FSIS Compliance Guideline
HACCP Systems Validation
April 2015

This guidance document is designed to help very small meat and poultry establishments meet the initial validation requirements in 9 CFR 417.4. In particular, the guidance covers:

- The difference between initial validation and ongoing verification;
- How to identify scientific support relevant to their process;
- What are critical operational parameters and how to identify them in the scientific or technical support;
- How to demonstrate that the critical operational parameters are being met during initial validation (i.e., through the collection of in-plant validation data); and
- How an existing establishment can incorporate this guidance into their HACCP system.

This Compliance Guideline follows the procedures for guidance documents in the Office of Management and Budget's (OMB) "Final Bulletin for Agency Good Guidance Practices" (GGP). More information can be found on the Food Safety and Inspection Service (FSIS) Web page.

This guidance has been revised in response to public comment. A summary of the comments received and responses to those comments can be found at http://www.fsis.usda.gov/wps/wcm/connect/3ba826ec-6e79-4f17-85fc-29200f4e8d05/2009-0019-2015.pdf?MOD=AJPERES. It is important to note that this Guideline represents FSIS's current thinking on this topic and should be considered usable as of this issuance.

Purpose

The purpose of this guidance document is to aid small and very small establishments in meeting the initial validation requirements in 9 CFR 417.4. This document provides **guidance** to assist establishments in meeting FSIS regulations. Guidance represents **best practice** recommendations by FSIS, based on the best scientific and practical considerations, and does not represent **requirements** that must be met. Establishments may choose to adopt different procedures than those outlined in the guideline, but they would need to support why those procedures are effective.

Is this version of the guideline final?

Yes, this version of the guideline, dated April, 2015 is final. FSIS will update this guideline as necessary should new information become available, although comments will no longer be accepted through regulations.gov on this guideline.

What if I still have questions after I read this guideline?

If the desired information cannot be found within the Compliance Guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the AskFSIS database or submit questions through AskFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances.

When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter HACCP Systems Validation Guideline
Question Field:	Enter question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.
Category Field:	Select **Sampling** from the drop-down menu.
Policy Arena:	Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue**.

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Who is this guidance designed for?

This guideline is focused on small and very small establishments in support of the Small Business Administration's initiative to provide small and very small establishments with compliance assistance under the Small Business Regulatory Flexibility Act (SBRFA). However, all FSIS regulated meat and poultry establishments may be able to 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 HACCP systems. Although large establishments can benefit from the guidance that FSIS provides, focusing the guidance on the needs of small and very small establishments provides them with information that may be otherwise unavailable to them.

Why did FSIS develop this guidance document?

FSIS has determined from its HACCP verification activities that many establishments have not properly validated their systems. In particular, establishments have not conducted adequate activities during the **initial validation period** to translate all the required critical operating parameters from the scientific or technical support into their processes and gather in-plant validation data demonstrating the HACCP plan is functioning as intended. In addition, Agency enforcement actions have identified instances in which inadequate validation has led to the production of adulterated product and in some cases even illnesses. Specific examples of when inadequate validation has led to the production of adulterated product and in some cases illnesses are provided in Appendix 1.

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Based on the findings from FSIS data analyses and outbreak investigations summarized in Appendix 1, FSIS recommends that establishments use this guidance document to ensure that their HACCP systems are properly validated. While most establishments have assembled the scientific or technical support for the judgments made in designing their HACCP systems, which is the first element of initial validation, many establishments have not gathered the necessary in-plant validation data demonstrating that the HACCP system is functioning as intended. FSIS has also found establishments have not:

HACCP System Design Issues

- Identified scientific support that properly relates to the establishments' current processes; or
- Identified the critical operating parameters in the scientific support necessary for the intervention to function as intended.

HACCP System Execution Issues

- Translated those critical operating parameters into their HACCP systems; or
- Documented that they have validated their HACCP systems under actual in-plant conditions.

By ensuring that the HACCP system is designed and executed properly, an establishment can reduce the likelihood for product contamination and illnesses in the future. Initial validation of any HACCP system must include scientific or technical support related to the establishment's process supporting the design of the HACCP system along with some practical in-plant validation data reflecting an establishment's actual early experience in executing the HACCP system. Validation must demonstrate not only that the HACCP system is theoretically sound (design), but also that the establishment can implement it and make it work (execution).

FSIS stated in the HACCP Final Rule that validation data for any HACCP system must include practical data or information reflecting an establishment's actual experience in implementing the HACCP system

What concepts and skills will small and very small establishments learn from this guidance?

Small and very small establishments that utilize this guidance will learn:

- The difference between initial validation and ongoing verification;
- How to identify scientific or technical support relevant to their processes;
- What are critical operational parameters and how to identify them in the scientific and technical support; and
- How to demonstrate that the critical operational parameters are being met during initial validation (i.e., through in-plant validation data).

Establishments that understand these topics should have the tools needed to successfully validate their HACCP systems.

What is the history of validation in the context of the HACCP regulations?

On July 25, 1996, FSIS published a final rule on Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems (PR/HACCP) (61 FR 38806). The PR/HACCP rule requires that meat and poultry establishments under Federal inspection take responsibility for, among other things, reducing the contamination of meat and poultry products with disease-causing (pathogenic) bacteria by implementing a system, known as HACCP, of preventative controls designed to improve the safety of their

products. An establishment must have an effective HACCP system to comply with regulatory requirements and prevent adulteration of product.

The HACCP requirements that establishments must meet are set out in 9 CFR Part 417. These requirements are based on the seven HACCP principles recommended by the National Advisory Committee on Microbiological Criteria for Food (NACMCF) in 1992. One of the principles identified by the NACMCF was "Verification" describing that HACCP systems should be systematically verified. In the NACMCF explanation of the verification principle, which FSIS follows, an establishment is responsible for the following three processes encompassing the verification principle:

- Validation,
- Verification, and
- Reassessment

NOTE: This guidance document speaks only to the initial validation component of the verification HACCP principle.

The recommendations in the verification principle form the basis for the requirements in 9 CFR 417.4. This section requires that every establishment validate the HACCP plan's adequacy in controlling the food safety hazards identified in the hazard analysis, verify that the plan is being effectively implemented on an ongoing basis, and reassess the plan at least annually, or when an unforeseen hazard or change occurs, or whenever any changes occur that could affect the hazard analysis or alter the HACCP plan.

Although the HACCP regulations were implemented over 15 years ago, FSIS has found through Food Safety Assessments (FSAs) that establishments have not complied with the initial validation requirement. In particular, establishments have not collected the necessary in-plant validation data demonstrating that the HACCP system is functioning as intended. Therefore, FSIS determined that additional validation guidance for HACCP systems is needed.

Key Requirement

9 CFR 417.4(a)(1) requires "upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities."

Key definition

HACCP is a scientific system for process control that has long been used in food production to prevent problems by applying controls at points in a food production process where hazards could be controlled, reduced, or eliminated.

The **HACCP system** is defined as the HACCP plan in operation, including the HACCP plan itself. The HACCP plan in operation includes the hazard analysis, any supporting documentation including prerequisite programs supporting decisions in the hazard analysis, and all HACCP records.

What is HACCP System Validation?

Validation is the process of demonstrating that the HACCP system as designed can adequately control potential hazards to produce a safe, unadulterated product. Validation encompasses activities designed to determine whether the entire HACCP system is functioning as intended. **Validation of a HACCP system involves two separate elements 1) design and 2) execution. Under 9 CFR 417.4(a)(1) establishments are required to assemble two types of supporting documentation to demonstrate these elements are met:**

1. The scientific or technical support for the HACCP system design (design) - that is the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards; and

2. The in-plant validation data (execution) - that is the in-plant observations, measurements, microbiological test results, or other information demonstrating the control measures in the HACCP system can perform as expected within a particular establishment to achieve the intended food safety objective.

Under 9 CFR 417.5(a)(1) and 9 CFR 417.5(a)(2), these supporting documents must be kept for the life of the plan. The two elements will be discussed in detail throughout this document. In summary, to validate the HACCP system, establishments should:

Element 1: Scientific or Technical Support (Design)

- Gather scientific or technical support (e.g., published processing guidelines, journal articles, challenge studies, etc.) for its HACCP system that:
- Closely matches the actual process; and
- Shows that the establishment's process prevents, reduces, or eliminates the hazard identified in the hazard analysis; and
- Identifies the critical operational parameters from the scientific support relevant to the establishment's process

Element 2: In-plant Validation Data (Execution)

- Implements critical operational parameters in the actual production process consistent with the parameters in the scientific or technical support;
- Identifies at least one product from each HACCP category to gather in-plant validation data;
- Collects in-plant data demonstrating the effectiveness of the implementation of the critical operational parameters for at least one product from each HACCP category; and
- Analyzes the data to determine whether the critical operational parameters are being implemented effectively.

What is the definition of a HACCP System, and do prerequisite programs have to be validated?

Validation of the HACCP system involves validation of the critical control points in the HACCP plan, as well as of any interventions or processes used to support decisions in the hazard analysis. The regulations provide that "[v]alidation … encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities" (9 CFR 417.4(a)(1)). Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). Said differently, when an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis (Element 1 of validation) and must collect in-plant validation data to support that the programs are implemented as designed (Element 2).

For this reason, the HACCP system rather than the HACCP plan only is discussed throughout the rest of this document.

KEY QUESTION

Question: Are establishments required to collect in-plant microbiological data to comply with the initial validation requirements?

Answer: FSIS encourages establishments to gather in-plant microbiological data as part of in-plant validation data but does not require that they do so, provided that the establishment has adequate scientific or technical support (the first element of validation), is following the parameters in the scientific or technical support, and can demonstrate that it can meet the critical parameters during operation through in-plant validation data (the second element of validation). A discussion of scientific and technical support can be found beginning on page 6 and a discussion of in-plant data can be found beginning on page 20.

What is the first element of HACCP Systems Validation?

The **first element of HACCP systems validation is the scientific or technical support** that demonstrates that the HACCP system is theoretically sound. To meet the first element of validation, establishments should:

- Gather scientific or technical support (e.g., published processing guidelines, journal articles, challenge studies, etc.) for it's HACCP system that:
  - Closely matches the actual process; and
  - Shows that the establishment's process prevents, reduces, or eliminates the hazard identified in the hazard analysis; and
- Identify the critical operational parameters from the scientific or technical support relevant to the establishment's process.

The scientific or technical support should reflect current thinking and not be outdated. In order to identify scientific or technical support that closely matches the actual process, establishments should understand the major types of scientific and technical support documents.

What are the major types of scientific and technical support documents used to satisfy the design element of HACCP Systems Validation?

There are several types of documents that can be used as scientific and technical support. These include:

1. Published processing guidelines that achieve a stated reduction of a pathogen are examples of scientific support. The time-temperature guidelines in *Appendix A* of the final rule "Performance Standards for the Production of Certain Meat and Poultry Products" (64 FR 746-748) is an example of a guideline that addresses process lethality. The guidelines in *Appendix B, Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization)*, address product stabilization to meet the requirements of 9 CFR 318.17(a)(2), 9 CFR 318.23(c)(1), and 9 CFR 381.150(a)(2). Published processing guidelines are not limited to those published by FSIS. Published guidelines from other agencies, trade organizations, or universities can also be used as scientific support. Extension publications may also be cited as scientific support; however, extension publications often reference the original journal articles that were used to develop the support. In those cases, establishments should have the original journal articles on-file referenced in the extension publication because the extension publications often do not include all of the critical operational parameters that establishments would need to implement. Establishments need information on all the critical operational parameters in order to determine whether the process in the publication matches their actual process.

2. Peer-reviewed scientific or technical data or information that describe a process, and the results of the process can provide adequate scientific or technical support. This type of support could include journal articles, graduate student theses, or information found in a textbook. All of these types of scientific data go through a process of evaluation involving qualified individuals within the relevant field. In addition to describing the microbiological results of the process, the data may also describe the role intrinsic and extrinsic product factors play on the growth of microorganisms. For example, a textbook may contain data on the growth limits of certain pathogens based on a food product's water activity and pH. For journal articles, the study should relate closely to the establishment's process with regards to species, product characteristics, and equipment (to the extent that the use of different equipment would result in an inability to achieve the critical parameters of the study). The establishment should use the critical operational parameters cited in the journal article that achieve the required or expected lethality or stabilization if the establishment does not intend to perform additional research to validate its process. In addition, for biological hazards, the scientific article should contain microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis. A lack of microbial data in the scientific support could raise questions concerning whether the process design has been adequately validated.

Key definitions

Intrinsic factors are those inherent parameters of a food that affect the growth of microorganisms. Examples of intrinsic factors include, among other things, pH, moisture content, 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, among other things, temperature of storage, time of storage, and relative humidity.

NOTE: Most scholarly journals use a process of peer review before publishing an article. As part of the review, scholars with expertise in the topic addressed by the draft article critically assess the article. Peer-reviewed journals only publish articles that have passed through a review process. The review process helps ensure that published articles contain solid research work. If an establishment uses scientific or technical data that is not peer-reviewed, the establishment may be subject to additional scrutiny by Agency personnel performing verification activities.

3. Expert advice from processing authorities may also be used as scientific or technical support. Such expert advice may include reference to established scientific principles as well as reference to peer-reviewed scientific data. Expert advice from processing authorities should not rely on expert opinion alone. The scientific principles and data should relate to the establishment's product and process as well as the hazard identified in the hazard analysis. One example of how expert advice may be used is a processing authority's justification for why a different level of a critical operational parameter from the one studied in the scientific support should

not impact the effectiveness of an intervention. As part of the justification, in addition to their own expert opinion, the processing authority should cite one or more peer-reviewed scientific data sets or documents that provide a science-based rationale for why the different level of the critical operational parameter should be at least equally as effective from the one in the scientific support. Another example of how expert advice from a processing authority may be used is as support for a scheduled process to produce a commercially sterile product. Prior to the processing of canned product for distribution in commerce, an establishment must have a process schedule for each canned meat or poultry product to be packed by the establishment. The process schedule used by an establishment is developed or determined by a processing authority. Any changes that may adversely affect the adequacy of the process must also be evaluated by a processing authority and that process schedule amended accordingly. When developing the process schedule, the processing authority should take into account established scientific principles as well as peer-reviewed scientific data in order to establish a thermal process that will specify the amount of time at a specific temperature necessary to ensure the destruction of *Clostridium botulinum* and spoilage organisms that may be present.

4. A challenge or inoculated pack study that is designed to determine the lethality or stabilization of a process also is an example of scientific support. These studies are performed in a laboratory or pilot plant by a processing authority or expert and sometimes can be accessed through the internet. The documentation on file should specify the level of pathogen reduction, elimination, or growth control (e.g., for stabilization); describe the process, including all critical parameters affecting the reduction or elimination; 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 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 recommended by the National Advisory Committee on Microbiological Criteria of Foods (NACMCF), the 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, 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.

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

published by the National Advisory Committee on Microbiological Criteria for Foods 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*.

5. Pathogen modeling programs are computer-based software that, based on such factors as growth, lethality, and survival in culture broth and food products, estimate the growth or decline of foodborne microbes in food samples in production. Examples of uses of pathogen modeling programs include those to support the development of custom cooling schedules; to support product safety following heating, cooling, and storage deviations; and to support the use level of antimicrobial agents. Establishments may use the results of modeling programs as scientific support provided that the establishment inputs accurate values into the modeling program, and that the modeling program has been validated for the product in question. Validation data for the model is often provided along with the modeling program or can be obtained by contacting the model developer. The modeling program chosen should also be specific for the pathogen identified in the hazard analysis. If the modeling program has not been validated for the product in question, the establishment should provide additional scientific support for its use. Such additional support could include in-plant data showing routine levels of pathogens in the product, or documentation addressing the production of the raw materials and the product's intended use. Establishments should have the modeling results on-file for review and should have documentation supporting the values entered into the model (e.g., time-temperature profile data, pH, salt concentration).

6. Data gathered by the establishment in-plant can also be used to validate a process as part of a research study or other study. This data gathering can be done if the establishment could not implement the process as documented in the literature within its processing environment. Examples of this approach could be if an establishment is introducing a new technology not established in the literature or applying a standard technology in an unusual way (e.g., modifying critical operational parameters from the literature). In these cases the establishment should gather scientific support and in-plant validation data for its HACCP system under commercial operating conditions. For example, microbiological data may show that a steam vacuum process is achieving a certain level of reduction for the specified microorganism. If the establishment is modifying the critical operational parameters of the steam vacuum process then the documentation gathered in-plant used to show that the HACCP system is valid as designed should contain information from all the tests performed, such as temperature of steam, time of exposure, and microbiological results of swab tests, and information that makes clear whether the testing was performed on a routine or specified schedule. When collecting data in-plant, the establishment should develop a sampling plan in advance of data collection to ensure that the data collected are adequate to make statistical determinations about effectiveness.

In-plant data could also be collected as technical support for an establishment's HACCP system design. For example, an establishment may identify foreign material as a hazard in ground product because of the wooden pallets it uses, and how the product is loaded to be dumped into a hopper. The establishment could determine that the foreign material hazard is not reasonably likely to occur because of a prerequisite program that includes steps the establishment takes to ensure that pieces of the pallet do not break off and fall into the grinder to contaminate the product. The establishment could collect in-plant data to demonstrate the effectiveness of these technical procedures for preventing the hazard from occurring in its process.

NOTE: FSIS does not advocate the introduction of pathogens in the plant environment.

Large corporations with multiple establishments often conduct studies in one establishment to gain scientific information to validate an intervention's design and then extend the use of the intervention to other establishments within the corporate umbrella. For the establishment at which the data were gathered, FSIS would consider the data to be data gathered in-house, and thus the data would meet both parts of validation (design and execution). However, for the establishments to which use of the intervention was extended, the data would meet only the first element of validation. To meet the second element of validation, the corporation would still need to demonstrate that the intervention will function as intended in each of those establishments by gathering data on the critical operating parameters' execution in those additional establishments. So, for biological hazards, microbial data collected at one establishment could be used to support effectiveness of the intervention or process (i.e., the first element of validation) at other establishments within the corporation that use the same procedures.

7. Regulatory performance standards, as defined in the Code of Federal Regulations, that outline specific prescribed procedures such as time/temperature combinations, product storage conditions, or product reconditioning procedures. The poultry chilling requirements defined in 9 CFR 381.66 or the trichinae requirements in 9 CFR 318.10 would be examples of instances where the regulations clearly define the performance standard for a processing step and can be used to support the HACCP system design.

8. Best practice guidelines are another example of scientific or technical support. These guidelines generally contain a list of procedures or a set of principles that have been identified by experts as having a scientific or technical basis for preventing a hazard from occurring when implemented. For example, the Beef Industry Food Safety Council (BIFSCO) has developed a document that contains *Best Practices for Beef Slaughter*. This document may be used as scientific support that an establishment's sanitary dressing program prevents contamination with

microbiological hazards such as *STEC* and ensures that the interventions the establishment has in place achieve their intended effect.

What are some examples of incomplete scientific or technical support?

The following are examples of incomplete scientific or technical support for validation:

- Documentation that specifies the log reduction achieved by the process but that does not include information about critical parameters, such as pH, critical to achieving that reduction. That information should be included in order for the process to be considered validated.

- Having a validated process on file but not following the process described.

- Validating a process for a specific log reduction of a pathogen in a product other than meat and poultry. This validation data alone would not be sufficient scientific support. For example, a process that achieves a 5-log reduction of *E. coli* O157:H7 in apple cider would not be sufficient scientific support for the reduction of *E. coli* O157:H7 in a beef product process.

- Implementing an intervention based on scientific or technical support that did not contain data supporting the process's effectiveness. For example, implementing a lactic acid intervention in a prerequisite program to support *E. coli* O157:H7 as a hazard not reasonably likely to occur but maintaining scientific support with microbiological data for *Salmonella.*

  NOTE: Ensuring that the scientific support contains microbiological data for the hazard listed in the hazard analysis is particularly important for slaughter processes where interventions have different efficacy depending on the species of product and the pathogen. In other cases, such as for lethality processes, *Salmonella* may be used as an indicator of lethality for other pathogens.

- Documentation in the form of a No Objection Letter or *FSIS Directive 7120.1* without additional scientific or technical support that provides information on the levels of all of the critical operational parameters used, and without support that demonstrates the effectiveness of the new ingredient or technology against the specific hazards identified in the hazard analysis. Examples of such necessary scientific and technical support are included on pages 6 through 11 of this document. This additional support is needed because the No Objection Letter and *FSIS Directive 7120.1 Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products* do not contain efficacy data or data on all of the critical operational parameters.

- Expert opinion from a processing authority stating the growth limit of a pathogen without any reference to established scientific principles or peer-reviewed data.

How can an establishment identify whether the scientific or technical support closely matches the process, product, and hazard analysis?

In all cases, the scientific or technical support should identify:

- The product studied (including formulation and intrinsic factors)
- The hazard (biological, physical, or chemical),
- The expected level of hazard reduction or prevention to be achieved,
- All critical operational parameters or conditions necessary,
- The processing steps that will achieve the specified reduction or prevention, and
- How these processing steps can be monitored.

The establishment should evaluate this information to determine whether it's scientific or technical support is sufficiently related to the process, product, and hazard identified in the hazard analysis. The scientific or technical support should be complete and available for FSIS review, so that FSIS personnel can also determine whether the support is sufficiently related to the actual process. Failure to take these steps would raise questions about whether the HACCP system has been adequately designed and validated.

How can an establishment identify scientific support that adequately addresses the expected level of hazard reduction or prevention to be achieved for biological hazards?

The type of scientific support (e.g., published processing guideline, peer-reviewed data or information, pathogen modeling program results) and the type of data or information contained in the support will differ depending on the product, biological hazards identified in the hazard analysis, and the intervention strategy the establishment designs to reduce, eliminate, or prevent the hazards. Some of these considerations for identifying scientific support for intervention strategies used to address hazards in RTE and raw products are outlined below.

Scientific Support for RTE Products

Establishments producing meat or poultry products that are RTE must support that potential hazards have been addressed in the product according to 9 CFR 417.2(a)(1). The *Listeria Rule* (9 CFR 430.1) defines RTE products as meat or poultry products that are edible without additional preparation to achieve food safety. To support that products are RTE, among other steps, establishments need to achieve lethality of pathogens in the product. To support decisions in the hazard analysis related to lethality of pathogens RTE products, establishments must provide scientific support that specifies the expected level of pathogen reduction achieved by the intervention strategy for the product being produced. For example, establishments producing RTE semi-dry fermented products must provide scientific support that the fermentation and drying steps achieve a specific level of pathogen reduction. In the *Salmonella Compliance*

Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products, FSIS recommends that these processes achieve at least a 5.0-$\log_{10}$ reduction on of *Salmonella* spp. Without data demonstrating a specific log reduction is achieved, it would be difficult for an establishment to support that a product is RTE.

KEY QUESTION

Question: Can an establishment use *Appendix A*, which was designed to address *Salmonella*, to support other pathogens such as *E. coli* O157:H7 or *Listeria monocytogenes* are controlled?

Answer: Yes, an establishment can cite *Appendix A* as support that *E. coli* O157:H7 and *Listeria monocytogenes* are controlled as a result of a thermal process. Although *Appendix A* was developed based on experiments measuring the efficacy of thermal processes on *Salmonella*, *Salmonella* can be used as an indicator of lethality for other pathogens such as *E. coli* O157:H7 and *Listeria monocytogenes.*

The scientific support for RTE products should be sufficiently related to the process, product, and hazard identified in the hazard analysis. For thermal lethality treatments (i.e., cooking), establishments can use scientific support that demonstrates reduction in one pathogen to support that another pathogen would also be reduced. For example, although establishments may identify several biological hazards (i.e., *Salmonella*, *Listeria monocytogenes* (*Lm*), and *E. coli* O157:H7) that are addressed by a lethality treatment, *Salmonella* is generally considered the reference organism for lethality for most RTE meat and poultry products because: (1) It is prevalent in raw poultry, beef, and pork; (2) it causes a high incidence of foodborne illness; and (3) foodborne illness associated with *Salmonella* is severe (66 FR 12593). In addition, FSIS recommends that establishments use *Salmonella* as an indicator of lethality because it tends to be more heat resistant than other pathogens. Therefore, if an establishment's scientific support demonstrates that its lethality treatment achieves sufficient reduction in *Salmonella*, it does not need to provide additional support that adequate reduction in other pathogens such as *Lm* or *E. coli* O157:H7 is achieved. For these reasons, establishments should not use pathogens other than *Salmonella* as indicators of lethality unless they can provide support that the pathogen studied displays similar resistance to the process that destroys the bacteria (e.g., heat, acid, or drying). For example, establishments should not use scientific support demonstrating reductions in *Lm* from a lethality treatment to support that similar reductions in *Salmonella* would be achieved without support that *Lm* is at least equally as resistant as *Salmonella* under the conditions being studied. Non-pathogenic indicator organisms may be used and will be discussed in a later section.

Scientific Support for Raw Products

Under 9 CFR 417.2(a)(1), establishments producing raw meat or poultry products must support that potential hazards have been addressed in the product. For the production of raw products, the scientific support should contain microbiological data specifying the expected level of pathogen control or prevention achieved by the intervention strategy so that the establishment can determine whether the intervention is adequate for its product and process. Using documentation that does not contain microbiological data on the specific level of reduction achieved could represent a vulnerability in an establishment's HACCP system design. For example, an establishment that identifies *Salmonella* as a hazard reasonably likely to occur in its poultry slaughter process because it has historically occurred would have a vulnerability in its process if it relies on scientific support that contains the number of samples that test positive for *Salmonella* before and after the application of an intervention. Using this type of data would represent a vulnerability because it would not provide information on the specific log reduction achieved. Without this information, the establishment would be unable to determine whether the intervention would reduce *Salmonella* in its process to acceptable levels.

The scientific support for raw meat and poultry products should also be sufficiently related to the process, product, and hazard identified in the hazard analysis. It is particularly important that the scientific support for intervention strategies used in the production of raw products include microbiological data that specifies the expected level of pathogen reduction for the same hazard identified in the hazard analysis. For example, in slaughter establishments, interventions such as lactic acid and peroxyacetic acid (PAA) have been found to perform differently for different pathogens (e.g., *Salmonella* and *E. coli* O157:H7) and different species (e.g., poultry vs. beef). Therefore, it would be important for a beef slaughter establishment that references a lactic acid intervention applied to beef carcasses as a control for *E. coli* O157:H7 in its hazard analysis during slaughter and dressing to provide support that a specific log reduction in *E. coli* O157:H7 is achieved when the lactic acid is applied to beef carcasses. One exception when the scientific support may not need to address the specific pathogen listed in the hazard analysis for raw products is for intervention strategies designed to control or prevent non-O157 shiga-toxin producing *Escherichia coli* (STEC). **At this time**, FSIS is not aware of any controls specific to non-O157 STEC. Interventions validated to control *E. coli* O157:H7 should be effective in controlling non-O157 STEC when properly implemented as described in the establishment's scientific support.

Can establishments use scientific support containing microbiological data from indicator or surrogate organisms?

In general, establishments should not rely on scientific support containing data only from indicator or surrogate organisms unless there is sufficient data to establish a relationship between the presence or level of a pathogen or toxin and the indicator organism. When selecting the appropriate surrogate organism, the establishment

should consider the process that destroys the bacteria (e.g, heat, acid, drying). For example, a surrogate organism that is at least as heat resistant as the pathogen of concern should be used if the process primarily relies on thermal destruction (i.e., heat). If the primary pathogen reduction mechanism is fermentation, then a surrogate should be at least as acid resistant as the pathogen of concern. The surrogate chosen in each of these situations may not be the same.

Data demonstrating a relationship between the presence or level of a pathogen or toxin and the indicator organism can be collected from studies using indicator organisms that parallel the data in a challenge study performed with the inoculated pathogen. This data could be collected by performing the study with the indicator and pathogen as part of a single study or separately in two studies performed under similar conditions. If similar and consistent reduction or control can be established, then control of the indicator organisms can be reliably used to indicate expected pathogen control in actual application.

An example of when similar and consistent reduction in an indicator or surrogate organism and a pathogen have been found is research that was done by the University of Wisconsin with ground-and-formed jerky that found that two *Pediococcus* strains (*Saga 200* and *Biosource*) have similar heat-resistance to *Salmonella* and can be used in validation studies (Borowski et al., 2009) for jerky lethality processes. In addition, FSIS has identified four surrogate organisms that have been shown to respond similarly to *E. coli* O157:H7 during cooking (see the following askFSIS Q&A[1] for more information) for use in validation studies designed to demonstrate a reduction in *E. coli* O157:H7. **At this time**, however, FSIS is not aware of supporting documentation demonstrating a strong correlation to support the use of generic *E. coli* testing in lieu of testing for *E. coli* O157:H7 or non-O157 STEC.

How can an establishment identify scientific or technical support that adequately addresses the expected level of hazard reduction or prevention to be achieved for physical and chemical hazards?

For physical and chemical hazards, establishments will often use technical support to demonstrate that particular process control measures can adequately address specific hazards. As with biological hazards, the scientific or technical support should closely match the product, process, and hazard. For example, if the establishment uses detection equipment to identify foreign material such as metal in a particular product, it should have technical support on-file that demonstrates that the equipment can in fact detect the targeted materials (e.g., metal of a defined size and type) in the product. The same is true for chemical hazards. For example, an establishment that uses a lactic acid intervention during a beef slaughter process may identify a chemical hazard from

[1] http://askfsis.custhelp.com/app/answers/detail/a_id/1392/kw/surrogate/session/L3RpbWUvMTMyNzUyMTY0Ni9zaWQvVFR6c3cyUGs%3D

excessive levels of lactic acid. The establishment may support that the hazard is not reasonably likely to occur based on instructions from the manufacturer on mixing the lactic acid with water to achieve a concentration that is safe and suitable in accordance with *FSIS Directive 7120.1*. In this case, the manufacturer's instructions or conditions of use are often provided as technical support that demonstrates the use of the chemical is controlled.

How can an establishment identify scientific support for prerequisite programs?

As previously discussed on page 5, when an establishment determines that a hazard is not reasonably likely to occur because the implementation of a prerequisite program prevents the hazard from occurring, that prerequisite program becomes part of the HACCP system. Therefore, prerequisite programs designed to support decisions in the hazard analysis (*e.g.* Sanitation Standard Operating Procedures [Sanitation SOPs], written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, antimicrobial interventions) must be validated to ensure that the overall system can operate effectively.

Although prerequisite programs within HACCP systems are often designed as multiple hurdles of control, establishments should be able to provide scientific or technical support that each hurdle or combination of hurdles provides the necessary level of prevention for the identified hazards. For some prerequisite programs that are implemented at a discrete point or step in the process, such as those for antimicrobial interventions, the guidance provided on the previous pages for identifying scientific support for the expected level of reduction necessary to prevent the hazard can be applied. When using an antimicrobial intervention as a prerequisite program, establishments should identify scientific support that matches the product, process, and hazard and that contains microbiological data specifying the expected level of pathogen reduction necessary to prevent the hazard from occurring. For other prerequisite programs that are implemented across multiple points or steps in the process, such as those for allergen control or programs that incorporate written sanitary dressing procedures, establishments may rely on scientific or technical support that contain best practices regarding the implementation of such programs. For example, the Beef Industry Food Safety Council (BIFSCO) has developed a document that contains *Best Practices for Beef Slaughter*. FSIS has identified, through both scientific literature review and best practice guidance created by industry, the points in the slaughter process where carcasses are most vulnerable to contamination and has included these steps in *FSIS Directive 6410.1 Verifying Sanitary Dressing and Process Control Procedures by Off-line Inspection Program Personnel (IPP) in Slaughter Operations of Cattle of Any Age*. These documents may be used as scientific support that an establishment's sanitary dressing program prevents contamination with microbiological hazards such as *STEC* and ensures that the interventions the establishment has in place achieve their intended effect.

See Appendix 4 page 55 for an example of scientific support and in-plant data that could be collected to validate Sanitation SOP's, page 56 for an example of scientific support and in-plant data that could be collected to validate a temperature control prerequisite program, and page 57 for an example of scientific support and in-plant data that could be collected to validate a sanitary dressing program.

What are the critical operational parameters of a process, and how does an establishment identify them in its scientific support?

Critical operational parameters are the specific conditions that the intervention must operate under in order for it to be effective. For an establishment to validate an intervention, it should first identify the critical operational parameters within its process that it needs to implement and monitor**.** These critical operational parameters are identified in documents gathered as part of Element 1 of validation and often include but are not limited to:

- Time
- Temperature
- Concentration
- Humidity
- Dwell Time
- Water Activity
- pH
- Contact Time
- Product Coverage
- Spatial Configuration
- Pressure
- Equipment Settings or calibration

To be effective, the process procedures should be consistent with the critical operational parameters in the scientific support. For example, if the scientific support listed a particular critical operational parameter such as the concentration of an antimicrobial, that same concentration should be used in the process. In some cases, establishments may be able to support using different levels of a critical operational parameter than that used in the support. For example, an establishment may be able to provide a justification for why using a higher lethality temperature than that used in the scientific support would result in the same level of pathogen reduction. When different levels of a critical operational parameter than those in the support document are used, establishments should consider developing a decision-making document that explains the scientific rationale for why the different level would not affect the efficacy of the intervention or process. See Appendix 2 for an example. This scientific rationale could be provided by a processing authority or other expert provided there is reference to established scientific principles or peer-reviewed scientific data and does not rely on expert opinion alone.

Developing a decision-making document and explaining the rationale for use of a critical operational parameter different from the one in the scientific support is important because changing a critical operational parameter can impact the intended result in unexpected ways. For example, antimicrobials have been determined to be safe and suitable up to specific concentrations at specific pH levels as listed in *FSIS Directive 7120.1* and 9 CFR 424.21(c)). Although the Directive and regulation provide maximum allowable concentrations for antimicrobials, the establishment needs to determine the

optimum concentration for its process based on the critical operational parameters in its scientific support (e.g., journal articles, challenge studies). The concentration chosen by an establishment is often the concentration at which maximum efficacy is observed. A synergistic or an additive effect may be observed when combinations of antimicrobials are used. Above the optimum concentration, although still within the allowable range, the chemical or antimicrobial efficacy decreases because the cells/membrane of the microorganism are saturated with the compound, and further inactivation of the bacteria is not observed. In other words, more of an antimicrobial is not always better. An establishment may be able support using a higher concentration of an antimicrobial in its process than that used in the scientific support but within the allowable range, provided that it evaluates whether changes to the concentration would affect the efficacy of the intervention or process, and that there is scientific support for its decisions.

To identify the critical operational parameters when evaluating the scientific support, there are several questions one can ask. For example:

- What parameters were measured in the research?
- Where in the process or on the product were the measurements taken?
  - Is the establishment taking measurements in these locations?
- What parameters, if any, were held constant across experimental conditions?
- What parameters, if any, were varied or changed in the research?
  - When these parameters were changed, did the effectiveness of the intervention change as well?
  - If so, are these parameters that you have considered in your process?
- Did the authors provide some guidelines as to the limitations of the research or any cautions against applying the findings outside of the scope of the study?
  - For example, were there some parameters that were controlled in the laboratory that differ in-plant that you should be aware of?
  - If so, have you considered if those apply to your process?

If the scientific support does not document the measurement of a critical operational parameter, the establishment should evaluate whether this parameter really needs to be met or measured, or whether additional support is needed for the level of that parameter in the actual process. For example, humidity is a critical operational parameter in the cooking or heating of many ready-to-eat meat and poultry products. For the production of some of these products, however, humidity does not need to be met or measured. For example, as addressed in the *Appendix A Guidance on Relative Humidity and Time/Temperature for Cooking/Heating and Applicability to Production of Other Ready-to-eat Meat and Poultry Products*, humidity does not need to be met or measured when a product is cooked in a sealed, moisture impermeable bag. Establishments producing such cook-in-bag products may develop a decision-making document and cite the *Appendix A Guidance* on relative humidity as support for why humidity does not need to met or measured in the process. What is important in this case is that the establishment considers the parameters that are relevant for their product and process

and does not assume that just because the parameter was not measured in the scientific support it is not important.

For prerequisite programs that are implemented across multiple points or steps in the process, such as those for allergen control or programs that incorporate written sanitary dressing procedures, establishments may rely on scientific or technical support that contains best practices regarding the implementation of such programs. When relying on these types of scientific or technical support, establishments may consider the recommended procedures that should be incorporated into the written prerequisite program as critical operational parameters. These procedures would be considered critical operational parameters because these steps need to be implemented and monitored in order to ensure that the program is effectively preventing a hazard from occurring.

See Appendix 3 for additional guidance as to how to identify critical operational parameters from the scientific support. Appendix 4 contains examples of critical operational parameters that have been identified for different types of processes and scientific support. Examples of the types of in-plant documentation expected are also provided.

Key Point: An establishment that gathers scientific support for its processes (and properly identifies the critical operational parameters in the support) as described above would meet the threshold indicated in the HACCP Systems Final Rule (61 FR 38806) for the first element of initial validation in designing a valid HACCP system. The establishment's processes would be considered by FSIS to be based on or supported with documented scientific evidence. These processes would not need any additional scientific support as part of the initial validation process. However, as stated in the HACCP Systems Final Rule (61 FR 38826), an establishment introducing a new technology not established in the literature or applying a standard technology in an unusual way (e.g., modifying critical operational parameters from the literature) should gather scientific support and in-plant validation data for its new or modified HACCP system under commercial operating conditions. The effort to develop such information may require that the establishment conduct, or have conducted for it, scientific studies either in a laboratory setting, pilot plant, or in-plant. An establishment that lacks experience with a technology should also gather scientific support and in-plant validation data with the exception of when the effectiveness of the new technology has already been studied, but the establishment lacks experience implementing the technology. In this case, the effort to develop such information may focus more on the collection on in-plant validation data (discussed further in the next section).

KEY QUESTION

Question: Can an establishment's process use a different level of a critical operational parameter (for example, a higher concentration of an antimicrobial or a higher processing temperature) than what was used in the scientific or technical support?

Answer: Generally, establishments should use the same critical operational parameters as those in the scientific or technical support. However, some minor differences are acceptable. For example, Table 1 of the Tompkin paper can be used to support a storage temperature CCP for raw meat of 45°F even though it cites 44.6°F as minimum growth temperature for *Salmonella*. This rounding is suitable because the growth rate of *Salmonella* at 45°F is not significantly different from its growth rate at 44.6°F. Furthermore, when temperatures are converted from Celsius to Fahrenheit, as in Table 1 of the Tompkin paper, numbers are often converted as fractions, which establishments may round to whole numbers because of practical measurement limitations of equipment in establishments. On the other hand, rounding may not be suitable for other critical operational parameters such as water activity and pH because minor changes in the values can have a significant impact on pathogen growth.

In some circumstances, establishments may be able to support using critical operational parameters (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures) that are different from those in the scientific or technical support. In these cases, establishments should provide justification supporting that the levels chosen are at least as effective as those in the scientific or technical support. This justification is needed because higher levels of a critical operational parameter may not always be equally effective. For example, antimicrobial agents may only be effective within a range of concentration after which point efficacy may decrease. Similarly, higher processing temperatures may result in the surface of the product drying out before adequate lethality is achieved. In addition to ensuring that the levels chosen are at least equally as effective, establishments should ensure the levels are also safe and suitable (*FSIS Directive 7120.1 Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products* and 9 CFR 424.21(c)).

What is the second element of HACCP Systems Validation?

The **second element of HACCP systems validation is initial in-plant validation** which may include in-plant observations, measurements, microbiological test results, or other information demonstrating that the control measures, as written into a HACCP system, can be executed within a particular establishment to achieve the process's intended result (61 FR 38806, 38826 (July 25, 1996)).

FSIS stated in the HACCP Final Rule that validation data for any HACCP system must include practical data or information reflecting an establishment's actual experience in implementing the HACCP system. The validation must demonstrate not only that the HACCP system is theoretically sound in its design (Element 1), but also that the

establishment can execute it as designed to reach the desired effect (Element 2). To meet the second element of validation, establishments should:

- Implement the critical operational parameters in the actual production process consistent with the parameters in the scientific support;
- Identify at least one product from each HACCP category for which to gather in-plant validation data;
- Collect in-plant data demonstrating the effectiveness of the implementation of the critical operational parameters for at least one product from each HACCP category; and
- Analyze the data to determine whether the critical operational parameters are being implemented effectively.

Once the critical operational parameters are identified, how should they be implemented in the actual process?

Once the critical operational parameters are identified, an establishment should implement the critical operational parameters in the actual process consistent with the scientific support.

If an establishment is using the scientific support as support for the development of a CCP and its critical limits (9 CFR 417.5(a)(2)) to prevent, reduce, or eliminate a hazard identified as RLTO, the establishment should incorporate all of the critical operational parameters into the critical limits of the CCP. An establishment may determine, however, based on its decision making, that some of the parameters can be monitored on an ongoing basis as part of a prerequisite program. An establishment may also determine that it only needs to ensure some of the critical operational parameters are implemented consistent with the support during the initial validation period (e.g., spatial configuration, equipment type to the extent that it affects other parameters, or ingredient formulation provided it does not change). These parameters should be included in a decision-making document, but they do not need to be monitored after the 90 days of initial validation unless there is a change.

I***f an establishment is using the scientific support as support for a decision that a hazard is not reasonably likely to occur (9 CFR 417.5(a)(1) because the implementation of a prerequisite program prevents conditions that make the potential hazard likely, then all of the critical operational parameters should be incorporated into the prerequisite program.*** An establishment may also determine that it only needs to ensure some of the critical operational parameters are implemented consistent with the support during the initial validation period (e.g., spatial configuration, equipment type to the extent that it affects other parameters, or ingredient formulation provided it does not change).

What types of data should establishments collect during the initial in-plant validation period?

Often establishments incorporate interventions into their processes to reduce the level of certain pathogens and use published scientific articles as scientific support for the design of the interventions (see above discussion of the first part of validation). Establishments may implement those interventions **consistent with** the scientific support or make modifications to the critical operating parameters that could affect the efficacy of the intervention. To implement an intervention consistent with the scientific support means that changes among the critical operational parameters used in the scientific support and those used in the actual process will not affect the efficacy of the intervention or treatment. Depending on how an establishment implements the critical operational parameters for an intervention and the type of support used, different data should be collected during the initial in-plant validation period. These two scenarios are described below:

Scenario 1 – In cases where the establishment's process **is implemented consistent with** the critical operational parameters described in the scientific support, **and when the scientific support used contains microbiological data** specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, to meet the second element of validation, the establishment should:

- ✓ Identify the critical operating parameters in the scientific support, AND
- ✓ Implement those critical operational parameters in the establishment's production process consistent with the scientific support, AND
- ✓ Collect in-plant data that demonstrates that the critical operating parameters are being met (e.g., data on quantifiable characteristics of the critical operational parameters such as pressure, temperature, and concentration).

Thus, if an establishment implements the actual process consistent with the critical operational parameters in the scientific support, the establishment should collect in-plant data demonstrating that the critical operational parameters can all be met, and no in-plant microbiological data would be needed. For example, if the scientific support for a carcass wash intervention includes critical parameters of water pressure at the nozzle, water temperature at the point of contact with the carcass, whole carcass coverage, and a water/carcass contact time, then the establishment should measure and gather data on whether those parameters are being achieved. The water temperature measured in a holding tank or at the nozzle may not be the actual water temperature at point of contact with a carcass, so it is crucial to design measurement procedures appropriately.

Scenario 2 - In cases where the establishment's process is **not implemented in a manner that is consistent with the** critical operational parameters described in the

scientific support without justification, **or when the scientific support used does not contain microbiological data** specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, to meet the second element of validation the establishment should:

- ✓ Identify the critical operating parameters in the actual process (either because they were modified from the scientific support without justification, or the scientific support does not contain microbiological data), AND
- ✓ Collect in-plant microbiological data that demonstrates the intervention's effectiveness under actual in-plant conditions or identify scientific support with microbiological data demonstrating the effectiveness of those critical operational parameters,
- ✓ AND
- ✓ Collect in-plant data that demonstrates that the modified critical operating parameters are being met.

Thus, if an establishment implements different critical operational parameters in the process from the scientific support, or if the scientific support does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND collect in-plant microbiological validation data or identify scientific support with microbiological data for the effectiveness of those implemented critical operational parameters.

The establishment should develop the appropriate in-plant data during the initial 90 days of implementing a new HACCP system, or whenever a new or modified food safety hazard control is introduced into an existing HACCP system (e.g., as implemented after a HACCP plan reassessment). During these 90 calendar days, as described in the HACCP Final Rule, an establishment gathers the necessary in-plant data to demonstrate that the critical operating parameters are being achieved. In essence, the establishment would repeatedly test the adequacy of the process steps in the HACCP system to establish that the HACCP system meets the designed parameters and achieves the intended results. These in-plant data become part of the validation scientific support along with the scientific support used to design the HACCP system. See the section below on records for more information. Failure to take these steps would raise questions as to whether the HACCP system has been adequately validated.

In addition to collecting the in-plant data described, it is critical that the establishment **analyze the data to whether the critical operational parameters are being implemented effectively**. This analysis should include a review of the records generated by the HACCP system during the initial validation period. Establishments may need to work with a statistician to conduct more in-depth statistical analyses of the in-plant data collected. For example, an establishment may need to work with a statistician to determine whether the in-plant validation data supports that it is implementing the critical operational parameters consistent with the scientific support.

An establishment may also need to conduct more in-depth analysis if it implements critical operational parameters that are different from the process in the scientific support, and, as a result, it would need to collect in-plant microbiological data.

For what types of processes and products should establishments collect in-plant validation data?

Establishments should maintain scientific support for all processes and products; however, establishments should collect in-plant data for at least one product from each HACCP process category at that establishment. Depending on the HACCP category and products, establishments should consider collecting in-plant data for more than one product within each category. The object is to collect in-plant data for a wide variety of different products and worst case scenarios. Establishments should collect in-plant data for all CCPs and prerequisite programs used to support decisions in the hazard analysis for at least one product from each HACCP category at that establishment. Establishments should use food science principles in their decision making when deciding which product types within a HACCP category should be used to gather in-plant data. In addition, establishments should use decision-making documents to describe how the HACCP team decided on the product or product types that would be used during initial validation. Similarities and differences in species, process, intrinsic factors, product public health risk, and food safety hazards should be considered. Some examples of food science principles that could be used to decide which product within a HACCP category should be used to gather in-plant data include:

- ***Fat content:*** Fat level in meat has been documented to influence bacterial heat resistance (Juneja et al., 2001). As the fat level increases, bacterial heat resistance increases. Therefore, higher fat content meat or poultry products require greater time or temperatures to achieve equal lethality compared with lower fat content products.
    - How this criterion could be used: If an establishment produces several fully cooked poultry products, the establishment should gather data for the product with the highest fat content. Similarly, if an establishment produces several ground poultry products, and some of the products are made from skin-on thigh meat while others are made with boneless, skinless thigh meat, the establishment should collect in-plant validation data for the ground product made from the skin-on thigh meat because of the additional fat from the skin.

- ***Size and shape of the food:*** The size and shape of food affects heat penetration, heating rate, and heating uniformity. Irregularly shaped products, for example, are subjected to non-uniform heating because of differences in product thickness. In addition, in thicker products, more time will be needed for the heat to penetrate to the center of the product.
    - How this criterion could be used: If an establishment produces several fully cooked deli meat products of various thicknesses, the establishment

should gather data on the thickest product because heat penetration is critical.

- ***Number and type of processing steps or ingredients:*** Certain processing steps, such as slicing of ready-to-eat product, are known to be potential sources of cross-contamination. In addition, some ingredients such as spices are known to introduce contamination (biological, chemical, or physical). Therefore, establishments should consider whether some products within a HACCP category undergo additional processing steps or contain additional ingredients that may introduce contamination and should collect in-plant validation data for that product.
    - How this criterion could be used: If an establishment fabricates beef manufacturing trimmings and uses the trimmings to produce ground beef and patties, the establishment should collect in-plant validation data for the patty process because the patty forming process introduces an additional step that could provide an opportunity for contamination.

- ***Product species:*** Studies have shown that there is a difference in bacterial resistance in products from different types of species. Therefore, establishments should consider collecting data separately for each species slaughtered or processed within a HACCP category.
    - How this criterion could be used: If an establishment slaughters hogs and cattle under one HACCP category, in-plant data should be gathered for both species because the slaughter process and the hazards associated with each are substantially different.

- ***Public health risk:*** Establishments should take past outbreaks into account when selecting a product to collect in-plant data for within a HACCP category.
    - How this criterion could be used: If an establishment produces several types of fully cooked ready-to-eat products, and one of the products is Lebanon bologna, data should be gathered for the Lebanon bologna because it was associated with an illness outbreak.

In some cases, an establishment may produce products that are all of equal risk. In those cases, FSIS recommends that establishments select the product with the highest production volume because that product would have the greatest public exposure.

- How this criterion could be used: If an establishment makes several types of fully cooked sausages and the only difference among these products are ingredients such as pimentos or pickles that are used as flavorings and that do not affect food safety, an establishment should gather data on the product produced in the highest volume.

Finally, in other cases establishments may consider selecting more than one product from a HACCP category.

- For example: If an establishment processes both hot dogs and RTE whole turkey breast that is sliced, both products should be validated because their

processes are substantially different, and both have been found to represent an increased risk of listeriosis illness to the consumer.

How long does an establishment have to complete initial validation (Elements 1 and 2)?

During the process of conducting a hazard analysis and developing a HACCP plan, establishments gather supporting documentation in the form of scientific or technical support for the HACCP system design **(Element 1)**. New establishments must conduct a hazard analysis (9 CFR 417.2) and develop and validate a HACCP plan (9 CFR 417.4) before being granted Federal inspection as required by 9 CFR 304.3(b) and 381.22(b). Additionally, establishments must conduct a hazard analysis and develop a HACCP plan (9 CFR 417.2) before producing a new product for distribution in commerce as required by 9 CFR 304.3(c) and 381.22(c). Consistent with these requirements, establishments should gather scientific or technical support for a modified HACCP plan before implementation, if the results of a reassessment indicate new or additional support is needed (e.g., if significant changes to an intervention are made or a new intervention is added). Establishments can begin gathering their support by conducting reviews of the available scientific literature, published processing guidelines, and regulatory performance standards to determine whether scientific documentation already exists matching their actual product and process.

After the hazard analysis has been conducted, and the HACCP plan has been developed, establishments gather in-plant validation data proving that the HACCP system can perform as expected **(Element 2)**. New establishments are issued a conditional grant of inspection for a period up to 90 days during which they must complete the initial validation as required in 9 CFR 304.3(b) and 381.22(b) (Element 2). Additionally, 9 CFR 304.3(c) and 381.22(c) require establishments producing a new product to complete the initial validation of the new HACCP plan during a period not to exceed 90 days after the date the new product is produced for distribution in commerce. Consistent with these requirements, initial validation should encompass the first 90 calendar days of an establishment's processing experience with a modified HACCP plan, if the results of a reassessment indicate in-plant validation data should be collected (e.g., if significant changes to an intervention are made or a new intervention is added).

For large establishments, 90 calendar days equates to approximately 60 production days. FSIS recognizes that many small and very small establishments do not operate daily. Therefore, FSIS recommends a minimum level of records from 13 production days within those initial 90 calendar days should be used to initially validate a small or very small establishment's HACCP system. FSIS also recognizes that there are some establishments that produce products so infrequently that they would not be able to gather records from 13 production days within those 90 initial calendar days. If the establishment infrequently produces several products that are each part of a separate HACCP category, there is inherent risk with the processes if the establishment does not have experience in producing them. Therefore, to determine whether the system is

properly designed and executed, even though the regulations provide 90 days for initial validation, an establishment needing more than 90 days can ask the District Office, in writing, for additional time to collect at least 13 production days of records when it first starts operating, or when it begins producing new product, or for a modified HACCP plan if the results of a reassessment indicate additional support is needed. In the request, an establishment should indicate why more than 90 days are needed to collect the in-plant validation data, and how it plans to gather at least 13 production days worth of in-plant validation data within the next 30 calendar days. The request will then be evaluated on a case by case basis. The establishment should consider focusing validation activities on the product produced most frequently within each HACCP category. In addition, the establishment may consider evaluating data collected for products across multiple HACCP categories to determine whether the data together can support its ability to meet critical operational parameters.

As previously discussed, if an establishment implements a process **consistent with** the process specifications described in the scientific support, **and the scientific support contains microbiological data** specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements **different critical operational parameters** in the process from the scientific support, or the scientific support identified **does not contain microbiological data**, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological validation data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameters.

Establishments can continue producing and shipping product into commerce during the 90 day initial validation period with the exception of establishments that are gathering in-plant microbiological data to support that a product is RTE. For example, if an establishment producing a RTE product is implementing a lethality process using different critical operational parameters (e.g., time, temperature, or relative humidity) from its scientific support, the establishment could commission a challenge study to demonstrate the effectiveness of the alternate parameters during the 90 day initial validation period. During this time, the establishment could not ship the RTE product into commerce because it does not have the necessary scientific support to demonstrate that all potential hazards have been addressed and that the product would meet the definition of RTE in 9 CFR 430.1 (that it is in a form that is edible without additional preparation to achieve food safety).

If an establishment has questions as to whether complete scientific support is needed for its products before the products can be shipped into commerce, then it can submit a question through askFSIS at http://askfsis.custhelp.com/ following the guidance on page ii of this document.

What types of records are validation documents, and how long should an establishment keep them?

The scientific support (design) and in-plant (execution) validation data support the decisions made in the hazard analysis and the adequacy of the process to control those hazards. Therefore, these supporting documents must be kept for the life of the plan to meet the requirements of 9 CFR 417.5(a)(1) & (2).

NOTE: Establishments using existing HACCP systems developed before the issuance of this document that do not have the documents from their initial validation on file will need to gather the necessary data. Appendix 5 contains further guidance for establishments that no longer have the in-plant validation data.

Key Requirement

The scientific or technical support for the design and initial in-plant execution validation documents must be kept on file as part of 9 CFR 417.5(a)(1) & (2) supporting documentation records.

KEY QUESTION

Question: If an establishment has not utilized a process for a year or more, is the process still validated?

Answer**:** Most likely, no. An establishment would need to perform a reassessment in order to determine whether changes have occurred that could affect the hazard analysis or alter the HACCP plan. If the reassessment led to modifications in the HACCP system, then the establishment would need to gather additional in-plant validation data. Meat and poultry establishments must document each reassessment and the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment (9 CFR 417.4(a)(3)). For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.

KEY QUESTION

Question: If an establishment moves physical locations, will it have to repeat the in-plant documentation element of its initial validation?

Answer: Most likely yes, as a result of the establishment's reassessment. Much like with large corporations with multiple establishments, the establishment will be able to transfer the scientific support from one location to another (meeting the first element of validation - design) but will most likely need to gather in-plant data to support the second element of validation (execution). There are often differences from location to location that may affect whether the critical operational parameters in the scientific or technical support can be implemented properly in the new establishment. For example, the same type of spray cabinet made by different manufacturers may have different flow rates for the intervention spray delivery that would require changes to other critical operational parameters in order to achieve equivalent application. The same may be true for the effect of employees or the size or shape of the physical location on the critical operational parameters.

What is the difference between initial validation and on-going verification, and what happens after the initial validation period is over?

Many agree that validation should be a distinct function from verification (see, e.g., Scott and Stevenson, 2006). **During the 90 calendar days of initial validation** following completion of the hazard analysis and development of the HACCP system, establishments check the validity or adequacy of the HACCP system. Establishments are to conduct validation activities during their initial experience with a new HACCP system. Establishments are required to complete the initial validation of the new HACCP plan in accordance with 9 CFR 417.4 during a period not to exceed 90 calendar days after the date the new process is used to produce product for distribution in commerce. During these 90 calendar days, an establishment gathers data from its monitoring and on-going verification activities at an increased frequency compared to the frequency listed in the HACCP plan and gathers additional data to demonstrate that the process is being executed effectively. During this period an establishment should be reviewing these data and making modifications to its system as necessary.

NOTE: Establishments may determine that modifications are needed to an intervention during the initial validation period either because the design did not result in the intended effect or because the establishment could not execute the intervention as designed. Such modifications are part of the initial validation process. However, establishments that make major modifications multiple times throughout the initial validation period and as a result do not generate sufficient records that support the

design and execution of the intervention used in the hazard analysis may not be able to support that the HACCP system is adequate.

Following the 90 calendar day period of initial validation, an establishment uses its findings during the initial validation period to fully implement its system and solidify its monitoring and **on-going verification** procedures and frequencies. The establishment then continues on a daily basis to perform monitoring and verification activities to ensure that the HACCP system continues to be implemented properly. Establishments are required to support both the monitoring and verification procedures selected and the frequency of those procedures as part of 9 CFR 417.5(a)(2). Data gathered during initial validation, during which critical operational parameters are monitored at an intense frequency, is one source of information that can be used to support monitoring and verification procedures and frequencies (see examples in Appendix 4).

Importantly, not all critical operational parameters that are measured during initial validation are monitored on an ongoing basis after the initial validation period is over. For example, some parameters, such as spatial configuration or ingredient formulation, may not change over time and therefore do not need to be monitored. In addition, ongoing verification may include activities that were not performed as part of initial validation because the purposes of these two processes differ.

The purpose of validation is to demonstrate that the HACCP system as designed can adequately control identified hazards to produce a safe, unadulterated product, while the purpose of ongoing verification is to support that the HACCP system is functioning as intended on an ongoing basis. Although it may be adequate to measure the critical operational parameters during initial validation to ensure that the HACCP system as designed can be executed, doing so does not negate the need for ongoing verification activities, such as testing for appropriate pathogens or other microorganisms, to support that the HACCP system is working as intended on an ongoing basis.

In addition to continuing ongoing verification following the completion of the initial validation period, it is also important to recognize the role of **reassessment** in the process. At every reassessment, establishments should reassess the hazard analysis taking into account information on any foodborne illnesses associated with the products to determine whether all relevant hazards have been considered. In addition, establishments should ask:

"Is my HACCP system adequate to control the identified food safety hazards?" Annually and whenever changes occur that affect the hazard analysis, the establishment should review records generated over the course of the previous year, or during the period the change occurred, that reflect how the HACCP system is performing as a whole, and analyze them to determine whether food safety goals are being met. This review should include records of the monitoring of critical limits and parameters of prerequisite programs to ensure that the critical operational parameters in the scientific support continue to be met and any records from ongoing verification

activities, such as microbiological testing, to ensure identified food safety hazards are being controlled.

If the establishment determines at the end of the reassessment that the HACCP system is effective and functioning as intended, the establishment can continue on with the same system and the same monitoring and verification procedures and frequencies. If the establishment determines at the end of the reassessment that either its HACCP system was not set up correctly, is not being implemented consistently, or is no longer effective, the establishment should make changes to its HACCP system (e.g., add another intervention) and then would, in most cases, be required to validate any changes to its HACCP system.

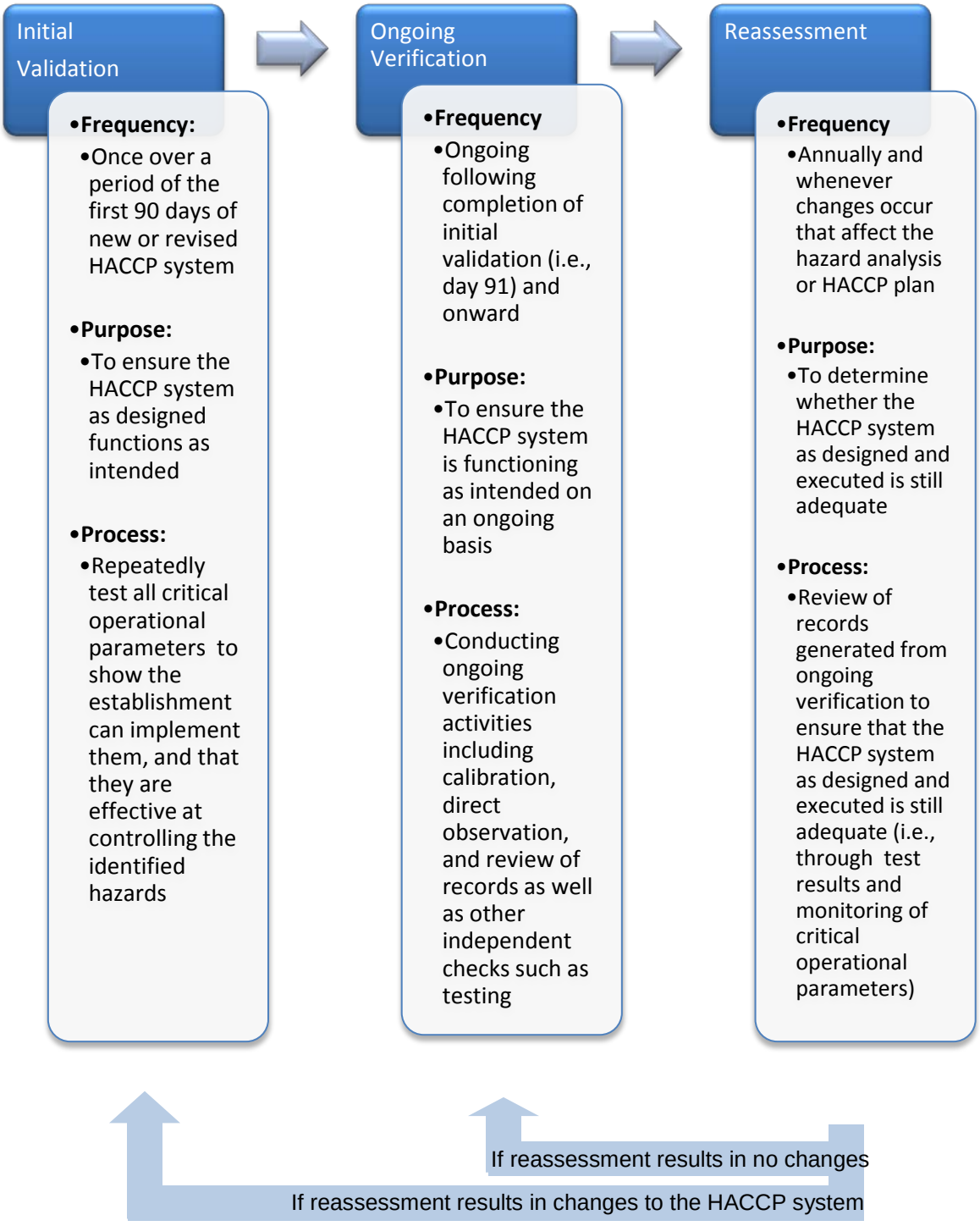
If the establishment determines at the end of the reassessment that the HACCP system is effective and functioning as intended, the establishment can consider continuing on with the same system and the same monitoring and verification procedures and frequencies.

In some cases, however, changes that result from reassessment would not require validation. For example, an establishment that reassesses its HACCP system following a change in supplier of a raw material may find that the change does not require validation because the composition of the raw material and its microbiological profile are not significantly different from the material provided by the previous supplier. In other cases, changes that result from the reassessment would not require additional scientific support but would require additional in-plant validation data. For example, an establishment may find through reassessment that the design of an intervention was adequate, but that the employees were not implementing it correctly. In that case, the establishment would only need to collect in-plant validation data demonstrating the intervention could be implemented appropriately. Finally, depending on the change, the establishment will likely only need to validate that the change is functioning as intended and not assess the entire HACCP system. For example, an establishment may change the thickness of a raw patty product and determine that it only needs to validate that the cooking instructions still achieve the desired endpoint temperature and does not need to validate the entire HACCP system.

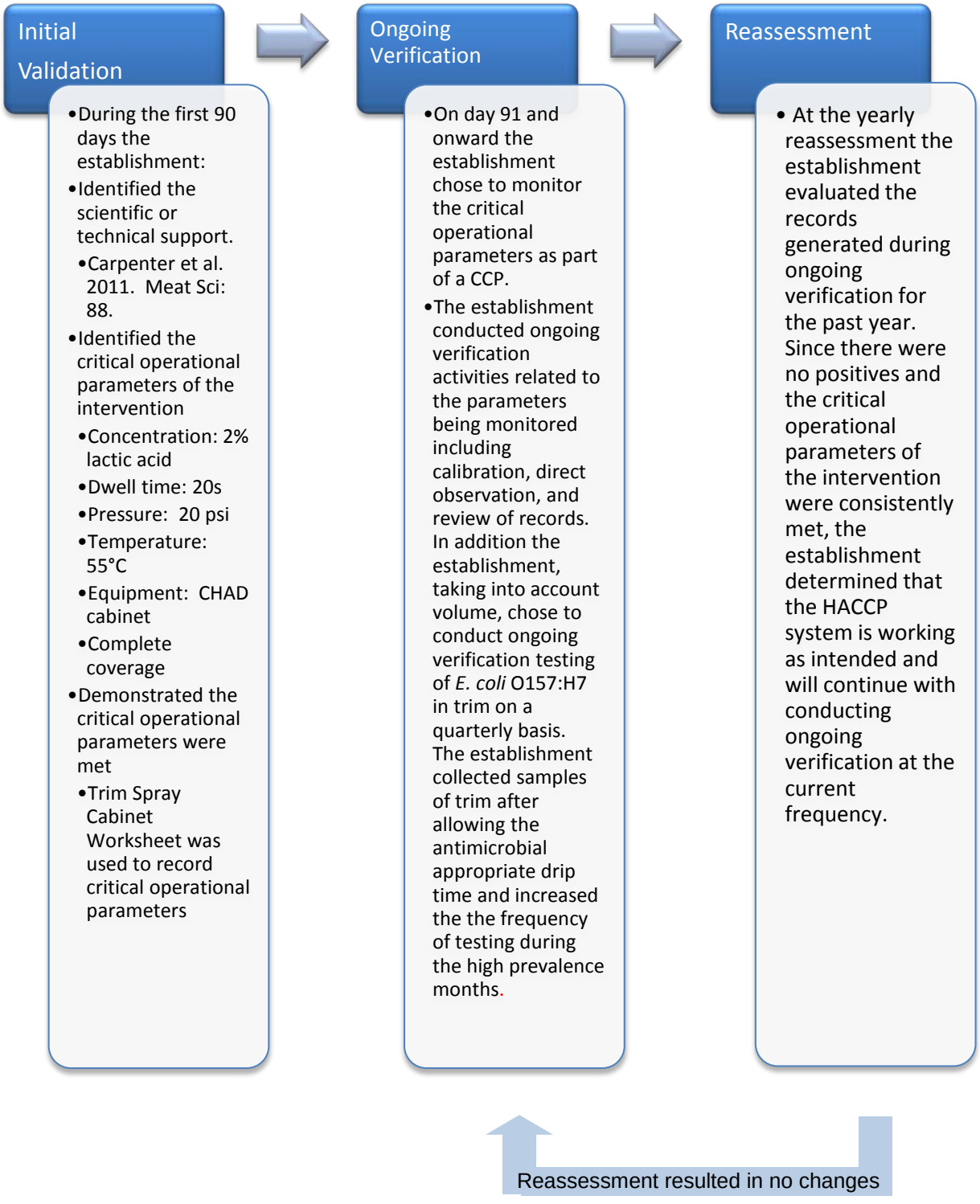
NOTE: Official establishments are to make a record of each reassessment required by 9 CFR 417.4(a)(3)(i). The regulations require establishments to document the reasons for any changes to the HACCP plan based on the reassessment or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, according to the regulation, if an official establishment determines that it does not need to make changes to its HACCP plan, it is not required to document the reasons for not changing the HACCP plan.

While the establishment is validating any changes it made to its HACCP system, the establishment continues to implement other parts of its HACCP system, such as any on-going verification activities, including testing that is done as part of its existing system. In other words, when an establishment makes changes to its existing HACCP

system and is validating those changes, this validation does not occur in a vacuum. While microbiological testing is not required specifically as part of initial validation, other HACCP principles, such as on-going verification activities, continue to apply, including verification testing that is done to support that the HACCP system addresses identified hazards on an on-going basis. The following chart illustrates some of the key differences between initial validation and ongoing verification and shows the sequence of these key steps.



An example of the dynamic process illustrated earlier for a ground beef establishment is shown below. In this example, the establishment has decided to add an antimicrobial intervention to trimmings prior to grinding. Please note that the example only shows one part of the entire HACCP system.



HACCP Initial Validation Self-Assessment

Does my HACCP system:

1. Contain supporting documents for each CCP or prerequisite program that is used to support decisions in my hazard analysis?
2. Contain supporting documents that relate sufficiently to my product/process?
3. Identify the critical operating parameters based on the supporting documents used as scientific or technical support?
4. Contain critical operating parameters that are aligned with the referenced supporting document?
5. Contain critical operating parameters that support rather than contradict the selected critical operating parameter if multiple supporting references are used?
6. Contain in-plant validation data from 90 calendar days (see pages 26-27 for expectations regarding the equivalent number of production days) documenting the critical operating parameters are implemented for at least one product within each HACCP category?
7. Contain HACCP system in-plant validation data for at least one product within each HACCP category that was reviewed and found acceptable by the HACCP team to support that the process is validated by the HACCP team or other group responsible for food safety?
8. Contain additional research data demonstrating the effectiveness of the process in instances where the critical operational parameters from the support were not followed?

For each HACCP category, identify at least one product from the category for which collect in-plant demonstration data and complete a validation worksheet for such product containing the following information. Examples can be found in Appendix 4.

Product: Name the HACCP plan type or product category.

Hazard: Name the hazard of concern. This should be the same content that is in the hazard analysis.

Process: Name the processing step or prerequisite program that addresses the hazard.

Critical Operating Parameters: Refers to the critical limits or other parameters cited in the scientific or technical support necessary for effective execution of the process step or program.

Validation:
Scientific or Technical Support - State the scientific or technical support document references and page numbers where the critical operating parameters are described.

In-plant Validation Data - State the name of the monitoring documents or other records where observations were collected including the time frame.

References

FSIS. 1996. Pathogen Reduction; Hazard Analysis Critical Control Point (HACCP) Systems: Final Rule. 9 CFR Part 304 et al., Federal Register 61(144), 38805-38989.

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

NACMCF. 1998. Hazard Analysis and critical control point principles and application guidelines. J. Food Prot. 61:762-775.

Scott, V.N., Stevenson, K.E., and Gombas, D.E. 2006. Verification procedures. Pp. 91-98. *In* Scott, V.N., and Stevenson, K.E. (ed.), HACCP - A Systematic Approach to Food Safety, 4th ed. The Food Products Association, Washington, D.C.

Web links

Food Safety Inspection Service (FSIS) –

HACCP Validation Webpage:
http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/resources-and-information/haccp-validation

Compliance Assistance:
http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance

State HACCP Contacts & Coordinators:
http://www.fsis.usda.gov/wps/portal/informational/contactus/state-haccp-contacts-and-coordinators

Ohio State University, Meat Science Extension – http://meatsci.osu.edu/home

University of Wisconsin, Center for Meat Process Validation – www.meathaccp.wisc.edu

Penn State University, Food Science – http://foodsafety.psu.edu/extension-people.html

HACCP Alliance - http://www.haccpalliance.org/sub/index.html

Appendix 1: Examples of Food Safety Problems Linked to Inadequate Validation

Below are some specific examples where FSIS has found that inadequate validation has led to adulterated product and in some cases illness outbreaks.

2012 – Veal *E. coli* O157:H7 and adulterant non-O157 STEC Positives from FSIS Testing

FSIS test results show that the percent positive for *E. coli* O157:H7 and adulterant non-O157 STEC from ground beef and raw ground beef components produced from veal appear to be higher than ground beef and raw ground beef components produced from other cattle slaughter classes.

Following up on these results, FSIS conducted a review of Food Safety Assessments (FSAs) and onsite visits to veal slaughter establishments to identify concerns unique to veal slaughter. FSIS found that veal slaughter establishments, in applying their antimicrobial interventions, failed to achieve carcass coverage because of the practice of suspending carcasses from the rail system with both hind limbs on a single hook. Because of this practice, antimicrobial or hot water interventions, such as sprays, did not reach all parts of the carcasses. Carcass coverage –ensuring that the entire carcass surface is treated -- is a critical operational parameter that is necessary for the intervention to operate effectively and as intended. **As a result of the incomplete carcass coverage, interventions were likely less effective than intended, and this ineffectiveness may have contributed to the production of products contaminated with *E. coli* O157:H7.**

In addition, during on-site visits to beef fabrication establishments, FSIS found that beef fabrication establishments, in applying their antimicrobial intervention, had also failed to achieve product coverage because establishments stacked products and folded longer pieces, particularly loins. These actions prevented antimicrobial sprays from reaching all product surfaces. Additionally, establishment personnel did not adjust the conveyor belt timing, properly design spray applications, or ensure that product was single-stacked and lying flat so that all product surfaces received the antimicrobial spray. *Validation Take-away:* Had establishments translated this critical operational parameter – product coverage – into their HACCP system (either through a pre-requisite program, CCP, or during the initial set-up of their system) the contamination of raw beef products with *E. coli* O157:H7 and other STEC may have been prevented.

2011 – Lebanon Bologna *E. coli* O157:H7 Illness Outbreak

In March 2011, there was a foodborne illness outbreak of *E. coli* O157:H7 associated with Lebanon bologna. The establishment that produced the product recalled it. An FSIS investigation into the processing of the product revealed that the establishment relied on scientific support that did not match the actual commercial process used. In the scientific support, to represent a commercial process for Lebanon bologna, raw

Lebanon bologna mix was compacted in 27 millimeter diameter impermeable sealed glass tubes that were immersed in a well-controlled water bath. However, in the actual process at the establishment, raw Lebanon bologna mix was compacted in 52 to 119 mm diameter permeable casings that were placed in a large smokehouse fitted with a single source of heat and humidity that was not well-controlled.

The difference in the diameter **and type of casing material** likely led to a lower reduction in foodborne pathogens of concern in the actual process than what was demonstrated in the support. If the diameter of the establishment's product is larger than that of the product used in the support, it is possible that the **product core will take longer** to reach the desired temperature and pH. Taking a longer time than expected to reach the desired temperature and pH may lead to a lower level of pathogen reduction. Critical operational parameters such as the product diameter and type of casing material can also affect the amount **of moisture exchange** between the product and the environment and can play a role in the effectiveness of the fermentation. For these reasons, it is important that the support used by the establishment is representative of the establishment's actual process so that the results can be repeatable.

Validation Take-away: Had the establishment ensured that its actual process matched its scientific support during the initial design of its system, the establishment could have addressed actual relative humidity and the time it took the actual product to reach the desired temperature and pH compared to that in the support, preventing product contamination and illnesses.

2007 – Chicken Pot Pie *Salmonella* Illness Outbreak and 2011 – Turkey Burger *Salmonella* Illness Outbreak

In October 2007, a number of varieties of frozen pot pies were linked to an outbreak of salmonellosis. The establishment that produced the product recalled it. The pot pies contained pre-cooked poultry products but raw vegetables and dough. Testing of two of the pies taken from case patient homes found that the filling of the pot pies tested positive for *Salmonella*. An investigation revealed that the likely cause of illnesses was that consumers were not cooking the products in the microwave to a lethality temperature. Specifically, the investigation revealed that the **instructions may have been confusing** because different parts of the package recommended different preparation times. In addition, microwave time varied by wattage; however, most case patients interviewed did not know the wattage of their microwave. Other patients reported not following the microwave directions, including not following the rest time and microwaving more than one pie at a time. Therefore, one of the primary conclusions of the investigation was that the **cooking instructions for such products should be validated** to account for variability in microwave wattage and common misconceptions among consumers regarding the nature of not-ready-to-eat foods (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5747a3.htm).

Between late December of 2010 and March of 2011, an outbreak of *Salmonella* Hadar linked to turkey burgers sickened 12 people, three of whom were hospitalized. Investigators were not able to determine consumption of turkey burgers for all case-patients. However, FSIS determined that at least three of the case-patients in three states specifically reported eating turkey burgers produced at the same establishment the week before their illness began. Samples of ground turkey burgers were collected by public health agencies from the homes of two case-patients who tested positive for the outbreak strain of *Salmonella* Hadar. Both turkey burger samples were positive for the outbreak strain. As a result of these findings, the establishment that produced the product recalled 54,960 pounds of potentially contaminated product (http://www.cdc.gov/salmonella/hadar0411/040411/index.html?s_cid=ccu041111_016).

In a post-outbreak investigation, FSIS found that the cooking instructions for the turkey burger were not sufficient to guarantee that a safe end-point temperature would be reached so that pathogens would be killed in the cooking process.

Validation Take-away: Had the establishments validated the cooking instructions on the pot pies and turkey burgers to ensure they would achieve the desired end-point temperature under actual consumer cooking conditions; these illnesses may have been prevented.

Appendix 2: Example Decision-making Document

The following is an example of a decision-making document that could be used by a beef jerky processing establishment to justify using modified levels of critical operational parameters. In this case, the establishment has identified scientific support for its process; however, it has modified the critical operational parameters (length of cooking time and dry-bulb temperature during drying) in the actual process from those used in the scientific support. A rationale is provided for why the modified critical operational parameters should also be considered validated.

XYZ Meat Company - October 5, 2012
Beef Jerky Decision-Making Documentation

Process Step: Cooking and Drying

Process Step Overview: This process step includes the cooking and drying of beef jerky using a modified Type 1A process from Buege et al (2006).

Scientific Support:

- Critical limit summary for shelf stability of beef jerky and related products:http://www.meathaccp.wisc.edu/validation/assets/CLSummary_WMJerkyJune2013.pdf.
- Buege, D.R., Searls, G., and Ingham, S.C. 2006. Lethality of commercial whole-muscle beef jerky manufacturing processes against *Salmonella* Serovars and *Escherichia coli* O157:H7. *J. Food Prot*: 69(9): 2091-2099.

Cooking and Drying Critical Operational Parameters:

Stage 1 –
170°F for 30 minutes.

Stage 2 –
Dry-bulb at 170°F and wet-bulb at 125°F for at least **90*** minutes

Stage 3 - Dry at **175**°F* dry-bulb to doneness

***Rationale for Modified Critical Operational Parameters (those with an *):** The length of Stage 2 and the dry bulb temperature during Stage 3 were increased from what was studied in Buege et al. In Buege et al. the length of Stage 2 with a wet bulb of 125°F was 60 minutes, while the dry bulb temperature during Stage 3 was 170°F. As stated in the critical limit summary that goes along with the article: Type 1-A processes with a higher wet-bulb temperature or longer time in Stage 2, or a higher dry-bulb temperature in Stage 3, can also be considered validated as long as other parts of the process are not changed. So, these changes can also be considered validated.

Appendix 3: Guidance to Identify Critical Operational Parameters from Scientific or Technical Support

If a journal article from the scientific literature is used as the scientific support, it is important to understand how to read it and to identify the critical operational parameters used in the study. Researchers may measure a number of parameters during the scientific study; however, not all of these parameters are critical to the efficacy of the intervention studied. The establishment should document and explain any differences in its production process relative to any of the studies it used as scientific support. Critical operational parameters are those parameters of an intervention that must be met in order for the intervention to operate effectively and as intended. Typically critical parameters, identified in scientific documents gathered as part of Element 1 of validation, may include but are not limited to:

- Time
- Temperature
- Concentration
- Humidity
- Dwell Time
- Water Activity
- pH
- Contact Time
- Product Coverage
- Spatial Configuration
- Pressure
- Equipment Settings or Calibration

The following discussion provides an overview of the sections of a journal article along with questions one can ask while reading each section to help identify the critical operating parameters in the scientific support.

Organization of Journal Articles

In most scientific journals, scientific papers follow a standard format. Papers are divided into several sections, and each section serves a specific purpose. Common sections include the:

- Abstract
- Introduction
- Materials & Methods
- Results
- Discussion
- Conclusion

Abstract

The paper begins with a short summary or abstract. Generally, the abstract gives a brief background to the topic, describes concisely the major findings of the paper, and relates these findings to the field of study.

When reading the abstract, first consider and review what you know about the topic. Discuss the study within the HACCP Team and gain an understanding of how you can apply the study in your HACCP decision making.

Introduction

This section presents the background necessary for the reader to understand why the findings of the paper are an advance on the knowledge in the field of study. Typically, the introduction:

- First, describes the accepted state of knowledge in a specialized field.
- Then, focuses more specifically on a particular aspect, usually describing a finding or a set of findings that led to the work described in the paper (i.e. objective or rationale).

Materials & Methods

In some journals, this section is the last one but not in most food science-related journals. Its purpose is to describe the materials used in the experiments and the methods by which the experiments were carried out.

Questions to ask when reading the Materials & Methods

- What food products did the researchers study?
- How similar are the products to the ones you are processing?
- If a product's characteristics were provided (i.e., % salt, fat, moisture, etc.), how similar are they to your product's characteristics?
- What hazards did the researchers study? Are they the same hazards you have identified in your hazard analysis? Or did they study surrogates or indicator organisms only?
- Can you identify which operational parameters were measured? For example:
  - pH of the product;
  - Temperature of the product or carcass;
  - Temperature of the laboratory and/or processing facility;
  - Pressure or temperature at which that wash or antimicrobial was applied;
  - Length of time intervention was applied for.
- Where in the process or on the product were the measurements taken?
  - Is your establishment taking measurements in these locations?
- What parameters, if any, were held constant across experimental conditions?
- What parameters, if any, were varied or changed in the research?

Although some parameters may or may not have been experimentally manipulated, they are all important and their impact on the effectiveness on the intervention should be considered. Note that some measured parameters in a study are not related to the efficacy of interventions and are not, therefore, critical operational parameters.

Results

- This section describes the experiments and documents the experiment outcomes.
- Generally, the logic of this section follows directly from that of the introduction.
- Usually contains the bulk of the data in the form of tables and graphs.

Discussion

In some journals the Results & Discussion section may be combined. When the discussion section is a stand-alone section it usually serves several purposes:

- Analyzing and interpreting the data in the results section.
- Explaining how the findings relate to other findings in the field of study.
- Explaining how the findings contribute to knowledge or correct errors of previous work.
- Sometimes provides guidance on appropriate applications of the research.

Questions to ask when reading the Discussion:

- Did the authors provide some guidelines as to the limitations of the research or any cautions against applying the findings outside of the scope of the study?
  - For example, were there some parameters that were controlled in the laboratory that differ in-plant that you should be aware of?
  - If so, have you considered if those apply to your process?

Conclusion

- This section summarizes key findings.
- Often includes implications of research for broader field.
- May highlight limitations of the study.

Figures & Tables

- Contain the data described in the paper.
- Give details of a particular experiment or experiments conducted.
- The “meat” of the article.

Appendix 4: Validation Worksheet Examples

The following pages include validation worksheet examples that can be used to help an establishment understand the types of scientific support and in-plant documentation that are needed to comply with the validation requirements. Please note that these are only examples. Each establishment will have to identify scientific support that closely matches its process and identify and implement the critical operational parameters in the support. Depending on the support chosen, different critical operational parameters may be identified. In addition, mention of trademarks or commercial names does not constitute endorsement by USDA.

Product	Hazard	Process	Critical Operational Parameters[2]	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Poultry Carcass	Biological - *Salmonella*	Final Chiller	Dilution of 15% peracetic acid/10% hydrogen peroxide mixture (PAHP) to a final concentration of 85 ppm peracetic acid in chiller; exposure in chiller for 20 minutes; pH = 4.5; complete carcass coverage	Bauermeister, L.J., J.W.J. Bowers, J.C. Townsend, and S.R. McKee. 2008. Validating the Efficacy of Peracetic Acid Mixture as an Antimicrobial in Poultry Chillers. *J. Food Prot.* 71(6): 1119-1122. Food and Drug Administration Environmental Decision Memo for Food Contact Notification No. 000323: April 10, 2003 FSIS Directive 7120.1 Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products	In plant monitoring records for 90 day period recorded on Final Chiller Monitoring Check Sheet (including PAHP concentration, estimation of exposure time, pH, and carcass coverage); Trial report showing consistent operational parameters and microbial analysis, if possible, for 90 days.

[2] Refers to the critical limit or other parameter cited in the scientific support necessary for effective execution of the intervention.

For Illustration Purposes Only

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Poultry Carcass	Biological - *Salmonella*	Spraying of carcasses with peroxy-acetic acid prior to chiller	25-230 ppm of peracetic acid (PAA). Pressure or flow rate, pH, contact time, and complete carcass coverage specified in challenge study.	Challenge study from "XYZ" laboratory demonstrating a 1 log reduction *Salmonella* on poultry carcasses after spraying with PAA using critical operational parameters specified. Food and Drug Administration Environmental Decision Memo for Food Contact Notification No. 000323: April 10, 2003. FSIS No Objection Letter for Use of PAA spray, June 12, 2007 on file with company "ABC". FSIS Directive 7120.1	In plant monitoring records for 90 day period confirm that antimicrobial solution was applied consistent with the critical operational parameters (pressure, pH, contact time, and carcass coverage)in the study.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Poultry parts intended for grinding and ground poultry (including mechanically separated poultry)	Biological - *Salmonella*	Acidified sodium chlorite applied to poultry parts as a dip prior to grinding and applied to ground poultry.	1200 ppm acidified sodium chlorite in combination with any GRAS acid at a level sufficient to achieve a pH of 2.5 in accordance with 21 CFR 173.325 and scientific support (*Note: The pH depends on the application, see 21 CFR 173.325)* Contact time of dip and complete coverage.	Chemical manufacturer's pamphlet demonstrating a 1-$\log_{10}$ reduction *Salmonella* on poultry parts following acidified sodium chlorite dip using critical operational parameters specified. 21 CFR 173.325 for poultry parts and acceptability determination for ground poultry. FSIS Directive 7120.1	In plant monitoring records for 90 day period that indicate the antimicrobial was applied to the poultry parts prior to grinding and the mechanically separated poultry prior to mixing according to the appropriate concentration and pH and that indicate contact time and complete coverage were achieved according to scientific support.

For Illustration Purposes Only

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Ground Poultry Patties	Biological - *Salmonella*	Validated cooking instructions for consumers	Time and temperature combinations specific to various cooking methods (skillet on electric stove, skillet on gas stove, gas grill, charcoal grill), diameter and thickness of patties produced, formulation of patties produced (80% lean patties vs. 95% lean patties), and state of patties during cooking (frozen and thawed).	Food Safety Inspection Service. 1999. *Appendix A of the Compliance Guidelines for meeting Lethality Performance Standards for Certain Meat and Poultry Products*. Available at: http://www.fsis.usda.gov/wps/wcm/connect/212e40b3-b59d-43aa-882e-e5431ea7035f/95033F-a.pdf?MOD=AJPERES. Cooking trials on-file supporting the time-temperature combination selected from *Appendix A* can be achieved using various cooking instructions provided on the label. Cooking trials should be for the thickest and largest diameter patties produced as these will need the greatest time to achieve the desired endpoint temperature.	In plant monitoring records for 90 day period that demonstrate establishment produces products that are of the thickness, diameter, fat level, and state for which the instructions are validated.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Hog Carcass	Biological - *Salmonella*	Hot Lactic Acid Spray Cabinet	A least a 2% Lactic acid solution at 131°F (55°C) for more than 60 seconds and 13-23 psi. Complete carcass coverage.	Van Netten. P., D.A.A. Mossel, and J. Huis In't Veld. 1995 Lactic acid decontamination of fresh pork carcasses: a pilot plant study. *Int. J. Food Micro.* 5: 1-9. Dormedy, E.S., M.M. Brashears, C.N. Cutter, and D.E. Burson. 2000 Validation of acid washes as critical control points in hazard analysis and critical control point systems. *J. Food Prot.* 63:1676-1680. FSIS Directive 7120.1	In plant monitoring records for 90 day period recorded on Spray Cabinet Monitoring Check Sheet (including parameters for water temperature, and water pressure), records of lactic acid concentration and Trial Reports run under specified critical parameters demonstrating complete coverage of carcass with spray and temperature of the spray at the carcass.
Hog Carcass	Biological - *Salmonella*	Scalding	Scalding in water at 145°F (62°C) for 5 minutes. Complete carcass coverage.	Gill, C.O. and J. Bryant. 1993. The presence of *Escherichia coli, Salmonella,* and *Campylobacter* in pig carcass dehairing equipment. *Food Microbiol.* 10: 337-344. Bolton, D.J., R.A. Pearce, J.J. Sheridan, D.A. McDowell, and I.S. Blair. 2003. Decontamination of pork carcasses during scalding and the prevention of *Salmonella* cross-contamination. *J Appl Microbiol*. 94: 1036-1042.	In plant monitoring records for 90 day period recorded on Scalding Tank Monitoring Check Sheet (including reading for temperature of water and transit time).

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Beef Carcass	Biological - *E. coli* O157:H7, non-O157 STEC	Hot Carcass Wash or Carcass Thermal Treatment	Hot Carcass Wash: Water Temp over 180°F, Pressure over 13 psi. Complete carcass coverage. Contact time: 10 or more seconds. Carcass Thermal Treatment: Ambient steam temp sufficient to achieve 160°F at the surface in five key anatomical locations.	K.R. Davey, M.G. Smith. 1989 A laboratory evaluation of a novel hot water cabinet for the decontamination of sides of beef. *Int J Food Sci Tech.* 24: 305-316. Dorsa, W.J., C.N. Cutter, G.R. Sirgusa, M. Koohmaraie. 1996. Microbial Decontamination of Beef and Sheep carcasses by Steam, Hot water Spray Washes, and a Steam-vacuum Sanitizer. *J. Food Prot.* 59: 127-135. AMI Lethality model, demonstrating lethality at 160°F at carcass surface. Nutsch, A.L., R.K. Phebus, M.J. Riemann, J.S. Kotrola, R.C. Wilson, J.E. Boyer, and T.L. Brown. 1998. Steam pasteurization of commercially slaughtered beef carcasses: evaluation of bacterial populations at five anatomical locations. *J. Food Prot.* 61:571-577. Nutsch, A.L., R.K. Phebus, M.J. Riemann, D.E. Schafer, J.E. Boyer, R.C. Wilson, J.D. Leising, C.L. Kastner. 1997. Evaluation of a Steam Pasteurization Process in a Commercial Beef Facility. *J. Food Prot.* 60:485-492.	In plant monitoring records for 90 day period documenting critical parameters and trial Reports run under specified critical parameters demonstrating complete coverage of carcass with spray and temperature of the spray at the carcass. In plant monitoring records for 90 day period of plant temperature mapping.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Beef carcass	Biological – *E. coli* O157:H7, *Salmonella* Typhimurium	Lactic Acid Spray	2% lactic acid applied within 12 inches of carcass surface and entire carcass covered using a stainless steel spray tank fitted with a pressure gauge and air compressor. Each side of beef should be sprayed for at least 1 minute and sprayed from top to bottom and sufficient lactic acid is applied such that some of it drips off. Note: The entire carcass is sprayed with lactic acid following washing each side of beef from top to bottom for at least 2 minutes with hot water and allowing a 5 minute drip time after the hot water wash.	Antimicrobial Spray Treatments for Red Meat Carcasses Processed in Very Small Meat Establishments. Pennsylvania State University. 2005. http://www.meathaccp.wisc.edu/validation/assets/acid_spray_intervention_booklet_from_Penn_State_2005.pdf. FSIS Directive 7120.1	In plant monitoring records for 90 day period recorded on Hot Water and Drip Time Monitoring Check Sheet (including parameters for the time the carcass is sprayed with hot water, carcass coverage, method application (from top to bottom and spray nozzle within 12 inches of carcass), and drip time. Records of lactic acid concentration. Trial Reports run under specified lactic acid critical parameters demonstrating complete carcass coverage, sufficient amount (lactic acid drips off carcass), contact time, method of application (spray nozzle within 12 inches of carcass and from top to bottom).

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Beef carcass	Biological -*E. coli* O157:H7	Lactic Acid Spray	Lactic Acid >2%; Pressure 40 psi (CHAD spray cabinet), Dwell time: minimum of 10 seconds Lactic Acid Temperature: 104°F at point of delivery. Complete carcass coverage. Design of the spray cabinet includes an oscillating (90 rpm) nozzle-header arrangement composed of four spray nozzles.	Gastillo, A, L.M. Lucia, K.J. Goodson, J.W. Savell, G.R. Acuff. 1998. Comparison of Water Washing, Trimming, and combined Hot Water and Lactic Acid Treatment for Reducing Bacteria of Fecal Origin on Beef Carcasses. *J. Food Prot.* 61: 823-828. Hardin, M.D., Acuff, G.R., Lucia, L.M., Oman, J.S., Savell, J.W. 1995. Comparison of Methods for Decontamination from Beef Carcass Surfaces. *J. Food Prot*. 58: 368-374. Delmore, R.J., J.N. Sofos, G.R. Schmidt, K.E. Belk, W.R. Lloyd, G.C. Smith. 2000. Interventions to Reduce Microbiological Contamination of Beef Variety Meats. *J. Food Prot.* 63: 44-50. FSIS Directive 7120.1	In plant monitoring records for 90 day period recorded on Pre-evisceration cabinet worksheet that monitored lactic acid percent, dwell time of the carcass in the cabinet, pressure, carcass coverage and lactic acid temperature at point of delivery.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Raw Ground Beef or Beef Trim for use in Raw Ground Beef	Biological -*E. coli* O157:H7	Prerequisite Program: Supplier Programs	Supplier program to demonstrate a pathogen intervention strategy, including a testing protocol and notification of test results.	Documentation from the supplier assuring that the supplier employs validated interventions addressing *E. coli* O157:H7, certificates of analysis or web based information that conveys same information, records of ongoing communication with supplier and verification data to support the achievement of the first two conditions. Beef Industry Food Safety Council. 2009. Best Practices for Raw Ground Beef Products.	In plant records for 90 day period that show plant employees obtain and review purchase specifications for adequacy at receiving for each lot and any additional verification testing results or web based information on incoming product lots.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Raw Ground Beef or Beef Trim for use in Raw Ground Beef	Biological – *E. coli* O157:H7	Trimmings prior to Grinding	Acetic acid (2%); OR Lactic acid (2%) sprayed on trim for 20s at 20psi and 55°C using a custom-made stainless steel washing apparatus (CHAD spray cabinet). Complete coverage of trimmings.	Carpenter, C.E., Smith, J.V., and Broadbent, J.R. 2011. Efficacy of washing meat surfaces with 2% levulinic, acetic, or lactic acid for pathogen decontamination and residual growth inhibition. *Meat Sci.* 88:256-260. FSIS Directive 7120.1	In plant monitoring records for 90 day period recorded on Trim Spray Cabinet Worksheet demonstrating that the antimicrobial is applied per concentration, pressure, dwell time, and temperature in the article during 90 day period. Records demonstrating that complete coverage of trimmings is consistently achieved.

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Beef Jerky	Biological – *E. coli* O157:H7, *Salmonella*, *Listeria monocytogenes*	Cooking and Drying	(For the Type 1-A Process) Stage 1* – 170°F (oven must reach 145°F within 10 minutes and 170°F within 25 minutes. Stage 2 – Choose either: Dry-bulb at 170°F and wet-bulb at 125F for at least 60 minutes; OR Dry-bulb at 170°F and wet-bulb at 130°F for at least 60 minutes; OR Dry-bulb at 170°F and wet-bulb at 135°F for at least 30 minutes; OR Dry-bulb at 170°F and wet-bulb at 140°F for at least 10 minutes. Stage 3- Dry at 170°F dry-bulb to doneness Relative humidity during wet-bulb temperature spike at Stage 2, water activity of the product at the end of wet-bulb temperature spike, and total drying time.	Critical limit summary for shelf stability of beef jerky and related products: http://www.meathaccp.wisc.edu/validation/assets/CLSummary_WMJerkyJune2013.pdf. Buege, D.R., Searls, G., and Ingham, S.C. 2006. Lethality of commercial whole-muscle beef jerky manufacturing processes against *Salmonella* Serovars and *Escherichia coli* O157:H7. *J. Food Prot*: 69(9): 2091-2099.	In plant monitoring records for 90 day period demonstrating Time and dry-bulb and wet bulb temperature data. Use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor to measure relative humidity during wet-bulb temperature spike and compare test results with relative humidity results in Table 2 of article. Test beef jerky product for water activity at the end of wet-bulb temperature spike and compare test results with water activity results in Table 2 of article.

*This example is for the Type 1-A process. Note that Type 1-A processes with a higher dry-bulb temperature in Stage 1, a higher wet-bulb temperature or longer time in Stage 2, or a higher dry-bulb temperature in Stage 3, as long as the oven reaches the minimum temperature as outlined in Stage 1.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Post-lethality exposed ready-to-eat meats	Biological - *Listeria monocytogenes*	Prerequisite program – SSOPs	*Listeria* control program for food contact surfaces. Sanitary design of equipment and sanitary zone concept. Frequency for collecting samples and number of samples that should be collected per line.	Joint Industry Task Force on Control of Microbial Pathogens in Ready-to-Eat Meat and Poultry Products. 1999. Interim Guidelines: Microbial Control During Production of Ready-to-Eat Meat and Poultry Products, Controlling the Incident of Microbial Pathogens. Sanitary Design Assessment Fact Sheet http://www.sanitarydesign.org/pdf/Sanitary%20Design%20Fact%20Sheet.pdf. Tompkin, R.B. 2004. Environmental Sampling – A tool to verify the effectiveness of preventative hygiene measures. *Mitt Lebens Hyg*. 95:45-51. Tompkin, R.B. 2002. Control of *Listeria monocytogenes* in the food processing environment. *J Food Prot*. 65: 709-725. FSIS. 2012. Compliance Guidelines to *Control Listeria monocytogenes* in Post-lethality Exposed Ready-to-eat Meat and Poultry Products. http://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling_LM_RTE_guideline_0912.pdf?MOD=AJPERES.	In plant records for 90 day period mapping food contact surface swab results for *Listeria spp.* collected on different processing dates and at different times and locations a 90-day period to potentially find hard-to-control areas in the plant and to support ongoing verification testing frequency after the initial validation period*. Assessment of sanitary design of equipment in the post-lethality environment using the AMI Sanitary Equipment Design worksheet and changes to *Listeria* control program based on assessment. Identification of all possible food contact surfaces.

*__NOTE:__ Establishments may also collect environmental swab samples on different processing dates and at different times during the 90-day initial validation period to potentially find hard-to-control areas and niches within the establishment.

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Post-lethality exposed ready-to-eat meats	Biological - *Listeria monocytogenes*	Storage - Time and Temperature GMP's	Storage temperature ≤ 50°F. Product remains in storage ≤ 24 hours.	Tompkin Paper. Table 2. http://www.meathaccp.wisc.edu/Model_Haccp_Plans/assets/raw_ground/TompkinPaper.pdf.	In plant records for 90 day period demonstrating ambient air temperature does not exceed 50°F and that product is not held during storage at that temperature for more than 24 hours.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Raw beef products (e.g., beef carcasses, beef manufacturing trimmings)	Biological -*STEC*	Sanitary dressing procedures prerequisite program (same question as above)	Employee procedures associated with each station as defined in the written sanitary dressing program (e.g., specific steps employees take at each station to prevent contamination during hide removal, evisceration, etc.)	BIFSCO. 2009. Best Practices for Slaughter. http://www.bifsco.org/CMDocs/BIFSCO/Best%20Practices/BestPracslaught%20Sept%2009.pdf FSIS. 2002. Guidance for Minimizing the Risk of *Escherichia coli* O157:H7 and *Salmonella* in Beef Slaughter Operations. FSIS. 2012. Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing *Escherichia coli* (STEC) Organisms or Virulence Markers. http://www.fsis.usda.gov/wps/wcm/connect/e0f06d97-9026-4e1e-a0c2-1ac60b836fa6/Compliance_Guide_Est_Sampling_STEC_0512.pdf?MOD=AJPERES	In plant records for 90 day period demonstrating employees consistently perform the sanitary dressing procedures as written. Review of additional records generated during the 90 day period as part of the HACCP system that support that the procedures are effective (e.g., carcass audits, generic *E. coli* test results, and any other microbial test results).

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Post-lethality exposed ready-to-eat smoked turkey deli meat with skin on*	Biological -*Listeria monocytogenes*	Hot water Pasteurization	Hot water temperature at 195°F; product submersed for at least 6 minutes.	Muriana, P.M., Quimby, W., Davidson, C.A., Grooms, J. 2002. Postpackage pasteurization of ready-to-eat deli meats by submersion heating for reduction of *Listeria monocytogenes*. *J. Food Prot*. 65(6): 963-969.	In plant monitoring records for 90 day period demonstrating time and temperature can be consistently achieved. In plant monitoring records for 90 day period in which temperature of water is mapped and measured at increased frequencies to support monitoring procedures and frequencies.

*__NOTE:__ Reduction of *Lm* was found to be less for smoked turkey deli meat with skin-on using these time/temperature parameters than smoked turkey deli meat without skin, although the log reduction was > 1 log. For products subject to 9 CFR 430, the post-lethality treatment should be designed to achieve at least a 1-log lethality of *Lm* before the product leaves the establishment.

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Semi-dry sausage	Biological - *Staphylococcus aureus*	Fermentation	Ferment product to a pH<5.3 within fewer than 1000 degree-hours*. Shrink to an MPR of 3.1:1 or less (which equates to <11% product shrink) and achieve a pH of 5.0 or less to be considered a shelf stable dry or semi-dry fermented sausage.	American Meat Institute. 1995. Interim Good Manufacturing Practices for Fermented Dry and Semi-Dry Products. Degree Hour Calculation - Degree-hours to reach a pH of 5.3 or less for a process when the highest chamber temperature is between 90 and 100°F = 1000 degree-hours or less. FSIS Food Standards and Labeling Policy Book and Ingham et al. 2005. Fate of *Staphylococcus aureus* on Vacuum-Packaged Ready-to-Eat Meat Products Stored at 21°C. Journal of Food Protection. 68:1911-1915.	In plant monitoring records for 90 day period demonstrating Degree Hour Calculation per GMP conducted and demonstrating Degree-hours are < 1000. For example on 10/24/99: Establishment process = (95°F-60°F) multiplied by 12 = 420 degree hours to a pH of 4.9, well within the guidelines for control of *Staphylococcus aureus.* In plant monitoring records for 90 day period indicating pH is ≤ 5.3 for the Degree Hours Calculation and ≤5.0 and a MPR of 3.1:1 or less for shelf stability.

*__NOTE:__ The limit for degree-hours will depend on the highest chamber temperature.

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Roast Beef (uncured)	Biological -*C. perfringens* and *C. botulinum*	Stabilization	Chilling should begin within 90 minutes after the cooking cycle is completed. All product should be chilled from 120°F to 55°F in no more than 6 hours. Chilling should then continue until the product reaches 40°F. Chilling between 120°F to 80°F should take no more than 1 ½ hours. pH = 6.2, salt concentration = 3%	*Appendix B: Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization)* available at: http://www.fsis.usda.gov/wps/wcm/connect/a3165415-09ef-4b7f-8123-93bea41a7688/95-033F_Appendix_B.pdf?MOD=AJPERES Results (including screen shots of the predicted growth) from the ComBase Perfringens Predictor model demonstrating no more than 1 log growth *C. perfringens* is achieved using the establishment's custom stabilization schedule and intrinsic factors. *Perfringens* Predictor User Manual (http://modelling.combase.cc/HelpPerPredictor/Perfringens_Predictor_Manual.pdf) supporting that the model has been validated for cured and uncured meat and poultry products.	In plant monitoring records for 90 day period showing each batch of product cooled from 120°F to 55°F in no more than 6 hours, and that all batches reached 40°F. In plant monitoring records for 90 day period demonstrating product chilling for each batch produced was between 120°F to 80°F in less than 1 ½ hours. Product testing results for pH at 6.2 and salt concentration at 3 %.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Semi-dry Sausage (Lebanon Bologna)	Biological - *Salmonella*, *E. coli* O157:H7	Fermentation and intermediate heating step	Diameter:115 mm ± 23 mm Starter culture: Pediococcus, Lactobacillus, and Micrococcus spp. Casing: Cellulose Smokehouse Schedule: Stage 1: Come-up to 80°F – 5 hours Hold at 80°F – 8 hours Relative humidity – 88 ± 2% Stage 2: Come-up to 100°F – 4 hours Hold at 100°F – 25 hours Relative humidity – 80 ± 2% Stage 3: Come-up to 110°F – 2 hours Hold at 110°F – 24 hours Relative humidity – 80 ± 2% During the last 2 hours at 110°F hickory smoke applied Product Composition: pH = 4.39 a_w = 0.94 % salt = 4.77 % fat = 10.43	Getty, K.J.K, Phebus, R.K, Marsden, J.L., Schwenke, J.R., and Kastner, C.L. 1999. Control of *Escherichia coli* O157:H7 in Large (115 mm) and Intermediate (90 mm) Diameter Lebanon-style Bologna. *J of Food Sci*. 64(6): 1100-1107.	In plant monitoring records for 90 day period recording time and dry-bulb and wet bulb temperature data. Use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor to measure relative humidity during wet-bulb temperature spike and compare test results with relative humidity results in article. Cold-spot determination in smokehouse to support monitoring procedures and frequencies. Records assessing variability in sausage diameter. Records supporting product composition data. Decision-making document showing that starter culture and casing used in actual process are the same as those used in support documents.

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Fully Cooked Not Shelf Stable Poultry Fillets	Biological - *Salmonella*	Impingement Oven Cooking	$D_{62°C}/_{145°F}$ -values for chicken with between 2 and 6.3% fat ($D_{62°C}/_{145°F}$ = 1.14 min). Cook to internal temp of ≥145°F, hold for ≥ 8 minutes. Product formulation: salt and phosphate concentration (%) and in-going sodium nitrite level (ppm); pH of the product. Thickness of the fillets; arrangement of fillets on the belt; conveyor belt speed; and air flow rate. Wet-bulb and dry-bulb temperature.	American Meat Institute Process Lethality Spreadsheet. Available at http://www.amif.org/process-lethality/. Juneja, V.J., B.S. Eblen, and H.M. Marks. 2001. Modeling non-linear survival curves to calculate thermal inactivation of Salmonella in poultry of different fat levels, *Int J Food Microbiol.* 70: 37-51. Documentation supporting that the D- and z-values of the product are comparable to the values used in the AMI spreadsheet. Factors that can impact D- and z-values include the salt and phosphate concentration (%), the in-going sodium nitrite level (ppm), the pH of the product, and the fat level.	In plant monitoring records generated during 90 day period demonstrating that process can achieve time and temperature. Records documenting that variability in thickness of the fillets; arrangement of fillets on the conveyor belt; conveyor belt speed; and the air flow rate used in the process will consistently meet time and temperature parameters. Records supporting that the % fat of product is consistently between 2 and 6.3%. Records generated during 90 days demonstrating the dry-bulb and wet-bulb temperatures meet those in the scientific support.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific or Technical Support	In-Plant Validation Data
Fully Cooked Roast Beef	Biological - *Salmonella*, *E. coli* O157:H7	Product Cooking	Internal temperature of 130°F for a minimum of 112 minutes. Relative humidity >90% for at least 25% of the cooking time and in no case less than one hour.	Food Safety Inspection Service. 1999. *Appendix A of the Compliance Guidelines for meeting Lethality Performance Standards for Certain Meat and Poultry Products*. Available at: http://www.fsis.usda.gov/wps/wcm/connect/212e40b3-b59d-43aa-882e-e5431ea7035f/95033F-a.pdf?MOD=AJPERES. Doyle, M.P., and J.L. Schoeni. 1984. Survival and growth characteristics of *Escherichia coli* associated with hemorrhagic colitis. *Appl. Environ. Microbiol*. 48:855-856.	In plant monitoring records for 90 day period indicating a minimum internal temperature of 130° F for 112 minutes is achieved. In plant monitoring records for 90 day period demonstrating use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor to measure relative humidity during cooking. Records should indicate that humidity can be maintained >90% for at least 25% of the cooking time and in no case less than one hour by use of steam injection for 90 days.

Appendix 5: Guidance for Establishments that No Longer Have the In-Plant Validation Data

FSIS realizes that some establishments may not have kept their initial in-plant validation data from when HACCP was originally implemented. These documents for example would generally include 90 days of production records and any additional data gathered to demonstrate the establishment is able to effectively execute the critical operating parameters of their system as described below. Those establishments that have not kept the records will be allowed the time to assemble their in-plant validation data.

For large establishments, FSIS will wait until January 4, 2016 before including verification that establishments have complied with the second element of validation (in-plant validation data) as part of its inspection activities. Thus, large establishments will have six months to gather all necessary in-plant validation documents.

Small and very small establishments will have until April 4, 2016 gather all necessary in-plant validation data before FSIS will verify and enforce the second element of validation (in-plant validation data).

Such documents may include HACCP records that are already generated as part of the monitoring of critical limits or parameters of prerequisite programs. Examples of documents that can be used by existing establishments that no longer have in-plant validation data include:

- HACCP records collected during 90 days when the current HACCP system is in operation.
- Decision-making documents related to CCPs and critical operational parameters data gathering methods.
- Records associated with initial equipment set up or calibration that contain data on additional critical operational parameters that did not become CCPs to support that the parameters were met during the initial set-up.
- Any establishment sampling results for the product and process of interest.

Establishments should review such in-plant validation data already being collected to ensure that they continue to support that the critical operational parameters identified in the scientific documentation are being met. If these documents do not address all of the critical operational parameters identified in the scientific or technical support, then additional data may need to be generated to demonstrate that those parameters can be properly implemented. Establishments may also wish to use the HACCP Initial Validation Self-assessment provided on Page 34 as a check to ensure that the HACCP system was designed correctly the first time.

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