FSIS Fact Sheet: Validation

The draft guidance material on validation has caused a fair amount of concern. We believe that it will help everyone if we put to rest some of the misconceptions about the Agency's expectations. With these concerns addressed, everyone will be able to focus on the issue at hand: what establishments will need to do to demonstrate that their HACCP system will function as designed and will result in the production of safe and wholesome products. If interested persons provide comments that focus on the problems that establishments have had in attempting to validate their HACCP system and on the aspects of the draft guidance document that are most troubling and confusing, the usefulness and clarity of the guidance that results from this process will be maximized.

What is validation?

Validation is the process of collecting scientific and technical information to establish that a HACCP system, when properly implemented, will effectively prevent or control the relevant hazards. The HACCP regulations require that there be two aspects to validation—scientifically demonstrating that the HACCP system is designed to address effectively the relevant hazards, and that the system will function as designed.

Can I use appendix A, B and the Tompkins publication as part of the validation of my HACCP program? Do I need to do a study to validate these documents?

Yes, you can rely on these and similar papers to meet the first aspect of validation, to demonstrate that the system has been scientifically designed to address the identified hazard. It is not necessary to do testing to establish that the processing parameters specified in these documents will produce safe product. These documents are well-accepted. To meet 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. Thus, if an establishment, for example, uses a certain time/temperature combination specified in Appendix A to address a particular pathogen, and the establishment has records that show that it regularly meets the specified time and temperature, it has done what it needs to do to validate its HACCP plan.

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

No. Establishments need to validate one plan per HACCP category.

Do plants have to do microbiological studies?

No. The Agency made clear that no one needs to do a study. We have stated that 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.

What are the next steps?

The Agency will revise the draft guidance document based on its review of the comments that it receives. Because this is significant guidance, the Agency will then publish a notice of the availability of the revised document in the Federal Register for a second round of comments.

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