



Capitol LINE-UP

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More Questions Than Guidance Within the Current Validation Guidance Document...Where Is The “Science” In Science-Based Inspection?

Within the validation guidance document, the Agency made it blatantly obvious 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 of concern could include *E. coli* O157:H7, *Salmonella*, *Listeria monocytogenes*, *Staphylococcus aureus*, *Clostridium botulinum*, *Clostridium perfringens*, etc. Some of these pathogens seem obvious and others do not. Years ago, the Agency requested, through their individual establishment Food Safety Assessments (FSA), 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 aware of only one peer-reviewed 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 the stated indicator organisms and/or test equals a specific scientific, microbial, and statistically 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 controversy 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. Establishments cannot provide such “scientific support” when faced with an FSA, and it will automatically place the establishment in a non-compliance situation.

Walmart’s new beef safety initiative includes asking for “scientific validation” and considers 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).

One of USDA’s own researchers, Terrance M. Arthur, who works for USDA’s Meat Animal Research Center located in Clay Center, Nebraska, and who was cited within the Draft Guidance on HACCP System Validation, published a peer-reviewed research paper on this issue. Within the research paper it was written that samples from higher aerobic plate counts (APC) and *Enterobacteriaceae* counts (EBC) classes were more likely to be positive for *E. coli* O157:H7. The authors also wrote that “caution should be taken when interpreting these 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."

Dr. Jim Dixon of Iowa State University has performed other research using nonpathogenic *Escherichia coli* cultures as surrogates for *E. coli* O157:H7. These were specific nonpathogenic *Escherichia coli* cultures utilized to determine if a reduction in the surrogates would also result in a reduction of *E. coli* O157:H7. Within another peer-reviewed paper, Dr. Dixon's team came to the conclusion that "the use of a combination of *E. coli* isolates may be required to accurately predict the effectiveness of microbial intervention methods on the reduction of *E. coli* O157:H7."

Piecing together all of the scientific peer-reviewed papers demonstrates that a reduction in specific indicator organisms (*i.e.*, previously identified as surrogates for *E. coli* O157:H7) may result in a reduction of *E. coli* O157:H7. Unfortunately, Dr. Dixon's identified *Escherichia coli* surrogates most likely are not readily available to the entire meat industry, and the overall concept of a reduction in indicator organisms does not lead to a straightforward reduction in harmful pathogens. While portions of Dr. Dixon's research may be applicable to certain meat industry processes, the industry still has many other HACCP plan categories to address in which peer-reviewed research is absent.

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, but when an establishment goes through a thorough Agency Food Safety Assessment, 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.

HACCP SYSTEM VALIDATION INFORMATION AVAILABLE

If you have not read the information regarding HACCP system validation, it is strongly recommended that you do so. AAMP has created a webpage (www.aamp.com/Validation.php) to provide the meat industry more information and help keep you up-to-date with this validation issue. Sample letters are available for you to use as a guide, if you choose to comment. Feel free to share this information with fellow processors. Submit your comments by June 19, 2010.

Senator Grassley Submits A Letter Regarding Validation

Senator Chuck Grassley (D-Iowa) recently sent a letter to USDA's Secretary of Agriculture, Tom Vilsack, regarding the Validation of HACCP System issue. Within the letter he stated:

"While I fully support efforts to improve food safety rules based on sound science, I share the concerns that Iowa processors have raised with me that this guidance could add additional requirements and substantial new costs to their businesses that serve our rural areas without adding to food safety improvements."

Senator Grassley urged Secretary Vilsack to take serious consideration of all comments received, particularly those received from small meat processors. He was specifically concerned that since this validation document is defined as a clarification or re-interpretation of the July 25, 1996 Pathogen Reduction, HACCP Systems, Final Rule (61 FR 38806), that it will not undergo the same scrutiny as regulatory rule making and an assessment of the impact on small businesses will not be required. It seems as though the industry meat and poultry trade associations are not the only organizations who believe this re-interpretation of validation is a major shift in USDA/FSIS policy.

While protecting the food safety is a critical function of the government, Grassley reiterated the importance of small and medium sized meat processors to Iowa's rural economy. He stated, "these businesses provide a critical service to our farmers, employ the local workforce, and generate income that is spent in the local communities."



FSIS Provides Federal Establishments With Validation Fact Sheet

If you are a USDA inspected establishment, you should have recently received a letter from the FSIS Office of Outreach, Employee Education and Training regarding the availability of the HACCP validation guidance information and an FSIS fact sheet on validation. It is well known that of approximately 6,000 USDA inspected establishments, only approximately half are members of national meat and poultry trade organizations. Through the suggestion of nine national meat and poultry trade associations, it was recommended to make this information readily available to the establishments that may not have heard of this issue. AAMP appreciates the efforts of the Agency to get this information out to the industry.

While the fact sheet information and ongoing communications seem like a step in the right direction, AAMP still remains cautious of the validation issue. The Agency continues to allude to the fact that documents (*i.e.*, supporting documents) must be followed precisely. A main concern was identified with the continued use of FSIS Appendix A (for lethality) because of the fact that it clearly states that Appendix A is for “ready-to-eat roast beef, cooked beef and corned beef products and certain ready-to-eat poultry products” and that it is also based on a reduction of *Salmonella* (not any other pathogen). Therefore, would establishments still be allowed to utilize Appendix A for all meat products (*i.e.*, cured, uncured, beef, pork, lamb, chicken, etc.) and to address all pathogens of concern (*i.e.*, *Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes*, etc.) without being required to perform further microbial testing? The answer is still factually unknown until the final validation guidance document is written and the industry knows how it will be implemented.

Another concern comes from the details identified within the Appendix A document that are currently not typically monitored. Appendix A includes statements about dwell times, relative humidity, or how humidity was achieved. Therefore, to rely on Appendix A, the establishment would need to have records that demonstrate that its process is achieving the critical parameters identified in Appendix A. If dwell time, relative humidity, or the mode of humidity is identified in Appendix A as critical to the success of the process (*which the Agency will most likely “suggest”*), then those aspects would need to be described during monitoring or verification procedures and thus in the records relied upon by the establishment to establish validation. Currently, throughout HACCP monitoring during thermal processing, most very small and small establishments record the product name, lot code, and internal product temperature or time temperature that is achieved (*along with the date, times, and initials of who monitored that critical limit*). So this reinterpretation about what will need to be recorded will most likely cause most processors to reassess their HACCP plans and completely revise their monitoring forms and invest in monitoring equipment such as data loggers and probes that must also be calibrated on a frequent basis, since it now becomes part of your critical control point.

Processors may have to analyze every smokehouse schedule (in written format) to provide one portion of the evidence that dwell times and humidity requirements are met, and then verify it through actual smokehouse data monitoring records. So, this is not as cut and dry as it seems to be written. The questions still remain surrounding this significant reinterpretation of validation. It currently stands that the industry doesn't specifically know what information will be required to provide validation evidence, and FSIS has not provided specific information on what they want or what they will accept.

The proof may be in the final validation document and the evidence of how it will exactly be implemented. AAMP continues to remain skeptical and not naïve enough to believe that this validation issue is as simplistic as the Agency is trying to portray it. Within the fact sheet, the Agency did make a very good point about making comments:

“If interested persons provide comments that focus on the problems that establishments have had in attempting to validate their HACCP system and on the aspects of the draft guidance document that are most troubling and confusing, the usefulness and clarity of the guidance that results from this process will be maximized.”

AAMP is requesting that you critically think about how all aspects of all of your HACCP plans, critical control points, pre-requisite programs, supporting documents, etc. will be affected as it is reviewed by the Agency when you are asked for your validation information. Will you be able to provide them with the proper information? What is the proper information that will be requested and/or required? Are you actually monitoring everything identified within all of your supporting documents to claim that data as your “validation documentation?” If not, is that going to be a significant burden to perform a complete mid-year reassessment, a potential re-write of your HACCP plans, a redesign of your HACCP monitoring forms, and potential implementation monitoring equipment? Could you be able to perform these activities for initial validation and then provide ongoing verification data for all of these aspects as a prudent establishment owner? These are all questions and concerns that you could address when submitting your comments to the Agency by June 19, 2010.