

AAMP's Perspective on Draft Guidance of HACCP System Validation



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Does it Affect You?

- If you think that these topics or regulations don't affect you, you may be wrong!
- Federal Inspection Program
- State Inspection Programs
 - Must enforce requirements "*at least equal to*" those imposed under the Federal Meat and Poultry Products Inspection Acts
- Retail Exemption
 - Must comply with the FDA Food Code in which HACCP plans are mandated for specific processes



HACCP Plan Validation

- AAMPlifier
 - October 1, 2008
- AAMP initially reported on the validation issue



OCTOBER 1, 2008

JAY E. WENTHER
EDITOR

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

HACCP Plan Validation

- Captiol Line-Up
 - April 1, 2010
- AAMP's current report on the validation issue



**Capitol
LINE-UP**
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April 1, 2010
Editor: Jay B. Wenther, Ph.D.

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 effect 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.



HACCP Plan Validation

Opposed by ALL
national meat and
poultry trade
organizations
regardless of who
they represent



HACCP Plan Validation

- Timeline
 - October, 2008 – Initial discussions
 - August, 2009 – Meet with FSIS officials
 - September, 2009 – Submitted industry letter
 - February, 2009 – Dr. Petersen letter
 - March, 2010 – Response letter and Guidance document released
 - April, 2010 – Meet with FSIS officials
 - June 19, 2010 – Industry comments due



HACCP Plan Validation

- Previous published regulation
 - Title 9 CFR – 417.4(a)(1) – Validation, Verification, Reassessment

“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.”

HACCP Plan Validation

- Previous published regulation
 - 1996 – Federal register 61 FR 38826-38827

“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.”

HACCP Plan Validation

- Trade association letter
- FSIS response letter
- Published guidance

Website access:

www.fsis.usda.gov

www.aamp.com

DRAFT GUIDANCE: HACCP SYSTEMS VALIDATION

Introduction

FSIS has developed this guidance document to aid small and very small plants and in particular low volume production plants in meeting the validation requirements in 9 CFR 417.4. On July 25, 1996, FSIS published the Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule ([61 FR 38806](#)) Docket No. 93-016F. This document presented the validation requirements for meat and poultry establishments in 9 CFR 417.4. The regulation states each establishment is required to validate the effectiveness of its HACCP plans in controlling those food safety hazards identified during the hazard analysis. The regulation also states that establishments are to conduct these validation activities during the establishment's initial experience with a new HACCP plan and encompasses additional activities that make up the entire HACCP system. In addition to the regulatory language, the final rule also stated what constitutes validation and this document is designed to review that understanding and to provide practical guidance for small and very small plants on how to validate their own food safety systems. Plants that do not incorporate these principles into their HACCP systems would raise questions whether the HACCP system has been adequately validated.

Definition of HACCP System

The HACCP system is defined as the HACCP plan in operation, including the HACCP plan itself. The HACCP plan in operation includes the hazard analysis, the supporting documentation including prerequisite programs supporting decisions in the hazard analysis and the HACCP records.

It is important for establishments to realize that those prerequisite programs designed to support a decision in the hazard analysis are part of the HACCP system. For example, when an establishment determines that a hazard is not reasonably likely to occur because the prerequisite program prevents the hazard, that prerequisite program then becomes part of the HACCP system. These prerequisite programs provide a foundation for the HACCP plan to operate effectively. Therefore, these prerequisite programs need to be part of the establishment's validation activities to demonstrate that the overall system is validated and can operate effectively. For this reason, the HACCP system rather than the HACCP plan only is discussed throughout the rest of this document.

Note: The HACCP system, rather than just the HACCP plan, is discussed throughout the rest of this document.

Validation Has Two Parts

HACCP Plan Validation

- According to interpretation of the draft guidance
 - This will be implemented to all
 - ALL HACCP plans
 - ALL CCPs
 - ALL prerequisite programs
 - Essentially ALL products within each HACCP category.
 - Guidance relies heavily on microbiological testing



HACCP Plan Validation

- What is validation?
 1. Supporting documentation
 - Provides theoretical food safety
 2. In-plant validation data
 - Provides proof of food safety
 - In-plant observations
 - Measurements
 - Microbiological test results



HACCP Plan Validation

- What data should be collected?
 - Indicator organisms along with additional side-by-side pathogen positive/negative detection testing
 - Indicator tests or organisms include
 - aerobic plate counts (APC), total plate counts (TPC), generic *e. coli*, etc.
 - Pathogens
 - *E. coli* O157:H7, *Salmonella*, *Listeria monocytogenes*, *Staphylococcus aureus*, *Clostridium botulinum*, *Clostridium perfringens*, etc.



HACCP Plan Validation

- Use of safe harbors and supporting document are now being questioned
 - Regulations
 - Documents (Appendix A, Appendix B, etc.)
 - Scientific supporting documents (peer-reviewed)

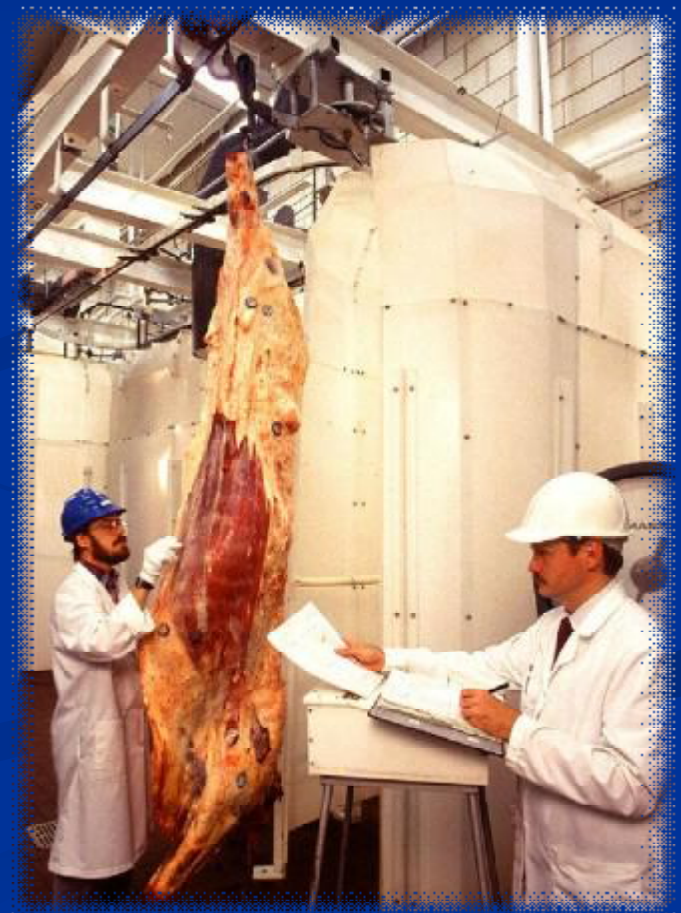


HACCP Plan Validation

- How much data should be collected?
 - Guidance is vague
 - Slaughter
 - Initial - 13 carcasses (with each species)
 - Ongoing - a prudent establishment would continue sampling at an alternative frequency
 - Other HACCP processes
 - Initial - unknown
 - Ongoing - a prudent establishment would continue sampling at an alternative frequency

HACCP Plan Validation

- Ongoing sampling
 - What happens if you have a positive test result?
 - Does that bring everything into question since the previous sample?



HACCP Plan Validation

- How many products should be sampled?
 - Guidance is vague
 - Microbial data for at least one product from each HACCP category utilized
 - Products can be grouped, **BUT** the similarities and differences in species, process, product public health risk, and food safety hazards should be considered



HACCP Plan Validation

- What is the expected timeline?
 - Truthfully it should already be done, but the previous FSIS interpretation never included microbial sampling
 - Initial validation – first 90 days of new HACCP plan
 - Timeline that the Agency will set out in an upcoming Federal Register notice



HACCP Plan Validation

- What is the estimated cost?

| | |
|---|--|
| • Slaughter HACCP plan (per species) | Initial validation cost was approximately \$2,300 Ongoing validation cost was approximately \$700 annually |
| • Fresh processing HACCP plan (per product) | Initial validation cost was approximately \$2,000 Ongoing validation cost was approximately \$650 annually |
| • RTE processing HACCP plan (per product) | Initial validation cost was approximately \$12,000 Ongoing validation cost was approximately \$3,600 annually |
| • Shelf stable HACCP plan (per product) | Initial validation cost was approximately \$3,700 Ongoing validation cost was approximately \$1,100 annually |

HACCP Plan Validation

- Consider your number of HACCP plans and product variability

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

Validation Cost Calculator

Microsoft Excel - ValidationCosts (Read-Only) [Compatibility Mode]

| | A | B | C | D | E | F | G | H | I | J | K |
|----|---|---------|----------|--|---|---|---|---|---|---|---|
| 3 | | | | | | | | | | | |
| 4 | | | | | | | | | | | |
| 5 | Microbial Test Prices | | | | | | | | | | |
| 6 | | | | | | | | | | | |
| 7 | Aerobic Plate Count (APC) | | \$8.00 | | | | | | | | |
| 8 | Generic <i>E. coli</i> petrifilm | | \$8.00 | | | | | | | | |
| 9 | PCR <i>E. coli</i> O157:H7 | | \$16.00 | | | | | | | | |
| 10 | PCR <i>Salmonella</i> | | \$20.00 | | | | | | | | |
| 11 | <i>Salmonella</i> FDA | | \$22.00 | | | | | | | | |
| 12 | <i>Clostridium perfringens</i> | | \$25.00 | | | | | | | | |
| 13 | <i>Clostridium perfringens</i> confirmation | | \$15.00 | | | | | | | | |
| 14 | <i>Clostridium botulinum</i> | | \$300.00 | | | | | | | | |
| 15 | <i>Listeria species</i> | | \$16.00 | | | | | | | | |
| 16 | <i>Listeria monocytogenes</i> | | \$20.00 | | | | | | | | |
| 17 | Environmental Swab Kit | | \$10.00 | | | | | | | | |
| 18 | | | | | | | | | | | |
| 19 | | | | | | | | | | | |
| 20 | | | | | | | | | | | |
| 21 | Validation Samples Required | 13 | | Change the number if you will require a different amount of initial testing. | | | | | | | |
| 22 | Freight Cost | \$44.00 | | Enter your freight rate if you know what it will be. | | | | | | | |
| 23 | Supplies Cost | \$0.20 | | Based on 50 swabs per test kit. | | | | | | | |
| 24 | | | | | | | | | | | |
| 25 | | | | | | | | | | | |
| 26 | | | | | | | | | | | |
| 27 | Total Cost Initial Validation Testing | | \$0.00 | | | | | | | | |
| 28 | | | | | | | | | | | |
| 29 | | | | | | | | | | | |
| 30 | Verification Tests Required | 4 | | Change the number if you will require a different amount of annual testing. | | | | | | | |
| 31 | | | | | | | | | | | |
| 32 | | | | | | | | | | | |
| 33 | Total Cost Ongoing Verification Testing | | \$0.00 | | | | | | | | |
| 34 | | | | | | | | | | | |
| 35 | | | | | | | | | | | |
| 36 | | | | | | | | | | | |
| 37 | Version - 3/31/2010 | | | | | | | | | | |
| 38 | NOTE: If you utilize one of the HACCP plans listed below, insert a 1 in the yellow box. If you don't utilize one of the HACCP plans listed below, insert a 0 in the yellow box. Within each HACCP plan category, enter the amount of products you produce in the red box. | | | | | | | | | | |
| 39 | | | | | | | | | | | |

Validation Cost Calculator - Sheet3

Validation Cost Calculator

- Allows you to modify:
 - Your microbial testing cost
 - Your shipping costs
 - Your initial validation sampling frequency
 - Your ongoing verification sampling frequency
 - Which HACCP plans you are utilizing
 - The amount of products you are producing within each HACCP plan
- Automatically generates your potential initial validation testing costs and ongoing verification testing costs

HACCP Plan Validation

- AAMP questions
 - What benefit the industry would get from the collection of this microbial data...how will it improve the safety of the meat products produced?
 - The scientific validity of the validation methods
 - Costs to the meat industry
 - Impact to the remaining very small and small independent inspected establishments



AAMP Validation Resources

- What is AAMP doing?
 - Meeting with other national meat trade associations
 - Meeting with FSIS officials
 - Communicating with AAMP affiliates
 - Providing the meat industry guidance
 - AAMPifier – October 1, 2008
 - Capitol Line-Up – April 1, 2010
 - Sample form letters
 - New webpage - www.aamp.com/Validation.php
 - EXCEL spreadsheet

AAMP Validation Resources



The screenshot shows a web browser window displaying the AAMP website. The browser's address bar shows the URL <http://www.aamp.com/validation.php>. The website header features the AAMP logo on the left, the text "Serving the Meat Industry Since 1939!" in the center, and an advertisement for EXCALIBUR SEASONING COMPANY on the right. Below the header is a red navigation bar with links: Home, About AAMP, Food Safety, Event Calendar, Regulations, Latest News, Links, Contact Us, and Members Only. The main content area is titled "North America's Largest Meat Trade Association" and features a section for "Validation of HACCP Systems". This section includes a definition of validation, a list of two key elements for validation, and a paragraph explaining the purpose of the validation page. To the right of the text are two advertisements: one for UniFirst uniforms and services, and another for GOURMET SMOKE products. Below the main text is a section titled "Information from AAMP" with a bulleted list of recent news items and draft comments.

AMERICAN ASSOCIATION OF MEAT PROCESSORS

Serving the Meat Industry Since 1939!

EXCALIBUR SEASONING COMPANY

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North America's Largest Meat Trade Association

Validation of HACCP Systems

Validation is the process of demonstrating that the HACCP system as designed can adequately control identified hazards to produce a safe product. There are two distinct elements to validation:

- The scientific or technical justification or documented basis for the system. This consists of having scientific and technical documentation that demonstrate that the designed process can control the identified hazard. In other words, will the HACCP work in theory?, and
- The initial practical demonstration proving the system can perform as expected. This consists of having records which demonstrate the plan in operation, the HACCP plan achieves what is expected to achieve. In other words, does the plan work in practice?

The validation page was developed to provide an information resource on validation to small and very small meat and poultry establishments in order to help them obtain information to assist in understanding the issue and comment on this issue.

Information from AAMP

- **AAMPifier - October 1, 2008**
- **Capitol Line-Up - April 1, 2010**
- **AAMP's Perspective of Draft Guidance on HACCP System Validation - PDF of Microsoft POWERPOINT**
- **HACCP Plan Validation Issue Requires Your Attention and Comments Are Needed - Independent Processor**
- **Draft comments - Meat Industry Establishments**
 - **Sample Comment Letter - Detailed - Microsoft WORD Format**
 - **Sample Comment Letter - Generic - Microsoft WORD Format**
 - **Talking Points - 4-1-201**

UniFirst
Uniforms & Services dedicated to HACCP compliance.
unifirst.com

GOURMET SMOKE
New from Excalibur

HACCP Plan Validation

- What can you do?
 - COMMENT
 - Due by April 19, 2010
 - Utilize the information provided to you
 - Communicate with your legislators
 - Communicate with your state Farm Bureau
 - Communicate with your customers
 - Communicating with fellow meat processors



HACCP Plan Validation

- Represents a drastic policy on Agency expectations on validation of HACCP systems
- Document is ambiguously written to including excessive microbial testing to validate all processes, regardless of whether the process is well-recognized scientifically as valid and effective
- No food safety problem has been identified to require this shift in Agency interpretation of validation
- Benefit to public health regarding microbial testing is unknown and not identified
- Significant costs to the meat industry

HACCP Plan Validation

- FSIS Administrator Al Almanza asks for comments on this draft validation compliance guide
- Submit your comments to:
 - Email: DraftValidationGuideComments@fsis.usda.gov
 - Mail: Docket Clerk, USDA, FSIS
Room 2-2127
5601 Sunnyside Avenue,
Beltsville, MD 20705
- Comments should be submitted by June 19, 2010

Questions

