



June 18, 2010

Docket Clerk
United States Department of Agriculture
Food Safety and Inspection Service
Room 2-2127 George Washington Carver Center
5601 Sunnyside Avenue Mailstop 5474
Beltsville, Maryland 20705-5474

Re: Comment on Draft Guidance: HACCP Systems Validation

To Whom It May Concern:

Formed in 1906, the American Meat Institute (AMI) is the nation's oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat products. AMI members manufacture more than 90 percent of these products. Also, approximately 80 percent of AMI member companies are classified as small or very small according to Small Business Administration standards. AMI members continue to adopt food safety practices to produce meat products, which are safe, affordable, and available. The safety of the products AMI members produce is their top priority.

AMI appreciates the opportunity to comment on the Food Safety and Inspection Service's (FSIS or the agency) *Draft Guidance: HACCP Systems Validation* (the Guidance). This sharing of information strengthens the partnership between industry and government in producing safe meat and poultry products. This process is an opportunity for the meat and poultry industry to provide meaningful feedback so regulations can be implemented with clarity; resulting in timely and cost effective policy changes.

Since making the Guidance available, the agency has issued a validation fact sheet¹, and created a central location for processors to find validation information that was previously scattered throughout multiple locations on the FSIS website. AMI commends FSIS for creating this centralized information site because it will facilitate the ability of the agency's constituents to locate information regarding validating HACCP plans.

The agency also stated that the Guidance is being created to help establishments understand the regulatory requirements, but is not intended to impose new testing or microbiological requirements on establishments.² AMI also applauds this premise of not imposing new testing or microbiological requirements on establishments.

¹ Factsheet Validation: http://www.fsis.usda.gov/PDF/HACCP_Validation_Fact_Sheet.pdf.

² USDA Press Release Number 0304.10, June 4, 2010

In response to the FSIS's request for comments regarding the Guidance, AMI submits the following comments, first addressing concerns and then suggesting opportunities to improve the Guidance.

Draft Guidance: HACCP Systems Validation Is Inconsistent With the HACCP Rule

Many statements included in the Guidance do not align with 9 CFR 417.4 of regulations, *Validation, Verification and Reassessment*. The regulation provides that an establishment shall repeatedly test the adequacy of the Critical Control Point (CCP), critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records routinely generated by the HACCP system, in the context of other validation activities. The remainder of the language within 9 CFR 417.4 addresses the ongoing verification activities, reassessment of the HACCP plan and reassessment of the hazard analysis that must be performed by the establishment.

Specifically, the preamble to the Final Rule provides, in pertinent part, “(2) in-plant observations, measurements, test results, or other HACCP information demonstrating that the control measures, as written into a HACCP plan, can be *operated* within a particular establishment to achieve the intended *food safety objective*.”³ The Guidance, however, takes liberties with this statement by instead stating, “or other information demonstrating that the control measures as written into a HACCP system, can be *implemented* within a particular establishment to achieve the process's *intended result*.”⁴ This distinction is significant and AMI questions the logic and propriety of deviating from the language in the HACCP Final Rule.

A simplistic, but accurate, description of validation can be summarized by asking – “Is the HACCP system functioning as intended?” The definition of validation in the Guidance focuses on the effectiveness of the establishment's HACCP system and the prescriptive use of, in effect, mandatory microbiological testing. It is quite clear that the Guidance continues to advance the perspective that increased microbiological testing of finished products, as well as testing throughout the production process, will produce a safer product. That approach, however, ultimately is a misdirection of the establishment's HACCP plan and does not embrace the theory of HACCP as defined in the Final Rule. Improvements to food safety and public health are not a function of more microbial testing. Other means, such as physical and chemical attribute monitoring, which are consistent with the focus of FSIS, are more timely and effective ways to demonstrate that the in-plant validation is being accurately and effectively implemented.

Although the Guidance provides instruction with respect to the agency's definition of the two parts of validation, *i.e.* the scientific support and initial validation, at issue is the specific reference throughout the Guidance to microbiological testing as a means of demonstrating the effectiveness of the plant's HACCP system. For example, the Guidance states, “the data from microbiological testing at various points throughout the HACCP system to ensure the multiple hurdle design of its entire HACCP system will result in the production of safe, unadulterated products.”⁵ The Guidance also states, “Establishments would need to provide support in

³ 61 *Fed. Reg.* 38826, col. 3 (July 25, 1996.)

⁴ Draft Guidance: HACCP Systems Validation, page 4

⁵ Draft Guidance: HACCP Systems Validation, page 6

instances where they believe microbiological testing data is not needed to demonstrate the effectiveness of the HACCP system in controlling biological food safety hazards.”

Fundamentally, HACCP is a systematic approach to food safety consisting of seven principles. Validation, which is part of the verification principle of HACCP, is a component of HACCP and not the only point in the process that will eliminate food safety hazards.

The Guidance Does Not Provide Basic Clarification of the Validation Definition, But Instead Creates Many Questions

Although the intent of the Guidance is to assist establishments, in particular low volume production plants, in meeting validation requirements as defined in 9 CFR 417.4, the Guidance falls short of this goal. Instead, the Guidance has created confusion and raised many questions that must be addressed in order for it to become a realistic and useful tool for the meat and poultry industry.

The agency has asserted that there is a widespread lack of understanding of validation and contends that food safety problems have occurred as a result. The mandatory HACCP system for meat and poultry establishments, however, has been in place for more than 12 years and such sweeping generalizations are a disservice to the industry and the agency. In that regard, such statements could create issues with trading partners and hurt consumer confidence in the FSIS food safety system. More likely, sporadic incidents have demonstrated that some establishments, such as establishments undergoing a ‘for cause’ Food Safety Assessments, may not fully understand the HACCP final rule definition of validation and verification but the vast majority of establishments have properly interpreted and applied the validation requirements in the Final Rule.

A more appropriate approach would be to focus resources on training and outreach, with accountability measures in place to assure all involved with the HACCP system, including establishments and federal inspectors, are engaged. Such actions have clear food safety improvement outcomes.

The Guidance also raises the question of whether validation concerns are a design issue or an implementation issue. In that regard, AMI strongly encourages the agency to consider these questions as the Guidance is finalized.

1. Throughout the Guidance, reference is made to sampling that is “statistically representative” of the HACCP systems. The Guidance provides that a mandatory generic *Escherichia coli* testing sampling program is designed for use in slaughter establishments and is referred to as a sampling tool. Ironically, there is no sampling guidance for packaged further-processed meat and poultry products prompting one to ask, Why is there such a discrepancy?
2. The preamble to the HACCP Final Rule addresses multiple means to demonstrate that the HACCP system is validated. The Final Rule provides,

This means that the data used to validate a HACCP plan may be derived from various sources, including the scientific literature, product testing

results, experimental research results, scientifically based regulatory requirements, FSIS guidelines, computer-modeling programs and data developed on factors such as the nature of the hazard and the control measures chosen to address it.⁶

The content of the Guidance is overwhelmingly focused on microbial testing of the incoming supply and finished product, prompting the question of whether the examples cited in the preamble to the Final Rule are now not applicable? To that end, safe harbors that have been historically acceptable should continue to be used by establishments.⁷

3. Attachment 3 to the Guidance, *Comparison of APC, Generic E. coli Levels and Presence of E. coli O157:H7 in Dehided Carcasses and Post Interventions Treated Carcasses*, demonstrates a relationship between the indicator organisms. However, as stated, these are *hypothetical results data*. Having hypothetical data in a compliance guide adds no value to the document or to establishments using the guide.⁸
4. The suggested time to complete an initial validation referenced in the document could be confusing. Page nine provides for 90 days, which could be interpreted to mean 90 production days. Page 10, however, states 90 calendar days, which equates to 60 production days. Which is correct?
5. The intent of a compliance guide is to aid establishments in meeting the regulatory requirements. The Guidance states, in three instances, “Failure to take steps will raise questions whether the HACCP system has been adequately validated.” To some establishments seeking guidance this is, in fact, regulatory in nature. The Guidance refers to validation and sampling examples found in the attachments to the guide. However, there is no further guidance on sampling methods. Many small and very small businesses may not know how to obtain these reference documents and the cost could be prohibitive.
6. The Guidance states that the validation process should also be implemented in the establishment as described in the supporting documentation.⁹ This statement, however, could be taken out of context and establishments could be required to use the same brand of equipment used in the supporting documentation.

The Implication of a Positive Sample Is an Indication of Improper Validation And Indicator Organisms Are Not Supportive of Process Control

The Guidance states

Testing for levels of both indicator organisms and presence/absence of the identified hazard is essential to ensure that not only is the establishment’s

⁶ 61 *Fed. Reg.* 38826 (July 25, 1996).

⁷ FSIS Validation factsheet has addressed this topic. AMI encourages the inclusion of the factsheet information in the revised compliance guide on validation.

⁸ Attachment 3 ‘CCP3: Carcass to be at a temperature of <45 degrees C within 24 hours of slaughter’ ‘This should be F instead on C. In addition, it should be stated if this is surface temperature or internal temperature.

⁹ Draft Guidance: HACCP Systems Validation, page 2

HACCP system (*i.e.* sum of all interventions) achieving the specific log reduction as described in that hazard analysis (indicated by indicator organism counts), but also that the interventions are successful at controlling the pathogens of interest to below detectable levels for adulterants or to acceptable levels for other raw processes. Any positive sample for an adulterant would be an indication that the process is either not being implemented properly (compare data with critical parameter measurements), or that the process is inadequate.¹⁰

Unclear from this statement is whether it refers to testing during the initial validation or during the routine verification testing. This issue needs further clarification by the agency. In the case of routine verification tests, the current corrective action measures in the HACCP plan should remain in place and not be affected by the Guidance.

Furthermore, the comments referenced in *Jay's Modern Food Microbiology*¹¹ are not from the most recent edition. The latest version of the text says, "has a historical association with the pathogen of concern is always found" whereas the Guidance says, "has a historical association with the pathogen of concern is usually found." This difference is significant considering the fact that the use of microbial indicator organisms for pathogenic bacteria is not as reliable as implied in the Guidance. Many microbiological experts agree that indicator organisms are not comparable to *E. coli* O157:H7 in the commercial processing environment; therefore the premise of microbiological testing inherent in the Guidance is flawed. AMI believes validation by monitoring of operating parameters is preferred.

Suggested Improvements To The Draft Validation Guide

Virginia N. Scott in *Food Control* (2005) entitled, *How does industry validate elements of HACCP plans?*¹² stated that verification and validation are often confused in part because validation is a component of verification. Scott noted there are times where there is not a clear distinction between verification and validation. Expanding on this concept, validation, verification, and also reassessment steps are all important parts of an effective HACCP system. The Guidance creates a potential for misunderstanding the principles in 9 CFR 417.4.

To do justice to the HACCP system, further education is needed on these three crucial areas-verification, validation and reassessment. AMI offers to work with the agency to develop an education program that addresses the agency's concern pertaining not only to validation, but also verification and reassessment. AMI members are currently engaged in a review of not only *what* validation is but also *how* validation would be completed to meet the current regulations. The questions raised earlier in this response and also prerequisite programs will be addressed. This AMI Interim Validation Guide will be available this summer and AMI will gladly share it with the agency.

¹⁰Draft Guidance : HACCP Systems Validation, page 8

¹¹ The current edition of the text is seven.

¹² *Food Control* 16(2005) 497-503

In a review of FSIS information on validation, AMI concurs with validation information presented by the agency prior to the issuance of the draft Guidance. Much of the information pertaining to validation is found on the FSIS website. Examples of available information include:

- HACCP Validation-The FSIS Perspective, Charles Gioglio, FSIS Foreign Material Contamination, Validation and Prerequisite Programs Meeting, September 24, 2002¹³
This presentation provided an example of validation of a slaughter steam pasteurization cabinet. The presentation identified two parts of validation. The supporting documentation would be the copy of the article or study not just a reference to the article or study. The second part is the recorded documentation or practical demonstration. There are the records confirming that the parameters or specifications in the study, or article can be routinely met in the plant setting. There was no reference to microbiological results, as stated in Attachment 1 *Validation Examples for Raw Products of the Guide*.

- Question and Answer from FSIS Form 10,240.1 state:

Question: What is meant by "validation?"

Response: Validation is defined as the process of ensuring that a defined set of control measures is capable of achieving appropriate control over a specific hazard in a specific food. For example, an establishment that subjects its fully cooked, sliced, and repackaged product to steam pasteurization would consider its product to be under Alternative 1 or 2. To be able to consider the product in Alternative 1 or 2, the establishment must have supporting documentation that the treatment (steam pasteurization) will reduce the number of *L. monocytogenes* in the product by a certain number. This supporting documentation must come from a validation of the treatment. The validation of the treatment can be achieved by a challenge study or by using a published study applying the same time/temperature of treatment on the product and other factors in the study.¹⁴

- Enforcement Investigation and Analysis Officer Educational Program, October 18-November 12, 2004, states, while no particular validation method must be used, the data assembled to support a HACCP plan are usually of two types: 1) theoretical principles from process authorities, scientific etc. and 2) in-plant observations, measurements, test results, or other information demonstrating that control measures achieve the intended food safety objective. This document further states, for example, a slaughter establishment with steam pasteurization has a CCP with a critical limit of 180 degrees F. for 10 seconds at the carcass surface. The plant supported this critical limit with a scientific journal article that indicated steam applied at 180 degrees F. for 10 seconds to the carcass surface reduces pathogens by 1 log. The plant also had records demonstrating

¹³ [http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/02-033N/Validation%20-%20FSIS%20Approach%20-%20Charles%20Gioglio.ppt#256,1,HACCP Validation](http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/02-033N/Validation%20-%20FSIS%20Approach%20-%20Charles%20Gioglio.ppt#256,1,HACCP%20Validation)

¹⁴ http://origin-www.fsis.usda.gov/Regulations_&_Policies/10240-1_Q&A/index.asp

their ability to meet the parameters of steam at 180 degrees F for 10 seconds on the carcass surface.

The concept presented by Assistant Administrator Phil Derfler at the June 14, 2010, FSIS public meeting on Draft Guidance: HACCP Systems Validation regarding data collection to show that a process or intervention achieves the intended result is unclear. AMI suggests that if specified parameters are met, *i.e.* in a safe harbor document, supplying effectiveness data need not be required. AMI believes that if the specified parameters are *not* met or if the supporting document does not apply to the process, then more information would be needed to confirm validation. This concept is the same idea as presented in the above FSIS information. Achieving an intended result can be accomplished through data collection that demonstrates that the operating parameters were met. But, if these operating parameters are not met then additional information would be needed, which could include microbiological data to demonstrate that the intended result is achieved.

Prerequisite programs are vital to food safety systems. Establishments have a wide array of prerequisite programs and methods to monitor that vary by product type and establishment. When prerequisite programs that are specifically used to conclude that a food safety hazard is not reasonably likely to occur, and in the absence of other CCPs, AMI would support further review of how validation of these specific prerequisite programs would be completed. Furthermore, when validation data collection is completed the supporting document should be sufficiently related to the process and the process should be realistically, not exactly, the same as contained in the supporting document.

The concept of implementing operating parameters and conditions exactly the same as the supporting document is impractical. Taken to its literal and illogical conclusion, this would mean that the establishment would use the identical type and size of grinder or method of application of an intervention. The crucial operating parameters are the metrics that should be documented. Usually these parameters are contained in the results discussion of the supporting document. Therefore, AMI believes implemented processes should be effectively, but not exactly the same as the supporting document. AMI acknowledges, however, that the validation document should be sufficiently related to the process. This determination is dependent on the intervention and product type. In general, however, the supporting document should be meat or poultry based, and involve a similar processing category (raw, ready to eat, shelf-stable, *etc.*).

Even though the Guidance is intended for use by the small and very small businesses, food safety knows no boundaries. Therefore, the Guidance should also be acceptable to implement at large plants.

In summary, AMI:

- Supports the ability to provide constructive comments on proposed changes that will have regulatory impact;
- Understands that the current agency validation definition and concepts, as well as recent agency clarifications follow accepted principles of HACCP and therefore should not be adjusted;

- Acknowledges that prerequisite programs are an integral part of HACCP systems but also recognizes that validation of these programs needs further investigation, especially in the absence of CCPs;
- Supports training of inspection program personnel, as well as the owners and operators of meat and poultry processing plants is essential to help them determine how validation is completed;
- Believes implemented processes should be effectively, but need not be exactly, the same as the supporting document and the validation document should be sufficiently related to the process; and
- Understands that the Guidance should be applicable to all meat and poultry slaughter and processing establishments no matter the size.

The American Meat Institute appreciates the opportunity to comment on this issue and looks forward to a continued dialogue with the agency on this topic. If you have questions regarding these comments or anything else regarding this matter, please contact me at: sgoltry@meatami.com.

Respectfully submitted,



Scott J. Goltry
Vice President, Food Safety and Inspection Services

cc: J. Patrick Boyle
Jim Hodges
Mark Dopp