



November 19, 2008

Docket Clerk, Docket Number FSIS-2008-0035
United States Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue, SW
Room 2534, South Building
Washington, DC 20250

**Re: Draft for Stakeholder Comment, Compliance Guideline for Sampling
Beef Trimmings for *Escherichia coli* O157:H7, August 12, 2008**

To Whom It May Concern:

The American Meat Institute (AMI) submits this letter in response to the Food Safety and Inspection Service's (FSIS or the agency) request for comments regarding the above-referenced Compliance Guideline. AMI is the nation's oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat products and our member companies account for more than 90% percent of U.S. output of these products. The Compliance Guideline for Sampling Beef Trimmings for *Escherichia coli* O157:H7 (hereinafter referred to as "the CG or the document") will affect a substantial number of AMI members. For that reason, AMI encourages the agency to consider carefully these comments before moving forward with the Compliance Guideline. The comments that follow highlight a number of significant concerns AMI has about the CG. Overshadowing all of those concerns, however, is a grave reservation that issuance of the CG, as written, would appear to establish and impose new regulatory requirements in the absence of required notice and comment rulemaking. Specifically, the document provides at best limited discussion and substantiating data to support establishing the concept of an "event day," and the clear implication in the CG is that the occurrence of such event days would trigger regulatory activity involving adulterated product, possible recalls, among other things. These issues in turn raise questions regarding the agency's obligation to follow the rulemaking process prescribed by the Administrative Procedure Act.

That such a process must be followed when establishing new regulatory standards is evident through past agency behavior, e.g., promulgation of the *Salmonella* performance standards -- flawed as they might be. Establishing parameters for what constitutes an event day and asserting that a plant encountering such a day has operated in an insanitary condition, thereby rendering the products processed that day adulterated is a regulatory position that must be developed through the APA. To do otherwise is at odds with the APA, and conflicts with the Federal Meat Inspection Act, which requires FSIS to conduct an inspection to determine whether a product is not adulterated and eligible to bear the mark of inspection.

AMI's overarching comments on several key topics are discussed below, followed by a specific provision-by-provision discussion of the document.

The Use of Science to Set Guidelines is Sporadic

This CG should be used to provide industry guidelines that, if implemented, will help companies meet regulatory requirements. Current practice is to implement processes that are science based. The CG relies upon anecdotal information or poorly supported concepts rather than sound, data-driven decision making. Concepts suggested in the guidance must be based upon accepted scientific principles and data, and in the case of major recommendations should be derived from data that has been peer reviewed and validated. In this case, the Compliance Guideline fails to meet that standard.

Suggested microbiological methods and processes in the document must agree with recommendations from the agency's own science arm, Office of Public Health Science, and preferably have been validated by an independent science review entity, such as the National Advisory Committee for Microbiological Criteria for Foods (NACMCF). The agency should encourage industry to adopt the valid methods available, which should be equal to or more sensitive than the FSIS method. Equivalency to the FSIS test method is a base requirement in the selection of a test method and if different requirements are needed, then the lab procedure manual should be updated.

Using process data and applying a basic Statistical Process Control (SPC) program is a method with roots in FSIS regulatory control programs, such as Net Weight Control Programs. The Compliance Guide should provide examples of how a process control program would work instead of creating an 'event day' number based on anecdotally shared industry information. As new information becomes available to FSIS through recalls or outbreak investigations, it should be shared with the industry without divulging company identity, in order to aid in the mitigation of future problems.

The document states “For each positive result, there should be an investigation of its cause. Once a possible cause is identified, the appropriate action should be taken to make corrections and to eliminate the cause. Doing so will bring a steady decline in the percentage of positive results.” Cattle are a consistent source of *E. coli* O157:H7 into the slaughter environment and at present there are no validated and approved methods to reduce the positive rate pre-harvest. Best practices and pathogen reduction technologies aimed at reducing the level of positives during the harvest stage have been shown to be effective. However, it is widely accepted that these methods have limitations. The focus of the CG must be on the appropriate implementation of these practices and technologies, using data to evaluate their effectiveness.

FSIS *E. coli* O157:H7 test methods have become more sensitive and sampling is more focused,¹ and the continued ‘steady decline’ implies that the positive rate for *E. coli* O157 should continue to drop. Although a laudable goal, the document should recognize that the objective of both industry and government is to ensure that products are safe and is not to arbitrarily and blindly pursue a simplistic goal of “steady decline” in percent positive rate. Doing so blurs the lines between using effective control programs that result in safe food and imposing unnecessary regulatory burdens that provide no benefit. In addition, the agency should apply statistics to the review of data prior to engaging in policy development. Agency officials have stated repeatedly that the rise in *E. coli* O157:H7 rates in ground beef for 2008 over 2007 is of concern. At the public meeting to discuss this Compliance Guideline, Dr. Esteban stated,

We went [sampled] about 12,000 samples that calendar year [2007], and we had about .24 percent of the samples that were positive. During calendar year '08, up until September 14th, we have close to analyzed 8,400 samples and almost doubled the rate of *E. coli* positives. Now, while it might appear that it is a significant difference, if you were to be very strict statistically, there is still not a significant difference because at those low levels of prevalence, the variation is enormous.

The agency should take into consideration the statistical validity of test results before issuing directives or compliance guidance material. Moreover, the relationship of *E. coli* O157:H7 prevalence and illness should be understood so that agency action improves public health. To that end, organizations such as the National Academy of Sciences could provide valuable insight to better understand the relationship between prevalence and illness.

¹ Constituent Update, June 20, 2008, provides that there have been two changes this year that might have influenced these [higher] results. First, the laboratories are using a new enrichment broth; FSIS believes the new procedure allows for recovery of a greater number of pathogenic organisms in some samples. Second, using a risk-based algorithm, a larger proportion of samples are now collected at establishments considered to be at higher risk for *E. coli* O157:H7 contamination.

The Document Asserts that 'Event Day' Product is Produced in an Insanitary Condition, and/or is Adulterated

The CG recognizes the concept of an 'event day,' with possible regulatory consequences. However, establishing a set number of positive test results during a production day and proclaiming an establishment to be out of control, thereby asserting an insanitary condition with a conclusion that product is adulterated has no basis. Specifically, there is no evidence that substantiates event days, as described in this document, and then leads to an "out of control" conclusion that in turn supports an assertion of insanitary conditions and therefore adulterated product. If the agency has supporting documentation, such as STEPS, or other information that suggests an 'event day' standard that has led to FSIS positive findings, that data should be shared so it can be used to aid in developing this guideline. Although AMI agrees that each establishment should develop or continue to use process control procedures that are based on findings, corrections, and tightened parameters of production or disposition and react appropriately when there are higher than normal positive tests, the absence of data in the document or elsewhere do not support the regulatory action contemplated by the document.

The Compliance Guideline Does Not Consider Other Regulatory Requirements.

There are many notices, directives, compliance guidelines (Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7, April 13, 2004), Question and Answers related to Directive 10,010.1, and ask FSIS clarifications, as well as ELAO training material associated with *E. coli* O157:H7. The Compliance Guideline as drafted will add to the confusion on the part of FSIS inspectors and inspected establishments. Although the document is identified as a 'Compliance Guideline,' the first paragraph states that this document "is intended to assist in the development of programs to assess the adequacy of process controls of *E. coli* O157:H7." No other compliance guideline contains a similar statement of purpose or intent. In making such a statement the document, in effect, transition from one of guidance to becoming a regulatory document, with attendant requirements. Supporting this conclusion is the fact that agency officials have stated that a FSIS Notice will be issued to reference this document.

There is no Consideration of the Disruptive Effect of the Guidelines

A review of the CG makes it clear that additional customer testing is the focus of the document. More testing in the producing plant would also be encouraged. The document does not take into consideration, however, the disruptions that downstream testing caused by a declaration of an 'event day' would have with respect to product that has already been used by customers. Food safety is of the utmost importance, but the disruptive nature of an event day, especially at the level defined in this document, needs to be fully understood and must be based on sound science.

Specifically, the CG states on page three that "Optimally, every production lot should be sampled and tested before leaving the supplier and again before used at the receiver." This optimal circumstance provides no consideration about the effect on quality when the product is held for such additional testing. A large portion of ground beef is sold fresh and additional, unwarranted testing would severely disrupt customer service with at best an unknown effect on food safety. Moreover, the CG does not appear to give any consideration to how such a procedure would be logistically implemented. Industry warehouse/cold storage capacity would need to increase dramatically to hold product pending extra product testing. Similarly, transportation capacity would have to increase to handle product that has shipped prior to the identification of an 'event day,' and customers would have to carry extra inventory just in case product would have to be returned for proper disposition. This description of process control will cause the public and customers to lose confidence in the beef supply. It should be clarified that any test will only be completed on product to be used in raw ground beef.

An alternative to agency ground beef testing would be a more focused ground beef raw material component testing program. Presentations made at the CG public meeting caused concern about the current FSIS trim testing program. AMI would support a short term testing program that focused on trim and other components of raw ground beef. Such a program would provide much needed information about previously tested raw ground beef components. Once completed, this information could and should be used to develop a scientific based *E. coli* O157:H7 monitoring program.

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The American Meat Institute appreciates the opportunity to comment on this guideline as well as future guidance documents that can be used by the industry to improve public health. However, because of the many conflicting statements in the document, the AMI encourages the agency to take into account all comments, revise the CG and reissue as a draft document for final comment.

Sincerely,



Scott Goltry
Vice President, Food Safety &
Inspection Services

Attachment I

A Detailed Review of the Specifics of the Document Supports Substantial Revisions

Detailed comments to the document are attached and addressed by each section, page, and paragraph. In that regard, a short excerpt from the document will be referenced, followed by comment.

Section I Introduction

Page 2

Paragraph 1: “...assist in the development of programs to assess the adequacy of process controls for *E. coli* O157:H7.” No other compliance document has as its purpose to address the adequacy of process control. This statement suggests that this document is to be regulatory in nature.

Paragraph 3: “Once a possible cause is identified, then appropriate action should be taken to make corrections and to eliminate the cause.” This statement makes the assumption that a ‘cause’ can be found. If there is a sporadic finding, no cause may be found. This conclusion is recognized in Directive 10,010.1, which provides that “In addition, the establishment should attempt to determine the cause of the positive findings and would likely need to examine its intervention methods to determine why they are not working.” An example of information that already addresses corrective actions, “Questions and Answers Regarding Directives 5000.2, 6420.2, and 10,010.1, Revision 1 and the Compliance Guidelines on *E. coli* O157:H7, 2004” Part XII, question 6 states, “..some samples of raw materials may test positive for *E. coli* O157:H7. These positives may be random events caused by common cause variation, or may have an identifiable, assignable cause that can be acted upon as part of corrective actions..... Through this statistical analysis, the establishment will be able to justify when follow-up actions are appropriate and sensible.” This is an example of redundant policy that confuses the industry.

“Doing so will bring a steady decline in the percentage of positive results.” There does not appear to be in the CG a scientific basis for this statement. Based on technology and the fact that cattle are creatures of the environment, the continued steady decline implies that the positive rate for *E. coli* O157 should continue to drop. However, since no new technology has been developed it is unknown if such a statement can be made, especially given the later statement ‘to the maximum extent practical.’

“Test and divert programs....in raw beef”. Testing programs for *E. coli* O157 have, over the years, been implemented as a means of eliminating or reducing *E. coli* O157. These programs were developed and were a starting point to keep product that tested positive out of commerce. Although such programs are not a silver bullet for food safety compliance, to downplay these programs as ineffective inappropriately discredits the efforts of the industry, which has invested millions of dollars on intervention improvements and has lost product value due to product destruction and diversion.

Paragraph 4: “...positive results that indicate a systemic cause of breakdown of the process controls (“high event days”). This statement should be changed to read “positive results where upper control limits are exceeded.”

Page 3

Third bullet: “Optimally, every production lot should be tested....and again before use at the receiver.” It is implied that even though ‘optimally’ is used there is no consideration for age and quality effect of holding product for additional testing. A large portion of ground beef is sold fresh and additional unwarranted testing would be disruptive to customer service and detrimental to product quality, with unknown effects on food safety. Additionally, this concept will cause the public and customers to lose confidence in the industry and beef.

Fourth bullet: “...contaminated product is not released into commerce for use in raw beef.” This bullet should be amended to read “raw ground beef.” Additionally, “...unless primal and sub-primal cuts are effectively treated with antimicrobials after trimming, these cuts and food contact surfaces should be assessed for the presence of *E. coli* O157:H7.” As stated in bullet two, to the maximum extent practical would not apply to this situation for two reasons. The test results will not be available for at least 24 hours. If an ‘event day’ occurred then product may not be available for testing because it could have been shipped into commerce. In addition, contact surfaces are cleaned and sanitized daily, therefore, sampling contact surfaces could be meaningless.

Fifth bullet: “The finding of an ‘out-of-control’ process for one production lot would likely implicate product in other productions lots (i.e., a negative test result could be viewed by FSIS as a false negative).” The use of the term false negative is inappropriate. This term applies to methodology review and should not be used interchangeably where the microbiological independence of the sample is at question. In addition, clarification is needed regarding how logically one can conclude that a single production lot, usually five combos, would be classified as ‘out-of control.’ The idea to implicate other production lots should be based on the implementation of plant specific ‘event day’ day programs.

Last paragraph: “In the recent years, the incidence of positives has not decreased as quickly as FSIS had hoped. This document is meant to help establishments define and implement sampling and testing programs that will lead to reductions of contaminated product reaching consumers.” The concept that the positive level has not dropped has been discussed previously. The agency needs to develop a sound basis for standard setting based on science and public health information that is available. Also, the last sentence is a better purpose statement than what was in the first paragraph of the introduction.

Page 4

Paragraph 2: “In the absence of such information, FSIS is, therefore, setting a percent positive guidance value of pre-tested trimmings at 1.5%. The 1.5% value is mid-way between the 1 to 2% positive rates that industry has anecdotally shared with FSIS as the annual average percent positive rate for pre-tested trimmings.” There are several problems with this statement. First, the definition of pre-tested trimmings is misleading. Pre-tested trimmings should mean that the product has been tested once prior to another test. If the product tested positive, it would not be allowed to be tested again because it did not pass pre-shipment review. A more appropriate terminology for the CG would be tested trimmings to signify the initial tests and a verification test to mean a test of previously tested product. Furthermore, there are concerns about anecdotally shared information, which include: Was the information seasonally adjusted? Was the information from all sizes of plants? Was the information from market steers and heifers, cows and bulls or both? What was the total number of samples and the standard deviation?

Paragraph 2 continues, “The 1.5% positive rate for pre-tested trimming is not a regulatory limit.to identify a statistical framework for identifying ...is not adequate to control the occurrence of *E. coli*...” [Emphasis added]. Although the document states that the 1.5% is not a regulatory limit, the agency has stated that the lack of control of *E. coli* could be considered a regulatory issue because the control limit was not met, not because the product tested positive.

“..during such event days, any negative test results might also be considered false negatives.” See comments above.

“ensure that adulterated product is not released for raw beef production.” The implication in this statement is that an event day creates adulterated product and again the term raw beef production instead of raw ground beef is used. This concept dramatically expands the current adulteration policy.

“Event days are viewed by FSIS as potential evidence of production of product under insanitary conditions whereby all associated raw beef product would be adulterated, including primal and sub-primal cuts.”

Again, this statement suggests that the current adulteration policy is being redefined. This statement also conflicts with an earlier statement that the 1.5% is not a regulatory limit. If, however, that number is used by FSIS to designate an event, then the number becomes a regulatory limit.

Paragraph 3: “This document does not discuss issues explicitly related to labeling of product as being tested negative for *E. coli* O157:H7. FSIS is developing guidance to labeling regarding testing.” This statement is a key component to controlling *E. coli* O157:H7 and the Compliance Guideline should not be released prior to the labeling guidance being completed. Compliance guidelines should be clear and transparent. (OMB Bulletin on Good Guidance Practices and executive Order 13433).

Section II General Guidance for Verification Testing of *E. coli* O157:H7

Page 5

Paragraph 1: “...contamination of beef carcasses with *E. coli* O157:H7 and other pathogens.” The reference to ‘other pathogens’ is outside the scope of this document and could confuse agency personnel and the industry.

Paragraph 2: “Consequently, FSIS recommends testing of source material both at the point of production (e.g. fabrication of primals and sub-primals) and prior to use of the trimmings for use in the production of ground beef. In addition, as a further verification activity, FSIS recommends testing of finished product even if the source material has been tested and found negative.” There is no indication as to what kind of testing is done, but for purposes of this discussion AMI assumes it is pathogen testing for *E. coli* O157:H7. If test results take an average of 24 hours, this FSIS recommendation will take an additional 3 days to complete, testing costs will increase dramatically, and significant business interruption will occur. All of this will occur with unknown improvement in food safety.

Paragraph 3: “FSIS recommends the establishments conduct verification testing directly for *E. coli* O157:H7. However, it is also acceptable to conduct verification testing for associated organisms that include this pathogen (e.g., a screen methodology for *pathogenic E. coli*) and maintain records of results as a quality control (QC) activity.” If industry decides to do verification testing for *E. coli* O157:H7 guidance should be provided regarding lot definition and the number of verification samples needed to truly verify that the process is meeting expected objectives. With a rate of 1%, at least 100 tests would be needed to confirm that *E. coli* O157:H7 is not present based on the test method. Moreover, a screening methodology must be commercially available and the methods need to be peer reviewed. A scientific reference would also add credibility.

Section III. Frequency of Sampling for Small and Very Small Establishments

Page 6

Paragraph 1: “The minimum frequencies recommended below assume that all lots of purchased source trimmings (as defined earlier) have been tested. If the trimmings have not been tested (e.g., in-house trimmings), sampling frequencies for finished ground beef should be much higher than those given below.” If asked by an EAIO to provide support for the selection of sampling frequency, would the frequency listed be acceptable? If not, support of the frequency should be provided. In addition, all plants should also use these sample frequencies.

Page 7

Paragraph 3: “...establishments can take the FSIS verification test into account in documenting that their food safety are operating properly.” There is no reason to preclude large plants from using FSIS verification tests.

Paragraph 4: “FSIS has stated that when one lot tests positive, lots constructed from the same source material would likely be implicated” The CG goes onto to provide two suggestions for defining independent lots. The agency should continue to accept that although the same type of product, i.e., 50’s or 75’s, could be involved in a positive test, the concept of a independent lot must be based on the sampled lot as it recognized currently. The second suggested example is impractical and not based on science.

Page 9

C 3: “Some establishments freeze combo bins of trimmings before being scheduled for grinding.” Since a combo is a bulk container of beef trimming that weighs between 1,600 and 2,000 pounds, freezing would create a huge block of frozen meat that would be impossible to process. AMI questions this practice and is unaware of this method being used in the production of ground beef.

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C6: “Multiple methods of trim sampling are mentioned with no scientific support for these methods.” The Beef Industry Food Safety Council has (BIFSCO) prepared ‘best practice’ guidance material. Methods should be fully documented and validated, and AMI supports the trim sampling guidelines developed by BIFSCO.

F. 1.a: “...it would need to assess whether: i) the positive was a random occurrence, or whether there was a loss of control, ii) bring the CCP under control.” The CG in this case is applying 9 CFR 417.3 to a deviation that may or may not be a CCP deviation. Furthermore, it could be interpreted that ‘the positive’ means a single positive and therefore results in excess of one would result in a loss of control. This statement conflicts with previously discussed event dsys.

F. 2: “A positive result implicates not only the lot from which the positive sample came from, but also other lots that might have common source material with that of the positive lot.” As stated in 1.a, this language implies that more than one positive now has the same implication as an ‘event day.’ There is no consistency with respect to actions to be taken when positive samples are detected.

B. “Placing product from a single supplier in one lot will facilitate tracking of that product....” Although this is a desirable method to track suppliers, it is virtually impossible from a practical and commercial processing standpoint. Not all suppliers create the product based on lean point, or availability to produce ground beef to meet customer specifications. Typically, different types of product are used to produce ground beef. However, industry would support guidance that encourages efforts to reduce the number of sources used in a lot of ground beef.

Section VI Product Disposition When There is a Positive Result

Paragraph 2: “When a sample is positive for *E. coli* O157:H7 the product within the lot and all other lots that are not independent from the positive lot are deemed to be adulterated.” This statement implies that ‘a positive’ is a single sample that would impact all lots in the day. There needs to be clarification regarding the number of positive samples.

Paragraph 2: ”the implicated product must be cooked before it leaves the establishment and be sold, be moved off-site for proper disposition under appropriate controls.” The section addresses labeling and the need to assure that the ‘to be cooked’ product has been received by a federal establishment. When product is transferred to another establishment, it should be the receiving establishment’s responsibility and the local inspector’s responsibility to control the product. The current system of product disposition needs to continue. This section needs clarification to include a more transparent, streamlined approach so that unnecessary paperwork in eliminated.

Paragraph 3, b: “However, if this determination cannot confidently be made, then FSIS strongly recommends further testing of product from lots that are not independent or that were produced on the same day or shift before the product can be released.” Again, this statement could cause inspectors or others to take action on product that has already shipped. Holding of a day’s worth of product is neither practical nor feasible. The food safety system should be based on process control instead of testing for food safety.

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Paragraph 3: “This plan was designed to detect contamination incidence of 5%: lower rates, averaged over the lot would not so readily be detected.”

When first discussed the sampling rates were based on a contamination rate of the carcasses. As contamination rates go down the number of samples taken would increase to a point where statistically significant sampling rates would be impractical. The N60 method was designed to detect the organism based upon a given contamination rate of 5%. This method is an appropriate verification tool for the food safety system when properly implemented and will afford an appropriate level of consumer protection. The method requires using a consistent and verified surface sampling approach, coupled with valid lab methods. To provide an alternative to the number of samples to be taken in Directive 10,240.1, FSIS has provided Q&A’s recognizing ICMSF sampling plans. The Q&A stated, “Although the agency will not dictate any particular sampling with regard to lot release following a *Listeria* spp. Positive FCS sampling, historically FSIS has recognized the use of ICMSF sampling plans for the release of product.” Furthermore, the Nationwide Microbiological Baseline Data Collection Program for the Raw Ground Beef Component: Domestic Beef Trimmings, May 2008, states, “The N60 sampling concept was based on the International Commission on Microbiological Specifications for Foods Case 15 sampling plan, which was the most robust of all sampling plans recommended by ICMSF.” Therefore, because FSIS has recognized N60 as the best sampling method for release of product for *Listeria* spp positive, and also in the May 2008 raw ground beef component baseline, N60 method should be considered appropriate for routine sampling.

Paragraph 4: “Care would need to be taken to ensure that the enrichment....” This paragraph deals with a method used to test for *E. coli* O157:H7. Unknown, however, is whether this method meets the FSIS methodology requirements. Also in this paragraph, the CG provides “if a single combo within the five combo lot tests positive the five combo lot is properly disposed of (diverted) and re-cooked.” Because this is raw product the product is ‘cooked’ not ‘re-cooked,’ as stated in the guideline.

Paragraph 1: “Release or disposition of the combo bin is dependent on the result of the further confirmation testing of each individual enrichment sample.” This section describes a different version of N60 testing. In this particular method, if confirmation is determined individual combos can be released based on negative tests results. Unknown is what type of confirmation is used and what type of verification is employed to assure a high level of confidence in the confirmation process.

Paragraph 2 (example 1) : “Finished ground beef-grab portions.... » The CG’s reference to “finished ground beef—grab portions” does not represent an appropriate sampling methodology. A better example is found on Page 19, “ground product portions of about 65-75 grams are taken every 24 minutes,” which is a much clearer definition for a sample amount. Again, conflicting direction that should be clarified.

Paragraph 1: “two or more positive samples (in ‘too few’ samples....) could indicate more systemic control problems so that the process could be considered as out-of-control. FSIS is aware of cases where many positive results occur within a day or a shift.” Again the terminology ‘out of control’ is used and, as stated previously in these comments, inappropriately ties to insanitary conditions and adulteration. Clarification is needed regarding what ‘too few’ means and the process control level should be applied based on an individual plant’s performance instead of an arbitrary regulatory performance standard.

Paragraph 2: “...help insure that contaminated product does not leave the establishment, the establishment should consider more intensive sampling...” A process that states how to investigate an ‘event’ and the re-establishment of process control should be developed instead of the very prescriptive method stated in the document.

Paragraph 4: “...high percent positive rate (i.e., low or poor incoming quality).” The association of a percent positive rate to incoming or outgoing quality confuses quality with food safety issues. Quality issues have not, and should not, be considered food safety issues. The CG should be clarified such that if incoming product has a high percent positive this product is diverted. The statement about finished product having a high positive rate is irrelevant.

Paragraph 1: “As stated above, FSIS believes that establishments should be concerned if their sampling of trimmings produce a positive rate of 1.5% or greater. For ground beef, based on FSIS sampling covering recent years, (2005-2007), FSIS recommends that establishments should be concerned by a percent positive rate in plant testing that is greater than 0.2%.” The 1.5% rate selected by the CG is based on anecdotal information and does not consider season, size of plant, or type of product produced. Likewise, the 0.2% rate for ground beef is arbitrary and establishes an *ad hoc* performance standard. In that regard, the document’s focus is misplaced and should be on process control and encouraging industry to collect data and use process control principles within a given establishment and process. Guidance should be provided to help develop SPC that addresses trend, abnormal incidences and high rates (runs that are above the control limit, but not abnormal).