



# Capitol LINE-UP

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## ***Draft Validation Guidance Comment Period Ends June 19, 2010***

On June 14, 2010, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) held a public meeting to gather input on new draft validation guidance. The meeting seemed to be expedited because the press release of the meeting was published only ten days prior to the actual meeting date.

Within the press release, it was announced that the June 14<sup>th</sup> public meeting was the first meeting in a series of meetings that will occur regarding the validation of HACCP systems issue. Comments on the preliminary draft guidance are still due **June 19, 2010**. FSIS will review the public comments on the preliminary guidance, and expects to then announce an updated draft document in the *Federal Register* in July, 2010, for a second round of comments. As part of the second comment period, FSIS will hold two additional public meetings. FSIS will provide information on the second and third public meetings once they are finalized.

AAMP participated in the public meeting. Other individuals representing FSIS, consumer groups, meat trade publications, and meat and poultry trade organizations attended the meeting. During the meeting, Agency representatives had presentations on how the validation developed and the guidance, implementation, and issues for future discussion. The Agency acknowledged that the validation guidance information had caused confusion, but they continued to repeat the rhetoric that the guidance does not establish any new requirements for establishments and microbiological testing is not a "requirement." For a document created to provide clarification of the Agency's expectations, it has definitely caused more confusion and frustration about the validation issue. Throughout the public meeting, detailed questions about the validation guidance remained unanswered. FSIS officials did say that, based on comments already received, there would be "significant changes" to the validation policy clarifications.

Over the years, the meat industry has learned that "guidelines" quickly become minimal Agency "expectations," and in the absence of any other supporting documents available to present to FSIS (*which in some cases, none exist*), microbial sampling data may be the only data that will satisfy those expectations. Currently, the validation guidance specifically states that the "establishments would need to provide support in instances where they believe microbiological testing data is not needed to demonstrate the effectiveness of the HACCP system in controlling biological food safety hazards." This simply means that if establishments chose not to perform microbiological testing, decision-making documents would need to be provided. Most likely, these documents don't exist and establishments would end up being required to perform microbiological testing.

For years, the meat industry has utilized scientific supporting documentation to support decisions made within HACCP food safety systems. Another major concern brought up during the public meeting was in regards to the statement made within the guidance document that, in order for an establishment "to provide adequate validation, the study needs to **relate closely to the process with regards to species, product, characteristics, and equipment**." This and other associated statements are very concerning because supporting documents very rarely "relate closely to the process with regards to species, product, characteristics, and equipment." Therefore, microbial sampling testing and/or data may be inadvertently required to satisfy the Agency's expectations of validation.

FSIS has already received approximately 2,000 comments on the draft validation guidelines. Have they received yours yet? Throughout the meeting, the FSIS officials sincerely requested that all interested stakeholders submit constructive comments and ideas of how establishments can more readily accomplish the two distinct elements of FSIS's reinterpretation of validation: 1) the scientific or technical support for the HACCP system and 2) the initial practical in-plant demonstration proving the HACCP system can perform as expected.

### ***HACCP SYSTEM VALIDATION COMMENTS DUE ON JUNE 19, 2010!***

***If you have not read the information regarding HACCP system validation and submitted comments, it is strongly recommended that you do so. Submit your comments by June 19, 2010.***