



**FOOD & BEVERAGE**  
Research, Development & Engineering  
655 Lone Oak Drive  
Eagan, MN 55121

June 1, 2010

Mr. Alfred Almanza, Administrator  
Food Safety and Inspection Service  
U.S. Department of Agriculture  
Washington, DC 20250-3700

**RE: Comments on "Draft Guidance: HACCP Systems Validation"**

Dear Mr. Almanza,

Ecolab is a global leader in cleaning, food safety and health protection products and services. Ecolab reaches customers in 160 countries, employing over 26,000 associates worldwide. Customers include hotels and restaurants; food service, healthcare and educational facilities; quick service (fast food) units; commercial laundries; light industry; dairy plants and farms; and food and beverage processors. Ecolab has 500 associates dedicated to supporting our food and beverage production and processing customers. Products and services provided to the food and beverage customers include cleaning and sanitizing products & services, and pathogen reduction interventions. Over 200 meat and poultry processing establishments in the United States use Ecolab interventions such as the SANOVA<sup>®</sup> food safety system, Inspexx<sup>™</sup> and Octa-Gone<sup>™</sup>. We are committed to our customers and work closely with them to help advance our vision to make the world and cleaner, safer, and healthier place.

Ecolab reviewed the draft guidance document issued by the Food Safety and Inspection Service (the Agency) entitled, "Draft Guidance: HACCP Systems Validation," and is pleased with FSIS efforts to emphasize the need to demonstrate that interventions applied are effective in practice. However, we identified several areas of the guidance that should be modified to accommodate innovative interventions that can further enhance the safety of meat and poultry products. Our comments are focused on the proposed in-plant validation testing to demonstrate the effectiveness of a HACCP system to achieve the intended result. This letter summarizes our comments on the Agency's guidance.

### **Accommodations for Targeted Interventions**

The draft guidance does not discuss intervention technologies that act specifically upon pathogens – hereafter referred to as targeted interventions. To be clear, targeted interventions are differentiated from non-targeted interventions as follows:

- Targeted interventions
  - These interventions have specific modes of antimicrobial action that target a characteristic typically associated only with a specific pathogen (e.g., *E. coli* O157:H7) or group of microbial pathogens (e.g., *Salmonella enterica* subspecies I of the O-antigen serogroup B). Examples of targeted interventions for in-plant use are bacteriophages<sup>1</sup> and modified R-type pyocins<sup>2</sup>. Vaccination is an example of a targeted intervention used prior to slaughter.
- Non-targeted interventions
  - These interventions have non-specific modes of antimicrobial action that target characteristics associated with broad classes of microorganisms that may include pathogens and non-pathogens alike. Examples of non-targeted interventions are chemicals (e.g., chlorine, lactic acid) and irradiation.

Our first recommendation is to modify the guidance for in-plant validation testing to clarify that enumeration of indicator organisms is not applicable for verifying or validating the efficacy of an intervention that targets and kills only a specific pathogen. For example, measuring reductions in traditional indicator organisms is not useful for a bacteriophage that targets and kills only *Listeria monocytogenes*; likewise, measuring reductions in indicator organism levels is not applicable for modified R-type pyocins that target and kill only *E. coli* O157:H7.

In order to accommodate pathogen-targeting interventions, we recommend revising the guidance to further emphasize that measuring pathogen reduction levels in a laboratory setting that mimics operating conditions may be a necessary and acceptable way to demonstrate the effectiveness of a HACCP system to achieve the intended result. This would be coupled with a means to validate and verify the delivery of the targeted intervention through indirect measures in the production process.

### **Accommodations for Pathogen Surrogates**

Validating the efficacy of an intervention by measuring reduction of naturally occurring pathogen levels is problematic and can be prohibitively time-consuming and expensive because incoming levels and prevalence can be quite low. A potential solution to this problem involves inoculation of food with appropriate non-pathogenic surrogates. For example, in the case of a targeted intervention that kills only *E. coli* O157:H7, there are

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<sup>1</sup> Federal Register. Friday, August 18, 2006. Food Additives Permitted for Direct Addition to Food for Human Consumption; Bacteriophage Preparation. Vol. 71, No. 160. Pages 47729-4732.

<sup>2</sup> Scholl, D., et al. 2009. An engineered R-type pyocin is a highly specific and sensitive bactericidal agent for the food-borne pathogen *Escherichia coli* O157:H7. *Antimicrobial Agents and Chemotherapy*. Vol. 53, No. 7. p. 3074-3080.

genetic variants of *E. coli* O157:H7 that are non-pathogenic, but react to the targeted intervention. A non-pathogenic microorganism (or substance) that reacts with a targeted intervention could be inoculated onto a food surface for the purpose of laboratory or pilot-plant verification. Thus, we recommend allowing inoculation of food product with non-pathogenic surrogates - either microorganisms or substances - for the expressed purpose of in-plant efficacy verification. If food product inoculated with the non-pathogenic surrogate is intended to enter commerce, then the surrogate would need to be reviewed by the Agency and considered safe and suitable for its intended use.

To further illustrate how the draft guidance can be modified to include targeted interventions and pathogen surrogates, sections of the draft guidance with Ecolab edits are included (see Attachment 1). We appreciate your careful consideration of our comments.

Best regards

John Hilgren  
Senior Scientist  
Ecolab Inc.

## ATTACHMENT 1 – Ecolab Recommended Changes

[Starting on page 6]

### In-Plant Validation: Demonstrating Effectiveness of HACCP System to Achieve Intended Result

In addition to demonstrating that each intervention or process step within a HACCP system can be implemented according to the critical operational parameters described in the scientific technical support, in-plant validation also includes gathering data to demonstrate that the collection of interventions and process steps together in sequence produce a safe, wholesome unadulterated product. In other words, is the HACCP system achieving the desired result? FSIS believes that microbiological testing that combines enumeration of indicators with the presence/absence of an identified pathogen in conjunction with monitoring critical parameters plays an important role in the initial validation of many, but not all, interventions for biological food safety hazards. Microbiological testing data, where appropriate, can provide establishments information about whether the overall system of interventions can achieve the desired log reductions documented in the scientific supporting documentation. Establishments would need to provide support in instances where they believe microbiological testing data is not needed to demonstrate the effectiveness of the HACCP system in controlling biological food safety hazards. For example, indicator organism tests in-plant may not be applicable for validating the effectiveness of an intervention that targets a specific pathogen, but methods to validate delivery of the intervention during operation would be important. Once the operational effectiveness of each individual intervention is determined, the establishment can use microbiological testing data in conjunction with the data on the individual interventions to establish that the process as a whole results in the production safe, unadulterated product. In this final part of step 2 initial in-plant validation, the establishment should pull together the data for each intervention and the data from microbiological testing at various points throughout the HACCP system to ensure that the multiple hurdle design of its entire HACCP system will result in the production of safe, unadulterated products. Failure to take these steps will raise questions whether the HACCP system has been adequately validated.

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[Starting on page 7]

### 2. What laboratory analyses should be performed?

FSIS does not advocate the introduction of pathogens into the establishment environment resulting in intentional adulteration of product. In this type of testing, enumeration of indicator organisms should be used with additional side-by-side pathogen positive/negative detection testing to gather data about the identified organisms of concern in the hazard analysis. Gathering data on the presence/absence of the pathogen fully demonstrates that the system is able to mitigate the food safety hazard that was identified in the hazard analysis as the desired result of the HACCP system. Enumeration of indicator organisms may not be appropriate when examining the efficacy of an intervention that targets only the identified organism of concern. For these

targeted interventions, measuring pathogen reduction levels in a laboratory setting that mimics operating conditions is an acceptable way to demonstrate the effectiveness of a HACCP system to achieve the intended result. This would be coupled with a means to validate and verify the delivery of the targeted intervention through indirect measures in the production process.

*An indicator organism is an organism that if present, indicates the possible presence of a particular pathogen. Jay's Modern Food Microbiology, 4th Edition, describes a good indicator organism as easily detectable and countable, has a historical association with the pathogen of concern, is usually present when the pathogen is present, is an organism whose number counts correlate with the pathogen's of concern, has similar growth requirements and rates, and is usually absent from, or present at minimum numbers, in finished products. For meat and poultry products, these criteria have generally translated into organisms associated with the GI tract of warm blooded animals because of their close relationship with fecal and ingesta materials. Examples of these organism groups are Enterobacteriaceae, coliforms, and generic E. coli. For certain circumstances, organisms recovered by performing aerobic plate counts (APCs) also known as total plate counts (TPCs) have been used in the scientific literature as indicators. The reference list at the end of this document includes additional information on indicator organisms.*

There is no gold standard list of indicators agreed upon by the scientific community that will fit every situation. The reference list includes information from the literature on potential indicators for certain situations. 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. Often, the scientific support (Part 1) contains microbiological data for both indicators and pathogens to validate the theoretical principle of the intervention. Establishments where possible, should use these scientific support documents to guide microbiological analyses choices. In the absence of this information, as stated above, the references at the end of this document contain further information to guide establishments in making indicator choices when appropriate.

The limit of detection for most indicator organisms is higher than the numbers of many pathogens present on meat and poultry products such as *E. coli* O157:H7. *E. coli* O157:H7, when present, is usually present at low levels. Therefore, when appropriate, it is important for the establishment also test for an indicator organism when validating an intervention's log reduction capabilities under in-plant conditions. It is important to note, however, that use of indicators may not be appropriate when targeted interventions are employed because they are designed to reduce the level of the pathogen and have little or no effect on general indicator organisms. Testing for levels of both indicator organisms (or critical parameters) and presence/absence of the identified hazard can be useful to ensure that not only is the establishment's HACCP system (i.e. sum of all interventions) achieving the specific log reduction as described in that hazard analysis (indicated by indicator organism counts), but also that the interventions are successful at controlling the pathogens of interest to below detectable levels for adulterants or to

acceptable levels for other raw processes. Any positive sample for an adulterant would be an indication that the process is either not being implemented properly (compare data with critical parameter measurements), or that the process is inadequate. A greater than expected microbial count or positive rate of other identified biological hazards would indicate that the HACCP system is unable to achieve the desired outcome and would need alteration.

Such an indication would be evidence there is a need for changes to the HACCP system and the establishment should review all records associated with the process to make appropriate modifications to its HACCP system.

Sample size and detection limit specifications can be found in the Microbiological Laboratory Guidebook.



Dear Mr. Almanza:

Desert Meats & Provisions appreciates the opportunity to comment on the recently released document, "Draft Guidance: HACCP Systems Validation" (Draft Guidance).

Desert Meats is located in Las Vegas Nevada. We employ approximately 70 employees and produce approximately 35,000 pounds of Beef, Poultry, Veal, Pork and Lamb per week. We have been in business for nearly 32 years.

We are dedicated to food safety, strive to work in a synergistic manner with FSIS to improve food safety and public health and are constantly evaluating our food safety programs for enhancements.

We believe the Draft Guidance, if finalized as written, would be overly burdensome to our company and the meat and poultry industry as a whole. We do not believe the guidance document would enhance our food safety programs, but only hinder it. We believe the Draft Guidance should be completely reevaluated and has the potential to be misused as a regulatory requirement.

Specifically we would like to make the following major points:

- It is common practice for FSIS guidance documents to be misinterpreted in the field as regulatory requirements. It is even more common to have Agency personnel measure establishment programs against such guidance documents and then, if interpreted by Agency personnel as failing to meet guidance expectation, to cite insufficient supporting documentation as a HACCP non-compliance (9 CFR 417.5 a(1) & a(2)). This has happened repeatedly in our company. We see this Draft Guidance as a document with the potential to add further to this issue. In effect, policy conflicts and misinterpretations manifesting themselves as alleged regulatory non compliances.
- The Draft Guidance appears to indicate a need to validate each supporting scientific technical document used as justification for decisions in the HACCP Plan, rather than specific critical points in the HACCP process. This would seem to go against current common food safety practices implemented in the industry and accepted by FSIS as instrumental in producing safe food. This expectation would be overly burdensome to our company as we have numerous processes and supporting science for our HACCP

decision making. We believe this would be counterproductive to us and the industry at large by creating a disincentive from amassing a thorough scientific review and documentation in support of our HACCP process. Also, if the guidance is indicating such a need for validation, what process will FSIS implement to prevent Agency personnel from singling out individual supporting scientific documents (or portions therein) in our company's HACCP process and citing inadequate validation as support for issuing noncompliance actions?

- The Draft Guidance indicates FSIS's belief that microbiological testing for indicator organisms and pathogens is an integral part of the initial validation process, with an establishment's need to provide support for why such testing is neither worthwhile nor necessary. This requirement would add an overly burdensome impact to our business by expecting in plant validation results from many different stages of our process, with no stated improvement in food safety. Also, most published scientific studies enumerate pathogens by log counts, whereas industry available pathogen tests and testing are absolute tests (i.e. absence/presence tests). We do not see how the tests commonly available to industry would validate cited science when the testing differs. The first cited Reference in the Draft Guidance (AMA. 1999. American Meat Science Association, Symposium: The Role of Microbiological Testing in Beef Food Safety Programs. January 20-22, 1999. American Meat Association, Kansas City, Missouri) clearly delineates the scientific shortcomings of microbiological testing, particularly for pathogens present at low incidences (such as *E. coli* O157:H7 has been proven to be in today's beef products). This science would seem to contradict FSIS's stated belief on the need for microbiological pathogen testing in many instances and processes. As a note, the citation is incorrectly cited as "AMA" instead of AMSA and incorrectly listed as the "American Meat Association" instead of American Meat Science Association.
- The Draft Guidance appears to indicate microbiological testing and other such validation data would be expected in support of commonly accepted supporting scientific documents such as FSIS's Appendix A to "Performance Standards for the Production of Certain Meat and Poultry Products" and Appendix B to "Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products". This despite the fact that FSIS already has the supporting microbiological data for the process relationships stipulated in those documents. Our currently accepted and FSIS approved practice for these documents is to provide supporting data for the operational parameters of temperature measurements when using these documents. If such testing is to become a FSIS expectation, why, after some many years of temperature control compliance (in our case), does FSIS now believe this new data is needed, and what will keep Agency personnel from singling out individual cooked products and citing inadequate microbiological data as support for issuing noncompliance actions?

We ask that FSIS reconsider and revise the Draft Guidance to better reflect long accepted science based and currently FSIS accepted industry practices. We also ask that the guidance document be written to remove ambiguity to minimize the potential for differing interpretations in the field.

Finally, we thank you for your past attempts to engage the industry in this process and ask that you continue to engage the industry in this process in the future.

Sincerely,

A handwritten signature in cursive script that reads "Chere Kern". The signature is fluid and elegant, with the first and last names being clearly legible.

Chere Kern  
Quality Assurance  
Desert Meats & Provisions



**Advocacy: the voice of small business in government**

May 10, 2010

Alfred V. Almanza  
Administrator  
Food Safety and Inspection Service  
US Department of Agriculture  
1400 Independence Ave., S.W.  
Washington, DC 20250-3700

Docket Clerk, FSIS  
Room 2-2127  
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Re: Draft Guidance on HACCP System Validation

Dear Administrator Almanza:

Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. Section 612 of the Regulatory Flexibility Act (RFA) requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.<sup>1</sup> Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration.

I am writing because my office has received several communications from small businesses and their associations that are concerned with the March 19, 2010, letter and attached agency guidance sent by you to various meat and poultry entities. Your letter was in response to their letter dated September 22, 2009, outlining their understanding of Hazard Analysis and Critical Control Point (HACCP) systems validation. Also, the SBA's Office of the National Ombudsman referred various small business inquiries to Advocacy relative to this matter. While my office supports the public policy behind ensuring food safety, small businesses—which comprise a large number of the entities that are covered by the Food Safety and Inspection Service's (FSIS) guidance—are concerned that the agency clarification of the requirements of systems validation will result in a significant economic impact upon their industry.

<sup>1</sup> Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat. 857 (1996), 5 U.S.C. § 612(a).

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## **Background**

On July 25, 1996, FSIS published the Pathogen Reduction: 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 states what constitutes validation.

On September 22, 2009, various meat and poultry organizations wrote FSIS with their understanding of HACCP validation and with suggestions to incorporate in the agency's validation clarification documents under development and review. Administrator Almanza responded on March 19, 2010, and provided the agency's position on the issues raised by the organizations, signaling that the agency intends to issue a number of documents to clarify the requirements of HACCP validation as described in the 1996 final rule. FSIS included a compliance guidance document tailored for small and very small establishments to assist them in complying with the validation requirements.<sup>2</sup> FSIS noted that plants that do not incorporate these principles into their HACCP systems would raise questions whether the HACCP system has been adequately validated. FSIS made the compliance guidance document available for public comment.

## **Small Business Concerns**

The businesses and industry groups that have contacted Advocacy suggest that food safety has always been of preeminent concern even before HACCP rules were promulgated and that implementation of the new system validation procedures will only add confusion and cost to a food safety system that is working under the current regulatory framework.

The concerned meat and poultry entities are primarily worried about FSIS' increased requirements for in-house microbiological testing of meat products to control pathogens instead of relying on pre-existing HACCP food safety systems. These businesses uniformly suggest that the requirements for microbiological testing will be extremely costly and a huge financial burden on small businesses in the meat and poultry industry as they operate on small revenue margins. The letters reviewed by Advocacy assert that the initial cost for system validation will be from \$60,000 to \$235,000 with annual costs ranging from \$30,000 to \$70,000. The businesses believe that FSIS should not mandate

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<sup>2</sup> Advocacy commends the FSIS for complying with Section 212 of the Small Business Regulatory Enforcement Fairness Act (SBREFA) by providing affected businesses with compliance guidance. Section 212 states: "For each rule or group of related rules for which an agency is required to prepare a final regulatory flexibility analysis under section 604 of the Regulatory Flexibility Act, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as 'small entity compliance guides.'"

in-house microbiological testing and they question whether sufficient testing facilities exist in certain areas of the country to handle the increased testing required by the guidance. As a result of the information contained in the validation system guidance, small businesses question whether they will be able to produce the same number of products for the consumer, and they voice real concern as to whether they will be able to stay in business.

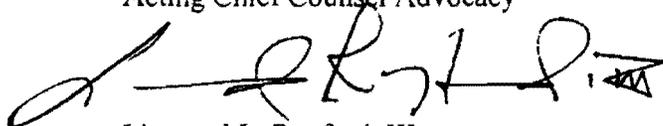
If FSIS' guidance document requires additional and/or increased microbiological testing as part of its review of the affected businesses' meat and poultry HACCP system validation, Advocacy would encourage the agency to consider proceeding through rulemaking rather than guidance. This would allow the affected businesses to provide FSIS with public comments on the agency's proposals adding to the rule's transparency. Also, pursuant to the RFA, the agency would either have to certify that this regulation would not have a significant impact on a substantial number of small entities along with a factual basis for the certification,<sup>3</sup> or perform an Initial Regulatory Flexibility Analysis (IRFA).<sup>4</sup> Advocacy suggests that by pursuing system validation through rulemaking FSIS would be in a position to analyze any benefits that would inure from increased system validation processes, any economic impacts that would result from the system validation procedures and whether any reasonable alternatives exist that would reduce the cost of the rule on small businesses.

Thank you for your attention to the above matter. If you have any questions or concerns, please do not hesitate to contact me or Assistant Chief Counsel, Linwood Rayford at (202) 401-6880, or [www.linwood.rayford@sba.gov](mailto:www.linwood.rayford@sba.gov).

Sincerely yours,



Susan M. Walthall  
Acting Chief Counsel Advocacy



Linwood L. Rayford, III  
Assistant Chief Counsel for Food, Drug  
And Health Affairs

cc: Esther H. Vassar, National Ombudsman, U.S. Small Business Administration  
Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs

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<sup>3</sup> See section 605 of the RFA.

<sup>4</sup> See section 603 of the RFA as to the analytical requirements of an IRFA.



**State of Oklahoma**  
**Department of Agriculture, Food, and Forestry**

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**Brad Henry**  
Governor

**Terry L. Peach**  
Secretary and Commissioner

June 2, 2010

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Email: [DraftValidationGuideComments@fsis.usda.gov](mailto:DraftValidationGuideComments@fsis.usda.gov)

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

Dear Mr. Almanza:

The Oklahoma Department of Agriculture, Food, and Forestry, Food Safety Division respectfully submits these comments regarding the Draft Guidance on HACCP System Validation that was publicly released on March 19, 2010.

The Oklahoma Department of Agriculture, Food, and Forestry, Food Safety Division is unaware of the existence of a clear food safety problem which this validation initiative will resolve. The Oklahoma Department of Agriculture, Food, and Forestry, Food Safety Division is troubled that the USDA's Food Safety and Inspection Service believes so strongly that the current HACCP system is so badly broken to such an extent that this reinterpretation of validation must occur, especially given the fact that the meat and poultry establishments inspected by the Oklahoma Meat and Poultry Inspection Program have been operating under HACCP for ten years. This initiative would push us back to the beginning without any clear and present need. Furthermore, if the Oklahoma State Inspected meat and poultry establishments collect all of this expected data; it is unknown what value any of this data would provide to make the meat products produced in our state inspected meat and poultry plants safer.

The overall purpose of HACCP was the prevention of harmful pathogens that could potentially be associated with meat products. It seems as though the Agency is continually reverting to excessive end product microbiological testing of meat products to control pathogens instead of relying on the established HACCP food safety systems. HACCP is by definition controlling the process rather than attempting to test safety into the system. There are several well-recognized, long-standing processes and supporting documents which, when followed, result in the production of safe meat products. These processes are found within: FSIS regulations; FSIS Federal Register documents; and Peer-reviewed scientific supporting documents.

All of the meat and poultry plants inspected by the Oklahoma Meat and Poultry Inspection Program are classified as either "small" or "very small". Most of these plants slaughter a number of different species of animals and produce a wide variety of fresh and processed meat products

## ODAFF Comments – Draft Guidance on HACCP System Validation

under multiple HACCP plans. For example, one Oklahoma Inspected meat and poultry plant that employs approximately 30 workers produces 97 different products under 12 different HACCP plans. When this plant discussed the development of the initial validation as described in Attachments 3 and 4 of the Draft Guidance with the laboratory that conducts their microbiological sampling it was estimated that the costs of the initial validation would be in excess of \$300,000 and the annual cost thereafter would be in excess of \$100,000. This is a tremendous burden to be placed on a very small business in any scenario and it becomes even more onerous when there is no apparent benefit that will result from it.

Since these 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 the state inspected establishments in Oklahoma and each inspected establishment that makes up the meat industry. Historically, guidelines are interpreted by each person differently. This could potentially cause a huge problem for these establishments, as well as the inspection personnel assigned to these establishments since guidelines are not regulatory requirements and cannot be directly enforced. In addition, since these guidelines were released, the Agency has sent a packet of information to the small and very small Federally Inspected plants which addresses this guidance. Included in this information was a document titled FSIS Fact Sheet: Validation which contradicts some of the information in the original draft guidance. For example this fact sheet states that establishments only need to validate one HACCP plan per HACCP category, while the guidance document clearly states in Paragraph 4 on Page 9 that more than one product should be sampled per HACCP category if they are not similar products. The fact sheet also states that microbiological studies do not need to be conducted, while the guidance states on Page 6 "Establishments would need to provide support in instances where they believe microbiological testing data is not needed to demonstrate the effectiveness of the HACCP system in controlling biological food safety hazards." It further states in the same paragraph "Failure to take these steps will raise questions whether the HACCP system has been adequately validated." It is imperative that any changes in policy by FSIS such as these proposals must be clearly and succinctly stated in plain English that can be understood by all parties involved.

The microbiological testing that may be potentially required by this proposed validation initiative would be extremely costly to the state inspected plants in Oklahoma. Based on estimates of the cost of this microbiological testing, the Oklahoma Department of Agriculture, Food, and Forestry, Food Safety Division is very concerned that the vast majority of the small and very small (both state and federal inspected) meat and poultry establishments will no longer produce inspected meat and poultry products. Instead they will begin producing the same products under the retail exemption with very little regulatory oversight, and no requirements for HACCP plans, anti-microbial interventions or sampling strategies. If this scenario does develop as we anticipate, this proposed change in policy by FSIS will be very counterproductive and will actually increase the risk of food-borne illness from meat products instead of making the food supply safer. In addition this will have a very significant detrimental effect on Secretary Vilsack's "Know Your Farmer, Know Your Food" Program. These small and very small plants that will be forced out of the inspected meat and poultry business by this proposed guidance are the plants that buy livestock from local farmers and produce products from them for local consumption.

The Oklahoma Department of Agriculture, Food, and Forestry, Food Safety Division encourages the Agency to reconsider this Draft Guidance on HACCP System Validation. Food safety is the justification for the existence of our division and we wholeheartedly support all reasonable efforts to improve food safety and to protect the public health of the citizens of our state. However, since there is no compelling food safety issue that would be resolved by the implementation of this proposed guidance and the potential detrimental economic effect on the small and very small meat plants combined with the increased risk of food-borne illness if these products are produced under the custom or retail exemption with little regulatory oversight by any government agency, the Oklahoma Department of Agriculture, Food, and Forestry can find no benefit that would be realized by the implementation of this very vague Draft Guidance.

## ODAFF Comments – Draft Guidance on HACCP System Validation

In the absence of a clear food safety problem that would be remedied by this proposed guidance, we encourage the Agency to take a more measured approach to address this issue. We further encourage the Agency to ensure that all expectations expressed in the proposed guidance document be based on sound peer reviewed scientific principles. The Agency already has a number of options available to deal with isolated instances where food safety systems are not scientifically sound or have not been validated. The comprehensive Food Safety Assessment (FSA) process is one example of the options where an establishment's food safety system is scrutinized either through a "routine" or a "for cause" FSA. It is extremely important that the Agency employees who are involved in the FSA process understand that food safety systems can be validated by means other than microbiological testing. For example, if a peer reviewed scientific article is used as support for the food safety system, the establishment should only be required to demonstrate that it is meeting all the parameters specified in the document and should not be required to conduct additional microbiological testing.

If on the other hand, the Agency has serious, justifiable concerns that there is a systemic problem where meat and poultry plants are depending on food safety systems that are not scientifically sound and have not been validated, the Agency should arrange for challenge studies to be conducted and make them available to all processors. This idea was proposed by Dr. James Marsden in his Safety Zone blog titled Validation of CCP's and prerequisite programs earlier this year, where he suggested the studies be done by product and process category. He further described how in plant validation could be conducted.

It is imperative that the Agency reconsider their position on this proposed draft guidance. The information that has been released so far indicates there will be a tremendous economic burden placed on the small and very small plants which will force many of them to discontinue inspected meat and poultry operations. At the same time this proposed change will provide, at best, a very dubious benefit to the improvement of food safety systems currently being used in the production of inspected meat and poultry products.

Thank you for your time and consideration.

Sincerely,

  
Stan Stromberg  
Director, Food Safety Division



**Eric, Lisa, Andrew, Benjamin, Katy, Sarah  
& Isaac Klein**

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May 23, 2010

I am in writing in regards to the proposed HACCP validation process that is being looked at by the FSIS and USDA.

I am a small farmer in Minnesota. On our farm we have worked hard to develop a business model where we sell 100% of what we raise as livestock directly to consumers, restaurants and institutions. We use a local USDA inspected plant to process and package our products weekly. Our business allows our local very small processing plant to operate under federal inspection 5 days a week. On occasion we also use 2 other USDA plants for specific needs and 1 Minnesota E-2 plant.

I have read the proposed HACCP validation regulations and would like to request that a few points be addressed during the comment and review period. Working directly and indirectly with our local processor 5 days a week, I have come to get an understanding of what they go through on a very rough level.

It appears that the basis for this validation is very justified based on the frequency of food recalls that have been made public over the last few years. However, I think that there needs to be an evaluation done of where the problems are at in the different processing companies through out the US. It appears that scale has a lot to do with the problems that are becoming more prevalent in our food system.

The category of very small plants have a very very small percentage of product if any that comes back positive for any food borne germs. In comparison to the large plants, the very small plants are micro-managed by your USDA inspectors. Every animal is looked at instead of a cross section or statistical amount. The inspectors can easily see what is going on and how things are handled when the total number of employees is sometimes only 3 – 5 people in a red meat plant, and 15 – 20 people in a very small poultry plant. I feel that this size of a plant should be exempt from having to go under this rigorous amount of product testing and expense incurred by these requirements. The livelihood of these very small plants is on the line everyday. If they don't consistently delivery a high quality product everyday then they will not be in business for very long. I think that a simple examination of each plants NR records would be a great way to determine if a very small plant needs to undergo the HACCP validation process. Plants that have had no NR's due to food handling issues should be exempt from undergoing this unnecessary expense which will only make there business harder to operate.

While agree with the USDA/FSIS in implementing this validation process I would like to see consideration given to where the problems lie in the industry as a whole. The very small plants, which are micro-managed everyday, should be exempt from undergoing this process. If this process does pass and affects the very small processing plants, the added work and enormous expense could cause them to close up their plants all together. If this happens then we (after building our direct marketing business for 13 years) will be out of business and be forced to sell our small farm. I feel this fits very closely with the USDA's program of "Know Your Farmer Know Your Food". We had the pleasure last fall of hosting Deputy Secretary Merrigan on our farm. We were able to explain how we market our animals and how the local food system is very fragile in its infancy. I would appreciate a very strong consideration of what I have written and would be happy to visit with anyone over the phone or in person as to how this could affect the future of our small family farm.

Thank you in advance for you consideration

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Eric Klein - President Hidden Stream Farm LLC

  
**NORTH COUNTRY**  
SMOKEHOUSE

ESTABLISHED 1912

APR 21 2010

April 19, 2010

US Senator Judd Gregg  
125 North Main Street  
Concord, NH 03301

Dear Senator Gregg,

I am writing you in regards to a draft guidance document recently published by the USDA's Food Safety and Inspection Service (FSIS) entitled "HACCP Systems Validation".

I operate a small business, North Country Smokehouse, which is located in Claremont, N.H. We employ 19 employees and produce over 40,000 pounds of smoked meat and poultry per week. We have been in business for 38 years.

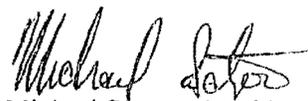
I am concerned about the direction FSIS is taking with the above mentioned guidance document. Food safety is the top priority at North Country Smokehouse and we willingly make changes that result in a safer food product. However, the draft guidance document "HACCP Systems Validation" will result in major expenditures in resources with no tangible benefit to food safety. As a small business owner, these new expectations will be especially burdensome.

There are some basic points about the guidance document I would like to share with you:

- Processes that have been in place and widely accepted will now have to be "proven" at each and every establishment that uses them. This is a colossal waste of time and resources across the entire industry.
- Many small businesses do not have the resources to design and conduct scientific experiments in their facilities. The draft guidance document does not provide small businesses with any real guidance on how to conduct these experiments in a way that would be acceptable to FSIS.
- If FSIS knows of specific processes that need additional validation, it should work with the industry to resolve those issues rather than make sweeping policy changes through guidance documents that have the potential to put small companies out of business.

I once again express my commitment to producing the safest food products possible. However, the recent release from FSIS has the potential to have a major impact on the viability of my business without any improvements to safety of my products. I respectfully request that your office contact FSIS with these concerns.

Sincerely,

  
Michael Satzow, President  
North Country Smokehouse

P.O. BOX 1415, CLAREMONT, NH 03743 | PHONE 800.258.4304 | FAX 603.543.3016

WWW.NCSMOKEHOUSE.COM

JUDD GREGG  
NEW HAMPSHIRE

COMMITTEES:

BUDGET, *Ranking Member*

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# United States Senate

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April 30, 2010

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Mr. Lowell Randel  
Assistant Secretary for Congressional Relations  
U.S. Department of Agriculture  
212A Whitten Building  
1400 Independence Avenue, SW  
Washington, DC 20250

Dear Mr. Randel:

Enclosed please find a copy of a letter from Mr. Michael Satzow, a constituent of mine from Claremont, New Hampshire. Mr. Satzow is concerned about the Food Safety and Inspection Service draft guidance document, "HACCP Systems Validation."

I would appreciate your consideration and attentiveness to this matter. Thank you in advance for your prompt reply.

Sincerely,



Judd Gregg  
U. S. Senator

JG/dr  
Enclosure