Validating HACCP in Small and Very Small Plants

Cover

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Late last year, USDA's Food Safety and Inspection Service (FSIS) issued a notice providing instructions to FSIS personnel regarding the April 2016 deadline for small and very small establishments to gather validation data. The deadline was originally announced in the final version of the Hazard Analysis and Critical Control Points (HACCP) Systems Validation Federal Register Notice.

KEY DATES:

HACCP System Validation Federal Register Notice	May 14, 2015
FSIS Notice 78-15 Verifying Validation Requirements	December 17, 2015
HACCP Validation Deadline for Small/Very Small Plants	April 4, 2016

Validating HACCP in Small and Very Small Plants

Although HACCP requirements were effective more than 15 years ago, FSIS determined from its verification activities that many establishments did not properly validate their food safety systems. Inadequate validation resulted in the manufacture of adulterated product.

Let's review what's required to validate the adequacy of your establishment's HACCP plan to control the food safety hazards identified in your documentation to comply with 9 CFR 417.4(a)(1).

First, you're required to assemble two types of supporting documentation to demonstrate your HACCP system's validation:

1. The scientific or technical support for the HACCP system **design**. In other words, the design element; and

2. The in-plant implementation (validation) data or the **execution** element.

These two elements are discussed in great detail in the various resources available for small/very small establishments such as the FSIS Compliance Guideline HACCP Systems Validation. Here's a brief overview:

- **Element One**: Scientific or Technical Support (Design)

  » Gather scientific or technical support (e.g., published processing guidelines, journal articles, challenge studies.) for your HACCP system that:

    ○ Closely matches the actual process;

    ○ Shows that your plant's process prevents, reduces or eliminates the hazard identified in the hazard analysis; and

    ○ Identifies the critical operational parameters from the scientific support relevant to your establishment's process.

- **Element Two:** In-Plant Validation Data (Execution)

  » Implement critical operational parameters in the actual production process consistent with the parameters in the scientific or technical support. The establishment should:

    ○ Collect in-plant data demonstrating the effectiveness of the implementation of the critical operational parameters for at least

one product from each HACCP category; and

  ○ Analyze the data to determine whether the critical operational parameters are being implemented effectively.

FSIS personnel began verification for small plants on April 4, 2016. As a small plant owner or operator, you'll want to discuss any concerns you have with the validation process you've put in place as soon as possible during your weekly meetings with FSIS personnel. (Possible concerns are discussed in greater detail in **FSIS Compliance Guideline HACCP Systems Validation 2015** to prevent potential regulatory noncompliance with 9 CFR 417.5(a)(1)(2).)
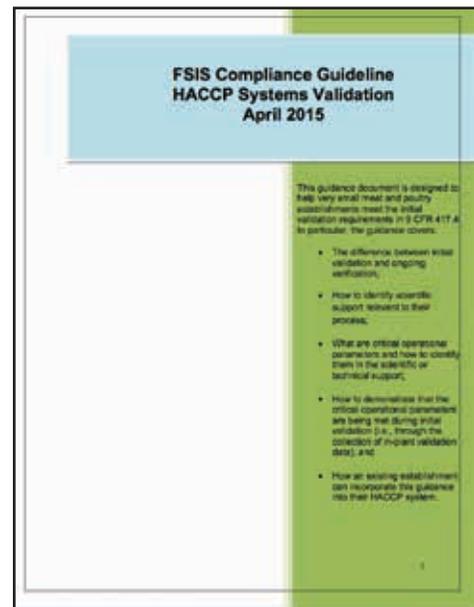
Some of these concerns when reviewing the scientific or technical support may include the following:

- The documentation is for a product that is different than the product that your establishment produces.

- The documentation references FSIS Directive 7120.1 "Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products," but your plant does not have additional support demonstrating the effectiveness of the intervention, if all the critical operational parameters are not contained in the directive.

- The documentation contains expert opinions from a processing authority without reference to scientific principles or peer-reviewed data.

- The documentation specifies the log reduction achieved by the process, but it does not include

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information on the critical informational parameters (e.g., pH, pressure, contact time, relative humidity, temperature) to achieve the reduction.

- Your establishment's Critical Control Points, prerequisite programs, or other programs do not incorporate the critical operating parameters described in the supporting documentation.

Also, potential concerns that might arise during the review of in-plant documentation that you'll want to resolve as soon as possible may include the following to preempt regulatory noncompliance with 9 CFR 417.4(a)(1):

- The documentation contains data for less than one product per HACCP category without support for why less data are sufficient. 9 CFR 417.2(b)(1) contains a list of HACCP processing categories.

- The documentation contains data from less than 90 calendar days without support for why less data are sufficient. For small and very small establishments, 90 calendar days may equate to a minimum level of records from 13 production days for HACCP categories that are infrequently utilized. Establishments may be able to provide scientific or statistical support for why less than 60 (large) or 13 production days' worth of records is sufficient.

- The in-plant validation data were collected from recent HACCP records or other data already being collected or were maintained by the establishment as part of its HACCP system, and the records do not include all critical operational parameters. 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.

The validation verification process began for large establishments as of January 4, 2016, and for small/very small establishments as of April 4, 2016.

Resources mentioned in this overview are listed below to provide further guidance and clarification. For additional guidance, you may contact the Risk, Innovations and Management Staff (RIMS) at (800) 233-3935 or submit a question through askFSIS at http://askfsis.custhelp.com/ under the "General Inspection Policy, Validation" category.

HACCP Systems Validation Web Resources

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

FSIS Compliance Guideline HACCP Systems Validation 2015: *http://www.fsis.usda.gov/wps/wcm/connect/ a70bb780-e1ff-4a35-9a9a-3fb40c8fe584/HACCP_Systems_Validation.pdf?MOD=AJPERES*

FSIS Notice 78-15 Verifying Validation Requirements: *http://www.fsis.usda.gov/wps/wcm/connect/0e2e04cb-2f4a-414c-8b81-b17236aab25c/78-15.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=0e2e04cb-2f4a-414c-8b81-b17236aab25c*

HACCP Systems Validation Federal Register Notice: *http://www.fsis.usda.gov/wps/wcm/connect/3ba826ec-6e79-4f17-85fc-29200f4e8d05/2009-0019-2015.pdf?MOD=AJPERES*

Commonly Asked Questions & Answers

Q: If I find a noncompliance and take appropriate corrective actions, would inspection program personnel also complete a noncompliance record (NR)?

A: No. If the establishment finds noncompliance and brings itself into compliance with the regulatory requirements, inspection program personnel verify compliance with the regulations and are not to issue an NR unless regulatory noncompliance exists.

Q: Do I have to respond in writing to an NR?

A: The establishment is not required to respond in writing to an NR. However, doing so may assist the establishment by creating a written record. When inspection program personnel document noncompliance, the establishment must comply with regulatory requirements by correcting the noncompliance or contesting the validity of the finding of noncompliance on the NR. In some situations, the establishment response will include documenting the corrective actions in the establishment Sanitation Standard Operating Procedure (SSOP) or HACCP records.