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Inside this issue:

FSIS Draft Guidance on Validation—Comments Needed	1
FSIS Proposed Rule: Notification, Documentation & Reassessment	3
FSIS Labeling Matters	4
Product Trace Back for <i>E. coli</i> O157:H7	5
FSIS Releases New <i>Salmonella</i> & <i>Campylobacter</i> Performance Standards	6



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FSIS Draft Guidance on Validation — Comments Needed

FSIS released a draft guidance document entitled, “*Guidance for HACCP System Validation.*” Validation requirements can have a significant impact on every establishment. Those operating under inspection need to review this draft guidance, and other related documents released by FSIS to understand the agency’s current thinking; and to comment with suggestions, improvements, or questions.

To facilitate communication, FSIS has developed a useful web page dedicated to validation. Beyond providing a summary of validation, the page includes links to: the draft guidance; correspondence with all major meat and poultry trade associations on validation guidelines; and a validation “Fact Sheet.” The web page can be found at:

http://www.fsis.usda.gov/Science/HACCP_Validation/index.asp

Comments will be accepted until June 19, 2010. Comments can be filed electronically at DraftValidationGuideComments@fsis.usda.gov, or by mail to the Docket Clerk, USDA, FSIS, George Washington Carver Center, Room 2-2127, 5601 Sunnyside Ave., Beltsville, MD 20705.

Elements of Validation

Under the HACCP regulations, each establishment must demonstrate (validate) that its HACCP plan is adequately controlling food safety hazards, 9 CFR § 417.4(a). In the 1996 regulation preamble, FSIS stated that there are two elements of validation: (1) scientific support that the process will adequately address the specified hazards and (2) “*in-plant observations, measurements, test results, or other information demonstrating that the control measures*” are followed by the establishment. 61 Fed. Reg. 38,826, col. 3 (July 25, 1996) (emphasis added). In other words, a plant should have scientific support for its HACCP plan, and demonstrate that the plan is effective when implemented in its facility.

The agency’s current thinking on the second element – in-plant validation – has been the topic of some concern since the release of the Draft.

(Continued on Page 2)

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Dennis R. Johnson
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FSIS Draft Guidance on Validation — Comments Needed (cont’d)

- Continued from Page 1

Existing Requirements for In-Plant Validation

FSIS first articulated its expectations for in-plant validation in the 1996 preamble. For well-recognized processes, *“it is not necessary”* for any research effort as part of the validation process. However, *“an establishment introducing a new technology, applying standard technology in an unusual way, or lacking experience with a technology, would have to undertake more extensive in-plant validation of its plan. . . .”*

In short, if a process is well-recognized, an establishment need not conduct micro-testing; it can validate with *“in-plant observations, measurements, test results or other information.”* For example, a plant using Appendix A as the scientific support for its cooking process could validate by taking temperature measurements to demonstrate that it consistently meets these temperatures in its operation.

If an establishment is implementing a “new” technology (new in terms: of historical use, new application, or new to the plant), more robust support would be required; and that may include micro-testing.

In-Plant Validation Under the Guidelines

There has been some confusion as to whether the Draft Guidelines mandate micro-testing for in-plant validation in all cases. As FSIS admitted in its Fact Sheet: *“The draft guidance material on validation has caused a fair amount of concern.”*

The Draft Guidelines can be read to imply that micro-testing is required for in-plant validation. To address any confusion, FSIS developed and disseminated its “Fact Sheet.” In the Fact Sheet, FSIS clarified that for well established processes, such as Appendix A, no micro-testing would be required. The establishment need only *“have verification records that establish that it consistently meets the parameters specified in the document upon which it relies for scientific support.”*

There was also confusion as to whether validation would be needed for each and every HACCP plan — a cause for concern at establishments with dozens or more individual HACCP plans. The Fact Sheet noted that: *“Establishments need to validate one plan per HACCP category.”*

Although the Fact Sheet did address many of the specific concerns, given the continuing potential for confusion (and that the Fact Sheet is not expressly contained in the Guidance itself), each company needs to review all the validation documents very carefully to determine how it will impact its business; and to submit comments, including suggestions for a better Guidance, such as express inclusion of the positions clearly articulated in the Fact Sheet.

Going Forward

After reviewing the comments, FSIS intends to issue a *Federal Register* Notice on validation and announce the final guidance and a Directive for in-plant inspectors.

