

NACMPI HACCP Systems Validation Sub-Committee

Question 1:

What innovative strategies can the Agency utilize to help establishment personnel identify critical operating parameters and then determine where in the HACCP system it is appropriate to ensure implementation?

Comments: The subcommittee recommends that the FSIS clearly and concisely explain the difference between validation and verification and include this discussion in all materials, with representative samples, to be made available to all stakeholders, including the public and processors.

PREAMBLE:

The committee appreciates the revisions made to the second version of the guidance document; it is significantly improved.

The committee recommends that this guidance and validation standards be applied equally to all establishments.

The committee recognizes the unique needs of small and very small establishments, and recommends that additional resources be developed to assist them in meeting validation requirements. Development of these resources should be prioritized based on public health risk.

In accordance with FSIS' Strategic Plan, Goals 4 and 7, the Subcommittee submits the following recommendations:

- FSIS should identify and broadly share the top priorities (categories, processes, etc.) in which there are validation problems that resulted in documented and confirmed food safety issues;
- To the extent that FSIS has not done so, the Agency should adopt a phase-in, risk-based approach of the new validation guidelines in normal HACCP re-assessments;
- FSIS should encourage and support the creation of a consortium of scientists, processors, academics/extension specialists, consumer organizations, trade organizations, regulatory / government officials, and NGOs to focus on validation principles;
 - The committee strongly recommends that the consortium activities be linked with other initiatives (FSIS HACCP Coordinator monthly calls, as an example) and utilize or review existing guidance documents developed by governmental agencies, industry, extension, and other NGOs, as a starting point.

- In collaboration with the consortium, develop a tool kit containing educational, training, and outreach materials that address the identified priority issues and supports diverse learning styles (e.g., diagram, pictures, listing, narratives, and audio-visual);
- Pilot test the tool kit by establishments of all sizes in various geographical areas;
- Require FSIS review consortium recommended materials and activities and provide feedback to NACMPI with a regular progress report; and
- Congress should provide funding to support the consortium and its activities.

Question 2

The Agency realizes that often establishments produce a wide variety of products within one HACCP category and it may be impractical and unnecessary to gather in-plant data as part of initial validation for all products. The Agency on P. 14 of the guidance has described a set of principles when making those decisions with some examples. Does the committee have additional suggestions as to how the Agency can better describe this important concept?

RECOMMENDATION: The principles identified in the guidance are a good starting point but would be strengthened by providing additional specific examples of strategies for efficiently and safely grouping product categories for the purpose of validation. Keeping the needs of small and very small processors in mind, the goal should be to provide sufficient practical examples to illustrate how:

1. Typical products can be grouped into a workable number of product categories, and
2. “Worst case” products within a grouping can be selected for validation purposes.

In the case of atypical products and/or extenuating circumstances, FSIS HQ would need to provide additional validation guidance on a case-by-case basis.

Question 3

What innovative strategies can the Agency use to help industry and FSIS inspection better understand the concepts of HACCP systems validation to improve food safety upon release of this document?

RECOMMENDATION: See recommendations in Question #1.