S.T.O.P. - Safe Tables Our Priority

America's Voice for Safe Food

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Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
FSIS Docket Room
1400 Independence Avenue, SW Room 2534
Washington, DC 20250

Re: Docket No. FSIS-2008-0035
Sampling and Testing Procedures for *Escherichia coli* O157:H7 in Beef Manufacturing Trimmings

Safe Tables Our Priority (S.T.O.P.) appreciates the opportunity to submit the following comments in response to the draft guidance documents issued by the Food Safety and Inspection Agency (FSIS) and the October 14-15, 2008 public meeting.

S.T.O.P. appreciates FSIS' pursuit in finding additional measures to combat *E. coli* O157:H7 in our nation's ground beef supply and its efforts at promoting preventive measures at the point of contamination, in the slaughterhouse. The slaughterhouse is the most logical and efficacious point to prevent pathogenic contamination of meat and also to contain or divert product that has accidentally become contaminated. A mere 35 plants harvest 95% of the cattle for human consumption in this country affording FSIS, and the industry, an opportunity to laser-focus efforts at preventing contamination of beef carcasses and its subsequent products.[1]

However, we submit that current efforts by the agency are being made in a piecemeal and reactive fashion rather than in a proactive way within a comprehensive approach to strengthening the safety of our meat and poultry supply. FSIS has developed these particular guidance documents and conducted this public meeting partly in reaction to the sharp spike in *E. coli* O157:H7 recalls and outbreaks in 2007 and 2008, and partly because of the results of the checklist FSIS conducted that revealed the agency's lack of awareness not only of industry practices but also practices of their own inspection force. S.T.O.P. maintains that this lack of awareness is indicative of a larger systemic

[1] Transcript from the October 14-15, 2008 public meeting, "Control of *E. coli* O157:H7: Addressing Sampling and Testing Methodologies, Compliance Guidelines, and N60 Labeling", p. 12. (Transcript)

problem and that recent hodge-podge attempts at gaining industry compliance is an unintentional result of the Pathogen Reduction/Hazard Analysis Critical Control Points (PR/HACCP) rule and the way it has been implemented and enforced over the past 10 years.

The abdication by FSIS of all "command and control" public health-based mandates to industry under HACCP has left some plants struggling as they try to figure out what they can and cannot do to be in compliance. Many plants operate under the misconception that they have a well-designed process control system when in fact they do not because it has never been properly validated or properly implemented. The way HACCP plans have been implemented has also made inspectors roles and task less precise and open to interpretations. These factors have left serious food safety gaps in the way that our meat and poultry is produced and puts the public at additional risk of foodborne illness, including *E. coli* O157:H7 poisoning. This is not only unnecessary, it's unacceptable.

The December 2008 issue *Food Protection Trends* published a study, "Adoption of Interventions to Improve Food Safety at Meat and Poultry Processing Plants in the United States". Among its findings, "Most plants sanitize hand tools during operations (89%) and treat drains with sanitizers for pathogen control (84%). About 64% of plants have purchase specifications to control pathogens in raw meat and poultry. However, less than one-third of plants apply antimicrobial chemicals. Seventy-one percent of plants conduct voluntary microbiological testing and 70% conduct environmental sampling."[2] S.T.O.P. contends that this variability of implementing even basic food safety practices demonstrates the need for some level of mandatory requirements to ensure the safeness of the food produced.

During the PR/HACCP rulemaking process, S.T.O.P. supported, and still does today, the concept of HACCP as a management tool for companies in designing and assessing process control within their plants. We never supported its use as a replacement for inspection functions or as an excuse for FSIS to abdicate public health–based command and control mandates. But that is exactly what has happened and that is why, from our perspective, a decade after HACCP's implementation, the United States is experiencing record numbers of recalls and foodborne illness outbreaks and foodborne illness statistics that remain static.

One of S.T.O.P.'s contentions during the PR/HACCP rulemaking process was the necessity for FSIS to validate plants' HACCP plans. Our concern was that some plants would lack the necessary scientific expertise and/or resources to develop an effective HACCP plan, resulting in a plan that would put the public at risk from unsafe food. And over the years that is exactly what has transpired with one result being the need for FSIS to "explain" that *E. coli* O157:H7 is a hazard reasonably likely to occur in slaughter plants (and requiring the identification of at least one Critical Control Point (CCP) and

[2] "Adoption of Interventions to Improve Food Safety at Meat and Poultry Processing Plants in the United States". Catherine L. Viator, Sheryl C. Cates, Shawn A. Karns and Mary K. Muth. *Food Protection Trends, Vol. 28, No. 12, Pages 917-927.*

intervention) and that processing plants and grinders needed to reassess their HACCP plans to consider O157 contamination.

By attempting to avoid "ownership" or "responsibility" of plants' HACCP plans and thereby liability for the safety of the product, FSIS has left some industry members without a life line and put the public's health at risk by increasing the chance that contaminated meat and poultry is being released into the marketplace, as plants operate within a system that is ineffective in preventing product contamination. S.T.O.P. maintains that HACCP plans need governmental approval and oversight in order to ensure that they will perform as intended and provide the highest possible level of food safety.

If FSIS established a team for the purpose of validating HACCP plans, we believe that it would serve to bring a better understanding at FSIS headquarters about what actually occurs out in the field. Dr. Engeljohn admitted that the checklist was conducted "in part (as) a result of needing to know more about the control procedures in place by the industry that we regulated." [3]

This latest guidance document, "Compliance Guideline for Sampling Beef Trimmings for *Escherichia coli* O157:H7" is just another example of FSIS' acknowledgement that the current system for controlling *E. coli* O157:H7 is not working and an effort to "guide" plants to produce a safer product. This is not acceptable. Consumers expect that <u>all</u> plants be <u>required</u> to produce a product that is as safe as possible. And if FSIS knows how this can be achieved, they must mandate such actions under command and control. Relying on industry's voluntary compliance to guidelines is not the way a public health-based regulatory agency should be conducting its business.

<u>S.T.O.P. is requesting that FSIS re-evaluate its decision to not validate HACCP plans and to once again issue public health-based command and control mandates as necessary.</u> FSIS has the advantage in assessing the strengths, opportunities and weaknesses in an individual plant and its place within the food chain—to the final product that arrives in the marketplace and onto consumers' plates.

Consumers expect the USDA inspection seal to be meaningful; that the meat in their package was produced in a manner to best ensure the wholesomeness and safety of the product under strict governmental inspection. S.T.O.P. maintains that the only way for FSIS to apply its seal of inspection with any degree of confidence is if the agency has validated the process under which the food was produced.

<u>FSIS' Adoption of N-60 as a Verification Program</u>

In his opening comments at the public meeting, Mr. Alfred Almanza, FSIS Administrator, stated, "I want to stress that today's meeting, this is an <u>information sharing and information gathering</u> session. We're looking to come away from this meeting with an understanding of sampling and testing from all angles, the Agency's standpoint, the

[3] Transcript, p. 12.

industry's perspective and, of course, we're interested in what consumer groups have to add to the discussion."[4] S.T.O.P. must respectfully challenge this statement for the following reasons.

The information sharing and information gathering had already taken place between FSIS and members of the beef industry in regards to N-60. Consumer groups first became aware of N-60 and the agency's decision to move forward using N-60 as verification testing for *E. coli* O157:H7 on trim at the April 9-10, 2008 public meeting on Shiga Toxin-Producing *E. coli* during a presentation by Dr. Daniel Engeljohn on the checklist that FSIS had prepared about control procedures in place by the industry.

The agency had already made its decision to move forward using N-60 as part of its *E. coli* O157:H7 verification testing for trim without any input from stakeholders other than industry. FSIS' decision was not based on published scientific research and relied heavily on industry anecdotal information.

While S.T.O.P. supports the beef industry's innovation in designing a sampling program as a tool for monitoring process control, we vehemently oppose the U.S. government utilizing, as a public health-based verification program, an industry-crafted protocol that has not been published or peer-reviewed or publicly presented.

Even if N-60 were the best tool for verification testing of *E. coli* O157:H7 in beef trim, which we most assuredly do not believe to be the case as we will explain, S.T.O.P. maintains that government agencies must follow sound scientific principals in developing their regulatory testing regimens. This should include generating research of their own and also analyzing peer-reviewed publications. S.T.O.P. finds it alarming that FSIS relied on anecdotal information on prevalence from industry as a basis to implement and drive an N-60 testing protocol as part of a government verification program.

S.T.O.P. commends the agency's desire to strengthen testing on beef trimmings in an effort to prevent contaminated trim being used in ground beef. However, an N-60 sampling program is most assuredly not the program in which to make regulatory decisions on disposition of beef trimmings.

In the draft compliance guidelines document, FSIS stated that it had done a nationwide baseline survey of trimmings and found 0.68% of the samples that it collected to be positive for *E. coli* O157:H7. The document further stated that some proportion of the test samples that FSIS collected were from production lots already pre-tested by establishments and found negative for *E. coli* O157:H7. It goes on to say that this percent positive is expected to be lower than what establishments might find in pre-tested trimmings.[5]

[4] Transcript, p. 5.

[5] The document uses the term "pre-tested" in two different ways and is very confusing. Pre-tested can mean "already tested" or it can mean "prior to testing".

FSIS did not conduct its baseline on the type of product that they would be sampling for regulatory purposes. FSIS should have developed a baseline on already-tested trim that had been cleared by the establishment for release. Therefore, the 0.68% positive statistic is probably higher than the actual prevalence level of *E. coli* O157:H7 in the trimmings that FSIS will be sampling.

Even if the actual percent positive rate for *E. coli* O157:H7 was 0.68% in the trimmings that FSIS would sample, the confidence level is a mere 34% in an N-60 sampling program. In order to attain a 95% confidence level, the agency would need to implement an N-439 sampling plan.

At the public hearing, Ms. Caroline Smith DeWaal of Centers for Science in the Public Interest (CSPI) had the following exchange with Dr. Emilio Esteban:

> Ms. Smith DeWaal: Dr. Esteban, …do you have any statistical backing for the N-60 as your number of samples? Did you test N-80 or N-100?
>
> Dr. Esteban: We followed the N-60 because that seemed to be the industry standard. And the only flaw I see with the N-60, and it's not a flaw. It's a simple description of a statistical—of where the N-60 came from, is that it assumes a 5% prevalence and if the prevalence were lower, of course, the N would have to go up, and so that's basically the information for the statistical background.
>
> Ms. Smith DeWaal: It was my understanding that the prevalence that N-60 is based on is a 5% positive which I mean we don't think we're—we hope we're nowhere near that. So has USDA looked at a number that would provide a higher confidence level given the prevalence that you think you may find in trim?
>
> Dr. Esteban: At this point we have not, but I'll take that into consideration.[6]

It would take an N-439 sampling plan to reach a 95% confidence level for detecting *E. coli* O157:H7 in beef trimmings based on a positive rate of 0.68%.

It takes an inspector 40-60 minutes to collect an N-60 sample.[7] S.T.O.P. feels that this is a complete waste of inspection resources when there is minimal confidence (34%) that the testing would be effective. Disposition of product must not be predicated on such an inadequate program.

Again, S.T.O.P. supports the concept of a regulatory sampling program for beef trimmings that an establishment has already tested and passed. However the N-60 program is completely ineffective and moving forward with it would be a great waste of government resources, taxpayers' money and put the public's health at greater risk. FSIS should halt their N-60 sampling program on beef trimmings immediately and commence research on an efficacious sampling program for *E. coli* O157:H7 in trim.

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[6] Transcript, p. 41-42.
[7] Transcript, p. 35.

S.T.O.P.'s Concerns with Industry's N-60

Tyson Foods has testified that N-60 provides a 95% or greater confidence level of detecting *E. coli* O157:H7 in beef trimmings.[8] For this to be true, the prevalence level of O157 in the trim would have to be 5% or higher according to the ICMSF calculator.

However, in its draft compliance guideline FSIS admits to not having actual data on the percent positive rate of trimming prior to testing. FSIS made the decision to accept anecdotal information provided by the industry of the number being between 1 and 2 percent and split the difference at 1.5%.

At a positive rate of 1.5%, N-60 sampling will provide a confidence level of only 60% in detecting O157 in beef trimmings, not the 95% espoused by industry.

S.T.O.P. does not believe that basing a determination that product is un-contaminated or that a process is in control on a sampling program, which if done correctly, has only a 60% confidence level, is in the public's best interest. There must be additional verification controls in place to make either determination.

An appropriate sample size (N) has to be based on an accurately measured prevalence rate. N-60 seems to have been chosen by industry on the basis of economy rather than on its scientific validity for protection of public health.

Interestingly, the Beef Industry Food Safety Council (BIFSCo) admitted that the N-60 level of sampling "should be sufficient to identify highly contaminated (emphasis added) lots of product."[9] S.T.O.P. maintains that "highly contaminated" lots may be appropriate for indicator organisms in assessing process control or product safety. Fewer than 10 organisms of O157H7 can cause debilitating illness and death, certainly not a number that would be considered "highly contaminated". The use of *E. coli* O157:H7 in an N-60 sampling program, with its 60% confidence level, as a determinant of either process control or product control is inappropriate and dangerous.

For any sampling program to yield meaningful results it must be done exactly to its protocol and utilize proper laboratory techniques. The actual sample collection methodology for N-60 is quite complex, time consuming and susceptible to worker error. It is human nature to cut corners when stressed and inconsistent methods will lead to inconsistent results, rendering the results worthless in assessing process control. It is therefore imperative that not only the process itself be validated but also verification is necessary that sampling and laboratory protocols are properly performed.

[8] Dr. Richard Roop in testimony before the House Agriculture Committee on behalf of Tyson Foods, October 30, 2007.
[9] BIFSCo "Best Practices for Using Microbiological Sampling", March 2008.

In her Power Point presentation at the public meeting, Dr. Barbara Masters identified two areas of concern about N-60 sampling. Dr. Masters detailed lessons learned from three *E. coli* O157:H7 foodborne illness outbreaks where they traced back to the trimmings suppliers. One supplier was conducting N-60 sampling incorrectly by not taking exterior slices and another was re-testing trim. It was determined that none of these establishments had high incident rates for *E. coli* O157:H7 in their own trim testing. Dr. Masters stated that:

> "…a virtual absence of positives should clearly trigger a review as to the adequacy of sampling and/or laboratory results…It tells you one of two things. Either their sampling plan is inappropriate and they're not catching contamination that's there or two, they've discovered some really remarkable intervention that has improved the process that much. Either way, you need to look into it, and it should flag something to both the plant and FSIS that there may be a potential problem…This certainly provides justification for the things that the consumer groups have been asking for and that plants need to develop reliable, robust sampling plans that are implemented correctly and then use that data to draw accurate generalizations about the population so that we can prevent illness. As Donna (Rosenbaum) said, we don't really want to find out a year and a half afterwards."[10]

Dr. Masters' real examples where contaminated trimming that had "passed" N-60 sampling and testing but then made it into ground beef and caused illness, emphasize the need for FSIS to verify that sample collection and laboratory protocols are being properly performed. These tasks are too important for public health to be relegated to industry self-monitoring.

In addition to not having any scientific studies regarding the prevalence level of O157 in beef trimmings and what the corresponding confidence level that N-60 would actually achieve, the complexity of the testing protocol is another concern that S.T.O.P. has with the N-60 sampling plan that has been portrayed as the gold standard in testing trim.

In its draft compliance document, FSIS states that defining lot size is perhaps the most important step in designing a sampling plan and that lots should be defined so that if a positive result is found on one lot, the product in other lots is not implicated. Prior to implementation in 2002 of industry's N-60 sampling program, FSIS policy dictated that a lot size was from clean-up to clean-up. That has changed with N-60 where plants are allowed to define their own lot size. Most companies recognize 5 combos as a lot, and unlike before, there is no required clean-up between lots. FSIS has stated (FR Oct. 7, 2002) that when one lot tests positive, lots constructed from the same source material would likely be implicated.

S.T.O.P. can't help wonder if there is any correlation between the implementation of N-60, without a clean-up step requirement between lot sizes, and the spike in O157 recalls and outbreaks in 2007 and 2008. Is this mere coincidence or could there be cause and

[10] Transcript, p. 315 and 327.

effect? Without a clean up step, any lots produced after a positive is found is subject to cross contamination by equipment, hands and surfaces that produced the positive lot. We contend that this is an area that needs deeper study and consideration especially considering the virulence of *E. coli* O157 and the fact that there is a zero tolerance policy in place.

S.T.O.P. contends that whatever the lot size, be it 1 combo, 2 combos, 5 combos, etc., that N-60 sampling must be spread out evenly among the combos. Therefore, if the lot size is 5 combos, 12 surface tissue samples will be taken from 12 different pieces of trim in each combo. In the case of 5 combos, it would be unacceptable for all 60 samples to be culled from a single combo, and after receiving a negative test result, have that designation apply to the other 4 combos.

It is our understanding that the above scenario of testing only a single combo in a 5-combo lot size is being done by industry and accepted by FSIS. It is also our understanding that, if after testing, a resulting negative for *E. coli* O157:7 is found, that FSIS will consider the other 4 combos as being negative as well. If so, S.T.O.P. takes issue with FSIS' decision. While ostensibly one might argue that one has a greater chance of finding O157 if all 60 samples are taken from a single combo, the single combo may not be representative of the other 4. Good scientific standards also maintain that sampling should be done randomly, and focusing only on a single combo further dilutes an already weak random sampling possibility (because samples are already only being taken from the tops of the combo bins).

This also begs the question of the opposite scenario when a single combo tests positive. Would the other 4 combos be considered positive by default or is industry allowed to conduct additional sampling on the other 4? We would consider this to be re-testing. S.T.O.P. would appreciate clarification on this issue.

We stated earlier that industry's use of N-60 as a tool in monitoring a plant's process control has some merit. However, it should be part of a comprehensive microbiological testing program that includes other indicator organisms. N-60 alone cannot be a litmus test for deciding that a process is in control for O157 or that a negative result means that the product is not contaminated. Reliance by industry or FSIS on a negative result from an N-60 testing protocol alone as a determinate of disposition of product must not be allowed. N-60 simply does not detect down to a low enough level to find the presence of *E. coli* O157:H7 and should not be used as a verification of product safety or verification that a process is in control.

The Need for Adequate Process Control within Plants

A robust, validated HACCP plan that is correctly implemented and includes a monitoring feedback loop on process control based on a robust microbiological testing program will provide a systematic approach to the production of safe food. S.T.O.P. asserts that process control in all plants is of paramount importance and that a lack of strict process control can lead to contaminated product being released and consumed.

Dr. Masters illustrated this fact in her presentation of lessons learned from three foodborne illness outbreaks.

> "Two slaughter establishments had questionable process controls, and I say that from the perspective that one of them had not properly validated the use of lactic acid for their carcass intervention step, and I would say to you that this particular slaughter establishment was only using lactic acid as their intervention for controlling O157:H7 on the slaughter floor, and they were using it at 1.5%. Most of the journal articles and research articles out there suggest using lactic acid, if you're going to use it to control O157, at at-least 2 percent. And so this was the only intervention step they had on their slaughter floor, and they had not properly validated it. Another establishment when you went back to look at their slaughter floor only was using hot water, which is a good intervention but they had not properly validated that on their slaughter floor. So questionable process control on (the) slaughter floor."[11]

S.T.O.P. maintains that FSIS, with a proper preventive regulatory program in place, should have detected these HACCP failures at the time that they occurred. FSIS should also have verified that the N-60 sampling and testing protocols used by these plants had been done correctly. FSIS needs to evaluate why these things did not occur and install measures to see that they don't recur.

In addition to Dr. Engeljohn's admission that FSIS' checklist was conducted to better understand the process controls within the industry regulated by FSIS, he went on to say "we identified that there was considerable inconsistency in the controls in place by industry as well as those procedures in place by the agency."[12] While we appreciate the agency's candor and transparency regarding how little the regulators know about the very companies that they regulate, it screams for the necessity for more comprehensive understanding and oversight by FSIS of the meat industry and the need for better communication between Washington headquarters and the field personnel.

We further recognize the importance of a robust, statistical process control program in place to monitor and ensure that performance standards are being met and in the instances that they are not, that the plant assess and adjust accordingly. As stated earlier, S.T.O.P. does not think that a verification program for process control that focuses only on *E. coli* O157:H7 is an effective method of determining that a system is under control.

Dr. Engeljohn identified instances in plants where O157 was in fact the only organism identified as an indicator of process control. "Indicators other than O157:H7 could and should be used to indicate process control and from the questions that we asked from our checklist, identified that establishments generally are not at least documenting that they're looking at other microorganisms than O157:H7 or necessarily having production

[11] Transcript, p. 309-310.
[12] Transcript, p. 13.

practices in place that would identify their systems are well controlled."[13] This once again stresses the point that FSIS must be validating plants' HACCP plans to ensure that adequate process control measures are in place.

S.T.O.P. contends that plants need both a good process and a good microbial testing system in place that are based on sound statistics. If lacking either one, plants are not able to perform to their fullest capabilities to produce a consistently safe product.

Requirements Behind the N-60 Label

S.T.O.P. found the qualifications and documentation necessary in place for an establishment to be able to use an N-60 label quite interesting, well-thought out and a positive approach to creating a feedback process between slaughter and processing facilities.

In fact, S.T.O.P. strongly urges FSIS to put this program in place for all establishments using N-60 whether they want to use a label or not. This strengthened oversight should not be limited to the label and could be very helpful for plants to produce safer trimmings. This is the type of proactive measure utilizing command and control currently lacking in our regulatory system with the result being plants not having optimal systems in place to produce the safest possible product.

Dr. Barbara Masters, former FSIS Administrator, made a personal comment, not as a representative of Olsson, Frank & Weeda, as was her presentation that:

> "I personally believe FSIS already has the authority to verify what they're asking for in the program related to the N-60, and so I would suggest they're already able to verify the things related to (the) N-60 label. And so I would suggest that the N-60 labeling is just a tool, and FSIS already has the ability and should, in fact, be verifying a lot of things that they're asking for around that labeling."[14]

In the comment period after Rosalyn Murphy-Jenkins presentation on the draft label guidance document, Dr. Engeljohn stated:

> "…product produced under this system is one for which as Rosalyn mentioned in her presentation, is an integrated system whereby the agency itself will be providing training and instruction to the FSIS employees in the plant to actually verify that the criteria is being met for the labeling claim program. So there will be a specific focus on the actual interaction between the performance at slaughter and the performance at trim, looking at the program to see that it is, in fact, being followed and those conditions being met. So that's a specific focus on a labeling claim process whereas today the inspectors are looking at a verification program for the system but not necessarily looking to verify that the pieces are tied together between the feedback between the slaughter and trim...

[13] Transcript, p. 221.
[14] Transcript, p. 329.

So we would certainly see it as a more robust mechanism for an integrated control in a more comprehensive food safety system."[15]

S.T.O.P. is concerned that industry will just abandon pursuing a label entirely if it's felt that to get the label you have to go to extraordinary measures that others aren't being made to do. Furthermore, further processors of beef trimmings have the right to have FSIS requiring all of these measures in place at slaughter and trim fabricating facilities so that the chances of their receiving a contaminated lot gets reduced. These enhanced food safety measures should not be tied to a label but should be required of all slaughter and trim-producing facilities. It would then be up to the individual company if they wanted to put a N-60 label on the product or not.

We are pleased that the agency is trying to make the label meaningful to receiving establishments by requiring companies using the labels to provide detailed documentation to a committee for overview and approval. This puts credibility behind the label.

In her presentation, Ms. Murphy-Jenkins noted:

> "This type of evaluation would be a little bit different than what we do in our traditional label evaluations. It would be more of like a technical review where we would have an ad hoc committee gather together technical experts from the agency to review the information, as I walk through what's included in the guidance, you'll see that there is quite a bit of documentation that should be submitted as part of the labeling application and that would be reviewed by this ad hoc committee."[16]

S.T.O.P. would also like to submit the following comments on *Section IV. Documentation to be included with the label submittal:*

1. A statement that all such documentation is incorporated into the establishment's HACCP plan, subject to verification by FSIS inspection program personnel.

Comment: FSIS should not approve the label request until FSIS has received written verification from an inspector at the plant.
Comment: FSIS should also require any changes to HACCP plans of plants that use an N-60 testing claim label for review by its ad hoc committee.

2. Documentation demonstrating that all beef trim used to produce the product originated from carcasses slaughtered at an official establishment using at least one validated intervention for *E. coli* O157:H7 at a CCP in the slaughter establishment's HACCP plan.

[15] Transcript, p. 296-298.
[16] Transcript, p. 284.

Comment: FSIS should also get written documentation of the validity of the intervention and also written verification from inspection personnel that the plant is implementing it correctly. We refer you again to Dr. Master's example of a slaughter establishment using an insufficient concentration of lactic acid in its rinse.

Comment: FSIS notes on the guidance document, "FSIS requires documented on-going communication between establishments that use or commingle products that bear N-60 claims to ensure any changes to the HACCP plan are made known." We suggest that this be put on the actual label as notice.

3. Documentation that all beef trim labeled with an N-60 testing claim is tested for *E. coli* O157:H7 (either via a screen method that includes this specific pathogen or a method specific to this pathogen) using the FSIS method or an equivalent method for *E. coli* O157:H7 analysis, and that the testing is incorporated into the establishment's HACCP.

Comment: S.T.O.P. suggests that if an equivalent method is to be used it needs to be validated as equivalent and supporting documentation be submitted along with the label request.

Note: Both Dr. Masters and an unidentified speaker referenced the MLG method. "I know that it came up before that the perception, and my perceptions also, as having used the previous and the current FSIS methods, that the method has improved. When you say something that's been shown to be equivalent to the FSIS method, I would encourage you to actually say that it has to be equivalent to the current MLG method. A lot of things are in the marketplace, a lot of different tests that were validated by AOAC or other agencies against methods previously in use by FSIS, not the method currently in use. And I think in the interest of keeping quality up and making sure the testing is equivalent, that the MLG Guidebook version be specified."[17]

4. Documentation that the sample collection methodology indicates that at least 60 randomly selected samples consisting of at least 325 grams of product are composited and tested.

Comment: The sample size should be 375 grams, not 325 grams.

5. Documentation that if any N-60 tested lot is positive for *E. coli* O157:H7, the lot represented by such N-60 sample is diverted from raw ground beef operations (i.e., the positive lots are diverted to cooking or other further processing that will destroy the pathogen). The documentation would need to explain how the establishment will ensure that such lots have been properly disposed to eliminate the adulterant.

6. If multiple operations within one establishment or multiple establishments are involved in creating the production lot of N-60 tested trim…documentation that

[17] Transcript, p. 290-291.

describes how and when communication between or among the establishments would be recorded regarding slaughter/dressing performance and trim testing results, how that documentation would be made available to the IICs for review at each establishment, how that information would be used to investigate and adjust the HACCP system ensure that the HACCP system is adequate to control *E. coli* O157:H7, and how this information would affect **microbiological independence of production lots.**

Comment: There is no microbiological independence when facilities are not pristine and cross contamination can occur at multiple points. Microbiological independence only occurs after clean up.

Comment: Plants should be required to inform inspection personnel directly when a positive is found as the event occurs so that inspection personnel can ensure that the product was properly disposed of.

Conclusion

S.T.O.P. wants to again express appreciation for the opportunity to comment on these important issues. We also appreciate FSIS' extension of the public comment period.

FSIS must halt its N-60 sampling program on beef trimmings immediately and commence research on an efficacious sampling program for *E. coli* O157:H7 in trim.

We support the requirements and additional government oversight that are "behind" the labeling policy but do not think that they should be tied to a label. FSIS has the authority to enact and enforce the additional food safety measures contained in these requirements and should do them regardless if the industry wants a label attached to it or not. These are public health-based requirements and FSIS has a responsibility to mandate them and enforce them.

FSIS, as a public health regulatory agency, and to better protect consumers, needs to put more command and control back into its regulatory program. Making the verification requirements recommended in the N-60 labeling proposal mandatory would be an excellent start.

In order to better protect consumers, FSIS needs to be more proactive and less reactive when it comes to food safety initiatives. FSIS needs to be more in touch with what is happening in the very plants that it's regulating. FSIS should put a Washington-based HACCP plan review team together to assess every plant's HACCP plan. This would result in better understanding of the industry and what the inspection force has to deal with and would lead to better communications between Washington and the field force.

Respectfully submitted,

Nancy Donley
President and mother of Alex, *E. coli* O157:H7 victim (1987-1993)

Donna Rosenbaum
Executive Director