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U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Ave., SW.
Room 1175 South Building
Washington, DC 20250

Dear Food Safety and Inspection Service:

The American Association of Meat Processors (AAMP) is pleased to submit comments regarding the "Compliance Guideline for Sampling Beef Trimmings for *Escherichia coli* O157:H7" and "Guidance for Small and Very Small Establishments on Sampling Beef Products for *Escherichia coli* O157:H7." We appreciate the Agency's effort to release guidance documents for industry on a topic that affects so many small and very small meat processors. While it took several months before these documents were published, AAMP welcomes the opportunity to review the documents and submit comments prior to their release in the final form.

AAMP is an international organization whose members include meat and poultry processors, slaughterers, caterers, food service companies, wholesalers, retailers, suppliers, and consultants to the meat and poultry industry. There are 32 state, regional, and provincial associations of meat processors that are also affiliated with AAMP. Majority of our members are small and very small businesses, with most of them being them family-owned and operated.

With all of the recent concern placed on *E. coli* O157:H7, this guidance material addresses some of our questions, but also raises several others. Based on our initial review of the information, we feel that the recommendations are going to be a challenge for small and very small establishments and do not reflect current, achievable business practices for small volume meat processors. We are concerned that this additional burden will force some of them to either quit producing ground beef or change their focus and process all of their ground beef under the retail exemption regulations. Inadvertently, the Agency may have negatively impacted food safety if more production is shifted to retail exemption in order to avoid burdensome requirements that are not achievable. HACCP was originally implemented because a massive amount of end product testing was not effective in protecting public health, and was also not feasible for industry. It seems as though these documents have a changed mindset and stress testing of everything along the production channel, instead of allowing plants to rely on the principles of HACCP implemented in their facilities and the purchase of raw materials that have previously gone through a HACCP plan at a USDA inspected facility. AAMP believes that this type of methodology is defeating the purpose of allowing plants to design and implement their own HACCP plans, and thus returning to more of the Agency's "command and control" mindset. It also creates an extraordinary expense for small and very small facilities to do such an extreme amount of unnecessary testing and validation of their HACCP plans. It seems as though further processors are taking the majority of the burden, even though they are being shipped previously USDA inspected product from their suppliers that may contain the pathogen. *E. coli* O157:H7 is not likely to be introduced in further processing steps, but instead is likely to be present from lack of proper procedures on the slaughter floor or through the early processing steps. Why is it that

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consumers are to rely on the federal mark of inspection, but further processors must do additional testing and implement interventions on product that has already been “inspected and passed?” This brings to light a whole different set of issues that AAMP has with regard to how FSIS is assessing food safety and regulating the meat and poultry industries. The Agency has clearly created a double standard on the meaning of the USDA grant of inspection, on one hand using it to ensure consumers that the food is considered safe, and on the other hand telling further processors that they are not to rely on the inspection legend as any indication of the safety of the product.

The compliance document references the word “investigations” throughout. While the idea of investigations to identify problem areas or trace back product to the source is an important concept, we are not sure that it is something that is feasible for a down-line processing establishment if they find *E. coli* O157:H7 contamination in product purchased from a large meat supplier. If further processors purchase the product on the open market in small quantities, they do not have the wherewithal to hold a supplier accountable for the contaminated product in order to initiate an investigation. More than likely, the supplier will apologize for the product, issue a credit, and then move on. Without intervention from the government (*i.e.*, FSIS), further processors have a slim chance that their complaints of contaminated raw beef materials will register concern with the supplier.

The Agency must note that small and very small plants will have no success with investigations without the assistance and involvement from the government. They simply do not carry enough weight with suppliers to have the clout necessary to initiate an investigation. The push back to the origination must occur with the help and primary leadership of FSIS in order to determine if a deficiency occurred previously at the supplier level that can be corrected. We hope that FSIS remembers the importance of determining where the source of the contamination originated from and understands how the marketplace works. At a recent *E. coli* O157:H7 conference for further processors held by the North American Meat Processors Association (NAMP), Dr. Engeljohn explained that this was an area where FSIS was considering developing some type of program similar to the STEPS database that would help further processors with investigations of suppliers related to plant positives. AAMP hopes that the Agency is serious about this possible program because it would truly be a benefit for further processors and assist them since they are not the source of contamination, but merely the processor that identified the contamination.

As we have brought to the Agency’s attention before, it is very challenging for small and very small establishments to obtain Certificates of Analysis’ (COAs) on their shipments from suppliers. Most of the small-volume meat industry purchases product through distributors, not directly from suppliers. Therefore, COAs are not available with individual shipments of product that was broken up during the distribution channel. Without COAs or other documentation that the product received was previously tested, the Agency has forced further processors to do additional testing for *E. coli* O157:H7 due to the information provided in the compliance guidelines. The expense of the additional testing is not only a problem, but it does not necessarily improve food safety to increase testing.

The guidelines provide a chart that breaks down appropriate minimum testing schemes for *E. coli* O157:H7 based on volume of ground beef produced. The document indicates that plants should be doing additional sampling than those minimum frequencies if their incoming product has not been tested by the supplying establishment. How much additional testing will be acceptable? For example, if a processor producing less than 1,000 pounds of ground beef/day ramps up testing to monthly instead of quarterly, would FSIS accept this increase in the minimum frequency (which is quarterly)? Plants cannot be expected to test each lot from every supplier because not only is it incredibly expensive, but it would not allow them to move product easily into commerce if they were constantly waiting for product sampling results.

Also, on page 6 of the guidance document, it states that “FSIS recommends that any product that is released should have been subjected to sampling and testing at least once.” If this is the Agency’s

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recommendation, then it needs to be upheld for all size categories of establishments. Therefore testing would have to be done prior to any product entering commerce and thus alleviate further processors from testing the raw beef materials again. Further processors would have significantly less problems with the sampling recommendations if the incoming product released from suppliers had previously been tested. Small and very small plants have been willing to use the guidelines that were released by FSIS for sampling to enhance their food safety systems with the increase in concern over *E. coli* O157:H7. However, because this guidance material indicates that FSIS recommends plants test at a higher frequency if the incoming product was not tested previously, AAMP is concerned about the feasibility over even more testing. Not only are these tests expensive, the costs associated with this amount of testing were not considered when the HACCP regulations went into place several years ago.

The examples within the small and very small plant guidance material are not representative of the quantities that these types of small-volume plants are working with. Typically, small and very small establishments are purchasing boxed beef and not combo bins of raw beef materials. Therefore, the example is not helpful for them to determine an adequate sampling plan for trim in their facility. During a recent meeting with Dr. Engeljohn, Dr. Petersen, Dr. Raymond, and Mr. Almanza, AAMP expressed these concerns and the Agency encouraged the Association to provide more relevant examples in order to assist FSIS with sharing the proper guidance. AAMP has followed up separately regarding these sampling examples and try to work with the Agency to provide examples that better suit small and very small plants in their *E. coli* O157:H7 trim sampling. In addition to the more relevant examples, it would be helpful if FSIS could more clearly explain the tables referenced within the document. This information tends to be confusing as it is currently written and AAMP feels it could be better written to convey the data more easily.

AAMP is aware that there is confusion among industry and FSIS field personnel over what is a regulation and what instead is only an Agency recommendation. It seems as though FSIS is attempting to push its boundaries in this area and requiring certain things (*i.e.*, testing, COAs, interventions, etc.) when there is no regulatory requirement specifically related to them. We encourage our members, as well as the entire meat industry to do the best job they can for food safety by implementing best practices, but it is frustrating to have FSIS inspection personnel trying to mandate practices that are not required by regulation. We have seen this occur numerous times in the last year as it relates to *E. coli* O157:H7. When establishments push back because they know their rights, they are threatened with being shut down if they do not implement the changes, regardless of the situation. AAMP has shared direct examples of these types of situations with you and it has taken correspondence with FSIS officials in DC to remedy the situation on an individualized basis. There is an apparent problem or disconnect over what is being taught to inspection personnel and what the requirements actually are.

FSIS is requiring additional validation for interventions implemented to reduce *E. coli* O157:H7. The latest challenges in the field show that inspection personnel are not accepting traditional supporting documentation for interventions such as lactic acid, and instead are asking establishments to essentially create validation to show direct pathogen reduction on the carcasses processed through their slaughter floor. In the past, FSIS has only accepted the testing specifically for *E. coli* O157:H7; not indicator organisms or even generic *E. coli* to prove that an intervention is verified. The draft guidance documents encourage plants to use such means as APC, TPC, and generic *E. coli* tests as part of their validation process. The scientific journal article referenced in the guidance document is very specific as it defines a certain number of carcasses, the locations samples were taken in the slaughter process, along with the number of interventions in place on the slaughter floor. Will FSIS require plants to employ all of these factors in order to utilize this supporting document as validation for their HACCP plan? The journal article referenced in the guideline even says that "caution should be taken when interpreting these results because the data set was limited to 288 samples from only two different plants in one season," and that "more data are needed to confirm these findings." We are concerned that while there is merit in the use of indicator organisms, there is not enough science to back it up in order for establishments to have appropriate and acceptable supporting documentation for their HACCP plans.

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Due to the nature of the pathogen, it is an unrealistic goal for “zero-tolerance.” This guidance document even brings questionability into the ability to rely on sampling data, stating on page 4 that “during such event days, any negative test results might also be considered false negatives.” This is confusing information because it can be read to say that just because we receive a negative result, we shouldn’t rely on it because there were other positives that day. This just solidifies the concept that the goals of FSIS with relation to *E. coli* O157:H7 are unrealistic and unattainable. Increasing testing will not eliminate the pathogen, nor will it ensure that less people get sick. The nature of the pathogen proves this theory.

We encourage FSIS to evaluate the impact that these guidance documents will have on small and very small meat processors. We are concerned that this additional burden will force some of them to either quit producing ground beef or change their focus and process all of their ground beef under the retail exemption regulations. Certainly, causing this shift to retail exemption is not what FSIS is expecting, but it is quite likely a possibility. It will be important that as Agency policy changes regarding *E. coli* O157:H7, that proper rulemaking ensues and that the burdens for small and very small businesses are considered. Simply making changes and trying to enforce them through guidance documents is not acceptable and leaves the inspection system vulnerable to interpretations by different FSIS Districts and different inspection personnel.

It is AAMP’s hope that improvements can be made to the communication and collaboration of industry to make strides to continually improve food safety. We appreciate the ability to comment on these guidance documents and hope that FSIS will seriously consider our recommendations for improvements.

Sincerely,



Andrea H. Brown
Director of Legislative and Regulatory Affairs

cc: Jay B. Wenther, Ph.D., AAMP Executive Director
Dennis Schaardt, AAMP President