



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

AAMP LIFELINE

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OCTOBER 1, 2008

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Are You Prepared To Validate Your HACCP Plans?

After 12 years of HACCP, the United States Department of Agriculture's (USDA) Food Safety Inspection Service (FSIS) is changing the rules or its interpretation of the rules once again. This entire issue took AAMP and the regulated meat industry by surprise. FSIS is now asking all federal establishments to prove that the supporting documentation they have for their Critical Control Points (CCPs) is valid by conducting validation studies of all CCPs. The Agency is quick to point out that they are not asking establishments to perform challenge studies, a very costly investment, but rather validation studies.

It is questionable whether the Agency has the regulatory authority over this recent interpretation of the regulation. It seems as though they are only doing it for *E. coli* O157:H7 interventions and antimicrobial interventions for ready-to-eat (RTE) products and AAMP does not want to make this interpretation worse, but no one seems to have an explanation of why this recent interpretation is not being implemented across the board to all establishments and with all CCPs. After all, if it is regulation, then shouldn't all establishments be complying with it? FSIS officials told AAMP that Enforcement, Investigation, and Analysis Officers (EIAOs) were the only inspection personnel that will be reviewing this issue and the issue will only be addressed through Food Safety Assessments (FSAs). This means that we will continually have establishments across the U.S. operating under different levels of inspection.



What Is Written In The Regulation?

To further expand on the details, this "interpretation" is already in writing and has been in writing since 1996. It was written in the Federal Register (Volume 61, Number 144, pages 38826-38827). Also, it is reiterated 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."

AAMP questioned FSIS officials (Dr. Richard Raymond, Dr. Ken Petersen, and Dr. Dan Engeljohn) about the Federal Register Volume 61 – 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."

AAMP's Interpretation

FSIS officials told AAMP that our interpretation (*what follows below*) was incorrect....

Take this as an example only...AAMP interpreted the previously statement on page 38826 to mean that if a processor were making a frankfurter and utilized a sodium lactate/sodium diacetate ingredients to control *Listeria monocytogenes* (*Lm*) at the level stated in the scientific supporting documentation (regarding sodium lactate/sodium diacetate in frankfurters), that no further

inoculation/validation studies or any other research efforts would be needed as part of the validation process. On the other hand, if the processor were utilizing the same scientific document (regarding sodium lactate/sodium diacetate in frankfurters) on a specialty product (*i.e., hot coppa for example*) to control *Lm*, then the processor would have to perform validation studies to demonstrate the use of sodium lactate/sodium diacetate does act as a control for *Lm* in this product. The processors would have to perform such validation because the process/product was significantly different than the supporting document and the sodium lactate/sodium diacetate (a standard technology) was applied in an unusual way.

Since AAMP was told that our interpretation was incorrect, we have asked FSIS officials to provide AAMP with an official written Agency interpretation of the statement on page 38826 in the Federal Register referenced previously. Currently, we have not received a response.

Since this was written in 1996, we are attempting to put all of the pieces of the puzzle together on this issue. AAMP believes the meat industry had our same interpretation in mind. Now, FSIS is pulling the rug out from underneath the entire meat industry and degrading the platform of the current HACCP food safety system. In the beginning, establishments needed critical limits and those critical limits must be established by supporting documents. Then, FSIS stressed that those supporting documents must directly correlate to the establishment's specific process/product. Now, FSIS is stating that the supporting documents are only "theory" until they are validated in each establishment. Therefore, after 12 years of HACCP, FSIS is mandating that establishments go back to the beginning and do initial validation.

How Does The New FSIS Interpretation Potentially Affect You?

The initial validation issue is so much more of a larger issue than the Agency has even considered. It is only a matter of time before the Agency will demand this of every HACCP plan, every CCP, and most damaging of all...every product in any HACCP category be validated. FSIS officials made the statement that, since every product is different, they feel that it is important that every product should be validated. As AAMP mentioned in a meeting with the Agency, if an establishment only produced one product such as frankfurters, it wouldn't be too difficult to comply with the Agency's interpretation. Unfortunately, this is not the typical AAMP member or very small processor in the U.S. So AAMP questioned...what about the processor that produces multiple products in a HACCP category such as fully-cooked, heat-treated, not shelf-stable? The response given...the establishment should focus on the products that are the most risky and the products that are being produced at the highest volume. The Agency told AAMP that processors should start there and work their way through all the products they produce. Unfortunately, the Agency also believes that if the formulation or process changes, the validation should be redone. Therefore, this interpretation will be an ongoing financial burden to the meat industry.



From what AAMP has been told, state meat inspection programs are not exempt from this same interpretation. FSIS is expecting the state meat inspection programs to follow the same interpretation to validate each CCP...starting with *E. coli* O157:H7 interventions and antimicrobial interventions for RTE products.

It has been mentioned that Carol Tucker Forman, long-time advocate for consumers and food safety, was concerned about a mass exodus of establishments that would change from federal inspection to state inspection if the interstate shipment bill for state inspected meat products was passed. Well, she hasn't seen anything until the Agency fully mandates their validation interpretation on to the meat industry. AAMP fears many establishments will simply withdraw from inspection (federal or state) and revert to compliance with retail exemption regulations or even worse...simply give up and close their business. When faced with unachievable goals, non-stationary demands of the Agency and HACCP, and the financial burden to get products into commerce through federal inspection, what other choice is available to the meat industry?

Meat Industry Guidance Information

So what guidance is available to the meat industry regarding validation for the effectiveness of *E. coli* O157:H7 interventions for beef slaughter and *Lm* interventions in RTE products? Not much, if any...

Specifically regarding the effectiveness of *E. coli* O157:H7 interventions for beef slaughter, Agency officials explained that scientific research papers were available that demonstrate a reduction in aerobic plate counts (APC) on beef carcasses. The Agency has said that if an establishment could demonstrate a reduction in APC, this reduction will equal a reduction in *E. coli* O157:H7, or so the "Agency will concede." AAMP has reviewed these scientific research papers, and no direct relationship or correlation has been established between a reduction of either APC or coliforms and a reduction in *E. coli* O157:H7. AAMP acknowledges that while it may be logical to conclude that a reduction in APC may demonstrate a reduction in *E. coli* O157:H7, logic in the absence of supporting documentation has not been an acceptable method to proceed in the HACCP system. Without any supporting documentation to show that a reduction of these "indicator" organisms actually correlates to a reduction of *E. coli* O157:H7, the use of these scientific research papers does not seem to be an effective solution. Any knowledgeable EIAO that would review these scientific papers would most likely draw the same conclusion.



In regards to the effectiveness of antimicrobial interventions for RTE products, AAMP has received no guidance on validation methodology. AAMP is aware of one member who recently went through an extensive FSA and the EIAO requested documentation for validation about the use of antimicrobials in the establishment's RTE products. Having none, the establishment answered the question and solved the problem quickly for the EIAO. The establishment switched from Alternative 2 (*sanitation program and the use of antimicrobial agent*) to Alternative 3 (*sanitation program only*), and is continuing to use the antimicrobial as a processing aid or as an ingredient. The establishment was already conducting *Lm* contact surface testing at the level recommended for establishments that chose Alternative 3, so if the establishment is going to be harassed by FSIS who so strongly encouraged the use of an antimicrobial in the first place, they weren't going to continue chasing a moving target. The result...the establishment didn't receive a Non-compliance Report (NR) for its fully-cooked, heat-treated, not shelf-stable HACCP plan.

As for the validation of the other HACCP plans and CCPs...the industry has not been given any guidance from the Agency on what constitutes appropriate validation methodology.

AAMP Is Not The Only One That Disagrees With The Agency's New Interpretation

Please understand...it is not only the AAMP membership that is affected by the Agency's recent interpretation. This issue has been discussed with other meat trade organizations and they are experiencing the backlash. AAMP is trying to determine a workable solution and work with other meat industry organizations to find answers.

AAMP has also heard that many EIAOs and inspection personnel don't agree with this new interpretation and have no practical guidance to give to the establishments that are currently affected. It seems as though Agency officials have given their inspection personnel that are on the front lines their marching orders, but failed to supply them with any guidance on this issue either. So much for the Agency's propaganda of "educate prior to regulate." Everyone is asking the same question...when is enough going to be enough and when is the Agency going to stop changing the rules by which they regulate?

What Can You Do As Establishment Owners?

Establishments should be very concerned about this issue and should be extremely vocal about this issue. If it doesn't affect you currently, it will someday. You should be voicing your concerns to your state

legislators as well as the Small Business Administration (SBA). Since HACCP was developed 12 years ago, AAMP highly doubts that the current interpretation was something the meat industry expected or agreed with. After reviewing some previous documents, AAMP cannot locate any economic impact analysis that was performed on what FSIS is currently mandating. AAMP acknowledges that some testing was always going to be required within the HACCP regulation, but definitely not at this level. This new Agency interpretation has the potential to be quite costly for the low-volume, independent meat processing industry.

To contact your state legislators and voice your concern over this issue, you can easily find their contact information by utilizing the following online tools:

House of Representatives search function to find your U.S. Representatives:
<https://forms.house.gov/wyr/welcome.shtml>

Senate search function to find U.S. Senators:
http://www.senate.gov/general/contact_information/senators_cfm.cfm



If you don't have access to the internet or cannot find the contact information you are searching for, you can also contact the AAMP office (877-877-0168) and the AAMP staff will assist with this process.

If you wish to contact the Office of Advocacy within the Small Business Administration:

Mail: Office of Advocacy
 U.S. Small Business Administration
 409 3rd Street, SW
 Washington, DC 20416

Phone: (202) 205-6533
 Email: advocacy@sba.gov
 Website: www.sba.gov/ADVO/



You can also contact the SBA Ombudsman, which offers the opportunity to submit online comments on regulatory unfairness for small business. The website is www.sba.gov/aboutsba/sbaprograms/ombudsman/index.html. On the online comment form, there is the option to keep your identity confidential.

Appealing An NR Is An Option

If you are approached to provide initial validation for *E. coli* O157:H7 interventions and antimicrobial interventions for RTE products, it is recommended that you appeal the NR you will receive regarding this issue. It is strongly recommended that you follow the proper channels when appealing an NR. AAMP has previously posted information on the appeals process on the member's section of the AAMP website (www.aamp.com). Appeal this issue based on:

1. *E. coli* O157:H7 interventions and antimicrobial interventions for RTE products are both processes that are well-documented in the scientific literature.
2. Most likely, the Agency (FSIS) has no data to support the determination that the establishment's HACCP system is not being effectively implemented or that products are or were produced under unsanitary conditions.
3. The establishment's historical data and documentation (*i.e.*, in-plant test results and FSIS test results) demonstrates that these two pathogens have been controlled.
4. The establishment has no knowledge of scientific supporting documents that demonstrate a direct relationship/correlation between a reduction of indicator organisms (*i.e.*, APC, coliforms, etc.) and a reduction in *E. coli* O157:H7.
5. No guidance has been provided to the industry on how to specifically validate every HACCP plan, every CCP, and every product in any HACCP category.
6. The Agency has never conducted a thorough economic impact analysis on this interpretation.