

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

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# FSIS NOTICE

32-17

6/7/17

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## INSTRUCTIONS FOR VERIFYING VALIDATION REQUIREMENTS DURING PERFORMANCE OF THE HAZARD ANALYSIS VERIFICATION (HAV) TASK

### I. PURPOSE

This notice reissues the instructions in FSIS Notice 78-15 for inspection program personnel (IPP) (Consumer Safety Inspectors [CSIs] and Public Health Veterinarians [PHVs]) to follow 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.

### II. BACKGROUND

A. Each establishment is required to validate the adequacy of its Hazard Analysis and 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 had determined from its verification activities that many establishments had not properly validated their food safety systems. Inadequate validation had led to the production of adulterated product and in some cases even illnesses. In particular, FSIS found that establishments had not 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: Hazard Analysis and Critical Control Points \(HACCP\) Systems Validation](#). FSIS announced the availability of the final version in the [Federal Register](#) on May 14, 2015 (80 Fed. Reg. 27557).

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**DISTRIBUTION:** Electronic

**NOTICE EXPIRES:** 6/1/18

**OPI:** OPPD

E. FSIS began issuing a non-compliance record (NR) or an enforcement action when an establishment lacked in-plant validation data on January 4, 2016 for large establishments and on April 4, 2016 for small and very small establishments.

### III. IPP RESPONSIBILITIES

A. IPP are to follow the instructions in this notice in addition to the methodology in [FSIS Directive 5000.6](#), when performing HAV tasks. The instructions in C - J below replace the instructions in [FSIS Directive 5000.6](#), under Step 7 – Verify Establishment Validation, A-G.

B. Additional information can be found in the HACCP systems validation training materials available at [<https://www.youtube.com/watch?v=O3zDTIb0Rbo&feature=youtu.be>] or by opening the “IPP Help” button.

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 there is noncompliance with [9 CFR 417.5\(a\)\(1\)](#). When determining noncompliance, IPP are to be aware:

1. The establishment must have scientific or technical support for Critical Control Points (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 concerns 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 of mammalian livestock (i.e., cattle, swine, sheep, goats) can be applied to another mammalian livestock species without additional support and research for an intervention's

effectiveness on one species of poultry (i.e., chickens, turkeys, ducks, geese, ratites, and squabs) can be applied to another species of poultry without additional support.

2. The establishment does not have additional support demonstrating the effectiveness of the intervention and all of the critical operational parameters in addition to documentation 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](#) given No Objection letters and [FSIS Directive 7120.1](#) do not contain this information.

**NOTE:** Critical operational parameters are the specific conditions that the intervention or treatment must operate under for effectiveness. Such parameters include, but are not limited to, pH, concentration, time, temperature, humidity, dwell time, water activity, pressure or other equipment settings.

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 critical operational parameters described in the supporting documentation, and the establishment does not maintain additional data to support the adequacy of the measures that incorporate different parameters. Establishments should be using the same critical operational parameters as those in the scientific or technical support. However, some minor differences may be 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 its in-plant validation data for the life of the plan.

**NOTE:** IPP are to be aware that establishments are to maintain the original in-plant validation data for the life of the plan (not just an analysis or summary of the data). In addition, if establishments make changes to the HACCP system and determine as part of reassessment that in-plant validation data should be gathered to demonstrate the modified system is being implemented effectively, that new data is to be kept 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 concerns IPP may identify and contact their supervisor about:

1. The in-plant validation data was collected from HACCP records or other data collected or maintained by the establishment as part of its HACCP system, and the records do not include all critical operational parameters. IPP are to be aware that establishments that did not keep their in-plant validation data from when their HACCP systems were first implemented were given time by FSIS (until January 4, 2016 at large establishments and April 4, 2016 at small and very small establishments) to collect in-plant validation data from HACCP records, provided the data included all critical operational parameters, or the establishment provided additional support that all critical operational parameters are being implemented. An establishment may use data from records generated as part of the HACCP system in place of their original data provided it has support for its monitoring procedures and frequencies per 9 CFR 417.5(a)(2) and there is no evidence that the monitoring procedures and frequencies are insufficient to monitor the critical limits and identify deviations. IPP are also 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.
2. The documentation does not contain data for at least one product per HACCP category and the establishment does not have support for why less data is sufficient. 9 CFR 417.2(b)(1) contains a list of HACCP processing categories. Depending on the HACCP category, products, and the frequency with which they are produced, establishments may be able to support collecting in-plant data for at least one product in some but not all of the HACCP categories used.
3. The documentation contains data from fewer than the total number of production days the establishment operated within its 90 calendar day validation period. 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. IPP are to be aware that establishments may be able to provide support for why gathering records from less days than the total number of production days it operated within a 90 calendar day period is sufficient (e.g., by providing a written justification that explains how the records it did gather demonstrate the system is validated).

**NOTE:** The documentation from small and very small establishments may also contain data from greater than 90 calendar days if a request is granted in writing by the District Office (DO) for additional calendar days to gather records from at least 13 production days.

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 notice.

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 DO in assigning an Enforcement, Investigations, and Analysis Officer (EIAO) to review the scientific support or in-plant validation data.

## V. QUESTIONS

Direct all questions regarding this notice to the Risk, Innovations, and Management Staff through askFSIS at <http://askfsis.custhelp.com> 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 <b>Notice 32-17</b>
Question Field:	Enter question with as much detail as possible.
Product Field:	Select <b>General Inspection Policy</b> from the drop-down menu.
Category Field:	Select <b>Validation</b> from the drop-down menu.
Policy Arena:	Select <b>Domestic (U.S.) Only</b> 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.



Assistant Administrator  
Office of Policy and Program Development