



If it affects you or the meat industry, you'll read about it in the...

AAMPALIFIER

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Validation Discussed At NACMPI Meeting

On September 22-23, 2011, the National Advisory Committee on Meat and Poultry Inspection (NACMPI) held a public meeting in Washington, D.C. Pre-harvest intervention was one of the topics discussed (see Capitol Line-Up – October 1, 2011, edition), and validation was the other topic discussed. Ironically, the meeting date occurred exactly two years after a hand-delivered letter was given to Al Almanza, administrator of the Food Safety and Inspection Service (FSIS), regarding the issue. Since information regarding the validation issue has remained somewhat unknown since the comment period for the first draft ended on June 19, 2010, AAMP attended the meeting to listen to any new information.

It is AAMP's understanding that the NACMPI members received the information for the meeting, including the second draft version of the validation guidance, approximately one week prior to the meeting so they had time to review the information. At the meeting, the second draft version of the validation guidance was publicly released. It is obvious that FSIS took the meat industry's comments seriously because they put forth effort to make significant clarifications to the validation issue and revisions to the previous validation guidance document.

With that being stated, AAMP still has significant concern regarding this validation issue. Readers must first step back and get past the idea that FSIS is making inferred comments that the meat and poultry industry has been operating for years illegally after the Agency has granted the mark of inspection to these establishments. Basically, if the meat industry never provided evidence of "validation" through the first 90 days after HACCP was initiated in establishments, they should have never been given the USDA grant of inspection after that probationary time. Yet, after the 90 day period, USDA made the symbolic determination to provide establishments with the USDA grant of inspection...ergo...the establishment's "validation" was acceptable and complete.

Since this issue first arose years ago, AAMP has continued to ask FSIS the question of where they have identified a systemic failure of the HACCP system and what specific evidence of problems exist in all establishments that makes this validation issue so crucial to address in the way it is currently being handled by FSIS. In fact, a member of the NACMPI group asked a very similar question of FSIS and it garnered a less than specific response. The NACMPI group seemed to recognized this point and it assisted the committee to develop the recommendation that the meat industry's and Agency's efforts be focused to resolve areas of concern. If a focused approach is not taken, the validation may be so overwhelming that it won't have a positive impact on food safety, even with the areas of greatest concern.

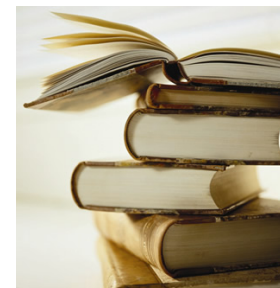
The basic premise of the validation guidance is that establishments should reevaluate their HACCP System Design and their HACCP System Execution. On its face value, these tasks don't seem difficult to perform, but known historical inconsistency with inspection personnel interpretation is most likely going to be the stumbling block.

HACCP System Design

- Identify documentation that properly relates to the establishments' current processes
- Identify the critical operating parameters in the supporting documents necessary for the intervention to function as intended

HACCP System Execution

- Translate those critical operating parameters into the HACCP systems
- Provide documentation demonstrating that they have validated their HACCP systems under actual in-plant conditions



Validation Discussed At NACMPI Meeting (*Continued*)

AAMP does acknowledge the obvious and pertinent need for establishments to identify critical control points and have functional prerequisite programs that are based on appropriate scientific supporting documents. Furthermore, there is a need to ensure those documents are similar to the processes, pathogens of concern, and critical parameters in the HACCP plan. Note, the word "similar" was used...not the word "same" because processes, formulations, equipment, etc. identified in scientific supporting documentation is many times not the "same" as implemented at the establishment level. It is next to impossible to "mirror" everything identified in supporting documentation, and most scientific documents are very detailed so they can pass the scrutiny of the peer review process. This issue may have been addressed in the validation guidance because it states, "Care should be taken to ensure that the scientific support documents are **sufficiently related** to the process, product, and hazard identified in the hazard analysis." In another section of the document they state, "the study [identified within a scientific article from a peer-reviewed journal] should **relate closely** to the establishment's process with regards to species, product characteristics, and equipment. Unfortunately, since there is no stringent detail to define "sufficient relation," the FSIS field interpretation may cause enormous controversy, debate, and problems for the industry.

One of the biggest issues during the NACMPI sub-committee discussion regarding validation was the identification of the critical operating parameters in the scientific support. The NACMPI group discussed who exactly was going to be the person that identifies these "critical operating parameters." It is important for the Agency to recognize that meat processors are not scientists and meat processing establishments are not meat science laboratories. Meat processors are extremely good at their jobs and food safety is a major concern of these establishments; but as the Agency understands, scientific documents are very detailed and complex, and may not be well understood. AAMP believes the Agency has similar struggles in regards to their inspection staff (*including EIAOs*) with understanding these scientific documents as well. Since the validation guidance document relies heavily on the identification of "critical parameters," AAMP believes this will be a continual debate, if there is not some structured third party that identifies these "critical parameters" that the industry can rely on and be recognized as acceptable by the Agency. In many cases, if it is left to interpretation, massive debate and confusion will ensue.

Take for example the use of FSIS Appendix A (*Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products*), which is a very common document used to justify the critical control point of thermal processing. Within that document, most individuals would recognize the critical parameters are temperature (or temperature/time relationship), relative humidity, and dwell times. In other scientific supporting documentation, research may measure a variety of factors throughout the research project. Most likely, not all factors identified within the scientific supporting document are critical to the effectiveness of the intervention. Who is supposed to make this determination...the meat processor...the inspection personnel...the EIAO? To address this issue, the NACMPI recommended the formation of a consortium made up of microbiologists, university extension, meat industry, meat trade associations, and Agency representatives.

At the conclusion of the NACMPI meeting, AAMP made public comments on behalf of the membership. AAMP is still concerned with the release of the validation guidance document. Now that the second version is released, the meat industry now has the ability to have an educated and continued discussion regarding the topic. AAMP's hope is that the discussions continue and the recommendations of the NACMPI be considered to make the validation guidance as useful as possible to the meat industry. The current draft validation document clearly identifies that, when it is released as a Federal Register Notice, the clock starts and the very small and small meat industry (*which is approximately 95% of the meat industry under federal inspection*) has 9 months to comply with the expectations outlined in the guidance document. It took us two years to get to this point, which should display the complexity of the issue, so AAMP believes the Agency shouldn't rush to publish the document. It may not ever be perfect, but Agency guidance is often manipulated and imposed as regulatory expectations. AAMP believes the Agency should make the best attempt to limit the confusion with this issue as much as possible....with both the meat industry as well as with the inspection personnel tasked with regulating the meat industry.

AAMP will continue to analyze the validation guidance document and keep you informed of the issue. If you would like to review the most recent version of the validation guidance document, visit AAMP's website at www.aamp.com or specifically visit www.aamp.com/Validation.php for information regarding the validation issue.