

**Compliance Guideline
HACCP Systems Validation
August 2011**

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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 FSIS Web page:

www.fsis.usda.gov/Significant_Guidance/index.asp

This Compliance Guideline articulates how industry can meet FSIS expectations regarding HACCP systems validation. 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. Guidelines will be continually updated to reflect the most current information available to FSIS and stakeholders.

Request for comments:

FSIS requests that all interested persons submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days. The document will be updated in response to comments.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments.

Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Room 2-2127, George Washington Carver Center, 5601 Sunnyside Avenue, Mailstop 5474, Beltsville, MD 20705-5474.

All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2009-0019. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information to <http://www.regulations.gov>.

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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 support into their processes and determined whether 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.

While most establishments have assembled the scientific or technical documentation needed to support their HACCP systems, which is the first element of initial validation, many establishments have not:

HACCP System Design

- Identified documentation that properly relates to the establishments' current processes; or
- Identified the critical operating parameters in the supporting documents necessary for the intervention to function as intended; or

HACCP System Execution

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

Initial validation of any HACCP system must include scientific or technical documentation relating to the current process supporting the design of the HACCP system along with some practical data or information 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).

The purpose of this guidance document is to aid small and very small plants in meeting the initial validation requirements in 9 CFR 417.4. Plants that do not incorporate these principles into their HACCP systems are likely to face questions from FSIS as to whether their HACCP systems have been adequately validated.

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 history of validation in the context of the HACCP regulation
- The difference between initial validation and ongoing verification
- The 2 elements of initial validation
- The 5 major types of scientific support documents
- How to identify critical operational parameters in the scientific support documents
- The types of products and processes that need to be validated

- The type of records that constitute validation documents

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

On July 25, 1996, the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) 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 meat and poultry plants under Federal inspection to take responsibility for, among other things, reducing the contamination of meat and poultry products with disease-causing (pathogenic) bacteria by implementing a system of preventative controls designed to improve the safety of their products, known as HACCP. 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. A plant must have an effective HACCP system to comply with regulatory requirements and prevent adulteration of product.

The HACCP requirements that plants 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

The recommendations in the verification principle form the basis for the requirements in 9 CFR Part 417.4. This section requires that every establishment validate the HACCP plan’s adequacy in controlling the food safety hazards identified during 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.

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

What is the definition of a HACCP System?

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, the supporting documentation including prerequisite programs supporting decisions in the hazard analysis, and the HACCP records.

It is important for establishments to realize that those prerequisite programs designed to support a decision in the hazard analysis are part of the HACCP system. For example,

when an establishment determines that a hazard is not reasonably likely to occur because the prerequisite program prevents the hazard, that prerequisite program then becomes part of the HACCP system. Prerequisite programs provide a foundation for the HACCP plan to operate effectively. Therefore, prerequisite programs need to be part of the establishment's initial validation activities to establish that the overall system is validated and can operate effectively. **For this reason, the HACCP system rather than the HACCP plan only is discussed throughout the rest of this document.**

What is HACCP System Validation?

Validation is the process of demonstrating that the HACCP system as designed can adequately control identified hazards to produce a safe, unadulterated product. **There are two distinct elements to validation:**

- 1) The scientific or technical support for the HACCP system design and**
- 2) The initial practical in-plant demonstration proving the HACCP system can perform as expected (execution).**

Validation encompasses activities that make up the entire HACCP system. Examples of some controls that would need validation are CCPs, prerequisite program interventions preventing a hazard from being likely to occur, purchase specifications, product formulations where the formulation contributes to the safety of the product, and cooking instructions.

What is the difference between initial validation and on-going verification?

There has been much confusion about which HACCP activities are on-going verification and which are initial validation. This confusion has been magnified by the fact that the NACMCF definition of the HACCP principle verification includes validation. Many agree that validation should be a distinct function from verification (Scott and Stevenson, 2006).

90 calendar days of initial validation takes place upon completion of the hazard analysis and development of the HACCP system. This period provides an opportunity to 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 than 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.

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 plan continues to be implemented properly. Ongoing verification activities include but are not limited to: the calibration of process-monitoring instruments; direct observation of monitoring activities and corrective actions; and the review of records generated and maintained in accordance with 417.5(a)(3). While reviewing records during ongoing verification, a prudent establishment would include a comparison to the initial validation data at some frequency.

What is the first element of HACCP Systems Validation?

1) Scientific Support: theoretical principles, expert advice from processing authorities, scientific data, peer reviewed journal articles, regulatory requirements, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately address specific hazards supporting the design of the HACCP system.

The scientific supporting documentation can consist of an article from a peer-reviewed scientific journal, a documented study, data underlying published guidelines, or in-house data. The documentation should identify:

- The hazard (biological, physical, and 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.

Care should be taken to ensure that the scientific support documents are sufficiently related to the process, product, and hazard identified in the hazard analysis. The supporting documentation should be complete and available for review. Failure to take these steps would raise questions about whether the HACCP system has been adequately designed and validated.

To be effective, the process procedures should relate and adhere to the critical operational parameters in the supporting documentation. For example, if the documentation 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 document. Guidance on these circumstances can be found in the key question on page 8.

In addition, the supporting documentation should contain microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis. Similarly, if detection equipment is used to identify foreign material in a particular product, the data used to validate the detection system should demonstrate that the equipment can in fact detect the targeted materials in the product.

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 support document?

Answer: Generally, establishments should use the same critical operational parameters as those in the support documents. In some circumstances, establishments may be able to support using critical operational parameters that are different from those in the support documents (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures). In these cases, establishments should provide justification supporting that the levels chosen are at least as effective as those in the support documents. 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 (<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7120.1.pdf>).

An establishment that gathers scientific support for its processes (and properly identifies operational parameters in 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 well-documented in the scientific literature. These processes would not need any additional research effort as part of the initial validation process. However, an establishment introducing a new technology not established in the literature, applying a standard technology in an unusual way (i.e., modifying operational parameters from the literature), or lacking experience with a technology would need to develop information to support that the technology will be effective for its intended purpose. 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.

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

What are the 5 major types of scientific support documents used to satisfy the design element of HACCP Systems Validation?

There are five primary types of scientific supporting documentation.

1. A scientific article from a peer-reviewed journal that describes a process and the results of use of the process can provide adequate supporting documentation. However, the study should relate closely to the establishment's process with regards to species, product characteristics, and equipment. The establishment should use the 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, 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 whether the process design has been adequately validated.

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.

2. Published processing guidelines that achieve a stated reduction of a pathogen are examples of scientific supporting documentation. The time-temperature guidelines in [Appendix A](#) of the final rule “Performance Standards for the Production of Certain Meat and Poultry Products” 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(d)(1), and 9 CFR 381.150(a)(2).
3. A challenge or inoculated pack study that is designed to determine the lethality or stabilization of a process also is an example of scientific supporting documentation. 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.
4. Data gathered 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, applying standard technology in an unusual way, or lacking data generated from a new technology. The establishment would need more extensive scientific and in-plant data implementing the process as part of 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

KEY QUESTION

Question: If I use [Appendix A](#) as the scientific support documentation for a fully cooked RTE process, do I need additional scientific information?

Answer: No, [Appendix A](#) has been validated to achieve the performance standards for the reduction of *Salmonella* contained in 9 CFR 318.17(a)(1) and 381.150(a)(1). Therefore, provided all critical operational parameters can be met, no additional support is needed.

microorganism. 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.

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 it 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. Microbial data could be used to determine effectiveness.

5. 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.

Examples of incomplete scientific support for validation include:

- Documentation that specified the log reduction achieved by the process but did not include information about critical parameters, such as pH, critical to achieving that reduction. That information would have to 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 could not be used as supporting documentation. For example, a process that achieves a 5-log reduction of *E. coli* O157:H7 in apple cider could not be used as the sole supporting documentation for the reduction of *E. coli* O157:H7 in a beef product.
- Having a hazard analysis that cited *E. coli* O157:H7 as a hazard reasonably likely to occur but implementing an intervention based on supporting documentation that didn't contain data supporting the processes effectiveness.

What is the second element of HACCP Systems Validation?

2) Initial In-Plant Validation: 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).

NOTE: The intended result of any HACCP system is to produce a safe, wholesome, and unadulterated product that will contain less than the maximum frequency or concentration of a hazard in a food at the time of consumption. FSIS through regulation has developed minimum performance standards encompassing sanitation, processing parameters, and microbiological criteria to ensure that the nation's food supply will be safe when consumed.

Often establishments incorporate intervention steps into their process to reduce the level of certain pathogens and use published scientific articles as supporting documentation for the design (see above discussion of the first part of validation). Establishments may implement those interventions in the same manner as the scientific support or make modifications.

In cases where the process specifications described in the supporting documentation are implemented in the same or similar enough way in the establishment's process, and when the scientific supporting documentation used contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the establishment should:

- Identify the critical operating parameters in the scientific support, AND
- Translate them in the HACCP system, AND
- Demonstrate that the critical operating parameters are being met by gathering execution data.

In cases where the process specifications described in the supporting documentation **are not implemented** in the same or similar enough way in the establishment's process, or when the scientific supporting documentation 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, the establishment should:

- Validate that the intervention as modified actually achieves the effect documented in the scientific supporting documentation (Element 1), AND

- Validate that the modified critical operating parameters are being met, AND
- Validate the intervention's effectiveness under actual in-plant conditions.

The establishment should develop the appropriate execution 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 as identified during a reassessment. During these 90 calendar days, an establishment gathers the necessary execution data to demonstrate 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 result as described in the HACCP Final Rule. These execution data become part of the validation supporting documentation along with the

KEY QUESTION

Question: Is microbiological data required to comply with the initial validation requirements?

Answer: No. Microbiological data is encouraged but not required to comply with the minimum initial validation requirements provided the establishment has adequate scientific supporting documentation (the first element of validation), is following the parameters in the scientific support, and can demonstrate that it can meet the critical parameters during operation (the second element of validation).

scientific support used to design the HACCP system (see records section for more information). Failure to take these steps would raise questions as to whether the HACCP system has been adequately validated.

What are the critical operational parameters of a process, and how does an establishment identify them in its scientific support (Element 1)?

For an establishment to validate an intervention, it should first identify the critical operational parameters within its process that it needs to monitor during the HACCP system design phase. Critical operational parameters are the specific conditions that the intervention must operate under in order for it to be effective. 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 | • pH |
| • Temperature | • Contact Time |
| • Equipment | • Product Coverage |
| • Humidity | • Spatial Configuration |
| • Dwell Time | • Pressure |
| • Water Activity | • Concentration |

KEY QUESTION

Question: If the establishment has demonstrated that it can meet the critical operational parameters in the supporting documentation during the initial validation, does FSIS require establishments to monitor all of the critical operational parameters as Critical Control Points (CCPs) or verify that they are being met on an ongoing basis through a pre-requisite program?

Answer: No. One or more of the critical operational parameters will likely need to be monitored as a CCP in response to a hazard that the establishment has identified as reasonably likely to occur or will need to be verified on an ongoing basis as part of a pre-requisite program in response to a hazard that the establishment has identified as not reasonably likely to occur because of the execution of that pre-requisite program. Other critical operational parameters may only need to be verified during the initial validation period (e.g., equipment, spatial configuration, product composition 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.

One or more of the critical operational parameters identified in the scientific support may be CCPs and have critical limits that need to be monitored whenever the intervention is in operation. Other critical operating parameters are important in the initial implementation of the intervention but do not necessarily become CCPs. When reading the supporting documentation, there are several questions one can ask to help identify the critical operating parameters. For example:

- What parameters were measured in the research?
- 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?
 - 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?

See Appendix 1 for additional guidance as to how to identify key critical operational parameters from the scientific supporting documentation. Appendix 3 contains examples of critical operational parameters that have been identified for different types of processes and scientific supporting documentation. Examples of the types of in-plant documentation expected are also provided.

NOTE: Establishments should design data gathering procedures to measure the critical operational parameters as defined in the scientific support and to measure them as close to the product contact point as possible. For example, if the scientific support for a carcass wash intervention includes critical parameters of water pressure at nozzle, water temperature at carcass, whole carcass coverage, and a water/carcass contact time, then the measurement procedures should be designed to gather data on whether those parameters are being achieved. For example, the water temperature measured at 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.

What types of processes and products need to be validated?

Establishments should collect execution data for all CCPs, interventions, prerequisite program requirements, and equipment to demonstrate they are being implemented as designed. Establishments should collect in-plant data for at least one product from each HACCP category process utilized, although, depending on the HACCP category and products, establishments should consider collecting in-plant data for more than one product within each category (see following examples). In general, additional data gathering for more than one product within a HACCP category is encouraged.

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. Establishments should use food science principles in their decision making when deciding which product types within a HACCP category should be used to gather execution data. Similarities and differences in species, process, product public health risk, and food safety hazards should be considered. The object is to collect execution data for a wide variety of different products and worst case scenarios. Some examples are listed on the next page:

- If an establishment slaughters pork and beef, in-plant data should be gathered for both processes because the slaughter process and the hazards associated with each are substantially different.
- 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.
- If an establishment makes several types of fully cooked sausages and the only differences are spices that impart no food safety attributes, an establishment may choose to gather data on any one or more of those products.
- If an establishment produces several fully cooked products of various thickness then the establishment should gather data for the thickest product because heat penetration is critical.
- If two products share almost an exact process, but one product has an additional step that contains a food safety control, the product with the additional step should be used to gather data. For example, an establishment produces cook-in bag roast beef and also sliced deli roast beef. The establishment should choose at a minimum to gather data on the sliced deli roast beef because the two

products share a significant part of the process, but the deli product receives additional processing steps that increase risk of contamination for that product.

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 supporting documentation 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 (e.g., employees, the size or shape of the physical location, and equipment) which may affect whether the critical operational parameters in the scientific supporting documentation can be implemented properly in the new establishment.

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

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

The scientific support design and initial in-plant execution validation documents support the decisions made in the hazard analysis and the adequacy of the process to control those hazards. These documents should be kept for the life of the plan to meet the requirements of 9 CFR 417.5(a)(1)(2).

Initial in-plant validation documents should encompass the first 90 calendar days of an establishment's processing experience with a new HACCP plan or a modified HACCP plan based on a reassessment as per 9 CFR 417.4(a)(3). 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, 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.

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. A future FR Notice that will announce the final version of this guidance document incorporating comments will provide a timeline for when FSIS inspection personnel will begin verifying HACCP systems validation documentation. Appendix 2 contains further guidance for establishments that no longer have the in-plant initial validation documents.

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 validation data.

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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 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 execution data from 90 calendar days (see page 15 for expectations regarding the equivalent number of production days) documenting the critical operating parameters?
7. Contain HACCP system execution data 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 System complete a validation worksheet containing the following information. Examples can be found in Appendix 3.

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 support necessary for effective execution of the process step or program.

Validation:

Scientific Supporting Documentation - State the scientific support document references and page numbers where the critical operating parameters are described.

Initial in-plant documentation - State the name of the monitoring documents 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.

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/Science/HACCP_Validation/index.asp

Compliance Assistance:

[http://www.fsis.usda.gov/Regulations & Policies/Compliance Assistance/index.asp](http://www.fsis.usda.gov/Regulations_&Policies/Compliance_Assistance/index.asp)

State HACCP Contacts & Coordinators:

http://www.fsis.usda.gov/contact_us/state_haccp_contacts_&coordinators/index.asp

Ohio State University – www.ag.ohio-state.edu/~meatsci/HACCPsupport.html

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: Guidance to Identify Critical Operational Parameters from Supporting Documentation

If a journal article from the scientific literature is used as the supporting documentation, it is important to understand how to read it and 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 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 supporting documentation. 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
- Equipment
- Humidity
- Dwell Time
- Water Activity
- pH
- Contact Time
- Product Coverage
- Spatial Configuration
- Pressure
- Concentration

Once the critical operational parameters are identified, establishments may determine one or more of the critical parameters will need to be monitored as a CCP in response to a hazard that the establishment has identified as reasonably likely to occur or will need to be verified on an ongoing basis as part of a pre-requisite program in response to a hazard that the establishment has identified as not reasonably likely to occur because of the execution of that pre-requisite program. Establishments may also determine that other critical operational parameters may only need to be verified during the initial validation period (e.g., equipment, spatial configuration, product composition 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.

The establishment should use the parameters, as cited in the literature that achieve the required or expected lethality or stabilization. Because meeting the critical operational parameters is essential to effectively use a specific document to validate a process, the parameters used or measured in the article should be addressed in the process. If one or more of the parameters are not addressed in the process, then the establishment should document a justification as to why that parameter does not need to be met or measured.

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.

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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 it 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 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.

Questions to ask when reading the Results:

- What were the significant findings?
- When the critical operational parameters were changed across experimental conditions, did the effectiveness of the intervention change as well?
- Can you identify which intervention you would use?
 - If so, can you identify the log reduction that intervention results in?
 - Did the authors examine whether that log reduction depends on any of the operational parameters?
 - Will you be able to implement all of the factors in your process?

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

Additional questions to ask when applying a scientific study to your own process:

- How will the critical parameters of the study be applied to the actual production process?
 - Can they be implemented exactly as used in the study or do deviations need to be made based on facility design, equipment design, processing, or equipment limitations, etc.?
- If you need to apply the parameters used in the study differently, what is your justification for doing so? Do you have documentation to support the change?
- What records do you have to support your process?
- How do you monitor that the critical parameters are being properly implemented in the plant?

Appendix 2: Expectations for Establishments that No Longer Have the In-Plant Initial Validation Documents

FSIS realizes that some establishments may not have kept their initial in-plant demonstration documents from when HACCP was originally implemented. Those establishments that have not will be allowed the time to assemble their in-plant demonstration documents. The Agency will describe and explain these documents in a Federal Register Notice that it intends to issue when it finalizes the Compliance Guideline.

For large establishments, FSIS intends to wait 6 months from the date of this future Federal Register notice before including verification that establishments have complied with the second element of validation (initial in-plant validation) as part of its inspection activities. Thus, large establishments will have six months to gather all necessary in-plant demonstration documents.

Small and very small establishments will have 9 months from the publication date of this future Federal Register Notice to gather all necessary in-plant demonstration documents before FSIS will verify and enforce the second element of validation (initial in-plant validation).

Such documents may include HACCP records that are generated as part of the monitoring of critical limits or parameters of prerequisite programs. If these documents do not address all of the critical operational parameters identified in the scientific supporting documentation, then additional data may need to be generated to demonstrate that those parameters can be properly implemented.

Examples of documents that can be used by existing establishments that no longer have in-plant initial validation documents include:

- HACCP records collected during 90 days from effective date of a future Federal Register Notice.
- 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.

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Appendix 3: Validation Worksheet Examples

(Mention of trade marks or commercial names does not constitute endorsement by USDA)

Product	Hazard	Process	Critical Operational Parameters ¹	Validation	
				Scientific Supporting Documentation	Initial In-Plant Documentation
Poultry Carcass	<i>Salmonella</i>	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.	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. <i>J. Food Prot.</i> 71(6): 1119-1122. Food and Drug Administration Environmental Decision Memo for Food Contact Notification No. 000323: April 10, 2003	Final Chiller Monitoring Check Sheet (including PAHP concentration and estimation of exposure time); Trial report showing consistent operation parameters and microbial analysis, if possible, for 90 days.
Poultry Carcass	<i>Salmonella</i>	Spraying of carcasses with peroxyacetic acid prior to chiller	25-230 ppm of peracetic acid (PAA). Pressure or flow rate.	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".	In plant monitoring records confirm that antimicrobial solution was applied at the specification in the study. Data collected for 90 days.

¹ Refers to the critical limit or other parameter cited in the scientific support necessary for effective execution of the intervention.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-Plant Documentation
Poultry parts intended for grinding and ground poultry (including mechanically separated poultry)	<i>Salmonella</i>	Acidified sodium chlorite applied to poultry parts as a spray or dip prior to grinding and applied to ground poultry.	1200 ppm in combination with any GRAS acid at a level sufficient to achieve a pH of 2.3 to 2.9 in accordance with 21 CFR 173.325 <i>(Note: The pH depends on the type of meat)</i>	21 CFR 173.325 for poultry parts and acceptability determination for ground poultry. FSIS Directive 7120.1 Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products.	In plant monitoring records for 90 days that indicate the antimicrobial was applied to the poultry parts prior to grinding and the mechanically separated poultry prior to mixing according at the appropriate concentration and pH.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-Plant Documentation
Hog Carcass	<i>Salmonella</i>	Organic Acid Cabinet	Water temperature (110°F - 130°F), Conductivity / Lactic Acid Concentration Level (5% or less), and Pressure Gauges on the supply pipes (13-23 psi).	<p>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. <i>J. Food Prot.</i> 63:1676-1680.</p> <p>Harris, K.; M.F. Miller, G.H. Loneragan, and M.M. Brashears. 2006. Validation of the use of organic acids and acidified sodium chlorite to reduce <i>Escherichia coli</i> O157 and <i>Salmonella</i> Typhimurium in beef trim and ground beef in a simulated processing environment. <i>J. Food Prot.</i> 69:1802-1807.</p>	Hog Carcass Sanitizing Spray Cabinet Kill Floor Monitoring Check Sheet and trial reports dated for 90 days.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-Plant Documentation
Hog Carcass	<i>Salmonella</i>	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.	<p>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. <i>Int. J. Food Micro.</i> 5: 1-9.</p> <p>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. <i>J. Food Prot.</i> 63:1676-1680.</p>	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 for 90 days.
Hog Carcass	<i>Salmonella</i>	Scalding	Scalding in water at 145°F (62°C) for 5 minutes.	<p>Gill, C.O. and J. Bryant. 1993. The presence of <i>Escherichia coli</i>, <i>Salmonella</i>, and <i>Campylobacter</i> in pig carcass dehairing equipment. <i>Food Microbiol.</i> 10: 337-344.</p> <p>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 <i>Salmonella</i> cross-contamination. <i>J Appl Microbiol.</i></p>	Scalding Tank Monitoring Check Sheet (including reading for temperature of water and transit time) for 90 days.

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-Plant Documentation
Beef Carcass	<i>E. coli</i> O157:H7	Hot Carcass Wash or Carcass Thermal Treatment	<p>Hot Carcass Wash: Water Temp over 180°F, Pressure over 13 psi.</p> <p>Carcass Thermal Treatment: Ambient steam temp sufficient to achieve 160°F at the surface in five key anatomical locations.</p>	<p>K.R. Davey, M.G. Smith. 1989 A laboratory evaluation of a novel hot water cabinet for the decontamination of sides of beef. <i>Int J Food Sci Tech.</i> 24: 305-316.</p> <p>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. <i>J. Food Prot.</i> 59: 127-135.</p> <p>AMI Lethality model, demonstrating lethality at 160°F at carcass surface.</p> <p>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. <i>J. Food Prot.</i> 61:571-577.</p> <p>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. <i>J. Food Prot.</i> 60:485-492.</p>	<p>Plant monitoring documentation of critical parameters.</p> <p>Plant temperature mapping completed for 90 days.</p>

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-Plant Documentation
Irradiated Ground Beef	<i>E. coli</i> O157:H7	Dose Mapping, each production run	Plant specific dosimetry procedures. 4.5 kGy fresh red meat, 7.0 kGy frozen red meat.	9 CFR 424.22(c), Irradiation of meat food and poultry products. Available at: http://cfr.vlex.com/vid/22-certain-other-permitted-uses-19611025 .	Documents per 9 CFR 424.22 (c) 3, for ten production runs during 90 days of initial validation.
Beef carcass	<i>E. coli</i> O157:H7, <i>Salmonella</i> 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.	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) for 90 days

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-Plant Documentation
Beef carcass	<i>E. coli</i> O157:H7	Lactic Acid Spray	<p>Lactic Acid >2%; Pressure 40 psi (CHAD spray cabinet), Dwell time: minimum of 10 seconds Lactic Acid Temperature: 104°F at point of delivery.</p> <p>Design of the spray cabinet includes an oscillating (90 rpm) nozzle-header arrangement composed of four spray nozzles.</p>	<p>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. <i>J. Food Prot.</i> 61: 823-828.</p> <p>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. <i>J. Food Prot.</i> 58: 368-374.</p> <p>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. <i>J. Food Prot.</i> 63: 44-50.</p>	Pre-evisceration cabinet worksheet that monitored lactic acid percent, dwell time of the carcass in the cabinet, pressure, and lactic acid temperature at point of delivery during 90 day period.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-Plant Documentation
Raw Ground Beef or Beef Trim for use in Raw Ground Beef	<i>E. coli</i> 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 <i>E. coli</i> 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.	Records 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 during 90 day period.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-Plant Documentation
Raw Ground Beef or Beef Trim for use in Raw Ground Beef	<i>E. coli</i> O157:H7	Trimming 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).	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. <i>Meat Sci.</i> 88:256-260.	Trim Spray Cabinet Worksheet demonstrating that the antimicrobial is applied per concentration, pressure, dwell time, and temperature in the article during 90 day period.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-plant documentation
Beef Jerky	<i>E. coli</i> O157:H7, <i>Salmonella</i> , <i>Listeria monocytogenes</i>	Cooking and Drying	<p>(For the Type 1-A Process)</p> <p>Stage 1* – 145°F for 15 minutes followed by heating at 170°F for 15 minutes.</p> <p>Stage 2 – Choose either: Dry-bulb at 170°F and wet-bulb at 125°F 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.</p> <p>Stage 3- Dry at 170°F dry-bulb to doneness</p> <p>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.</p>	<p>Critical limit summary for shelf stability of beef jerky and related products: http://www.meathaccp.wisc.edu/validation/assets/CL%20Jerky%20Staph%20&%20LM.pdf.</p> <p>Buege, D.R., Searls, G., and Ingham, S.C. 2006. Lethality of commercial whole-muscle beef jerky manufacturing processes against <i>Salmonella</i> Serovars and <i>Escherichia coli</i> O157:H7. <i>J. Food Prot.</i> 69(9): 2091-2099.</p>	<p>Time/dry-bulb and wet bulb temperature data for 90 days.</p> <p>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.</p> <p>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.</p>

*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 other parts of the process are not changed, can also be considered validated because they should have greater lethality.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-plant documentation
Post-lethality exposed ready-to-eat meats	<i>Listeria monocytogenes</i>	Prerequisite program – SSOPs	<p><i>Listeria</i> control program for food contact surfaces.</p> <p>Sanitary design of equipment and sanitary zone concept.</p> <p>Frequency for collecting samples and number of samples that should be collected per line.</p>	<p>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.</p> <p>Sanitary Design Assessment Fact Sheet http://www.sanitarydesign.org/pdf/Sanitary%20Design%20Fact%20Sheet.pdf.</p> <p>Tompkin, R.B. 2004. Environmental Sampling – A tool to verify the effectiveness of preventative hygiene measures. <i>Mitt Lebens Hyg.</i> 95:45-51.</p> <p>Tompkin, R.B. 2002. Control of <i>Listeria monocytogenes</i> in the food processing environment. <i>J Food Prot.</i> 65: 709-725.</p> <p>FSIS. 2006. Compliance Guidelines to Control <i>Listeria monocytogenes</i> in Post-lethality Exposed Ready-to-eat Meat and Poultry Products. http://www.fsis.usda.gov/oppde/rdad/FRPubs/97-013F/LM_Rule_Compliance_Guidelines_May_2006.pdf</p>	<p>Records mapping food contact surface swab results for <i>Listeria spp.</i> collected on different processing dates and at different times during 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*.</p> <p>Assessment of sanitary design of equipment in the post-lethality environment using the AMI Sanitary Equipment Design worksheet along with changes to <i>Listeria</i> control program based on sanitary design assessment.</p> <p>Identification of all possible food contact surfaces.</p>

*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.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-plant documentation
Post-lethality exposed ready-to-eat smoked turkey deli meat	<i>Listeria monocytogenes</i>	Hot water Pasteurization	<p>Hot water temperature at 195°F; product submersed for at least 6 minutes.</p> <p>Reduction of <i>Lm</i> 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*).</p>	<p>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 <i>Listeria monocytogenes</i>. <i>J. Food Prot.</i> 65(6): 963-969.</p>	<p>Records demonstrating time and temperature can be achieved for 90 days.</p> <p>Data from 90 days in which temperature of water is mapped to support monitoring procedures and frequencies.</p>

*NOTE for products subject to 9 CFR 430, it is FSIS expectation the post-lethality treatment will be designed to achieve at least a 1-log lethality of *Lm* before the product leaves the establishment.

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-plant documentation
Semi-dry sausage	<i>Staphylococcus aureus</i>	Fermentation	<p>Ferment product to a pH<5.3 within fewer than 1000 degree-hours*.</p> <p>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.</p>	<p>American Meat Institute. 1995. Interim Good Manufacturing Practices for Fermented Dry and Semi-Dry Products.</p> <p>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.</p> <p>FSIS Food Standards and Labeling Policy Book and Ingham et al. 2005. Fate of <i>Staphylococcus aureus</i> on Vacuum-Packaged Ready-to-Eat Meat Products Stored at 21°C. Journal of Food Protection. 68:1911-1915.</p>	<p>Degree Hour Calculation per GMP conducted during first 90 days of initial validation demonstrating Degree-hours are < 1000. For example on 10/24/99:</p> <p>Establishment process = (95°F-60°F) * 12 = 420 degree hours to a pH of 4.9, well within the guidelines for control of <i>Staphylococcus aureus</i>.</p> <p>Records from 90 days 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.</p>

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

	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-plant documentation
Semi-dry Sausage (Lebanon Bologna)	<i>Salmonella, E. coli</i> O157:H7	Fermentation and intermediate heating step	<p>Diameter: 115 mm Starter culture: <i>Pediococcus</i>, <i>Lactobacillus</i>, and <i>Micrococcus</i> spp. Casing: Cellulose</p> <p>Smokehouse Schedule: Stage 1: Come-up to 80°F – 5 hours Hold at 80°F – 8 hours Relative humidity – 88 ± 2%</p> <p>Stage 2: Come-up to 100°F – 4 hours Hold at 100°F – 25 hours Relative humidity – 80 ± 2%</p> <p>Stage 3: Come-up to 110°F – 2 hours Hold at 110°F – 24 hours Relative humidity – 80 ± 2%</p> <p>During the last 2 hours at 110°F hickory smoke applied</p> <p>Product Composition: pH = 4.39 a_w = 0.94 % salt = 4.77 % fat = 10.43</p>	<p>Getty, K.J.K, Phebus, R.K, Marsden, J.L., Schwenke, J.R., and Kastner, C.L. 1999. Control of <i>Escherichia coli</i> O157:H7 in Large (115 mm) and Intermediate (90 mm) Diameter Lebanon-style Bologna. <i>J of Food Sci.</i> 64(6): 1100-1107.</p>	<p>Time/dry-bulb and wet bulb temperature data for 90 days.</p> <p>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.</p> <p>Cold-spot determination in smokehouse to support monitoring procedures and frequencies.</p> <p>Records assessing variability in sausage diameter.</p> <p>Records supporting product composition data.</p> <p>Decision-making document showing that starter culture and casing used in actual process are the same as those used in support documents.</p>

Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-plant documentation
Fully Cooked Not Shelf Stable Poultry Fillets	<i>Salmonella</i>	Impingement Oven Cooking	<p>$D_{62^{\circ}\text{C}/145^{\circ}\text{F}}$ -values for chicken with between 2 and 6.3% fat ($D_{62^{\circ}\text{C}/145^{\circ}\text{F}} = 1.14$ min). Cook to internal temp of $\geq 145^{\circ}\text{F}$, hold for ≥ 8 minutes.</p> <p>Product formulation: salt and phosphate concentration (%) and in-going sodium nitrite level (ppm); pH of the product.</p> <p>Thickness of the fillets; arrangement of fillets on the belt; conveyor belt speed; and air flow rate.</p> <p>Wet-bulb and dry-bulb temperature.</p>	<p>American Meat Institute Process Lethality Spreadsheet. Available at http://www.amif.org/ht/d/sp/i/26870/pid/26870.</p> <p>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, <i>Int J Food Microbiol.</i> 70: 37-51.</p> <p>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</p>	<p>Records generated during 90 days demonstrating that process can achieve time and temperature.</p> <p>Records documenting that variability in thickness of the fillets; arrangement of fillets on the conveyor belt; conveyor belt speed; and air flow rate to used in the process will consistently meet time and temperature parameters.</p> <p>Records supporting that the % fat of product is consistently between 2 and 6.3%.</p> <p>Records generated during 90 days demonstrating the dry-bulb and wet-bulb temperatures meet those in the scientific support documents.</p>

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Product	Hazard	Process	Critical Operational Parameters	Validation	
				Scientific Supporting Documentation	Initial In-plant documentation
Fully Cooked Roast Beef	<i>Salmonella, E. coli</i> O157:H7	Product Cooking	<p>Internal temperature of 130°F for a minimum of 112 minutes.</p> <p>Relative humidity >90% for at least 25% of the cooking time and in no case less than one hour.</p>	<p>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/oa/fr/95033f-a.htm.</p> <p>Doyle, M.P., and J.L. Schoeni. 1984. Survival and growth characteristics of <i>Escherichia coli</i> associated with hemorrhagic colitis. <i>Appl. Environ. Microbiol.</i> 48:855-856.</p>	<p>Records indicating a minimum internal temperature of 130° F for 112 minutes is achieved for 90 days.</p> <p>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.</p>