

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

78-15

12/17/15

INSTRUCTIONS FOR VERIFYING VALIDATION REQUIREMENTS DURING PERFORMANCE OF THE HAZARD ANALYSIS VERIFICATION (HAV) TASK AND FOOD SAFETY ASSESSMENTS

DO NOT IMPLEMENT THIS NOTICE UNTIL JANUARY 4, 2016, AT LARGE ESTABLISHMENTS AND APRIL 4, 2016, AT SMALL AND VERY SMALL ESTABLISHMENTS.

I. PURPOSE

This notice provides instructions to inspection program personnel (IPP) (Consumer Safety Inspectors [CSIs] and Public Health Veterinarians [PHVs]) to follow starting January 4, 2016, at large establishments and April 4, 2016, at small and very small establishments when verifying compliance with validation requirements (9 CFR 417.4) as outlined in [FSIS Directive 5000.6, Performance of the Hazard Analysis Verification \(HAV\) Task](#). This notice also instructs supervisory personnel (Supervisory Public Health Veterinarians [SPHV], Supervisory Consumer Safety Inspectors [SCSI], the Inspector-in-Charge [IIC], Multi-IPPs Supervisors, and Frontline Supervisors [FLS]) to assist IPP if they have concerns regarding the technical aspect of the scientific support or in-plant validation data. It also provides instructions to Enforcement, Investigation, and Analysis Officers (EIAOs) when verifying compliance with validation requirements as outlined in [FSIS Directive 5100.1, Enforcement Investigations and Analysis Officer \(EIAO\) Food Safety Assessment Methodology](#).

II. BACKGROUND

A. Each establishment is required to validate the adequacy of its Hazard Analysis Critical Control Points (HACCP) system in controlling the food safety hazards identified in its hazard analysis per 9 CFR 417.4.

B. Under 9 CFR 417.4(a)(1), establishments are required to assemble two types of supporting documentation to demonstrate a HACCP system has been validated:

1. The scientific or technical support for the HACCP system design (design), and
2. The in-plant implementation (validation) data (execution).

C. Although the HACCP requirements were effective over 15 years ago, FSIS has determined from its verification activities that many establishments have not properly validated their food safety systems. Inadequate validation has led to the production of adulterated product and in some cases even illnesses. In particular, FSIS has found that establishments have not

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collected the necessary in-plant validation data demonstrating that the HACCP system is functioning as intended.

D. To help establishments ensure that their HACCP systems are properly validated, FSIS developed the *FSIS Compliance Guideline: HACCP Systems Validation*. FSIS announced the availability of the final version of the *FSIS Compliance Guideline: Hazard Analysis and Critical Control Points (HACCP) Systems Validation* in the [Federal Register](#) on May 14, 2015 (80 Fed. Reg. 27557), and that the guideline is available at: [FSIS Compliance Guideline: Hazard Analysis and Critical Control Points \(HACCP\) Systems Validation](#).

E. FSIS will begin issuing non-compliance records (NRs) if an establishment lacks in-plant validation data on:

1. January 4, 2016 for large establishments, defined as all establishments with 500 or more employees;
2. April 4, 2016 for small establishments, defined as all establishments with 10 or more employees but fewer than 500; or
3. April 4, 2016 for very small establishments, defined as all establishments with fewer than 10 employees or annual sales of less than \$2.5 million.

F. Establishment size is maintained within the Establishment Profile in the Public Health Information System (PHIS) as outlined in [FSIS Directive 5300.1, Managing the Establishment Profile in the Public Health Information System \(PHIS\)](#).

III. IPP RESPONSIBILITIES

A. During the next HAV performed on or after January 4, 2016, IPP at large establishments (500 or more employees) are to follow the instructions in this notice in addition to the methodology in [FSIS Directive 5000.6](#). IPP at small and very small establishments (500 or less employees) are to begin following the instructions in this notice during the next HAV performed on or after April 4, 2016. The instructions in C - J in this section of this notice replace all of the instructions in [FSIS Directive 5000.6](#) under Step 7 – Verify Establishment Validation, A-G.

B. IPP are to review the HACCP systems validation training materials available at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/resources-and-information/haccp-validation/haccp-validation-resources> while following the instructions in this notice. If after reviewing the training materials, IPP would like additional reference materials or refresher information, or to view short videos on specific HACCP validation requirements, IPP will be able to open the “IPP Help” button from the Icon in his or her FSIS Computer Desktop once it is launched in early 2016, shortly after this notice is to be implemented in large establishments.

C. When verifying that establishments meet validation requirements, IPP are to review the scientific and technical support and the documents associated with the effectiveness of the HACCP plan in operation in-plant (i.e., in-plant validation data). IPP are to verify whether the establishment maintains both types of validation documents. If the establishment does not make documents or data available to IPP to demonstrate both parts of validation, there is noncompliance with [9 CFR 417.5\(a\)\(1\)](#).

D. When IPP review the establishment’s scientific or technical support, they are to verify that the establishment maintains references and copies of relevant portions of text from the scientific or technical support for the effectiveness of the CCPs and prerequisite programs used to support decisions in the hazard analysis.

E. If the establishment does not maintain documents to support the scientific or technical basis for the CCPs and prerequisite programs used to support decisions in the hazard analysis then there is noncompliance with [9 CFR 417.5\(a\)\(1\)](#). When determining noncompliance, IPP are to be aware that:

1. The establishment must have scientific or technical support for CCPs as well as prerequisite programs used to support decisions in the hazard analysis because these programs are considered part of the HACCP system and, therefore, must be validated.
2. Establishments may use more than one scientific or technical support document to support the effectiveness of an intervention in its HACCP system.

F. If while reviewing the scientific or technical support, IPP have a concern about a technical aspect of the documentation, they are to contact their supervisor. The following are potential issues IPP may identify and contact their supervisor about:

1. The documentation is for a product that is different than the product that the establishment produces. In general, the establishment should be using scientific or technical support that is related to the product produced or provide support for why research with a different product applies to the product in question. For example, documentation that shows a process achieves a 5-log reduction of *E. coli* O157:H7 in apple cider would not be sufficient scientific support for the reduction of *E. coli* O157:H7 in a beef product without additional justification. In addition, documentation that shows a process achieves a 1-log reduction in *Salmonella* in poultry would not be sufficient scientific support for the reduction of *Salmonella* in beef without additional justification. However, research for an intervention's effectiveness on one species within a slaughter class may be applied to another species within the same slaughter class without additional support (e.g., research for an intervention's effectiveness on beef may be applied to pork without additional support).
2. The documentation is in the form of a No Objection Letter or [FSIS Directive 7120.1 Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products](#), and the establishment does not have additional support demonstrating the effectiveness of the intervention and of all of the critical operational parameters since No Objection letters and [FSIS Directive 7120.1](#) do not contain this information.
3. The documentation contains expert opinion from a processing authority without any reference to scientific principles or peer-reviewed data. The documentation should contain reference to scientific principles or peer-reviewed data in addition to the processing authority's opinion to ensure that the decision is science-based.
4. The documentation specifies the log reduction or prevention achieved by the process but does not include information on the critical operational parameters, such as pH, pressure, contact time, temperature, or relative humidity, critical to achieving that reduction. That information should be included in order for the process to be considered validated, and so that the establishment can implement the process consistent with the support.
5. The establishment's CCPs, prerequisite programs, or other programs do not incorporate the limits described in the supporting documentation, and the establishment does not maintain additional data to support the adequacy of the measures that incorporate different limits. Establishments should be using the same critical operational parameters as those in the scientific or technical support. However, some minor differences are

acceptable, and establishments may be able to provide additional data to support different parameters.

G. When IPP review the records that document initial in-plant validation, they are to verify that the establishment maintains in-plant validation data for the life of the plan.

H. If the establishment does not maintain in-plant validation data, there is noncompliance with [9 CFR 417.4\(a\)\(1\)](#). When determining noncompliance, IPP are to be aware that FSIS does not require establishments to collect in-plant microbiological data provided that the establishment has adequate scientific or technical support, is following the parameters in the scientific or technical support, and has in-plant validation data demonstrating that it can meet the critical parameters during operation.

I. If, while reviewing the in-plant validation data, IPP have a concern about a technical aspect of the documentation, they are to contact their supervisor. The following are potential issues IPP may identify and contact their supervisor about:

1. The in-plant validation data was collected from recent HACCP records or other data already being collected or maintained by the establishment as part of its HACCP system, and the records do not include all critical operational parameters. Establishments that did not keep their original in-plant validation data may have collected data from recent HACCP records, provided the data includes all critical operational parameters, or the establishment provides additional support that all critical operational parameters are being implemented. IPP are to be aware that, although FSIS recommends that establishments gather in-plant validation data at an increased frequency compared to the frequency listed in the HACCP plan or prerequisite program, an establishment can gather in-plant validation data from recent HACCP records or other data it already collects or maintains as part of its HACCP system, provided that it has support for its monitoring procedures and frequencies per 9 CFR 417.5(a)(2), and that there is no evidence that the monitoring procedures and frequencies are insufficient to monitor the critical limits and identify deviations.
2. The documentation contains data for less than one product per HACCP category without support for why less data is sufficient. 9 CFR 417.2(b)(1) contains a list of HACCP processing categories. Establishments may be able to support gathering data for less than one product per HACCP category when products are produced infrequently.
3. The documentation contains data from less than 90 calendar days without support for why less data is sufficient. For large establishments, 90 calendar days equates to approximately 60 production days. For small and very small establishments, 90 calendar days may equate to a minimum level of records from 13 production days. Establishments may be able to provide support for why less than 60 or 13 production days' worth of records is sufficient.

J. IPP are to contact their supervisor for assistance if he or she has any other concerns regarding the establishment's scientific or technical support or in-plant validation data not covered in this notice.

IV. SUPERVISORY RESPONSIBILITIES

A. The supervisor plays a key role in ensuring that decisions made by IPP are consistent with FSIS statutory authority and regulations, and that the IPP's duties are performed in accordance with prescribed inspection methods and procedures addressed in this directive.

B. IPP are instructed in Section III. to seek assistance from their supervisor if he or she has concerns regarding the technical aspect of the scientific support or in-plant validation data. The supervisor's role in addressing IPP concerns and questions is very important. Supervisors are to assist IPP in obtaining answers to their concerns and questions;

C. Supervisors are not expected to know the answer to every question, but they need to assist IPP in getting them to the proper resources, e.g., policy documents, regulations, guidance documents, askFSIS.

D. Once IPP have obtained information from askFSIS or other resources, supervisors are to be actively engaged with IPP in reviewing the information and to assist IPP in their process to make a final decision of compliance or noncompliance.

E. If IPP have concerns about the technical aspects of the scientific support for the hazard analysis or the in-plant validation data, supervisors need to address these questions and concerns. If needed, the supervisor is to seek assistance from the District Office in assigning an EIAO to review the scientific support or in-plant validation data.

V. EIAO RESPONSIBILITIES

A. During an FSA, as instructed in FSIS Directive 5100.1, Chapter V, Section VI, an EIAO is to evaluate whether the establishment has adequate scientific support for the design of its HACCP system (e.g., CCP, prerequisite program, or other program design), and whether in-plant validation data demonstrates that the establishment can implement its system as designed I. The following information supplements the instructions in FSIS Directive 5100.1, Chapter V, Section VII.

B. To determine whether the establishment maintains adequate scientific support for the design of its CCP, prerequisite program, or other program, the EIAO is to evaluate whether:

1. The establishment maintains the scientific and technical support for the design of its HACCP system on-file.
2. The scientific support is complete and contains the methodology and results.
3. The methodology is appropriate for the purpose.
 - a. EIAOs are to be aware that the microbiological data may consist of data for indicator or surrogate organisms (e.g., aerobic plate count, generic *E. coli*, etc.) provided there is sufficient data to establish a relationship between the presence or level of a pathogen or toxin and the indicator organism.
4. The results demonstrate that the establishment's process prevents, reduces, or eliminates the hazard to acceptable levels.
5. The scientific and technical support closely relates to the establishment's actual process, product, and hazard identified in the hazard analysis. If it does not closely relate, the EIAO is to evaluate whether the establishment has support or justification (science-based rationale) for why the scientific support still applies to its process.
 - a. EIAOs are to be aware that establishments can cite Appendix A as support that *E. coli* O157:H7 and *Listeria monocytogenes* are controlled as a result of a thermal (heat) process in addition to *Salmonella*. Although Appendix A was developed based on experiments measuring the effect of thermal processes on

Salmonella, *Salmonella* can be used as an indicator of lethality for other pathogens such as *E. coli* O157:H7 and *Listeria monocytogenes*.

- b. EIAOS are to be aware that there can be significant differences in the efficacy of interventions when applied to carcasses during slaughter and dressing than when applied during further processing. If an establishment is applying an intervention during slaughter but has scientific support for application during further processing, the establishment should have additional support for why that research applies to that process.
6. The establishment incorporates the same critical operating parameters for the process control measure or intervention described in the scientific and technical support into its CCPs, prerequisite programs, and other programs. If it does not, the EIAO is to evaluate whether the establishment provides additional support or justification (science-based rationale) for the adequacy of the process control measures or interventions that *do not* incorporate the same parameters in the scientific or technical references (e.g., higher or lower concentrations of antimicrobials or higher or lower thermal processing temperatures).
- a. EIAOs are to be aware that establishments should use the same critical operational parameters as those in the scientific or technical support. However, some minor differences are acceptable. For example, rounding the storage temperature for raw meat from 44.6°F (the minimum growth temperature for *Salmonella*) to 45°F is suitable because the growth rate of *Salmonella* at 45°F is not significantly different from its growth rate at 44.6°F. On the other hand, rounding may not be suitable for other critical operational parameters such as water activity and pH because minor changes in the values can have a significant impact on pathogen growth.
 - b. In some circumstances, establishments may be able to support using critical operational parameters that are different from those in the scientific or technical support (e.g., higher or lower concentrations of antimicrobials or higher or lower thermal processing temperatures). In these cases, establishments should provide justification supporting that the levels chosen are at least as effective as those in the scientific or technical support.
 - c. An establishment may determine based on its decision-making that some or all of the parameters may need to be monitored on an ongoing basis as part of a CCP or prerequisite program, and that some parameters may only be measured during the initial validation period (e.g., spatial configuration, equipment type to the extent that it affects other parameters, or ingredient formulation provided it does not change). Parameters that are monitored as part of a CCP or prerequisite program are typically included within the critical limit or target value as a minimum or maximum value to be achieved (and not as a range), although some parameters may be observed for presence or absence.

C. To determine whether the establishment maintains adequate in-plant validation data demonstrating that it can implement its CCP, prerequisite program, or other programs, the EIAO is to evaluate whether:

1. The establishment collected in-plant validation data for at least one product from each HACCP processing category.
 - a. EIAOs are to be aware that establishments should collect in-plant data for at least one product from each HACCP process category utilized, although,

depending on the HACCP category and products and the frequency with which they are produced, establishments may be able to support that collecting in-plant data for less than one product within each category is sufficient.

2. The in-plant validation data consists of data demonstrating that the critical operational parameters of the process are being met. The EIAO is to evaluate whether the in-plant validation data also consists of microbiological data when the establishment does not have adequate scientific or technical support, or when it is not following the parameters in the scientific or technical support. If the establishment has adequate scientific or technical support and can demonstrate that it is following the parameters in the scientific or technical support, then in-plant microbiological data is not needed to comply with the initial validation requirements.
 - a. EIAOs are to be aware that, although FSIS recommends establishments gather in-plant validation data at an increased frequency compared to the frequency listed in the HACCP plan or prerequisite program, there is no requirement that an establishment do so.
 - b. Establishments that did not keep their in-plant validation data may have collected data from recent HACCP records or other data already being collected or maintained by the establishment as part of the HACCP system, provided that the establishment has support for its monitoring procedures and frequencies per 9 CFR 417.5(a)(2), and that there is no evidence that the monitoring procedures and frequencies are insufficient to monitor the critical limits and identify deviations.

NOTE: Establishments can continue to produce and ship product into commerce during the 90-day initial validation period with the exception of establishments that are gathering in-plant microbiological data to support that a product is ready-to-eat (RTE) because these establishments do not have support that all potential hazards have been addressed, and that the product would meet the definition of RTE in 9 CFR 430.1 (that it is in a form that is edible without additional preparation to achieve food safety). FSIS expects that very few establishments producing RTE products will need to gather in-plant microbiological data because most establishments that produce these products already have scientific or technical support demonstrating that the products are RTE (e.g., Appendix A). Establishments that will need to gather in-plant microbiological data to support that a product is RTE will likely be only those establishments that producing RTE products that rely on a multi-hurdle lethality (for example, fermentation and drying) where there is limited support available.

3. The establishment collected in-plant validation data for 90 calendar days. In large establishments, 90 calendar days equates to approximately 60 production days. In small and very small establishments, 90 calendar days equates to a minimum level of records from 13 production days.
 - a. EIAOs are to be aware that establishments may have less than 60 or 13 production days' worth of records and be compliance with 9 CFR 417.4(a)(1). For example, some establishments operate seasonally and may not have been able to gather 13 production days' worth of records since the final guidance was issued in May, 2015.
4. The data reflects the process as designed.

5. The establishment analyzed the in-plant validation data (e.g., reviewed records) during the initial validation period to determine whether it supports that the system can be implemented as designed.
 - a. EIAOs are to be aware that the establishment should analyze the in-plant validation data (e.g., review records) during the initial validation period to determine whether it supports that the system can be implemented as designed, and that the HACCP system is effective at preventing or controlling the identified food safety hazards. However, there is no requirement that the establishment conduct a formal analysis.

D. If the EIAO determines that the establishment has inadequate in-plant validation, he or she is to document noncompliance beginning on January 4, 2016 (large establishments), or April 4, 2016 (small and very small establishments). Until then, if the EIAO finds the in-plant validation data inadequate, the EIAO is to continue to note this fact in the FSA but is not to use the lack of in-plant validation data as the only reason for a finding of noncompliance or an enforcement action.

VI. QUESTIONS

Direct all questions regarding this notice to the Risk, Innovations, and Management Staff through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Notice 78-15**
Question Field: Enter question with as much detail as possible.
Product Field: Select **General Inspection Policy** from the drop-down menu.
Category Field: Select **Validation** from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.



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