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FSIS Releases HACCP Validation Guidance...Industry Should Comment Or Be Prepared To Spend A Lot Of Money!

As you know, AAMP has been aware and concerned about the issue of HACCP validation since October, 2008. As you may recall, AAMP reported on the issue of HACCP validation in the October 1, 2008, edition of the AAMPifier. At that time, the issue didn't look very promising for the meat industry and that opinion hasn't changed much since the release of the draft validation guidance. We have met with the Agency on a variety of occasions and communicated with fellow meat industry trade organizations regarding this issue as well. It was almost six months to the day that nine national meat trade associations met with officials of the Food Safety and Inspection Service (FSIS) regarding the validation issue, expressed our concern, and hand-delivered a letter to the Agency regarding this issue. On March 19, 2010, FSIS dropped the bombshell by responding to the association letter and publishing draft guidance on HACCP system validation.

FSIS made available three documents on the validation of HACCP systems on its website at http://www.fsis.usda.gov/PDF/HACCP_Validation_Ltrs.pdf. You can also easily download this information from the AAMP website (www.aamp.com).

AAMP has read the guidance material several times, talked with other meat trade organizations and AAMP members, and the same conclusion is drawn every time. Unless you have microbiological data to prove that your critical operational parameters and "data" that your food safety systems produce safe products, you will have to provide validation documentation. Validation will be required for ALL HACCP plans, ALL prerequisite programs (e.g., *Listeria monocytogenes*, *E. coli* O157:H7, etc.), ALL critical control points (CCPs), and essentially ALL products. This would affect all federally inspected establishments and most likely be expected of state inspected establishments, if they want to maintain their equal-to status for USDA/FSIS.

What is Validation?

According to FSIS, validation includes two aspects:

1. 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)
2. In-plant validation (e.g., in-plant observations, measurements, microbiological test results, other information demonstrating that the control measures can be implemented within the particular establishment)

Essentially, FSIS is wanting proof whether the establishment is meeting the critical operational parameters and that the overall objective of the system to produce safe products is being achieved. If an establishment has the supporting documentation, they would meet the first requirement of validation. Although the establishment may be collecting the monitoring and verification activities over the years, that only demonstrates that the procedure was followed as dictated in the supporting documentation, but does not ensure that the activity was sufficient enough to control the pathogens identified in the hazard analysis. Therefore, microbial sampling would most likely be required.



What Data Should Be Collected?

The Agency specifically states that it does not advocate the introduction of pathogens in the plant environment. On the other hand, they are encouraging the enumeration of indicator organisms along with additional side-by-side pathogen positive/negative detection testing to gather data about the identified organisms of concern in the hazard analysis.



Considering establishments are continually asked to provide more information to inspection personnel, multiple indicator organisms and pathogens would most likely have to be addressed, since most establishments have clearly identified these pathogens within their HACCP plans. Well-known indicator tests or organisms include aerobic plate counts (APC), total plate counts (TPC), generic *e. coli*, etc. The pathogens could include *E. coli* O157:H7, *Salmonella*, *Listeria monocytogenes*, *Staphylococcus aureus*, *Clostridium botulinum*, *Clostridium perfringens*, etc.

Although 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)*) both clearly state "FSIS considers these guidelines, if followed precisely, to be validated process schedules, since they contain processing methods already accepted by the Agency as effective," the Agency may be reversing this consideration. After reading the validation guidance, it seems as though the Agency is now saying these documents can no longer be considered safe harbors. Therefore, validation at each establishment and of essentially all products must occur. In regards to a lethality CCP, the establishment may have to validate the destruction of *E. coli* O157:H7 (if the product contained beef), *Salmonella*, and *Listeria monocytogenes*. If the establishment identified cooling as a CCP, they may also be required to test for *Clostridium botulinum* and *Clostridium perfringens*.

How Much Data Should Be Collected?

The validation guidance outlines that FSIS believes that collecting samples at a point in the beginning of the process is necessary to establish the process' initial microbial load. FSIS also believes that collecting samples at a point after all interventions or ideally from finished and packaged products is necessary to determine whether the HACCP system, as designed, is capable of producing safe, unadulterated products. This would mean that establishments may have to take a series of microbial samplings throughout the process, or at least at two points in the process (raw material point and finished product point) for ALL HACCP plans, ALL prerequisite programs (e.g., *Listeria monocytogenes*, *E. coli* O157:H7, etc.), ALL CCPs, and essentially ALL products.

The document does provide some guidance as to how much data should be collected. The Agency does differentiate the expectations of large establishments from very small and small establishments. They allow establishments to collect the amount of samples that statistically represent the HACCP system's production volume. Since most meat processors are not statisticians, the Agency has provided further generic guidance for very small and small establishments. For slaughter, establishments can follow the regulations for the mandatory generic *E. coli* testing that is currently in place. This essentially means that the initial validation would most likely be 13 carcasses (with each species). After initial validation, the Agency has the expectation that a prudent establishment would continue sampling at an alternative frequency. The amount of samples for other HACCP processes is somewhat more vague, but sample collection could be determined by daily average production of 1,000 pounds or less per process category. This guidance is similar to what the Agency provided within the *E. coli* O157:H7 testing guidelines previously released. You should understand that the volume parameters identified with the *E. coli* O157:H7 testing guidelines was not established by science or statistics. It was simply an identified figure.

How Many Types Of Products Should Be Sampled?

The validation guidelines identify that establishments should collect microbial data for at least one product from each HACCP category utilized. They acknowledge that products can be grouped, but the similarities and differences in species, process, product public health risk, and food safety hazards should be considered. This means that if your products slightly vary, you may be required to perform validation on all of them. This could amount to the fact that most all products produced within an establishment would require validation. Many establishments have utilized a variety of formulations, so this could be a huge hurdle. An all beef snack stick may be considered different from beef and pork snack stick. The Agency gives an example that a whole product may be different than a sliced product, thus requiring validation for both. For the establishment that is producing a wide variety of RTE products, this is going to be a huge problem and an even bigger expense!



What Is The Expected Timeline?

A specific timeline has not been established to complete this complex initiative. In all truthfulness, establishments should have been required to perform this validation during the first 90 days after HACCP was implemented over 10 years ago. According to FSIS, establishments should develop these data during the initial 90 days of implementing a new HACCP system. Establishments should also develop these data whenever a new or modified food safety hazard control is introduced into an existing HACCP system. Establishments using existing HACCP systems developed prior to the issuance of this validation guidance that do not have the documents from their initial validation on file will need to gather data according to the timeline that the Agency will set out in a Federal Register notice that will be issued in the near future clarifying the validation requirement.

The validation guidance goes on to identify that a prudent establishment would continue sampling at an alternative frequency beyond the initial 90 day period as part of on-going verification to ensure that the HACCP system continues to be effective in controlling the identified hazards. This means that this expensive microbiological testing would continue FOREVER!

Regardless of the timeline that the Agency provides, this new validation initiative may be so financially burdensome that time won't be the issue. It will come down to the fact of whether you have the money to comply!

What Is The Potential Cost?

AAMP utilized a few supplier members who operate independent microbiological laboratories to get a variety of microbial sampling costs. With that information, AAMP did a cost analysis. It is very common for AAMP member establishments to utilize a variety of HACCP plans within a single establishment which could include:

- HACCP Plan – Beef Slaughter
- HACCP Plan – Pork Slaughter
- HACCP Plan – Lamb Slaughter
- HACCP Plan – Raw, Not Ground Meat and Poultry Products
- HACCP Plan – Raw, Ground Meat and Poultry Products
- HACCP Plan – Fully Cooked, Not Shelf Stable Meat and Poultry Products
- HACCP Plan – Not Fully Cooked, Not Shelf Stable Meat Products
- HACCP Plan – Heat-Treated, Shelf Stable Meat and Poultry Products



Since the new validation guidelines and scenarios are written so vaguely, it is difficult to determine what exactly will be accepted and what exactly will be expected from establishments. Historically, guidelines are interpreted by each person differently. The challenge most of the time comes when inspection personnel request supporting documentation for an establishment's food safety related decisions. Since supporting documentation is lacking for a majority of common sense food safety decisions, inspection personnel rely on guidelines to establish their minimal expectation of what is required.

Therefore, AAMP conducted the cost analysis with a very conservative approach. The financial figures were shocking!

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| <ul style="list-style-type: none"> • Slaughter HACCP plan (per species) | <p>Initial validation cost was approximately \$2,300
Ongoing validation cost was approximately \$700 annually</p> |
| <ul style="list-style-type: none"> • Fresh processing HACCP plan (per product) | <p>Initial validation cost was approximately \$2,000
Ongoing validation cost was approximately \$650 annually</p> |
| <ul style="list-style-type: none"> • RTE processing HACCP plan (per product) | <p>Initial validation cost was approximately \$12,000
Ongoing validation cost was approximately \$3,600 annually</p> |
| <ul style="list-style-type: none"> • Shelf stable HACCP plan (per product) | <p>Initial validation cost was approximately \$3,700
Ongoing validation cost was approximately \$1,100 annually</p> |

Other AAMP members have conducted similar cost analysis regarding the potential expectations of this issue. Their financial figures are very similar and resulted in initial validation costs for their entire food safety system of over \$120,000. This figure doesn't include the cost of ongoing validation if they survive the financial burden of initial validation.

Does this HACCP system validation issue have your attention yet?

Will This HACCP System Validation Affect You?

This will affect all federally inspected establishments and most likely be expected of state inspected establishments, if they want to maintain their equal-to status for USDA/FSIS. If an establishment has retail exempt status, this most likely may not affect them now, but those establishments should recognize that HACCP is beginning to be pushed further into retail with the Food and Drug Administration's (FDA) Food Code. Therefore, it may only be a matter of time before validation is requested of retail exempt establishments as well.

During the initial meeting with the Agency regarding this validation issue, AAMP presented an example of a federal establishment that had 8 HACCP plans with over 20 different CCPs, not to mention pre-requisite programs. This example federal establishment produced over 200 different types of products. While my example given in the meeting may be extreme, even if an establishment had half as many HACCP plans, half as many CCPs, and half as many products, this validation initiative would still be oppressive. AAMP recognizes the type of businesses that make up the membership and understand that many of the members operate a business with a structure that closely resembles the example provided.

Food safety is been a top priority for both AAMP and the members of the association. 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 nearly 10 years and this initiative pushes the industry back to the beginning without any clear and present need. Furthermore, if the industry collected all of this expected data, it is unknown what value any of this data will provide to make the meat products produced in the U.S. safer.

So why wasn't validation mandated 10 years ago when HACCP went into effect? AAMP believes the financial burden to the meat industry answers that question. The meat industry observed a decrease in the number of establishments when HACCP was implemented. This initiative 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 any 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.

If this validation initiative goes through 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 ironic 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.

So what can you do? COMMENT... COMMENT... COMMENT...

It is STRONGLY advised that you take the time to review the information provided and COMMENT appropriately. FSIS Administrator Al Almanza asks for comments on this draft validation compliance guide. Submit your comments to the email address DraftValidationGuideComments@fsis.usda.gov or to the Docket Clerk, USDA, FSIS, Room 2-2127, 5601 Sunnyside Avenue, Beltsville, MD 20705. Comments should be submitted by April 19, 2010. After April 19th, FSIS will begin its review on the comments it receives and its process of deciding how it will proceed with respect to the validation of HACCP systems.

Although AAMP will be commenting as an association on your behalf, it is extremely important that the Agency truly understand how this validation initiative will impact your business. The only way they will know how it impacts your business is if you personally tell them your story. Again, FSIS Administrator Al Almanza is asking for your comments on this draft guidance...give them to him!

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. A sample letter is available for you to use as a guide if you choose to comment. An EXCEL spreadsheet is also available so you can determine your estimated cost associated with all this potential microbiological testing. Feel free to share this information with fellow processors.