



One Meating Place  
Phone: (717) 367-1168  
Email: [aamp@aamp.com](mailto:aamp@aamp.com)

Elizabethtown, PA 17022  
Fax: (717) 367-9096  
Website: [www.aamp.com](http://www.aamp.com)

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Docket Clerk  
U.S. Dept. of Agriculture, FSIS  
Room 2-2127  
5601 Sunnyside Avenue  
Beltsville, MD 20705

**Re: Comments - Draft Guidance on HACCP System Validation**

The American Association of Meat Processors (AAMP) is pleased to and respectfully submits these comments regarding the Draft Guidance on HACCP System Validation that was publically released on March 19, 2010. AAMP applauds the efforts of the Food Safety and Inspection Service (FSIS) to hold this public meeting on the New Draft Validation, its willingness to extend the initial comment period to allow a greater opportunity to comment on this very complex issue, and its efforts to get the draft HACCP validation guidance into the hands of the affected federally inspected establishments. AAMP sincerely appreciates that the Agency sought more extensive comments from stakeholders regarding the development of more applicable guidance for the meat industry.

AAMP is an international organization whose members include meat and poultry processors, slaughterers, caterers, food service companies, wholesalers, retailers, suppliers, and consultants to the meat and poultry industry. There are 32 state, regional, and provincial associations of meat processors that are also affiliated with AAMP. The majority of our members are small and very small businesses, with most of them being family-owned and operated. While small and very small meat processors represent about 5% of the meat production volume in the U.S., our members represent about 95% of the total number of meat processing businesses.

In what seems to be a continuously consolidating industry, the AAMP membership consists of a very unique group of very small and small independent meat processors that do not simply produce one meat product in a single establishment. Most all members produce a wide variety of fresh and processed meat products under numerous HACCP plans. This should come as no surprise to the Agency since its inspection personnel are conducting inspection activities in these establishments on a daily basis, but it seems as though this fact has had little impact on the Agency's decision to reinterpret the validation requirement which implies excessive, non-science based microbial sampling.

Food safety has been a top priority for the AAMP membership, not only since the implementation of HACCP, but long before the HACCP regulation was implemented. The AAMP membership's family-operated businesses continue to produce safe, high quality meat products for consumers on a daily basis. It is also important to recognize that AAMP members are not only producing these meat products for the general public, but also for their own families. Many AAMP member establishments have been operating under HACCP since its initiation, and others have been operating under HACCP food safety systems for a number of years. To get to that point, they had to already "validate" their food safety systems. This activity was conducted and already approved by the Agency to enable establishments to produce meat products to this day. These same establishments have reassessed their HACCP food safety systems

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annually to address emerging food safety related concerns as well. It is also likely that they have all been through extensive Food Safety Assessments (FSA) conducted by the Agency's Enforcement, Investigation, and Analysis Officers (EIAO).

Overall, AAMP is disappointed that the Agency chose to ignore the initial specific points provided to them by a consolidated voice of nine national meat and poultry trade associations. Within the first sentence of the document, the Agency states that it developed the guidance to "aid" the meat industry in meeting the validation requirements in 9 CFR 417.4. Unfortunately, it has caused more confusion and frustration about the validation issue. AAMP does appreciate the efforts of the Agency to get the validation guidance information out to the industry through a variety of Agency correspondence documents and is hopeful that the Agency may follow the same protocol in the future when it releases important information that will impact the meat industry.

Through the years, HACCP plans and food safety systems have been designed, redesigned, and/or reassessed at each federally inspected establishment annually. The HACCP food safety systems have also been addressed on an even more frequent than annual basis, when it is needed. These reassessments help processors focus on any emerging food safety related concerns. Processors have taken many steps to keep their food safety plans current and have addressed issues such as: potential *E. coli* O157:H7 contamination on beef carcasses and the production of ground beef, potential *Listeria monocytogenes* contamination in ready-to-eat (RTE) meat products, Bovine Spongiform Encephalopathy (BSE) concerns in older beef animals, and the thermal processing of jerky items. These are just a few examples of focused reassessments that lead to the production of safer meat products.

The USDA FSIS is interpreting validation in a completely different fashion compared to what has been accepted since its creation in 1996. The industry has been following the initial intent of validation since the HACCP regulations were initiated. The establishments developed the HACCP plans and food safety systems. After the plans were established, they were critically evaluated to determine that the plans were functioning as they were intended. Critical limits were established using supporting documents and monitoring activities were conducted. Through the years, with the assistance of the Agency in some instances, establishments have made improvements to their food safety system by refining their supporting documentation, monitoring activities, or processes.

The Agency is proposing to create an impractical level of standards that is unlikely to produce safer food, and may harm the consumer by potentially discouraging meat establishments from implementing new or existing food safety strategies or interventions due to the cost of validation, eliminating current food safety strategies due to the expected validation obligations, and will ultimately increase food prices for food produced by fewer companies.

The following AAMP comments have been consolidated to focus on a limited number of main points regarding the issuance of any guidelines regarding HACCP system validation.

### ***The Reinterpretation of the Preexisting Validation Requirements***

Since the implementation of HACCP, the meat industry has utilized the Agency endorsed practice of justifying critical food safety points with supporting documentation (e.g., published processing guidelines, scientific articles from peer-reviewed journals, a challenge or inoculated pack study, data gathered in-house, or regulatory performance standards, etc.). This well-recognized practice should still be acceptable without the implementation of further microbial testing.

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The “interpretation” of validation is already in writing and has been in writing since 1996 in 9 CFR 417.4(a)(1) Validation, Verification, Reassessment which states:

*“Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP’s, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan.”*

Throughout the years and countless Agency FSAs, this has been interpreted to mean that the HACCP plans are functioning as intended and the monitoring was being conducted. At no time during the initial implementation was the fact acknowledged that such extensive microbial testing should occur such as the methodology that is currently outlined in the guidance document.

The Agency seems to also want to ignore the written information within the Federal Register (Volume 61, Number 144 – pages 38826–38827) where it specifically states on page 38826:

*“Where processes are well-documented in the scientific literature, it is not necessary to require inoculation studies or any other research effort as part of the validation process. However, an establishment introducing a new technology, applying standard technology in an unusual way, or lacking experience with a technology, would have to undertake more extensive scientific and in-plant validation of its HACCP plan under commercial operating conditions.”*

It seems as though, if the Agency would have followed this information during the development of the draft guidelines, it would have narrowed the scope of the validation issue. AAMP has continually supported this concept and worked with the meat industry to provide the appropriate scientific supporting literature. In some instances, scientific literature was not available and the establishments have then had to conduct more extensive scientific and in-plant microbial testing.

For the meat industry, it has been well understood that if an establishment is utilizing supporting documents that are commonly accepted, that no further microbial sampling would be required. These documents would consist of, but not limited to:

- FSIS regulations (e.g., beef patty thermal processing, trichinae control, etc.)
- FSIS guidance documents (e.g., FSIS Appendix A (*Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat And Poultry Products*) and FSIS Appendix B (*Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization)*))
- Peer-reviewed documents (e.g., Tompkins paper, Journal of Food Protection articles, etc.)

After nearly 12 years of HACCP, the Agency is suggesting that establishments go back to the beginning and redo initial validation. Since the meat industry and the Agency have been following the same interpretation of validation since it was written in 1996, it is completely inappropriate for the Agency to make such a significant reinterpretation and drastic change to their long-standing policy regarding validation. This potential reinterpretation is degrading the platform of the current HACCP food safety system and gives the impression to the meat industry and the public that the current food safety system is so badly broken that everyone needs to start over from the beginning. It is AAMP’s opinion that the current food safety system is not broken, but may be flawed. The Agency should acknowledge and except the usage of such well-known and implemented supporting documentation. The documentation coupled with sufficient monitoring procedures should be enough to satisfy the validation criteria. All of this information is available to Agency personnel to verify that validation criteria have been met.

***The Use of Scientific Supporting Documentation***

For years, the meat industry has utilized scientific supporting documentation to support decisions made within HACCP food safety systems. The Agency should acknowledge that such documentation does not exist for every action conducted in establishments, and therefore decision making documents are not available for every process. After a decade of functioning under the HACCP regulations, the Agency should have knowledge whether an establishment has the overall proper scientific supporting documentation (e.g., scientific supporting documentation vs. supplier specification information). This is especially true considering the fact that inspection personnel are in the establishments on a daily basis and extensive EIAO FSAs are conducted.

AAMP is concerned that, with this reinterpretation of the validation requirements, more unneeded scrutiny will be placed on the supporting documents that establishments have utilized for years that haven't resulted in the occurrence of food safety issues. This concern is the result of statements made within the draft guidance such as "care should be taken to ensure that the supporting validation documentation is sufficiently related to the process" and "the process should also be implemented in the establishment as described in the supporting documentation." Another statement made within the guidance document refers to the fact 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."

All of these statements are very concerning because supporting documents very rarely "relate closely to the process with regards to species, product, characteristics, and equipment." A perfect example is the use of FSIS Appendix A and Appendix B. The specific research that was performed to develop the contents of Appendix A is somewhat unknown to most within the meat industry. Furthermore, initial statements made within Appendix A allude to the fact that it was developed for establishments that produce ready-to-eat roast beef, cooked beef and corned beef products and certain ready-to-eat poultry products. Therefore, when statements are made that documentation must "relate closely to the process with regards to species, product, characteristics, and equipment," AAMP is concerned that many commonly used supporting documents will not be acceptable in the eyes of Agency inspection personnel because they may not be related closely enough to the establishment's process, species, product, characteristics, and/or equipment.

The Agency has made the statement during the public meeting regarding validation on June 14, 2010, that "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." The Agency should realize that all "parameters" specified in scientific supporting documents may not be critically needed for the intervention or control measure to effectively work. Nonetheless, the Agency is now mandating that establishments have verification records of all parameters identified or else further decision making information will be needed (i.e., microbiological test results). An example of this can be displayed with the use of Appendix A as supporting documentation of thermal processing within fully cooked, not shelf stable HACCP plans. During the production of jerky products, humidity has been identified as a critical parameter that needs to be addressed for the effective destruction and control of *Salmonella*. On the other hand, is humidity a critical parameter that needs to be measured during the production of high-moisture processed meat products such and boneless ham and/or sausage? Also within Appendix A, the Agency has determined that dwell times of greater than 6 hours in the 50°F to 130°F range should be viewed as especially hazardous, as this temperature range can foster substantial growth of many pathogens of concern. Therefore, during the production of products that have a slow increase of internal temperature or the production of large diameter products (e.g., bone-in hams, etc.), this may be a parameter that needs to be measured. On the other hand, is dwell time a critical parameter that needs to be measured during the of rapidly thermally processed meat products such as small diameter cooked sausage? Unfortunately, now the Agency has made public statements that if establishments "rely on Appendix A, the establishment would need to have records that demonstrate that its process is achieving the critical parameters (e.g., dwell time, humidity) identified in Appendix A."

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AAMP believes there may be many other examples where parameters identified in scientific supporting documents may not be critical to the effectiveness of the intervention. While credible Universities conduct research, many factors may be measured throughout each project. Some factors may be measured because they are critical to the effectiveness of the intervention and other factors may be measured and collected simply because it is basic data that may be needed to pass the scrutiny of the peer review process. Unfortunately, the data is not identified as critical and non-critical. Also, it may be difficult for the establishments to determine this distinction and provide Agency inspection personnel with this evidence. Therefore, the establishments will be forced to measure all parameters.

AAMP believes the Agency should work with the meat industry in regards to this issue and provide some latitude because scientific supporting documentation does not exist for every process, species, product, characteristic, and/or equipment. Nor can the meat industry afford to provide individualized research on every process, species, product, characteristic, and/or equipment at each establishment. Inspection personnel should be directed not to overextend the use of the validation regulation simply because the supporting document does not match the establishment's production precisely.

### ***The Demonstration That a Food Safety Problem Exists***

Currently, AAMP is struggling to determine the existence of a clear food safety problem which this validation initiative will resolve. AAMP is troubled that FSIS believes so strongly that the current HACCP system is so badly broken to such an extent that this type of focus on validation must occur, especially given the fact that the very small plants started HACCP in January, 2000, and the small plants started HACCP in January, 1999. The meat industry has been under HACCP for 10 years (if not longer) and this initiative pushes the industry back to the beginning without any clear and present need.

The Agency identified a very limited number of examples in which it claims that the meat industry's inadequacy to address validation has resulted in recalls. It is unknown if these inadequacies were related to public illnesses or recalls, since details of each and every example are unknown to all stakeholders. AAMP questions whether the contamination was truly due to an inadequately validated critical control point (CCP) or an establishment's failure to properly execute the CCP that was identified in the HACCP plan, or due to post-CCP contamination that may have occurred.

The Agency has portrayed the limited examples given as overall meat industry systemic problems, and AAMP has doubt whether this is truly the case. Years ago, the Agency identified a potential food safety issues that could occur with jerky products if they were not properly thermally processed with humidity being addressed. After observing the issues that caused the concern, it was determined that a problem was identified with only three processors, two of which were not officially confirmed. The point being, if the Agency identifies an issue in a limited number of establishments, it does not necessarily mean that a universal problem exists.

FSIS has the responsibility to assure that meat products produced in the U.S. and imported into the U.S. are safe and wholesome. Agency inspection personnel can review records contained in an establishment's HACCP, SSOP or prerequisite programs to make a determination that the food is wholesome, not adulterated and properly labeled. FSIS has the responsibility to verify the adequacy of the HACCP plan, not the entire food safety system. The HACCP regulations describe those activities as primarily records review, observations and sample collection. The idea that the Agency can require endless sampling and validation activities is simply not supported by the HACCP regulations. The criteria for applying the marks of inspection are described in the meat and poultry laws, not in the interpretation of those laws by an endless number of Agency employees.

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The Agency should acknowledge and accept an establishment's implementation of peer-reviewed documents, regulations, and regulatory guidance as being adequate to address validation. AAMP does understand and recognize that if such documentation is utilized to justify prerequisite programs and CCPs then they should be understood, utilized, and implemented properly to ensure the production of safe meat products.

Overall, as AAMP reviewed the validation document, it became obvious that the Agency tended to be concerned with a few points: *E. coli* O157:H7 contamination during beef slaughter, presence of *E. coli* O157:H7 in the production of ground beef, and *Listeria monocytogenes* contamination of ready-to-eat meat products. If this is the case, the Agency should refocus its efforts to provide specific and clear guidance on those issues.

### **The Benefit of Collecting Validation Microbial Data**

Regardless of Agency personnel statements and the Agency's publication of the validation fact sheet, the fact remains that the March 19, 2010, draft guidance on HACCP system validation states in several locations that in-plant documentation should include microbiological results. This is clearly dictated by the use of the word "and."

If the meat industry collected all of this expected microbial data, it is unclear to AAMP what value any of this data will provide the Agency and what impact it will have to make the meat products produced in the U.S. safer. The validation guidance demonstrates that establishments should perform microbial testing of pre-intervention or pre-CCP and post-intervention or post-CCP activities. If the Agency truly wants to have a science-based inspection system, which it has proclaimed for years, this validation methodology demonstrates a complete lack of scientific principles such as statistical soundness and microbiological criteria correlated to the pathogens the establishment is attempting to control.

AAMP believes the Agency should reevaluate the benefit of performing microbial sampling if the initial sample and the final sample are both negative for the pathogen of concern. At that point, the Agency and the establishments have achieved absolutely nothing. This is not validation, but rather it is simply microbial sampling for the sake of satisfying an Agency expectation. Unfortunately, in the end, very little benefit is achieved.

An example of a well-focused Agency expectation is demonstrated when an establishment conducts microbiological verification testing. Currently, the meat industry conducts focused microbial sampling which is dependent on the products produced in each establishment. If an establishment is slaughtering livestock, then they are already conducting generic *E. coli* testing on the slaughter floor to ensure proper sanitary dressing procedures are being implemented. If an establishment is producing ground beef or non-intact beef products, they are conducting *E. coli* O157:H7 testing of the raw materials and/or final product as part of a verification activity. If an establishment is producing RTE meat products, they are conducting *Listeria monocytogenes* testing of meat contact surfaces and final products. These are only a few examples to demonstrate focused testing to achieve the production of safe meat products from a systematic and structured approach.

The intent of the implementation of the new HACCP system in 1996 was based on the prevention of harmful foodborne pathogens from entering commerce because end product testing was not solving the food safety related issues. Unfortunately, the Agency is continually reverting to excessive end product microbial testing of meat products to control potential pathogens instead of relying on an establishment's HACCP food safety systems. The fact of the matter still stands: The Agency and the meat industry cannot test its way to the production of safer meat products.

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### ***The Lack of Scientific and Statistical Correlation between Indicator Organisms and Pathogens***

HACCP is a science-based process control system for food safety that promotes systematic prevention of biological, chemical and physical hazards. With the publication of the draft validation guidance, the Agency is moving away from a science-based system when it attempts to make theoretical links between indicator organism reductions and pathogen reductions.

Within the guidance document, the Agency made it clear that FSIS does not advocate the introduction of pathogens in the plant environment. Instead, the guidelines continually describe that well-known indicator tests or organisms such as aerobic plate counts (APC), total plate counts (TPC), generic *E. coli*, etc. should be utilized. The guidance document makes inferences that a reduction in such indicator organisms results in a mirrored reduction in pathogens of concern. The pathogens could include *E. coli* O157:H7, *Salmonella*, *Listeria monocytogenes*, *Staphylococcus aureus*, *Clostridium botulinum*, *Clostridium perfringens*, etc. Years ago, the Agency requested, through their individual establishment FSAs, that establishments should identify particular pathogens within their hazard analysis, instead of simply identifying “microbial hazards.” The Agency wanted specifics, and many establishments listed these individual pathogens.

Within the guidance document, the Agency admits that “there is no gold standard list of indicators agreed upon by the scientific community that will fit every situation” and that “the establishment should have supporting documentation that the indicator organisms chosen are appropriate to validate interventions for the pathogen of concern documented in the hazard analysis.” To this day, AAMP is only aware of one peer-reviewed, scientific paper in which a reduction in APC is related to a reduction in generic *E. coli*. Agency officials have continually acknowledged that many peer-reviewed scientific articles display indicator organism reduction figures as well as pathogen reduction figures. Unfortunately, these same peer-reviewed scientific documents DO NOT provide direct evidence that a reduction in stated indicator organisms/test equals a specific scientific, statistical, and correlated reduction to pathogens of concern. AAMP acknowledges that common scientific thinking leads readers to believe this theory; but at this point, it is only theory and not factual nor scientific.

Within the guidance document, the Agency clearly outlines the definition of what it perceives to be “scientific support.” In direct contradiction with this definition, the Agency seems to be endorsing that processors test for indicator organisms in which the meat industry currently cannot conclusively provide the “scientific support” to link indicator organism reductions to reduction of pathogens of concern. If the Agency has such a significant problem with establishments “cherry-picking” details from scientific documents, then the Agency should follow its own advice and not advocate the theoretical link between a reduction in indicator organisms and pathogens of concern.

This unscientific thinking is already spreading through the meat industry with Walmart’s new beef safety initiative, in which they are asking suppliers for “scientific validation” and consider the testing of naturally occurring organisms (*i.e.*, non-pathogen microorganisms) with results demonstrating measured reductions as scientific validation. Ironic that Walmart is claiming this to be “scientific validation” when thus far no peer-reviewed scientific paper has made the direct scientific and statistical correlation between “naturally occurring organisms” and pertinent microorganisms (*i.e.*, *E. coli* O157:H7). Yet, the Agency seems to be encouraging this unsupportable science.

Within the validation draft guidance, the Agency cites one of USDA’s own researchers, Terrance M. Arthur, who works for USDA’s Meat Animal Research Center located in Clay Center, Nebraska. AAMP encourages the Agency to closely review the cited peer-reviewed document and not take statements made in the paper out of context. Within the research paper, it was written that classes of samples with higher total aerobic plate counts (APC) and *Enterobacteriaceae* counts (EBC) were more likely to be positive for *E. coli* O157. The authors also wrote that “caution should be taken when interpreting these

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results because the data set was limited to 288 samples from only two different plants in one season. This relationship may be the result primarily of differences among trips or between plants rather than a direct relationship between APC and EBC and prevalence of *E. coli* O157.” The authors also wrote that “although indicator organism levels cannot be used for direct presence or absence analysis of *E. coli* O157, they may be useful as a guideline for the minimization of *E. coli* O157 contamination.” Unfortunately, “guidelines” don’t constitute “scientific validation.”

This theoretical thinking - that a reduction in indicator organisms equals a reduction in potentially harmful pathogens identified in an establishment’s hazard analysis - may not be an issue that surfaces right away after the guidance is officially published, but when an establishment goes through a thorough Agency FSA, the lack of supporting documents in regards to this theoretical indicator organism-pathogen link will be identified. Therefore, the Agency is placing establishments in a non-compliance situation with the recommendations outlined within the draft validation guidelines.

Moreover, the draft validation guidance implies that, if an establishment attempts to conduct indicator organism/pathogen testing, that the Agency will be expecting a reduction from initial to final product. Unfortunately, the document never defines what constitutes a “reduction.” The Agency should set specific parameters on what defines an acceptable “reduction” so there is not future confusion. It is recommended that the Agency consider the possibility of some results not showing a reduction. If that occurs, what guidance is going to be given to establishments? Would the establishment then not be allowed to use that supporting documentation or redefine its critical limit? Would the wholesomeness and safety of the establishment’s previously produced meat products then be questioned by Agency inspection personnel?

Establishments define CCPs that will control, reduce, and/or eliminate the hazard. The Agency should acknowledge that some meat production systems don’t fit well with the theory of HACCP. An example of this is the raw ground HACCP category. Many establishments typically monitor product temperature to control pathogen growth, and other establishments have chosen to incorporate antimicrobial interventions. These interventions are used to control the outgrowth of pathogens and may not reduce the pathogen. Therefore, establishments may not be able to demonstrate a “reduction” in indicator organisms as suggested within the validation guidelines.

Overall, this entire issue is very complex because the Agency must consider the variety of HACCP plans available, products produced, prerequisite programs, and established critical control points. Due to the extreme ambiguity within the document, the Agency has not given the meat industry much direct guidance. This unscientific indicator organism/pathogen testing may work within HACCP slaughter plans, but the Agency has given no applicable examples of how it would be applied in other HACCP plans or food safety systems. Again, the meat industry would not be able to provide credible scientific supporting documentation when it is requested by Agency inspection personnel or Agency EIAOs.

If the Agency continues to “encourage” or have “expectations” that the meat industry should conduct microbiological testing to prove validation of HACCP systems have been achieved, AAMP encourages the Agency to seek the advice of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). The knowledgeable individuals that make up the NACMCF should be able to research the applicability and application of a more science-based system that links the use of indicator organism to pathogen reductions. They also may be able to set standards regarding appropriate reductions.

### ***These Validation Guidelines will be Perceived as Minimal Agency Expectations***

Although the Agency continually reinforces that the validation information is “guidance” and not “regulation,” it seems as though the Agency has taken a very naïve approach of how these guidance documents are interpreted at the establishment level by its own inspection personnel. Over the years, the

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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.

The U.S. meat inspection system is very robust; and although specific regulations exist, many times the inspection that is implemented is based on “expectations” and “interpretations” of those written regulations. The Agency is very effective at manipulating the written HACCP regulations to “encourage” the use of Agency guidelines, because they understand that in some instances no further supporting documentation exists.

FSIS has laid the groundwork to tell the industry that monitoring is good, but “a prudent establishment” would include microbial data as part of validation. This is clearly implied within the current draft guidance on HACCP system validation. It is important to understand that with the lack of any scientific, peer-reviewed supporting documents regarding validation and lack of defense why microbial sampling validation is not needed, the Agency will use 9CFR 417.5(a)(2) against the meat industry and use this guideline as a minimum expectation of validation. This includes the microbial sampling issue.

The validation draft guidance is so ambiguously written with many vague aspects, it gives Agency inspection personnel open-ended authority to harass establishments with frivolous non-compliance reports citing 9CFR 417.4 (Validation, Verification, Reassessment).

### ***Cost and the Impact to the Meat Industry and Businesses Associated with the Meat Industry***

Although the Agency has published a “fact sheet” on validation which seems to dispute that microbial testing will not be required and other Agency officials have publically implied that this current reinterpretation will not be a financial burden to the meat industry, AAMP respectfully disagrees and believes this issue could have a significant financial burden dependent on its overall interpretation and implementation by inspection personnel. These comments are submitted on what the draft validation guidelines currently state and the implications of excessive microbial testing to provide evidence of HACCP system validation.

AAMP has assisted many meat industry members and non-members to understand the potential financial impact that could be realized if the Agency continues to pursue this validation initiative. AAMP has communicated with various meat industry establishments regarding the microbial testing costs and believes the financial burden to the meat industry would be extraordinary, especially to the very small and small meat industry. Although the Agency states that products can be “grouped” to reduce the amount of microbial testing, this grouping can be interpreted a variety of ways. A sausage product that contains one species may be considered different from a sausage product containing a different or multiple species because the “specie” is different. A boneless ham product may be considered different from a sliced ham product because the “process” is different. All of this potentially leads establishments to perform more microbial testing to fulfill Agency “expectations.”

The potential costs are variable to the very small and small meat industry that the Agency inspects. AAMP has heard of validation costs as low as \$125,000 to as high as \$1.4 million in establishments that are classified as very small. Moreover, those costs were only the initial microbial sampling and do not include the cost of ongoing verification testing expected by the Agency. In 1996, the Agency estimated that the cost of HACCP implementation would be less than \$0.01 per pound of product produced. AAMP would like to know if that included the costs that the industry is now expected to absorb in association with this current reinterpretation of validation. It is AAMP’s belief that the Agency failed to perform the appropriate cost analysis to include this excessive microbial testing when HACCP was first initiated and believe that the current reinterpretation of validation was never properly researched.

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### ***Other Concerns***

Years ago, the information provided to the Agency inspection personnel in regards to validation was obviously accepted by the Agency after the first 90 days of HACCP plan implementation. In regards to the validation issue, the Agency shouldn't make statements that this shift in validation policy is due to the fact that HACCP is "evolving" or is a "living document." The HACCP regulation has been in place for over a decade, and the Agency is now stating that the meat industry needs to go back to the beginning steps of HACCP development and provide initial validation information. By telling the industry that what they did a decade ago was acceptable, but now suggesting change in validation policy, it unfortunately creates mistrust and an adversarial relationship when, the main goal for both the meat industry and the Agency is food safety.

The Association and its membership would like some assurance that the validation information that is given today will be accepted in the future and not challenged by rotating inspection personnel or EIAOs each time an FSA is conducted at establishments. Simply put, the meat industry trusted that they previously satisfied the validation years ago only to be currently challenged because the Agency decided to reinterpret the regulation, clarify the existing regulation, or change its policy.

In an effort to be transparent and open with the meat industry, AAMP would like to know, as this process continues, what Agency personnel are going to be tasked with reviewing all of the provided validation information and making the determination that the validation information provided is adequate. Is the Agency going to rely on its inspection personnel that conduct daily inspections at each establishment, the EIAOs, or some other inspection personnel within FSIS? Moreover, if FSIS is going to rely on EIAOs to audit the efficacy of the validation information provided, AAMP would like to know how the Agency expects to expedite this process. After all, if the Agency is currently so concerned that establishments don't have the proper validation information a decade after HACCP was implemented, then it would seem that the Agency would attempt to expedite the process quicker than waiting until each establishment goes through an FSA. AAMP would also like to know who is going to provide each establishment with the final approval that validation has been met, and would this be documented in a fashion so that establishments are not continually challenged regarding the information provided?

At this point, AAMP is unsure how the Agency is making statements that establishments will only need to validate one plan per HACCP category. AAMP questions whether this will be truly acceptable to inspection personnel and won't be scrutinized when the validation information is provided. This concept doesn't seem logical when considering that different species are slaughtered and processed under similar and/or different HACCP plans. There are also a wide variety of products produced under the fully, cooked not shelf stable HACCP plan category. Although the products are produced under one HACCP plan, they have variable formulations, production processes, and thermal processing schedules. It is assumed that inspection personnel will want the establishment to provide supporting decision making documents on why the establishment chose one product or process over another. In most instances no credible reason will be available to justify this decision. The Agency seems to be instructing the meat industry to conduct its own individualized risk assessment of the products produced and make the appropriate determination without any guidance from the Agency. Therefore, if the establishment is challenged on its decision, it will be put into a situation of conducting initial validation whenever inspection personnel deem necessary.

The Agency seems to be giving the meat industry and consumers more reason to have less confidence in the USDA mark of inspection with the Agency's publication of guidance that inadvertently instructs further processors that they cannot rely on the USDA mark of inspection. The publication of the draft validation guidance is another example where it can be interpreted by trading partners and consumers that they should not to have confidence in the established FSIS food safety system. Within the FSIS website it states that "meat that has been federally inspected and passed for wholesomeness is stamped" with the USDA mark of inspection. Unfortunately, the Agency has also made public statements that the mark of inspection only means that the product has been produced under a HACCP program. If this is the case,

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then the products have undergone controls and/or interventions to control, inhibit, or prevention pathogens. Currently, there is no 100% guarantee that all meat product produced are 100% free of pathogens in some HACCP plans (e.g., raw not ground meat and poultry products, raw ground meat and poultry products, etc.). The Agency seems to be trending farther away from the theory of HACCP (i.e., prevention) towards the concept that the meat industry can perform microbiological testing to achieve food safety.

### **Conclusion**

The meat industry observed a decrease in the number of establishments when HACCP was implemented. This reinterpretation of validation has the capability of removing a majority of the remaining very small and small meat industry establishments from inspection. It will hinder commerce. It will stifle the meat industry by removing the variety of products currently available. It will obstruct the production of new products from being produced and being commercially available in commerce. It will raise the cost of the products being produced, thus the overall cost the consumers will pay. It will cause establishments to cut jobs as they downsize due to the lack of inspected meat product production. It will force more of the meat industry to put more products out of the current reach of inspection and into retail exemption. This validation initiative is extremely counterproductive to increasing the safety of meat products produced in the U.S.

It is ironic that the Agency would implement a reinterpretation that would have such a devastating impact on the same industry it is publicly trying to help and promote. If this validation initiative is imposed as it is currently presented, it will definitely put the nail in the coffin of the very small and small meat industry. Many processors are already viewing this validation initiative as another Agency action that may systematically kill the remaining inspected (state and federal) independent processors that make a wide variety of meat products. It is extremely disconcerting that this would occur during a time when independent processors have had success within a bad economy and the USDA Secretary of Agriculture, Tom Vilsack, has so publically promoted the "Know Your Farmer, Know Your Food" initiative.

Imposing new costs for further documenting and/or testing well-recognized processes may act as a disincentive to adopt or maintain such food safety interventions. Years ago, the regulations established that validation could be achieved where processes are well-documented in the scientific literature and no in-plant microbial data should be required to validate processes and food safety systems.

FSIS should consider the broader public policy implications before reinterpreting long-standing, acceptable practices regarding HACCP system validation. The increased costs for consumers and subsequent negative impact to businesses by formulating new interpretations that will most likely not create a positive impact on increasing food safety should be considered before decisions are made. Additionally, FSIS should consider that there are other areas where it may better expend efforts to decrease the number of outbreaks of food-borne illness. Education of consumers is a key part of the food safety equation that could be improved. Validating thermal processing methods will not help food safety if consumers do not follow proper product handling and cooking procedures in their kitchens. Meat producers can only control what happens to their product while it is in their establishments.

Although the Agency currently is making statements that "they [the draft validation guidance] do not impose new testing or microbiological requirements on establishments," the proof will be evident when the document is fully published and implementation is established by Agency personnel. Most likely, the microbiological testing component will be clearly known as not being "required," but Agency actions will dictate whether microbiological testing is "expected" to the point where it is the only data that inspection personnel will accept to fully acknowledge that an establishment has provided adequate validation information.

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Currently, it is well understood by the meat industry that produces raw ground beef products that *E. coli* O157:H7 testing is not “required,” but in many instances the meat industry also knows that testing for *E. coli* O157:H7 is the only way to satisfy Agency “expectations.” So, although in some instances microbiological testing is not “required,” it is inadvertently mandated on the meat industry with the command-and-control attitude of yesteryear. It is AAMP’s expectation that this current reinterpretation of the validation expectations will not result in the manipulation of current HACCP regulations in which excessive, unscientifically-based microbiological testing will be the component that satisfies the Agency expectation of proper validation information that is provided by establishments.

As the June 19, 2010, public comment period concludes, from press releases it appears as though the Agency has the lofty goal of reviewing all of the comments and making revisions to the validation guidance document in slightly over one month. Due to the complexity of this validation issue, AAMP encourages the Agency to take the appropriate time needed to provide clear and concise guidance to the meat industry. AAMP looks forward to reviewing the revised draft validation guidance document when it becomes available as well as working with the Agency to provide the meat industry with achievable expectations. AAMP strongly encourages the Agency to provide more than a 30-day comment period in regards to the second draft of validation guidance. The 30-day comment period is simply not enough time to make the information available to the affected stakeholders and provide constructive comments to such a complex issue.

Just as the meat industry performs an annual reassessment of the HACCP food safety systems, AAMP strongly recommends that the Agency review, reassess, and revise published guidance documents after they are published at some frequently. Too often guidance documents are published and never reviewed again. This information should be reviewed because after guidance is implemented within the meat industry, minor flaws are identified and improvements could be made.

AAMP encourages a working relationship between the meat industry and the Agency to create guidance documents in the future. We all may not always agree on the guidance to provide, but guidance should be realistic and achievable. The current process of allowing the meat industry to properly comment ensures that more accurate industry guidance is provided and AAMP encourages the Agency to repeat this practice in the development of future guidance documents.

Due to the complexity of this validation issue and vagueness of how the meat industry can achieve Agency expectations, it is recommended that the Agency seek the guidance of the National Advisory Committee on Meat and Poultry Inspection (NACMPI). This committee advises the Secretary of Agriculture on matters affecting federal and state inspection program activities. Validation guidance is a perfect example of an issue that will affect federal and state meat inspection programs.

Since the release of the validation guidance on March 19, 2010, AAMP has critically researched the validation issue. AAMP is still extremely unsure what specific problem within HACCP food safety systems that the Agency expects the meat industry to resolve with vague validation guidance. The Agency and the meat industry may be better served if establishments focused their reassessment activities at the end of this year on ensuring that the scientific supporting documentation identified within HACCP food safety systems relates to the hazard that is being controlled and that all pertinent critical parameters of the scientific supporting documentation are identified. This aspect seems much more beneficial than performing non-science based indicator organism testing.

The meat industry thought they had achieved the requirements of validation after they went through the probationary grant of inspection process. Unfortunately, now the Agency is portraying to the meat industry and the public that, due to the fact that the meat industry hasn’t performed proper validation activities, that food safety problems have occurred as a result. This is not factual and does an extreme disservice to the meat industry and the Agency. Such activities have a negative impact on the confidence

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consumers have of U.S. meat products and the confidence the meat industry has in the USDA/FSIS food safety inspection system.

AAMP supports the clarification of food safety issues and appreciates the opportunity to comment on the Draft Guidance on HACCP System Validation. We respectfully request that the Draft Guidance on HACCP System Validation be significantly revised to clearly state that no new in-plant microbial testing be required as part of validation when an establishment is following the long-standing, safe processes of HACCP. It is extremely important that if the Agency provides guidance to the meat industry, that guidance should be clear and concise. Specific examples within the guidance documents are always extremely helpful, as long as they are related to the affected industry (*i.e.*, very small and small independent processors). The guidance should not consist of unrealistic expectations that create excessive burdens, depending on how they are implemented or potentially misinterpreted/manipulated by Agency inspection personnel.

AAMP once again appreciates being provided with this opportunity to comment and encourages FSIS to carefully analyze our views. Thank you for your time and consideration.

Sincerely,

A handwritten signature in cursive script that reads "Jay B. Wenther".

Jay B. Wenther, Ph.D.  
Executive Director  
American Association of Meat Processors

cc: AAMP Board of Directors  
AAMP Affiliate Organizations