	
		Oregano+Sodium Citrate	≤ 1	≤ 1	≤ 2	
		Clove	≤ 2	≤ 2	> 2	
		Clove+Sodium Lactate	≤ 1	≤ 2[5]	≤ 1	
		Clove+Sodium Citrate	≤ 1	≤ 1	≤ 2	
		Sodium Lactate	≤ 1	≤ 1	≤ 2	
		Sodium Citrate	≤ 1	≤ 2[5]	≤ 1	

[17] Establishments should be aware that the 21-hour treatment time had less growth than the 18-hour treatment time. FSIS recommends establishments assume the longer cooling time would result in the same amount of growth if not higher than the shorter time.

This Appendix is not considered adequate support on its own because it does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process. Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used.

Product	Critical Operational Parameters Provided	Experimental Conditions for Chilling/*C. perfringens* Growth					Reference
Cooked Ground Beef (70% Lean)	➢ Thymol ➢ Cinnamaldehyde ➢ Oregano Oil ➢ Carvacrol ➢ Single rate exponential cooling	**54.4°C (130°F) to 7.2°C (45°F)**	**12 h**	**15 h**	**18 h**	**21 h**	**Juneja, V.K., Thippareddi, H., and Friedman, M. 2006.**
		0.10% Thymol	≤ 1	≤ 2	> 2	> 2	
		0.50% Thymol	≤ 1	≤ 2	> 2	> 2	
		1.00% Thymol	≤ 1	≤ 2	> 2	> 2	
		2.00% Thymol	≤ 1	≤ 1	≤ 1	≤ 1	
		0.10% Cinnamaldehyde	≤ 1	> 2	> 2	> 2	
		0.50% Cinnamaldehyde	≤ 1	≤ 2	≤ 1[18]	≤ 1	
		1.00% Cinnamaldehyde	≤ 1	≤ 1	≤ 1	≤ 1	
		2.00% Cinnamaldehyde	≤ 1	≤ 1	≤ 1	≤ 1	
		0.10% Oregano oil	≤ 1	> 2	> 2	> 2	
		0.50% Oregano oil	≤ 1	> 2	> 2	> 2	
		1.00% Oregano oil	≤ 1	≤ 2	> 2	> 2	
		2.00% Oregano oil	≤ 1	≤ 1	≤ 1	≤ 1	
		0.10% Carvacrol	≤ 1	> 2	> 2	> 2	
		0.50% Carvacrol	≤ 1	> 2	> 2	> 2	
		1.00% Carvacrol	≤ 1	≤ 1	> 2	> 2	
		2.00% Carvacrol	≤ 1	≤ 1	≤ 1	≤ 1	
Cooked Ground Beef (93% Lean)	➢ GTE=Green tea polyphenols ➢ GTL=powdered tea sample with 20% of green tea polyphenols ➢ Single rate exponential cooling	**54.4°C (130°F) to 7.2°C (45°F)**	**12 h**	**15 h**	**18 h**	**21 h**	**Juneja, V.K. *et al.*, 2007.**
		0.5% GTE	> 2	> 2	> 2		
		1% GTE		≤ 1	> 2	> 2	
		2% GTE		≤ 1	≤ 1	≤ 1	
		0.5% GTL	> 2	> 2			
		1% GTL	> 2	> 2	> 2	> 2	
		2% GTL	> 2	> 2			

[18] While the 18-hour and 21-hour times have less growth than the 15-hour treatment, FSIS recommends that establishments assume the longer cooling time would result in the same amount if not more growth than the 15-hour results.

This Appendix is not considered adequate support on its own because it does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process. Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used.

Product	Critical Operational Parameters Provided	Experimental Conditions for Chilling/*C. perfringens* Growth	Reference
Cooked Ground Pork	➢ GTE=Green tea polyphenols ➢ GTL=powdered tea sample with 20% of green tea polyphenols ➢ Single rate exponential cooling	**54.4°C (130°F) to 7.2°C (45°F)** 0.5% GTE: 12 h ≤ 2; 15 h > 2; 18 h > 2 1% GTE: 15 h ≤ 1; 18 h ≤ 2; 21 h > 2 2% GTE: 15 h ≤ 1; 18 h ≤ 1; 21 h ≤ 1 0.5% GTL: 12 h >2; 15 h > 2 1% GTL: 12 h >2; 15 h > 2; 18 h > 2; 21 h > 2 2% GTL: 12 h ≤2; 15 h > 2	**Juneja, V.K. *et al.*, 2007.**
Pork Scrapple	➢ Salt ≤1.11(g/100g) ➢ Moisture ≤70.28 (g/100g) ➢ a_w ≤ 0.97 after cooking, before cooling ➢ pH ≤ 6.40 ➢ Cook to ≥ 200°F for at least 20 minutes	**54.4°C (130°F) to 27.8°C (82°F) ≤ 4 h** **27.8°C (82°F) to 7.2°C (45°F) ≤ 8 h** **12 h**: ≤ 1 **54.4°C (130°F) to 26.5°C (80°F) ≤ 5 h** **26.5°C (80°F) to 7.2°C (45°F) ≤ 8 h** **14 h**: ≤ 1	**Juneja, V.K. et al. 2010.**
Bacon	➢ Liquid smoke (or natural smoke) ➢ ≥1.6% salt ➢ ≥2.9% brine that contained: 120 ppm sodium nitrite 547 ppm sodium erythorbate 0.5% sodium phosphate	**54.5°C (120°F) to 26.7°C (80°F) in 5 hours** **26.7°C (80°F) to 7.2°C (45°F) in 10 hours** **15 h** [19]: ≤ 1	**Taormina, P.J. and Bartholomew, G.W 2005.**
Ham A (Commercially Obtained)	➢ Salt (NaCl) ➢ Sodium nitrite ➢ Sodium erythorbate ➢ Sodium phosphates ➢	**54.4°C (130°F) to 8.5°C (47.3°F)** NaCl 2.4%: 15 h ≤ 2; 18 h ≤ 2; 21 h >2 NaCl 3.1%: 15 h ≤ 1; 18 h ≤ 1; 21 h ≤1 NaCl 3.6%: 15 h ≤ 1; 18 h ≤ 1; 21 h ≤1 NaCl 4.1%: 15 h ≤ 1; 18 h ≤ 1; 21 h ≤1	**Zaika, L. 2003.**

[19] Bacon was heated to 120°F (48.9ºC) with a 6-hour heating CUT

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Product	Critical Operational Parameters Provided	Experimental Conditions for Chilling/*C. perfringens* Growth				Reference
Ham B (Commercially Obtained)	➢ Salt (NaCl) ➢ Sodium nitrite ➢ Sodium erythorbate ➢ Sodium phosphates ➢	**54.4°C (130°F) to 8.5°C (47.3°F)**	**15 h**	**18 h**	**21 h**	**Zaika, L. 2003.**
		NaCl 2.8%	≤ 2	> 2	≤ 2[20]	
		NaCl 3.3%	≤ 1	≤ 1	≤ 1	
		NaCl 3.8%	≤ 1	≤ 1	≤ 1	
		NaCl 4.3%	≤ 1	≤ 1	≤ 1	
Ham C (Commercially Obtained)	➢ Salt (NaCl) ➢ Sodium nitrite ➢ Sodium erythorbate ➢ Sodium phosphates ➢	**54.4°C (130°F) to 8.5°C (47.3°F)**	**15 h**	**18 h**	**21 h**	**Zaika, L. 2003.**
		NaCl 2.0%	> 2	≤ 2^7	> 2	
		NaCl 2.5%	≤ 1	≤ 1	≤ 1	
		NaCl 3.0%	≤ 1	≤ 1	≤ 1	
		NaCl 3.5%	≤ 1	≤ 1	≤ 1	
Ham	➢ pH 6.22 ➢ a_w 0.987 ➢ Nitrite ➢ Sodium erythorbate	**54.4°C (130°F) to 7.2°C (45°F)**		**15 h Stored 3 h**	**15 h Stored 24 h**	**Redondo-Solano, M. *et al.*, 2013.**
		Control		≤ 2	> 2	
		Nitrite 50 ppm		≤ 1	> 2	
		Nitrite 100 ppm		≤ 1	> 2	
		Nitrite 150 ppm		≤ 1	> 2	
		Nitrite 200 ppm		≤ 2	≤ 1	
		Nitrite 50 ppm erythorbate 557 ppm		> 2	> 2	
		Nitrite 100 ppm erythorbate 557 ppm		≤ 2	> 2	
		Nitrite 150 ppm erythorbate 557 ppm		≤ 2	≤ 1	
		Nitrite 200 ppm erythorbate 557 ppm		≤ 2	≤ 1	

[20] Establishments should be aware that the 21-hour treatment time had less growth than the 18-hour treatment time and the 18-hour treatment had less growth than the 15-hour treatment time. FSIS recommends establishments assume the longer cooling time would result in the same amount of growth if not higher than the shorter time.

This Appendix is not considered adequate support on its own because it does not provide the details of each study (such as the concentration of salt and other ingredients) that an establishment needs to determine if the study is representative of the actual process. Establishments need to have the complete copy of the article on file as part of its supporting documentation to determine the levels of the critical operating parameters used.

Product	Critical Operational Parameters Provided	Experimental Conditions for Chilling/*C. perfringens* Growth	Reference
Whole-Muscle Ham	➢ a_w (Raw batter) = 0.98 ➢ a_w (Peak cook temp) = 0.97 ➢ Sodium nitrite (103 – 140 ppm ingoing) ➢ Sodium phosphate ➢ Sodium erythorbate ➢ 4% brine concentration	**54.4°C (130°F) to 7.2°C (45°F)** — **4.5 h**: ≤ 1	**Taormina, P.J. and Bartholomew, G.W 2005.**
Chunked Ham (Pork)	➢ a_w (Raw batter) = 0.97 ➢ a_w (Peak cook temp) = 0.96 ➢ Sodium nitrite (103 – 140 ppm ingoing) ➢ Sodium phosphate ➢ Sodium erythorbate 3% brine concentration	**54.44°C (130°F) to 7.2°C (45°F)** — **4.5 h**: ≤ 1	**Taormina, P.J. and Bartholomew, G.W 2005.**
Pork	➢ pH 5.8 ➢ a_w=0.992 ➢ Salt ➢ Phosphate ➢ SAPP=sodium acid pyrophosphate (Source 1=Sigma-Aldrich, Source 2=BK Giulini) ➢ TSPP=tetrasodium pyrophosphate	**54.4°C (130°F) to 7.2°C (45°F)**	**Singh, AA. *et al.*, 2010.**
		6.5 h / 9 h / 12 h / 15 h / 18 h / 21 h	
		Control: ≤ 1 / >2 / > 2 / > 2 / > 2 / > 2	
		SAPP[1]+SAPP[2]: ≤ 1 / ≤ 1 / ≤ 1 / ≤ 2 / > 2 / > 2	
		SAPP[1]+TSPP: ≤ 1 / ≤ 2 / > 2 / > 2 / > 2 / > 2	
		SAPP[2]+TSPP: ≤ 1 / ≤ 2 / > 2 / > 2 / > 2 / > 2	
Pork (Pale, Soft, and Exudative, PSE)	➢ pH=5.31 ➢ a_w=0.993 ➢ Salt ➢ Phosphate ➢ SAPP Source 1 and 2 ➢ TSPP	**54.4°C (130°F) to 7.2°C (45°F)**	**Singh, AA. *et al.*, 2010.**
		6.5 h / 9 h / 12 h / 15 h / 18 h / 21 h	
		Control: ≤ 1 / ≤ 2 / ≤ 2 / > 2 / > 2 / > 2	
		SAPP[1]+SAPP[2]: ≤ 1 / ≤ 1 / ≤ 1 / ≤ 1 / ≤ 1 / ≤ 1	
		SAPP[1]+TSPP: ≤ 1 / ≤ 1 / ≤ 1 / ≤ 1 / ≤ 2 / > 2	
		SAPP[2]+TSPP: ≤ 1 / ≤ 1 / ≤ 1 / ≤ 1 / > 2 / > 2	

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Product	Critical Operational Parameters Provided	Experimental Conditions for Chilling/*C. perfringens* Growth						Reference
Pork (Dark, Firm, and Dry, DFP)	➢ pH=5.92 ➢ a_w=0.992 ➢ Salt ➢ Phosphate ➢ SAPP Source 1 and 2 ➢ TSPP	**54.4°C (130°F) to 7.2°C (45°F)**	**6.5 h**	**9 h**	**12 h**	**15 h**	**18 h**	**Singh, AA. *et al.*, 2010.**
		Control	≤ 1	> 2	> 2	> 2	> 2	> 2
		SAPP[1]+SAPP[2]	≤ 1	≤ 2	≤ 2	> 2	> 2	> 2
		SAPP[1]+TSPP	≤ 1	≤1	> 2	> 2	> 2	> 2
		SAPP[2]+TSPP	≤ 1	≤ 1	> 2	> 2	> 2	> 2
Acidified Ground Beef, Beef, Pork and Poultry	➢ pH 4.74 – 6.35 ➢ Single rate exponential cooling	**54.4°C (130°F) to 7.2°C (45°F)*[21]**	**6 h**	**9 h**	**12 h**	**15 h**	**18 h**	**Juneja, V.K. *et al.*, 2012.**
		Rotisserie-cooked pork shoulder (pH 6.35)	≤2	> 2	> 2	> 2	> 2	**21 h**
		Boiled beef (pH 5.63)			≤ 1	≤ 1	≤ 2	
		Acidified ground beef (pH 5.0)					≤ 1	> 2
		Acidified poultry (pH 4.77)						≤ 1
Bologna (Beef, Pork, Chicken)	➢ a_w (Raw batter) = 0.97 ➢ a_w (Peak cook temp) = 0.96 ➢ Sodium nitrite (103 – 140 ppm ingoing) ➢ Sodium and potassium phosphates ➢ Sodium erythorbate ➢ 4% brine concentration	**54.44°C (130°F) to 7.2°C (45°F)**	**4.5 h**					**Taormina, P.J., Bartholomew, G.W., and Dorsa, W.J 2003.**
			≤ 1					

[21] *Only results for low inoculum level are reported.

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Product	Critical Operational Parameters Provided	Experimental Conditions for Chilling/*C. perfringens* Growth						Reference
Turkey (Injected Turkey Breast)	➢ pH=5.26 to 6.11 ➢ a_w=0.987 ➢ Salt ➢ Calcium lactate ➢ Potassium lactate ➢ Sodium lactate ➢ Potassium tetrapyrophosphate	**54.4°C (130°F) to 7.2°C (45°F)**	**6.5 h**	**9 h**	**12 h**	**15 h**	**18 h**	**21 h**	**Velugoti, P.R., Bohra, L.K., Juneja, V.J., and Thippareddi, H. 2007.**
		Control	≤ 1	> 2	> 2	> 2	> 2	> 2	
		Calcium lactate 1%	≤ 1	≤ 1	≤ 2	≤ 2	> 2	> 2	
		Calcium lactate 2%			≤ 1	≤ 1	≤ 1	≤ 1	
		Calcium lactate 3%			≤ 1	≤ 1	≤ 1	≤ 1	
		Calcium lactate 4.8%			≤ 1	≤ 1	≤ 1	≤ 1	
		Postassium lactate 1%	≤ 1	≤ 2	> 2	> 2	> 2	> 2	
		Postassium lactate 2%	≤ 1	≤ 1	≤ 1	≤ 2	≤ 2	> 2	
		Postassium lactate 3%			≤ 1	≤ 1	≤ 1	≤ 1	
		Postassium lactate 4.8%			≤ 1	≤ 1	≤ 1	≤ 1	
		Sodium lactate 1%	≤ 1	≤ 1	≤ 1	> 2	> 2	> 2	
		Sodium lactate 2%	≤ 1	≤ 1	≤ 1	≤ 2	> 2	> 2	
		Sodium lactate 3%			≤ 1	≤ 1	≤ 1	≤ 1	
		Sodium lactate 4%			≤ 1	≤ 1	≤ 1	≤ 1	
Deli-Style Turkey Breast	➢ At least 75 ppm nitrite from a natural source and at least 500 ppm ascorbate from a natural source OR ➢ At least 100 ppm nitrite from a natural source and at least 250 ppm ascorbate from a natural source	**54.4°C (130°F) to 26.5°C (80°F) ≤ 5 h** **26.5°C (80°F) to 7.2°C (45°F) ≤ 10 h**				**15 h**			**King, A.M., *et al.*, 2015**
						≤ 1			

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Product	Critical Operational Parameters Provided	Experimental Conditions for Chilling/*C. perfringens* Growth					Reference
Cooked Ground Chicken	➢ GTE=Green tea polyphenols ➢ GTL=powdered tea sample with 20% of green tea polyphenols. Single rate exponential cooling	**54.4°C (130°F) to 7.2°C (45°F)**	**12 h**	**15 h**	**18 h**	**21 h**	**Juneja, V.K. *et al.*, 2007.**
		0.5% GTE	> 2	> 2	> 2		
		1% GTE		≤ 1	≤ 1	≤ 2	
		2% GTE		≤ 1	≤ 2	≤ 1[22]	
		0.5% GTL	> 2	> 2			
		1% GTL	> 2	> 2	≤ 2[23]	> 2	
		2% GTL	> 2	> 2			

[22] Establishments should be aware that the 21-hour treatment time had less growth than the 18-hour treatment time. FSIS recommends establishments assume the longer cooling time would result in the same amount of growth if not higher than the shorter time.

[23] Establishments should be aware that the 18-hour treatment time had less growth than the 15-hour treatment time. FSIS recommends establishments assume the longer cooling time would result in the same amount of growth if not higher than the shorter time.

Journal Articles not Acceptable without Further Support

The table above summarizes journal articles that may be used as support. The following three articles are not acceptable as support because FSIS has identified methodological errors or flaws in the research or reporting:

- Haneklaus A.N., Harris K.B., Cuervo M.P., Ilhak O.I., Lucia L.M., Castillo A., Hardin M.D., Osburn W.N., and Savell, J.W. 2011. Alternative Cooling Procedures for Large, Intact Meat Products to Achieve Stabilization Microbiological Performance Standards. Journal of Food Protection. Vol. 74: 101-105.

- Juneja, V.K., Snyder, O.P., and Cygnarowicz-Provost, M. 1994. Influence of Cooling Rate on Outgrowth of *Clostridium perfringens* Spores in Cooked Ground Beef. Journal of Food Protection. 57: 1063-1067.

- Steele, F.M. and Wright K.H. 2001. Cooling Rate Effect on Outgrowth of *Clostridium perfringens* in Cooked, Ready-to-Eat Turkey Breast Roasts. Poultry Science. 80: 813-816.

FSIS does not recommend establishments use these three articles **alone** because of the methodological errors identified, without additional support. If an establishment chooses to use one of these articles as support for its stabilization process, FSIS recommends the establishment gather additional data (*e.g.*, microbiological data gathered in-plant or an inoculation challenge study) to address the concerns outlined below.

The following information explains the methodology errors or flaws that FSIS has identified in each of the three articles of concern.

Alternative Cooling Procedures for Large, Intact Meat Products to Achieve Stabilization Microbiological Performance Standards (Haneklaus *et al.*, 2011)

FSIS does not recommend establishments use this article **alone** based on the method the authors used to measure bacterial load in the final product. In this article, *C. perfringens* spore counts were used to measure bacterial load in the final product and to determine product safety. 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 recommends establishments 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, some of the cells will survive passage in the stomach and produce toxin during sporulation in the intestines to cause illness.

Several published studies (Juneja, Thippareddi, and Friedman, 2006; Juneja, Bari, Inatsu, Kawamato, and Friedman, 2007; Sabah, Juneja, and Fung, 2004; Sánchez-Plata, Amézquita, Blankenship, Burson, Juneja, and Thippareddi, 2005; Velugoti,

Rajagopal, Juneja, and Thippareddi, 2007) have used similar stabilization parameters to that used in the Haneklaus *et al.* (2011) article [*i.e.*, cooled from 129.9°F (54.4°C) to 45°F (7.2°C) in 9, 12, or 15 hours] to measure total *C. perfringens* growth in cooked, uncured pork and beef products that are exponentially cooled. These studies have shown that, when these processes are used, significant growth (>1 Log increase) of *C. perfringens* will occur. The amount of total *C. perfringens* growth ranged from 1.72 to 5.37-Log depending on the experiment and the product's intrinsic factors (*e.g.*, pH, percent salt, and percent phosphate) (Juneja *et al.*, 2006; Juneja *et al.*, 2007; Sabah *et al.*, 2004; Sanchez-Plata *et al.*, 2005; Velugoti *et al.*, 2007). FSIS believes these studies accurately represent the combined vegetative and spore load of *C. perfringens* present in products that are exposed to stabilization parameters that are similar to those used in the Haneklaus, *et al.* (2011) study. When the published studies use shorter stabilization parameters [*i.e.*, cooled from 129.9°F (54.4°C) to 45°F (7.3°C) in 6.5 hours], lower levels of growth of *C. perfringens* (≤ 1 Log increase)[5] are observed, which is consistent with FSIS guidance in Option 1.1 of this guideline.

Influence of Cooling Rate on Outgrowth of *C. perfringens* Spores in Cooked Ground Beef (Juneja *et al.*, 1994)

FSIS does not recommend establishments use this article **alone** based on the methods the authors used in which ground beef was packaged in Whirlpak bags as opposed to Spiral Biotech pouches, which are more commonly used in these types of studies. Juneja *et al.* (1994) study used the Whirlpak bags and demonstrated minimal growth of *C. perfringens* in cooked ground beef for cooling periods up to 15 hours that were supposed to represent anaerobic conditions. Subsequent research conducted by Smith *et al.* (2004) demonstrated that ground beef packaged in Whirlpak bags shows significantly less growth of *C. perfringens* than ground beef packaged in Spiral Biotech bags (Smith *et al.*, 2004). This is probably due to the Whirlpak bag's greater oxygen permeability. For example, more than a 5-Log increase in *C. perfringens* was seen in ground beef contained within Spiral Biotech pouches compared with only a 0.81 to 2.05-Log increase in samples within WhirlPak bags during a 21-hour cooling cycle. Smith *et al.* (2004) concluded that the study demonstrates that the use of Whirlpak bags is "unsuitable for use in challenge studies," because of the bags apparent high oxygen permeability, which probably suppresses or slows the growth of the anaerobe *C. perfringens*.

Several published studies support that similar cooling profiles result in significant growth (> 1 Log increase) of *C. perfringens* in cooked beef products that are non-linearly cooled from 130°F (54.4°C) to 45°F (7.2°C) in 15 hours. The amount of *C. perfringens* growth ranged from 1.72 to 5.37-Log depending on the experiment and the product's intrinsic factors (*e.g.*, pH, percent salt, and percent phosphate) (Juneja *et al.*, 2006; Sabah *et al.*, 2004; Smith *et al.*, 2004; Zaika, 2003). Furthermore, the same studies showed that non-linear chilling from 54.4 to 7.2°C in 12 or 9 hours also resulted in more than 1 Log increase in *C. perfringens* (Juneja *et al.*, 2006; Sabah *et al.*, 2004; Zaika, 2003). Consequently, these more recently published studies contradict the 1994 Juneja study that showed no growth of *C. perfringens* in cooked ground beef cooled from 54.4°C to 7.2°C during a 15-hour cooling period.

Cooling Rate Effect on Outgrowth of *C. perfringens* in Cooked, Ready-to-Eat Turkey Breast Roasts (Steele and Wright, 2001)

FSIS does not recommend establishments use this article **alone** because the paper included inadequate information to allow comparison to an establishment's actual process. Published research and predictive microbial models have shown that the product's intrinsic factors (*e.g.*, pH, sodium nitrite, salt, and phosphate concentration) can have a profound impact on the growth of *C. perfringens* during cooling, or temperature abuse of cooked/heated, not shelf-stable meat and poultry products. For example, research has shown that a high salt concentration can have a significant inhibitory effect on the growth of *C. perfringens* during cooling (Zaika, 2003). However, information on the product's intrinsic factors was not included in the article. Therefore, it would not be possible for establishments to assess how their products compare to the product(s) studied.

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