United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

March 19, 2010

American Association of Meat Processors
American Meat Institute
Eastern Meat Packers Association
Grocery Manufacturers Association
National Chicken Council
National Meat Association
National Turkey Federation
North American Meat Processors Association
Southwest Meat Association

RE: Response to HACCP Validation Letter dated Sept. 22, 2009

In a letter dated September 22, 2009, you provided the Food Safety and Inspection Service (FSIS) with your organizations' understanding of HACCP validation, a component of HACCP Principle 6 verification, and with suggestions to incorporate into the Agency's validation clarification documents under development and review within the Agency. We have taken time in responding because we want to ensure that our response fully reflects the Agency's thinking.

FSIS does intend to issue a number of documents to clarify the requirements of HACCP validation as described in the July 25, 1996 Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule (61 FR 38806). FSIS considers it appropriate to issue these documents because of the widespread lack of understanding of validation that FSIS has found among establishments, whether large or small in HACCP size or high or low in production volume, and because of the food safety problems that have occurred as a result. Among the documents that FSIS will issue will be a *Federal Register* document clarifying validation requirements, a guidance document tailored for small and very small establishments to assist them in complying with validation requirements, and an issuance to inspection program personnel providing instructions on how to verify an establishment's validation. A copy of the guidance document is enclosed. We are making it available for public comment.

In your letter, you describe validation as focusing on whether an establishment's HACCP plan in general, or a critical control point (CCP) in particular, has the scientific or other supporting documents to demonstrate that it "should" work, and "real life" evidence to demonstrate that it can be implemented as designed and have its intended effect at the facility. FSIS agrees with your description with one addition. More than CCPs must be validated. Increasingly, establishments use prerequisite programs as part of their HACCP

system, particularly as support for why the establishment considers a food safety hazard to be not reasonably likely to occur. It is essential that the on-going effectiveness of these prerequisite programs be part of the overall food safety system controls that are validated. These prerequisite programs plus other controls, including pathogen reduction treatments that may be applied in a multi-hurdle approach, collectively constitute the overall food safety system.

Your letter also provided a number of suggestions for the Agency to consider in developing the HACCP validation clarification documents. We have considered those suggestions.

1. **Clarify the Elements of Validation**

The preamble to the Pathogen Reduction/HACCP regulation states that validation has two parts: "(1) theoretical principles, expert advice, scientific data or other information... and (2) in-plant observations, measurements, test results, or other information....to achieve the intended food safety objective" 61 Fed. Reg. at 38826. In your letter you contend that this phrasing is a source of confusion, and that the in-plant part of validation should be further broken down to include data collected to demonstrate the establishment "can follow operational parameters" and "evidence of the process/intervention's effectiveness" to denote the two distinct types of data.

This suggestion is useful, and the agency intends to make clear in its guidance that an establishment should collect data to demonstrate that the critical operational parameters are being met, and that the overall objectives of the system to produce safe products is being achieved.

2. **Explain the Relationship Between the Expectations and the Language of the Regulation**

In your letter, you contend that the regulatory language addressing validation is sparse, and merely quoting the regulatory language could engender confusion. The Agency's goal is to enhance public health protection by providing information that clarifies the requirement for validation with scenarios that illustrate what is necessary to validate that the overall food safety system is effective.

3. **Explain Agency Expectations Regarding When Evidence of In-plant Process Effectiveness Data is not Required**

Your letter suggests that there are some well-recognized processes that do not need to be validated in the manner that we are putting forth. You contend that, with respect to these processes, there is no need for the establishment to generate data, beyond showing that they achieve certain specified operational parameters.

We agree but only to a limited degree. Inspection experience has shown that operational parameters can be interpreted and implemented in various ways by establishments, and

that slight modifications to a process or an intervention, even if made to fit the process to the establishment's unique environment, can have substantial consequences for the process or intervention as well as for the overall effectiveness of the food safety system. Thus, for all processes for which food safety performance standards or guidance criteria have been articulated, it is essential that establishments gather data during their initial experience with a HACCP system to ensure that the collective controls can work together to routinely produce safe product within the boundaries of the performance standards or guidance criteria. Adulterants, such as *E. coli* O157:H7 in certain raw beef products and *Salmonella* and *Listeria monocytogenes* in ready-to-eat (RTE) products must not be present at greater than a non-detectable level in a specified sample size. For certain classes of slaughter and ground products, *Salmonella* can not be present more than a specified number of times in a sample set. While FSIS would agree that extensive challenge studies are not necessary, the establishment does need to implement the process in a manner that ensures that the operational parameters specified in the literature for application of a particular antimicrobial treatment are consistent, and that, as implemented with all the attendant controls, including prerequisite programs, the process produces the expected effects.

For example, there has been a demonstrated failure to adequately address validation for certain RTE products. FSIS has had more than one finding of *Salmonella* in its routine verification testing of head cheese, pork barbecue, sausage (other than patties), and patties (sausage and chicken). These findings resulted in recalls.

In addition, processes are designed to achieve a certain result. It is important to be able to document a basis for confidence that the process will achieve that result. For example, collecting data on initial and finished product microbial loads using an appropriate indicator to demonstrate a log reduction capability, along with presence/absence data for the food safety hazard of interest, is extremely useful. These data can be used to demonstrate that a process, as designed, will mitigate to a specified extent a food safety hazard occurring in the raw materials that the establishment typically receives.

As you reference in your letter, there is a limited number of interventions that are required by regulation, including heat for canning, chlorine to recondition poultry, freezing for *trichina* control in pork, chilling of poultry to 40°F, and cooking beef patties. In these limited circumstances, we would agree that the process can be validated by developing evidence that the specified endpoint is achieved. Thus, it would not be necessary to develop microbial effectiveness data in circumstances in which good manufacturing practices (GMPs) have been employed throughout the handling of the source materials. However, when GMPs are not fully assured (e.g., raw beef is produced during a period of higher than normal pathogen-positive findings), the microbial load may be greater than the controls are capable of correcting.

Your letter goes on to argue, however, that if an establishment uses FSIS guidelines, it should not need to develop food safety effectiveness data as part of its validation. We do not agree with this argument. The Agency looks at documents such as Appendix A: Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat

and Poultry Products and Appendix B: Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products as valuable documents describing well-recognized processes that establishments can use to satisfy the first part of validation, scientific technical support. While the use of these documents would mean that an establishment would not need to conduct challenge studies as for new processes, the establishment would still need to adapt the guidance so that the process works effectively in the establishment's unique processing environment and within a degree of variation that can be expected in any establishment's operations. For existing establishment processes, these data can be drawn from the establishment's existing HACCP monitoring and verification records. For new establishments and new processes, however, these data would need to be gathered during the initial validation period.

Moreover, it is necessary to step back from the individual interventions and to look at the effectiveness of the system as a whole. One way an establishment could do this is to gather microbial data by testing incoming raw materials and finished products during its initial experience with the process, including enumeration of indicators and presence/absence testing for the identified food safety hazard. These data can be used to set the boundaries for the degree of variation that the system will need to address. These data can be used to determine whether the process is able to reduce the level of pathogens associated with the raw materials received at the establishment to the extent contemplated by the establishment in designing the process. These data can be used to assess whether the individual process steps, when done together, along with product handling in between those steps, produces a safe, unadulterated product. If they do, the process is successfully validated.

In those circumstances in which the Agency has not articulated performance standards or guidance criteria (e.g., raw, intact beef steak, chicken parts), a prudent establishment would be expected to have quantifiable data, such as for levels of indicator organisms, to show that the production process is aware of an acceptable level of contamination of its products as determined by the capability of the food safety system.

4. Providing Guidance on How to Generate Evidence of In-Plant Effectiveness

Your letter also suggests to the Agency that guidance be developed to provide clear guidelines as to how such in-plant effectiveness evidence can practically and effectively be generated. In particular, for microbial data collection, you suggest providing clear expectations as to possible organisms to be used, degree of reduction expected, and number of samples collected.

The draft guidance document, which is enclosed, includes some information on to how to collect in-plant effectiveness data with an emphasis on microbial data collection, using scenarios for some common processes. Scenarios will include both raw and processed products, so that establishments can see the difference in approach that are necessary because of differences in the processes and in the hazards associated with these processes. These examples depicting the validation principles can then be applied to the many processes that encompass meat and poultry production. However, the Agency

believes that the scientific technical support documents satisfying the first part of validation for each process are the best source of information for establishments to use in determining the data necessary to validate their HACCP systems in-plant. These documents provide the specific information associated with the process/intervention the establishment has chosen to incorporate into their HACCP system.

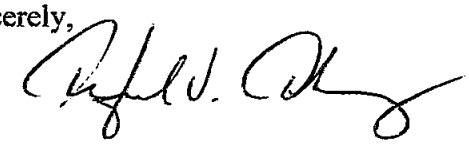
5. Comments on the First Component of Validation: The Scientific or Other Support

Your letter states that the soon-to-be-issued FSIS validation documents are limited to plant evidence as to effectiveness at the facility. The Agency would like to clarify that the validation documents will include information about both parts of validation. The first part of validation, scientific technical support, is more widely understood by stakeholders. Therefore, the agency believes that it is advantageous to emphasize the second part of validation as part of a comprehensive HACCP validation communication effort.

6. General Comments on Implementation of the Three Issuances

In your final suggestions to the Agency, you request that all documents be completed together before any single one is issued, and that draft documents be issued for review before implementation. The Agency would like to assure you that all the documents are being developed by a single working group to ensure consistency of content. The Agency believes that it would be advantageous to share a draft of the guidance document for small and very small establishments with interested parties. Those interested parties could provide constructive feedback to the Agency about how the guidance on HACCP validation is being communicated since those interested parties interact with industry stakeholders on a daily basis. We intend to share the draft guidance in the near future.

Sincerely,



Alfred V. Almanza
Administrator
Food Safety and Inspection Service

DRAFT GUIDANCE: HACCP SYSTEMS VALIDATION

Introduction

FSIS has developed this guidance document to aid small and very small plants and in particular low volume production plants in meeting the validation requirements in 9 CFR 417.4 On July 25, 1996, FSIS published the Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule (61 FR 38806) Docket No. 93-016F. This document presented the validation requirements for meat and poultry establishments in 9 CFR 417.4. The regulation states each establishment is required to validate the effectiveness of its HACCP plans in controlling those food safety hazards identified during the hazard analysis. The regulation also states that establishments are to conduct these validation activities during the establishment's initial experience with a new HACCP plan and encompasses additional activities that make up the entire HACCP system. In addition to the regulatory language, the final rule also stated what constitutes validation and this document is designed to review that understanding and to provide practical guidance for small and very small plants on how to validate their own food safety systems. Plants that do not incorporate these principles into their HACCP systems would raise questions whether the HACCP system has been adequately validated.

Definition of 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. These prerequisite programs provide a foundation for the HACCP plan to operate effectively. Therefore, these prerequisite programs need to be part of the establishment's validation activities to demonstrate 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.

Note: The HACCP system, rather than just the HACCP plan, is discussed throughout the rest of this document.

Validation Has Two Parts

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 and 2) the initial practical in-plant demonstration proving the HACCP system can perform as expected**. Examples of some controls that would need validation are CCPs, pre-requisite 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.

1) <u>Scientific Support</u>: 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.

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 level of hazard prevention to be achieved, all critical parameters or conditions, the processing steps that will achieve the specified reduction or prevention, and the way these processing steps will be monitored. Care should be taken to ensure that the supporting validation documentation is sufficiently related to the process, product and hazard identified in the hazard analysis. The supporting documentation should be complete and available for review. The process should also be implemented in the establishment as described in the supporting documentation. Failure to take these steps would raise questions whether the HACCP system has been adequately validated.

To be effective, the process procedures should relate and adhere to the specifications in the supporting documentation. If the documentation listed a particular critical parameter such as concentration of an antimicrobial, that concentration should be used in the process. 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. If , for example, the process specifications described in the supporting documentation are not implemented in the same or similar enough way in the establishment's process, additional research studies need to be conducted and documented to ensure the modified implementation achieves the desired result. These additional studies could be conducted either in a laboratory setting or in-plant.

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

<u>Guidelines for Scientific Supporting Documentation</u>

There are five primary types of scientific supporting documentation.

1. 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" and the guidelines in the Blue Ribbon Task Force report on dry fermented sausage are examples of guidelines that address 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).

2. A scientific article from a peer-reviewed journal that describes the process and the level of reduction or process stabilization that results can provide adequate supporting documentation. However, to provide adequate validation, the study needs to relate closely to the process with regards to species, product characteristics, and equipment. The establishment should use the exact parameters cited in the journal that achieves the required or expected lethality or stabilization. If not, an establishment needs to provide additional support for the process.

Note: Most scholarly journals use a process of peer review prior to publishing an article that includes additional scholar's in the field of expertise critically assess the draft 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.

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 the source of the documentation. .

4. Data gathered in-house 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 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 in the specified microorganism. The documentation used for in-plant validation should contain information from all the tests performed, such as temperature of steam,

time of exposure, and microbiological results of swab tests, and 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 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. However, for the establishments to which use of the intervention was extended, the data would meet only the first part of validation. The establishments would still need to demonstrate that the intervention will function as intended in each of those establishments.

5. Regulatory performance standards as defined in the Code of Federal Regulation 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.

   Examples of incomplete 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.

2) Initial In-Plant Validation: in-plant observations, measurements, microbiological test results, or other information demonstrating that the control measures, as written into a HACCP system, can be implemented 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 (Part 1), but also that the establishment can implement it as designed to reach the desired effect (Part 2). The establishment should develop these 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. During these 90 days, an establishment gathers the necessary data by repeatedly testing 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. These data become part of the validation supporting documentation.

Note: The intended result of any HACCP system is to produce a safe, wholesome, and unadulterated product which will contain less than the maximum frequency and/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 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 support (see above discussion of the first part of validation) to implement the process within the establishment. In the second step of validation, an establishment needs to demonstrate that the intervention implemented within the specific establishment environment actually achieves the effect documented in the scientific supporting documentation. This second step is important because often laboratory conditions may be different than actual conditions in the establishment. Laboratory conditions present a highly controlled environment. Specific log reductions or ease of monitoring critical parameters achieved in the laboratory may not be easily attainable in an actual establishment setting.

<u>In-Plant Validation: Critical Operational Parameter Observations and Measurements for Individual Process Steps and Interventions</u>

For an establishment to validate an intervention, it should first identify the critical operational parameters that it can monitor within its process. These critical operational parameters are identified in documents gathered as part of step one of validation and often include time, temperature, pressure, concentration, or log reduction. Critical parameters are the elements of an intervention that must be met in order for the intervention to operate effectively and should be incorporated into the HACCP system. Once the critical parameters are identified from the scientific support and incorporated into the HACCP system, the establishment should repeatedly test the HACCP system by gathering rigorous operational data during the 90 days of initial validation to demonstrate that the establishment can achieve the values set forth in the scientific supporting documentation. The establishment needs to collect enough data to support that the process can operate effectively on a daily basis. These data would establish that the establishment can implement each intervention as designed in the scientific support. Failure to take these steps would raise questions whether the HACCP system has been adequately validated.

NOTE: Establishments should design data gathering procedures to measure the critical parameters as defined in the scientific support and to measure them as close to the product contact point as possible. If a carcass wash intervention has critical parameters in the scientific support 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.

In-Plant Validation: Demonstrating Effectiveness of HACCP System to Achieve Intended Result

In addition to demonstrating that each intervention or process step within a HACCP system can be implemented according to the critical operational parameters described in the scientific technical support, in-plant validation also includes gathering data to demonstrate that the collection of interventions and process steps together in sequence produce a safe, wholesome unadulterated product. In other words, is the HACCP system achieving the desired result? FSIS believes that microbiological testing that combines enumeration of indicators with the presence/absence of an identified pathogen in conjunction with monitoring critical parameters plays an important role in the initial validation of many interventions for biological food safety hazards. Microbiological testing data, where appropriate, can provide establishments information about whether the overall system of interventions can achieve the desired log reductions documented in the scientific supporting documentation. Establishments would need to provide support in instances where they believe microbiological testing data is not needed to demonstrate the effectiveness of the HACCP system in controlling biological food safety hazards. Once the operational effectiveness of each individual intervention is determined, the establishment can use microbiological testing data in conjunction with the data on the individual interventions to establish that the process as a whole results in the production safe, unadulterated product. In this final part of step 2 initial in-plant validation, the establishment should pull together the data for each intervention and the data from microbiological testing at various points throughout the HACCP system to ensure that the multiple hurdle design of its entire HACCP system will result in the production of safe, unadulterated products. Failure to take these steps will raise questions whether the HACCP system has been adequately validated.

For large establishments and larger volume small establishments, FSIS would advocate collecting samples at multiple points throughout the process such as before and after each intervention along with collecting a number of samples that statistically represent the establishment's production volume. FSIS realizes that this type of sampling might be financially and logistically difficult for small and very small plants that process low volumes of product or that do not process every day. Therefore, the examples discussed in this document are minimum expectations for these production types. Additionally, the

examples in this document also only apply to establishments that are implementing interventions as described in the scientific support (Part 1).

NOTE: Low volume for the purposes of this document is defined for slaughter processes in 9 CFR 310.25 and 9 CFR 381.94. Low volume for other HACCP processes is defined as a daily average production of 1,000 pounds or less per process category.

There are several questions an establishment should answer for itself as the validation plan is being determined.

1. Where should samples be collected?

It is important here to clarify that FSIS is not suggesting that a complete challenge study or research study be conducted to replicate the scientific supporting documentation performed in a laboratory. However, FSIS expects some level of in-plant data collection to substantiate that interventions are achieving the desired effect within the establishment environment as designed in the HACCP system.

At a minimum, FSIS believes that collecting samples at a point in the beginning of the process is necessary to establish the process' initial microbial load. This information can provide data for the establishment to determine whether the interventions chosen for the HACCP system are adequate to control the identified hazards. For livestock slaughter, sampling could be done on the lagging half carcass after de-hiding and for poultry the samples could be collected after de-feathering, i.e. post pick. Sampling for processed products could be performed on raw materials. These are examples of where samples could be collected but the important point is that a system of selecting the sample be determined.

Also at a minimum, FSIS believes that collecting samples at a point after all interventions or ideally from finished and packaged products is necessary to determine whether the HACCP system, as designed, is capable of producing safe, unadulterated products. These data can be used in conjunction with the data gathered measuring the critical parameters of each intervention to determine whether the HACCP system is functioning as intended. For slaughter processes, samples could be collected at post chill from the leading half carcass for livestock and a poultry sample collected from a carcass from the same flock but not the same bird as sampled at the beginning to produce a paired sampling situation. For processed products samples could be collected from final packaged products from the same lot as the raw materials to produce a paired sample situation.

2. What laboratory analyses should be performed?

FSIS does not advocate the introduction of pathogens into the establishment environment resulting in intentional adulteration of product. In this type of testing, enumeration of indicator organisms should be used with additional side-by-side pathogen positive/negative detection testing to gather data about the identified organisms of

concern in the hazard analysis. Gathering data on the presence/absence of the pathogen fully demonstrates that the system is able to mitigate the food safety hazard that was identified in the hazard analysis as the desired result of the HACCP system.

An indicator organism is an organism that if present, indicates the possible presence of a particular pathogen. Jay's Modern Food Microbiology, 4th Edition, describes a good indicator organism as easily detectable and countable, has a historical association with the pathogen of concern, is usually present when the pathogen is present, is an organism whose number counts correlate with the pathogen's of concern, has similar growth requirements and rates, and is usually absent from, or present at minimum numbers, in finished products. For meat and poultry products, these criteria have generally translated into organisms associated with the GI tract of warm blooded animals because of their close relationship with fecal and ingesta materials. Examples of these organism groups are Enterobacteriaceae, coliforms, and generic E. coli. For certain circumstances, organisms recovered by performing aerobic plate counts (APCs) also known as total plate counts (TPCs) have been used in the scientific literature as indicators. The reference list at the end of this document includes additional information on indicator organisms.

There is no gold standard list of indicators agreed upon by the scientific community that will fit every situation. The reference list includes information from the literature on potential indicators for certain situations. The establishment should have supporting documentation that the indicator organisms chosen are appropriate to validate interventions for the pathogen of concern documented in the hazard analysis. Often, the scientific support (Part 1) contains microbiological data for both indicators and pathogens to validate the theoretical principle of the intervention. Establishments where possible, should use these scientific support documents to guide microbiological analyses choices. In the absence of this information, as stated above, the references at the end of this document contain further information to guide establishments in making indicator choices when appropriate.

The limit of detection for most indicator organisms is higher than the numbers of many pathogens present on meat and poultry products such as *E. coli* O157:H7. *E. coli* O157:H7, when present, is usually present at low levels. Therefore, it is important for the establishment also test for an indicator organism when validating an intervention's log reduction capabilities under in-plant conditions. Testing for levels of both indicator organisms and presence/absence of the identified hazard is essential to ensure that not only is the establishment's HACCP system (i.e. sum of all interventions) achieving the specific log reduction as described in that hazard analysis (indicated by indicator organism counts), but also that the interventions are successful at controlling the pathogens of interest to below detectable levels for adulterants or to acceptable levels for other raw processes. Any positive sample for an adulterant would be an indication that the process is either not being implemented properly (compare data with critical parameter measurements), or that the process is inadequate. A greater than expected microbial count or positive rate of other identified biological hazards would indicate that the HACCP system is unable to achieve the desired outcome and would need alteration.

Such an indication would be evidence there is a need for changes to the HACCP system and the establishment should review all records associated with the process to make appropriate modifications to its HACCP system.

Sample size and detection limit specifications can be found in the Microbiological Laboratory Guidebook).

3. How many samples should be collected?

As part of the in-house validation process, the establishment should determine how many samples to collect to statistically represent the HACCP system's production volume. At a minimum for low volume small and very small establishments, the regulations for the mandatory generic *E. coli* testing (9 CFR 310.25/381.94) can be used as a guideline for determining the frequency of validation testing at each point chosen in the process. Doing so would mean a low volume of sampling (for both indicator organisms and the identified pathogen at each point in the process chosen). Only 13 samples as described above would need to be collected and analyzed at the early point in the process and 13 samples at a point after all controls have been applied paired to the early point samples, preferably finished packaged product where possible, for a total of 26 samples. Paired samples should be collected throughout the initial 90 day validation by low volume producers. Conversely, large establishments and large volume small establishments should collect a statistically representative number of samples according to production volume. It is important to spread sample collection over the initial validation period to adequately establish process control and to demonstrate the establishment's ability to implement their HACCP system, because this testing is designed to initially validate the HACCP system not individual products on a specific day. This is the difference between validation and on-going verification. Although the establishment would do a minimal level of sampling to validate its interventions (and maintain this initial validation on-file as part of its supporting documentation for its HACCP plan), a prudent establishment would continue sampling at an alternative frequency beyond the initial 90 day period as part of on-going verification to ensure that the HACCP system continues to be effective in controlling the identified hazards.

4. How many types of products should be sampled?

Establishments should collect microbial data for at least one product from each HACCP category utilized. Establishments should use decision making documents to describe how the HACCP team decided which products or product types would be sampled. Establishments should use food science principles in their decisionmaking when deciding which product types within a HACCP category should be sampled. Similarities and differences in species, process, product public health risk, and food safety hazards should be considered. For example, if an establishment slaughters both pork and beef, microbiological 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, then both products should be sampled because their processes are substantially different. Another example, an establishment produces cook-in-bag roast beef and also sliced deli roast beef. An

establishment should choose at a minimum to sample the sliced deli roast beef because the two products share a significant part of the process, but one product receives additional processing steps that increase the risk of that product. Conversely, if two products share almost an exact process, but one product has an additional step that contains a food safety control, both products should be sampled.

Validation Examples

There are examples of scientific support and initial in-plant validation described in the attachments to this document. There are tables containing general examples of validation procedures to further help small and very small establishments to develop validation data based on their processes and are not all inclusive. The examples are divided into raw and processed products. Additionally, there are detailed scenarios that walk a low volume production establishment through possible microbiological data gathering designs. These examples are designed as additional guidance tools to illustrate how the requirements of validation discussed in this document could be applied by establishments and are by no means the only way an establishment could validate their HACCP systems.

Validation Records

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

The scientific support and initial in-plant 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 process 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 their HACCP system.

NOTE: Establishments using existing HACCP systems developed prior to the issuance of this document that do not have the documents from their initial validation on file will need to gather data according to the timeline [that the Agency will set out in the Federal Register notice that it issues clarifying the validation requirement].

Rigorous data gathered during the initial validation period to satisfy the second part of validation may also be able to support monitoring and ongoing verification procedures as

the establishment moves beyond the first 90 days of HACCP system implementation. By repeatedly testing the adequacy of the monitoring and verification procedures using increased frequencies during the initial validation, an establishment can gather knowledge about its system and use those data to support its routine monitoring and ongoing verification procedures after the initial validation period.

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Weblinks

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

ATTACHMENT 1. VALIDATION EXAMPLES FOR RAW PRODUCTS

Product	Hazard	Process	Critical Parameter	Validation	
				Scientific Supporting Documentation	Initial In-plant Documentation
Poultry Carcass	Pathogens	Spraying of carcasses with TSP prior to chiller.	15 sec. or less of spraying with max. conc. of 12% @ 1034.2kPa for 30 sec.	A copy of the article or study not just a reference to the article or study. See reference list.	Records confirming that the antimicrobial solution is achieving the specifications in the study including critical parameter data and microbiological results.
Pork Carcass	Pathogens	Steam vacuum after evisceration	equipment designed t draw a vacuum of -0.0093 bar and simultaneously, the water nozzle ejects ≥179.6°F(83°C) water at 0.34 to 1.03 bar	1. Published scientific articles stating time and temperature of process and the level of pathogen reduction, or. 2. In-house data collection with a specified time and temperature that shows the resultant reduction of pathogens.	Records confirming that the intervention is applied per the specifications in the study and is achieving the desired food safety objective (i.e. log reduction) including critical parameter data and microbiological results.
Beef Carcass	Fecal matter	excision before trim rail	no visible feces	Information cited in FSIS Directive 6420.2 Verification of Procedures for Controlling Fecal Material, Ingesta and Milk in Slaughter Operations	Records showing that fecal matter is trimmed from carcass by plant employees and microbiological results.

Ground Beef	*E. coli* O157:H7	1. Irradiation	1. 5-log reduction of *E. coli* O157:H7.	1. Documentation from the irradiation facility that the specified absorbed dose will result in an adequate 5-log reduction of *E. coli* O157:H7.	1. Documentation from the irradiation facility on dose mapping. Test data demonstrating that the level of pathogen reduction was consistently achieved.
		2. Receiving	2. Purchase specifications	2. Documentation from the supplier assuring that the supplier employs validated interventions addressing *E. coli* O157:H7, certificates of analysis, records of ongoing communication with supplier and verification data to support the achievement of the first two conditions.	2. Records that show plant employees obtain and review purchase specifications for adequacy at receiving for each lot and any additional verification testing results on incoming product lots
		3. addition of acidified sodium chlorite to raw ground beef components	3. addition of the acidified sodium chlorite at the specified conc. that is below regulatory limits	3. Scientific article or in-house study on the log reduction achieved by the antimicrobial.	3. Records confirming that the anitimicrobial is applied per specifications in the article in the article and microbiological test results.

Raw Beef Patties	Non-toxic metal particles	In-line metal detection after packaging	Smallest sensitivity to reliably detect the hazard, 0.8mm or less	Technical specifications of metal detector used.	Data demonstrating that the metal detectors can consistently detect the minimum particle size.

ATTACHMENT 2. VALIDATION EXAMPLES FOR PROCESSED PRODUCTS

Product	Hazard	Process Step	Critical Parameter	Validation	
				Supporting Documentation	Recorded Documentation
Fully-cooked Roast Beef	*Salmonella* (*E. coli* O157:H7 for beef) and *L. monocytogenes* for exposed products	Product Cooking	Internal 145°F for 4 minutes	Appendix A of the final rule "Performance Standards for the Production of Certain Meat and Poultry Products"	Records showing that an internal temperature of 145°F for 4 minutes is achieved and microbiological test results.
Partially-Cooked Beef Patties	*Clostridium perfringens* *Clostridium botulinum*	Product Cooling	Patties Cooled to 40°F within 20 minutes.	Challenge study demonstrating that continuous cooling for 20 minutes to 40°F meets the performance standard in 318.23(c) – no more than 1 log growth of *C. perfringens* and no growth of *C. botulinum*	Records showing that 40°F was achieved within 20 minutes of continuous cooling.
Fully-cooked turkey	*Clostridium perfringens* *Clostridium botulinum*	Product Cooling	Product cooled from 130°F to 80°F within 1.5 hours and from 80°F to 40°F within 5 hours	Appendix B (stabilization guideline) of the final rule "Performance Standards for the Production of Certain Meat and Poultry Products"	Records showing that the product was cooled within the time and temperature guidelines.

Product	Hazard	Process Step	Critical Parameter	Validation	
				Supporting Documentation	**Recorded Documentation**
Salami	*Salmonella* (*E. coli* O157:H7 for beef) and *L. monocytogenes* for exposed products	Fermentation	Fermentation at 90°F to pH 4.6 and hold at 90°F for ≥ 6 days; 55mm casing	Blue Ribbon Task Force Study on Dry, Fermented Sausages	Records showing that the fermentation and drying were controlled at the parameters listed for the size of product casing.
Partially-Cooked breaded chicken product	Salmonella	Cooking Instructions on label	1. Preheat oven to 400°F 2. Remove frozen breast from pouch and place on baking sheet 3. Bake in preheated oven for a minimum of 28 minutes-cook to a minimum internal temperature of 165°F measured by a meat thermometer 4. *Salmonella* non-detectable in raw, finished product intended for individual consumers	In-house research study including microbiological testing performed by the research and development department at the corporate headquarters pilot plant using the specific partially-cooked breaded chicken product. A copy of the study is on file with the product label.	Research and development department at the corporate headquarters conducted a sensory panel where 10 individuals were asked to follow the cooking instructions and data was collected to substantiate that the instructions resulted in a fully cooked product. A copy of the results is on file with the product label.

ATTACHMENT 3 POTENTIAL SAMPLING VALIDATION SCENARIO FOR A LOW VOLUME SLAUGHTER ESTABLISHMENT

Introduction

A very small beef slaughter establishment slaughters 10-12 head of beef (steer) a day for 2 days a week.

Initial process flow diagram:
1. Receiving live cattle------2. Pre-slaughter wash------3. Stunning/bleeding------4.Head and shank removal-----4. Head processing-----5.dehiding------6. Evisceration------7 Variety Meats Processing------8. Splitting carcass------9. Trim Zero tolerance------10. Final wash (ambient temp)-----Organic Acid Spray------Chilling

The Hazard Analysis has identified *E. coli* O157:H7 as a Biological food safety hazard reasonably likely to occur.

Selected Microbial Intervention Strategies and are CCPs:

CCP1: Trim off any visible fecal/ingesta with zero tolerance. Monitor trimming by visual inspection
CCP2: Organic acid spray (2% lactic acid w/ temperature range of 43-54^{o}C) with concentration and temperature of acid being monitored. Carcass is to be thoroughly sprayed.
CCP3: Carcass to be at a temperature of <45^{o}C within 24 hours of slaughter.

These intervention strategies are implemented as documented in the supporting documentation.

Materials and Methods
The establishment will conduct an initial in-plant validation using a microbiological sampling procedure recommended by T.M.Arthur (2004). The microbial sampling will determine the effectiveness of the selected interventions used to reduce *E. coli* O157:H7 to an acceptable level as described in the hazard analysis.

1. Individual animals and carcasses were tagged and tracked throughout the process. A carcass will be divided into two halves (the lagging and the leading halves). The lagging carcass half is sampled after dehiding (baseline) and the leading carcass half of the carcass is sampled after the carcass had been in chiller for 24 hours.
2. The required microbial sampling will be composed of swabs taken from the carcass half at the following sites in a specified order (flank—brisket—round).
3. An area comprised of 8,000 cm^2 is to be swabbed for each sponge sample.
4. Swabs will be analyzed for:
   a) Aerobic Plate Count using the method detailed in FDA's Bacteriological Analytical Manual, chapter 3.
   b) Generic *E. coli* enumeration using the method detailed in FDA's Bacteriological Analytical Manual, chapter 4.
   c) *E. coli* O157:H7 detection using the method detailed in FSIS's Microbiology Laboratory Guidebook, Chapter 5.04
5. The paired sampling (leading and lagging carcasses halves) are to be taken once per week for 13 weeks.

Hypothetical Results Data

COMPARISON OF APC, GENERIC *E. coli* LEVELS AND PRESENCE OF *E.coli* O157:H7 IN DEHIDED CARCASSES AND POST INTERVENTIONS TREATED CARCASSES

CARCASS NUMBER	APC (CFU/cm^2)		GENERIC *E. coli* MPN/cm^2		E.coli O157:H7 PRESENCE/ABSENCE	
	Dehided [1]	Chilled[2]	Dehided	Chilled	Dehided	Chilled
1	2.2 X 10^5	4.7 X 10^2	210	3	NEG	NEG
2	1.7 X 10^4	8.8 X 10^1	75	<3*	NEG	NEG
3	4.7 X 10^5	3.6 X 10^2	240	3	NEG	NEG
4	2.5 X 10^6	5.6 X 10^2	1,100	3.6	**POS**	NEG
5	1.8 X 10^5	8.2 X 10^2	210	<3	NEG	NEG
6	5.2 X 10^4	4.3 X 10^2	160	<3	NEG	NEG
7	6.3 X 10^6	7.1 X 10^1	1,100	8.7	**POS**	NEG
8	9.4 X 10^4	9.6 X 10^1	43	<3	NEG	NEG

9	3.7×10^5	1.2×10^2	240	<3	NEG	NEG
10	1.8×10^6	5.4×10^2	1,100	7.4	**POS**	NEG
11	7.2×10^5	3.7×10^2	460	3.6	NEG	NEG
12	4.8×10^4	9.8×10^1	160	<3	NEG	NEG
13	8.3×10^5	4.8×10^2	460	1.4	NEG	NEG
Mean ($\bar{x}$) =	**1.04×10^6**	**3.5×10^2**	**428**	**2.4**		
$Log_{10}\bar{x}$ =	**5.513**	**2.412**	**2.444**	**0.391**		
Standard Deviation	**0.745**	**0.377**	**0.438**	**0.279**		

1. Sponge sample taken immediately after carcass had the hide removed.
2. Sponge sample taken 24 hours after carcass halves placed into chiller.
*** For purposes of calculating the mean and a standard deviation <3 equals 0.**

ATTACHMENT 4. EXAMPLE OF A POTENTIAL SAMPLING PLAN FOR LOW VOLUME RTE ESTABLISHMENT

Introduction

A small establishment produces ready to eat all beef hot dog product under the O3G (fully cooked, not shelf stable) HACCP code This product is post-lethality exposed, and the plant addresses *Listeria monocytogenes* food safety hazard under alternative 3 (sanitation only) with the additional provisions required for hot dog or deli product.

The hazard analysis identifies the following hazards as being likely to occur during the process: *Salmonella* and *Clostridium perfringens* spore outgrowth. Cooking and cooling are identified as critical control points (CCP1B, CCP2B) in the HACCP plan. Additionally, the establishment will prevent contamination of cooked hot dog product with *Listeria monocytogenes* by maintaining sanitary conditions on food contact surfaces by complying with its Sanitary Standard Operating Procedures (SSOPs).

Materials and Methods

CCP1B Cooking. The establishment will use a time and temperature from Appendix A of the final rule "Performance Standards for the Production of Certain Meat and Poultry Products" as scientific support for the cooking CCP. To validate the cooking step, the establishment will monitor temperature and time during the cooking step using data-loggers for all production lots to ensure that the critical limits are consistently met.

On 13 evenly spaced production days throughout the initial validation period, the establishment will test aerobic plate count (APC) and for Salmonella detection on raw hotdogs immediately before cooking. Approximately 2 lb. of product will be aseptically collected and submitted to a laboratory for analysis.

.Samples will be analyzed for:

a) Aerobic Plate Count using the method detailed in FDA's Bacteriological Analytical Manual, Chapter 3.
b) *Salmonella* detection using the method detailed in FSIS's Microbiology Laboratory Guidebook, Chapter 4.04

The following data were collected:

week	collection date	APC (cfu/g)	Log APC	Salmonella (detection)
1	7/7/2009	100	2.0	neg
1	7/9/2009	500	2.7	neg
2	7/13/2009	5,000	3.7	neg
2	7/15/2009	600	2.8	neg
3	7/21/2009	1,000	3.0	neg
3	7/23/2009	10,000	4.0	pos.
4	7/27/2009	2,000	3.3	neg
4	7/29/2009	100,000	5.0	neg
5	8/4/2009	2,000	3.3	neg
5	8/6/2009	300	2.5	neg
6	8/10/2009	200,000	5.3	pos.
6	8/12/2009	200	2.3	neg
6	8/14/2009	10,000	4.0	neg

CCP2B Cooling. The temperature of the cooked product is reduced using a brine chiller. The cooling parameters will meet those specified in Appendix B for RTE products containing 100 ppm ingoing sodium nitrite (130 to 80 °F in 5 hours and from 80 to 45 °F in 10 hours). Data loggers will again be used to validate the cooling process by ensuring that the critical limits are met. Finished product samples (2lb.) from the same lot (creating paired samples with the before cooking sample) will be collected in their final package form, submitted to the laboratory, and analyzed as discussed above.

Sanitary conditions: The establishment developed SSOPs to prevent contamination of food contact surfaces *with Listeria monocytogenes* (Lm) and thus prevent adulteration of product after cooking and before packaging. These Lm controls refer to

guidance documents published by Penn State University and FSIS[1] To validate the effectiveness of the SSOPs, the establishment proposes to conduct testing of selected food contact surfaces using two indicators of sanitary conditions: ATP bioluminescence (ATP) and *Listeria* species by enrichment test. Testing of 1 ft2 surface area samples is performed each day over a minimum of 13 evenly spaced production days during the phase-in period. On each sample day, an ATP sample is taken immediately following pre-op and a *Listeria* sample is taken 2-3 hours into the production shift. A fixed sample site is chosen for each analysis. ATP levels and *Listeria* spp results are recorded. The SSOPs are judged to be inadequate if 1 or more ATP measurements indicated "suspect" or "unclean" surfaces based on the manufacturers recommendations, or if 1 or more samples are positive for *Listeria* spp. Inadequate SSOPs are re-evaluated using the same protocol.

The following data were collected:

week	collection date	APC (cfu/g)	Salmonella (Detection)	ATP (RLU)	Listeria spp.
1	7/7/2009	10	neg.	0	neg
1	7/9/2009	<10	neg.	50	neg
2	7/13/2009	50	neg.	10	neg
2	7/15/2009	<10	neg.	0	neg
3	7/21/2009	10	neg.	50	neg
3	7/23/2009	17	neg.	100	neg
4	7/27/2009	23	neg.	20	neg
4	7/29/2009	12	neg.	10	neg
5	8/4/2009	<10	neg.	200	neg
5	8/6/2009	32	neg.	20	neg
6	8/10/2009	44	neg.	30	neg
6	8/12/2009	<10	neg.	10	neg
7	8/17/2009	<10	neg.	0	neg

[1] "Control of Listeria monocytogenes in Small Meat and Poultry Establishments" (Penn State University, College of Agricultural Sciences, Agricultural Research and Cooperative Extension); "Compliance Guidelines To Control Listeria Monocytogenes In Post-Lethality Exposed Ready-To-Eat Meat And Poultry Products" (FSIS, May 2006, available at http://www.fsis.usda.gov/oppde/rdad/FRPubs/97-013F/LM_Rule_Compliance_Guidelines_May_2006.pdf

7	8/19/2009	na	10	na
8	8/25/2009	na	100	na
8	8/27/2009	na	50	na
9	8/31/2009	na	20	na
9	9/2/2009	na	40	na
10	9/8/2009	na	90	na
10	9/10/2009	na	100	na
11	9/14/2009	na	90	na
11	9/16/2009	na	70	na

RLU: Relative light units
Na: testing not performed.

According to the ATP bioluminescence system manufacturer, RLU measurements exceeding 100 are unacceptable on pre-op 1 ft^2 food contact surfaces. During the initial validation period, a single measurement at pre-op on 8/4/09 exceeded 100 RLU. The establishment took corrective action and retested the surface before production began for the day. In addition, some adjustments were made to the SSOP, and 13 additional ATP measurements were made over the subsequent 60 days to validate the changes made to the SSOP. No Listeria spp. positives were detected over the first 60 days.

September 22, 2009

Hand Delivered

Mr. Alfred Almanza, Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture
Washington, DC 20250-3700

Re: FSIS Expectations as to HACCP Validation

Dear Mr. Almanza:

The undersigned trade associations respectfully submit these comments to the Food Safety and Inspection Service (FSIS or the agency) as it moves forward with new issuances regarding in-plant validation of Hazard Analysis, Critical Control Point (HACCP) plans.[1]

FSIS has announced it will issue various documents on validation. According to a memorandum from Dr. Kenneth Petersen, Assistant Administrator, dated February 12, 2009, FSIS "intends to issue a *Federal Register* notice to explain validation requirements under the regulations and to provide a deadline for establishments to comply with the requirements as they apply to in-plant conditions." Dr. Petersen noted that FSIS also would be issuing "guidance to establishments" and "instructions to the field."

Before turning to our comments, we thought it would be helpful to articulate our understanding of "validation." Under HACCP principles, "validation" is a component of Principle 6 – verification. Validation focuses on whether the establishment's HACCP plan in general (or a critical control point (CCP) in particular) has the scientific or other supporting documents to demonstrate that it "should" work and the "real life" evidence that demonstrates it can be implemented as designed and that it has the intended effect at the facility.

As discussed within this letter, we support FSIS efforts to improve the clarification of the validation requirements. In that spirit, we respectfully submit the following suggestions:

1. Clarify the Elements of Validation

In the preamble accompanying the Pathogen Reduction/HACCP regulation, the agency noted that "Data assembled to validate a HACCP plan are usually of two types: (1) theoretical principles, expert advice, scientific data or other information . . . and (2) in plant observations, measurements, test results, or other information . . . ." 61 *Fed. Reg.* 38,826, col. 3 (July 25, 1996).

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[1] During a webinar FSIS recently held on validation (September 10, 2009), agency officials indicated that the release of these documents is imminent.

The dichotomy created by the language above has been a source of confusion. In reality, there are three components of validation: (1) the scientific or other support that the process or intervention is capable of controlling a hazard; (2) the evidence that the establishment is capable of delivering the operational parameters specified in the support being used; and (3) the evidence that the process has the intended effect in the plant environment.

Significantly, the last two components are both "in-plant." Given that there are two different "in-plant" elements of validation, we suggest the agency ***not*** use the unqualified phrase "in-plant" without further identifying which type of in-plant data is intended. We suggest that FSIS consistently use the phrases "can follow operational parameters," and "evidence of the process/intervention's effectiveness" to denote the two distinct types of in-plant validation.

We further submit that previous attempts by FSIS to do this for agency employees, such as in FSIS Directive 6410.1, have not provided the necessary clarity. In this Directive, FSIS does not clearly delineate between the two in-plant elements of validation. In fact, the Directive includes the statement that "establishments can validate their individual decontamination and antimicrobial intervention treatments by ensuring that the interventions used to control hazards at the CCP are implemented in a manner that is consistent with the parameters of any scientific, peer-reviewed, published studies, or challenge studies being used as support for decisions in their hazard analysis," but completely fails to discuss the "evidence of the process/intervention's effectiveness" component.[2]

2. Explain the Relationship Between the Expectations and the Language of the Regulation

The regulatory provisions applicable to HACCP validation are sparse. Section 417.4(a) merely indicates that the establishment "shall validate the HACCP plan's adequacy in controlling the food safety hazards . . . ." Specifically, subsection (a)(1) speaks to ***initial*** validation. "During the initial validation period, the establishment shall repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan." Finally, that subsection also speaks in terms of reviewing records "routinely generated by the HACCP system, in the context of other validation activities."

With the PR/HACCP rule in effect for more than 10 years at most establishments, we think that merely quoting the language from the beginning of § 417.4(a)(1), regarding the initial validation, could engender confusion. We submit that FSIS should issue its

[2] This example was discussed during the recent validation webinar. During one of the validation webinars, there was a question posed concerning the need to conduct microbial testing in connection with validation of Appendix A. the cooking guidelines. The answer was "yes," but the justification given was that products could be exposed/contaminated in the post-lethality environment, a concern that does not relate to whether the product was properly cooked in the first instance. This justification shows the continuing confusion surrounding validation.

validation documents as providing guidance on the first line of § 417.4(a); that the establishment "shall ***validate*** the HACCP plan's adequacy in controlling the food safety hazards . . . ."

3. Explain Agency Expectations Regarding When Evidence of In-Plant Process Effectiveness Data is Not Required

We respectfully submit that the need for evidence of in-plant effectiveness should not be mandated for well-recognized processes. For some of these processes, the long-standing use in literally hundreds of plants for numerous years, and in many cases decades, has demonstrated that the processes are indeed effective, regardless of the plant in which the process is employed, provided, of course, that the operational parameters are being followed.

Although there are other widely substantiated processes and/or interventions, below are some examples of the more common ones that we respectfully submit are within this class of processes.

a. *Regulatory Requirements*

FSIS has adopted certain regulatory standards which, when followed, ensure a safe product. It makes little sense to require an establishment to demonstrate the effectiveness of the regulations below:

- Canning Regulations (9 CFR Part §§ 318.300, *et seq.* (meat) and 381.300 *et seq.* (poultry));
- Use of Chlorine for Reconditioning of Poultry (9 CFR 381.91(b)(1));
- Trichina Control in Pork (9 CFR 318.10);
- Chilling of Poultry to 40 Degrees (9 CFR 381.66); and
- Cooked patties (9 CFR 318.23).

b. *FSIS Guidelines Adopted in Federal Register Notices*:

Likewise, even if not technically a regulation, FSIS has recognized certain processes in *Federal Register* Notices as needing no validation. FSIS commented in the context of Appendices A and B that "FSIS will consider such process schedules validated, since they will consist of processing methods already accepted by the Agency as effective." 64 *Fed. Reg.* 741, col. 1 (January 6, 1999).

- Appendix A: Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products; and
- Appendix B: Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization).

c. *Controls on Out-Growth of Certain Pathogens*:

A variety of HACCP plans include critical control points to prevent the outgrowth of certain pathogens. The science is well established on the minimum temperatures at which growth can occur. A review of this literature was prepared by Dr. Bruce Tompkin.[3] In addition, Table 5 in an NACMCF Guidance can be used as a source.[4] We submit that any establishment adopting a critical limit for temperature that is consistent with this literature need not develop any in-plant data to show the limit is effective (provided, as always, that the establishment follows the operational parameters, *i.e.*, ensures product temperature remains below the critical limit). We also recognize these establishments would conduct on-going in plant verification that their system was working (e.g., maintaining temperature, *etc.*).

4. Providing Guidance on How to Generate Evidence of In-Plant Effectiveness

Beyond the well-recognized processes discussed previously, we recognize that an establishment must demonstrate in-plant effectiveness by some means. Obviously, we would not expect that an establishment would conduct a challenge study in its facility using a pathogen. That said, there are a variety of questions surrounding how such data could and should be generated. The agency needs to develop clear guidelines as to how such evidence can practically and effectively be generated.

If the establishment chooses to support in-plant effectiveness with microbial data, FSIS should indicate the possible organisms that could be used and the expectations as to what degree of reduction needs to be shown for processes that reduce the level of a pathogen. In addition, the guidance needs to discuss the number of samples and the frequency of re-validation. For example, for certain established practices, such as lactic acid rinses, the amount of in-plant data necessary should not be as robust as a newly developed process. Likewise, less data may be required when data show a high degree of consistency, as opposed to wide variation in results.

We recognize that a detailed discussion of the variables that need be considered is beyond this submission. However, we would appreciate the opportunity to visit with you and your staff to develop practical guides, especially for small and very small establishments.

5. Comments on the First Component of Validation: The Scientific or Other Support

Although we understand that the soon-to-be-issued FSIS validation documents are limited to plant evidence as to effectiveness at the facility, we would be remiss if we did not also comment on the other components of validation: (1) the scientific or other

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[3] The Tompkin review is widely referenced. An on-line version can be found at: http://www.meathaccp.wisc.edu/assets/TompkinPaper.pdf

[4] http://www.fsis.usda.gov/PDF/NACMCF_Inoculated_Pack_2009F.pdf

support for the HACCP plan and (2) evidence that the plant can follow the operational parameters.

We applaud the agency for its recent webinar on the first component of validation. The agency needs to continue to make resources available to help establishments validate their HACCP plans, including guidance on identification of the operational parameters of interventions so establishments can meet the second component of validation.

In addition, we request that the agency work with all regulated stakeholders to develop guidance on FSIS expectations as to what constitutes adequate scientific and other support.

6. General Comments on Implementation of the Three New Issuances

As mentioned previously, FSIS is apparently developing three issuances: the *Federal Register* Notice, guidance for establishments, and instructions to in-plant program personnel. We request that all three documents be completed, at least in draft, before any single one is issued so as to ensure their mutual compatibility.

Likewise, we must stress the need for adequate training and discussion before any requirements are imposed or enforced. Given the potential for continuing confusion, we suggest that draft guidelines/instructions be issued first so as to identify and resolve unforeseen issues before proceeding to implementation. Once again, we request that the agency work with the regulated stakeholders to maximize the likelihood of a uniform understanding before undertaking implementation.

Conclusion

We appreciate the opportunity to submit our views on FSIS expectations as to HACCP validation. We look forward to working with you and your staff on a smooth and effective implementation of validation requirements.

Respectfully submitted,

American Association of Meat Processors
American Meat Institute
Eastern Meat Packers Association
Grocery Manufacturers Association
National Chicken Council
National Meat Association
National Turkey Federation
North American Meat Processors Association
Southwest Meat Association