

Validation –The Guidance; Next Steps

Philip S. Derfler

Assistant Administrator

Office of Policy and Program Development

USDA/FSIS

Validation

Validation is required in HACCP regulations, 9 CFR 417.4(a)(1). FSIS is not imposing any new requirements.

What is “Validation?”

That element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the relevant hazards.

Validation

Thus, appropriate validation is essential if an establishment is to have a successful HACCP program.

Guidance document

FSIS prepared guidance document because it determined that validation needs greater attention in FSIS verification activities.

Purpose of guidance document was to ensure that establishments had as good an understanding of what the validation requirement entails as possible.

Validation has two aspects:

- Scientifically demonstrate that HACCP system is designed to address effectively the relevant hazards
- In-plant observations, measurements, and evaluations, or scientific studies, to demonstrate that system will function as designed

Guidance document addresses each of these aspects of validation

Important factors about guidance document:

1. It has been out since March 19
2. It is a draft. We made it available informally to obtain advance input, so that final product will be as useful as possible
3. We made the document publically available through Constituent Update. However, to ensure that all very small plants are aware of draft and have an opportunity to comment on it, we mailed the draft directly to all establishments in our inventory

Guidance document

1. Reviews types of scientific supporting documentation that can be used
2. Talks about types of observational data and in-plant measurements that can be used
3. Discusses microbiological testing that could be done to demonstrate effectiveness of HACCP system
4. Sets out examples of types of documentation that can be used as validation for raw and processed product

Guidance document

- Opportunity to comment closes June 19. We have already received approximately 2000 comments.
- Because we made the document available informally, comments have not come in through regulations.gov. Comments have come in by mail and e-mail. We are doing the best we can to post the comments. They can be viewed at http://www.fsis.usda.gov/PDF/HACCP_Validation_Ltrs.pdf

Guidance document

Some key concerns about the draft guidance document became apparent almost immediately, and we have done our best to address them through a fact sheet that we sent out with the mailing of the draft guidance.

Key Concern:

Does an establishment have to validate
each of its HACCP plans?

No. Establishments need to validate one plan per HACCP
category

Key Concern

Can establishments continue to rely on Appendix A and B as part of the validation of their HACCP programs?

Yes. Establishments can rely on these and similar documents to meet the first aspect of validation. These documents are well-accepted. The Agency is not looking for establishments to do testing to validate these documents.

Key Concern

If an establishment relies on Appendix A, for example, what does it need to do to satisfy the second aspect of validation?

An establishment needs to have verification records that establish that it consistently meets the parameters specified in the document upon which it relies for scientific support. To rely on Appendix A, for example, the establishment would need to have records that demonstrate that its process is achieving the critical parameters (e.g., dwell time, humidity) identified in Appendix A.

Key Concern

Do plants have to do microbiological studies?

No. No one needs to do a study. If a plant, for example, is using an FSIS guidance document that suggests a certain time/temperature combination to address a particular pathogen, and the plant has records that show that it is meeting those times and temperatures, it has done everything that it needs to do to validate its HACCP plan. Of course, an establishment may decide that the best way to validate its plan is to do a study, but the Agency is not requiring establishments to do so.

Going forward

Comments have raised concerns about the guidance but what comments do not do is provide input on what information needs to be included in the guidance to make it as useful as possible to small and very small plants.

Would it be useful for FSIS to provide guidance on:

- Identifying critical parameters of HACCP system?
- How to gather data to show critical parameters are being met?
- How to gather data to show that a process or intervention achieves the intended results?

Next Steps

- Once comment period closes, we will analyze comments we received
- Try to identify changes needed to guidance to make it as useful a document as possible
- Significant rewrite of document likely

Next Steps

- Document is obviously significant guidance
- Will be reviewed by the Office of Management and Budget
- Availability announced in Federal Register
- Additional comment period
- Likely there will be public meetings

Next Steps

When guidance document is ready, FSIS will announce its availability and describe its enforcement strategy for validation