



## Final Transcript

### **USDA, Food Safety and Inspection Service: STEC Public Meeting**

December 1, 2011

1:00 p.m. EST

#### **SPEAKERS**

Greg DiNapoli

Dr. Daniel Engeljohn

#### **PRESENTATION**

Moderator

Welcome to the STEC Public Meeting conference call. At this time all participants are in a listen-only mode. Later we will conduct a question and answer session. Instructions will be given at that time. As a reminder this conference is being recorded.

I would now like to turn the conference over to our host, Mr. Greg DiNapoli.

G. DiNapoli

Great thank you very much. This is Greg De Napoli from the Office of Congressional and Public Affairs here at the Food Safety and Inspection Service. We appreciate that you're joining us for today's public meeting on the Shiga toxin-producing *Escherichia coli* in certain raw beef products.

I just want to reiterate before we begin and hand it over to Dr. Engeljohn, the Assistant Administrator for the Office of OPPD (Office of Policy and Program Development) here at FSIS, he's going to make some comments on the proposed rule. And after that we're going to go into the comments here.

I want to reiterate that there is no question and answer period. Dr. Engeljohn will make clarification, so if you do have a statement to make and you want clarification, he will do that for you, but we will not be taking any questions. So comments will be three minutes long. We have a number of commenters that we have to get through.

With that, I'm going to turn it over to Dr. Engeljohn.

Dr. Engeljohn

Thank you very much and welcome to the call. I'm glad to hear the interest in this particular *Federal Register* notice policy. As a background, the agency did issue on September 20<sup>th</sup> a *Federal Register* notice on our final determination for the six Non O157 Shiga toxin-forming *E. coli*, which I'm going to call STEC as adulterants under the same conditions for O157 STEC. Those six Non O157 STEC were 026, 045, 0103, 0111, 0121 and 0145, those being the most prevalent causes of food borne illness in the United States at this time.

Although the comment period was set to close on November 21<sup>st</sup>, FSIS extended the comment period to December 21<sup>st</sup>, so you still have time to submit written comments on this policy that we're talking about today. For our policy considerations, we considered that all six Non O157 STECs have been isolated from beef carcasses or retail beef in the United States. The Non O157 STEC illnesses exceed those for O157 illnesses with regards to latest CDC report (inaudible) this year.

Here at the U.S. government, the Food Safety Working Group has focused on prevention as a fundamental principle for building a modern food safety system and this policy on Non-O157 STEC does, in fact, push forward this policy as a proactive strategy to reduce illnesses and to address threats.

Within that *Federal Register* notice from September, the agency provided a draft risk profile, which answered six questions that the agency asks about the issues related to Non-O157 STEC and we provided a test kit compliance guideline for manufacturers to use that could in fact assist in terms of validation for testing kits that might be used to assess for pathogens in products that FSIS regulates.

In the *Federal Register* notice we've identified that we intend to begin verification testing on March 5, 2012, in beef trim and other components from cattle. I want to stress that that would be from cattle slaughtered on or after March 5<sup>th</sup>.

For import products we do know that we have issues related to products that would be on the water or in the transit that would be arriving in the country after March 5<sup>th</sup>, but would be from cattle that likely were slaughtered prior to March 5<sup>th</sup>. And so you should expect that the agency will be providing guidance as to how we would implement the program to ensure that when we test for the Non-O157 STEC, that we will be testing in beef products that were slaughtered on or after March 5<sup>th</sup>. Those products that arrive that are from prior to March 5<sup>th</sup> likely would be tested only for O157 STEC.

We ask for comment on the implementation strategy considerations identifying that FSIS was planning on conducting a new checklist of beef operations to identify what interventions are being used and what control practices are in place. We also identified that we're considering pilot testing on issues related to multiple suppliers to enhance our traceback program and that we would be initiating a broader verification testing program for all products that we currently test for O157 STEC at a later point.

What you should expect in terms of next steps from the agency will be that we take all comments that we received including those that we get orally today and written comments through December 21<sup>st</sup>. We will be preparing a response to those comments and putting them in the form of another *Federal Register* notice that we would expect to publish as soon as we can after the beginning of the new calendar year, but prior to March 5<sup>th</sup>.

And in that *Federal Register* notice will be an affirmation as to whether or not we still will be conducting our verification testing in trim on March 5<sup>th</sup>, which that is the expectation of the agency at this time. And we'll be providing our implementation strategy for the broader range of products that the agency considers to be adulterated if they contain non-O157 STEC. We will also be providing responses to any of the issues raised in the comment period that would articulate how we would further implement this program and provide guidance.

With that I think that gives you an overview about what the policy is. I know that we have a number of callers and that you will have questions. I am not intending to answer questions today, but if there is something that's presented that I think needs clarification, I will provide that clarification, so that commenters won't be commenting on an issue that's misguided. So we'll try our best to note that in those clarifications.

But I do want you to know that if you have comments and they're going to be longer than three minutes, I would encourage you to give your most salient points that you want to say and then follow that up in written comments that we will also accept and you can do that by going to the *eRulemaking.gov*, which is the portal for supplying comments on this policy. You can also provide those comments in writing by faxing or sending in to the agency and we will make a note of that. So thank you very much.

G. DiNapoli

Ok Donna, this is Greg DiNapoli, we're ready for comments. Do you have your first commenter?

Moderator

Our first comment will come from the line of Jim Hodges from American Meat Institute.

J. Hodges

My full testimony will be submitted to the public record. As an initial matter AMI respectfully disagrees with FSIS' decision to implement a new regulatory program because the scientific evidence shows that it is unlikely to make beef safer than it is today. AMI has several concerns and recommendations that it wishes to share with the agency.

First, the draft risk profile is appropriately named because it is incomplete and includes significant data gaps. Independent experts commissioned by FSIS to review the draft risk profile raised several concerns about the strength of the evidence used to draw conclusions about the public health risk associated with Non-O157 STEC. The available public health data do not indicate that these particular aspects posed an unusual or urgent public health challenge.

To our knowledge one outbreak in U.S. involving three individuals have been associated with Non-O157 STEC in ground beef. Given the data gaps and unknown outcomes that the agency's actions will have on public health, a more considered approach is warranted. FSIS should complete a comprehensive risk assessment to provide a better understanding of the public health impact associated with Non-O157 STEC in beef products, and FSIS should conduct a baseline survey on the prevalence of these organisms in various beef products to assess the impact of implementing this new regulatory program.

Second, FSIS needs to initiate an open and transparent process to validate its analytical laboratory test methods under field conditions. A precise and

accurate rapid screening test must be available for commercial use before the agency implements any new testing program. Considerable misinformation and confusion exists regarding test methods.

The issue is not about the availability of rapid screening methods that could provide quick results. The issue is how many of the commercial samples that initially screen positive will be confirmed positive by accepted laboratory methods. Because fresh beef is perishable, it is logistically impossible to hold excessive amounts of product that initially screened positive and ultimately are confirmed several days later to be negative for the target pathogen.

Third, FSIS should commission an independent firm to conduct an economic analysis of implementing the new FSIS policy. AMI preliminary analysis indicates the cost of implementing this policy has been grossly underestimated by the agency. Our initial estimates show that cost will exceed \$100 million annually for trim testing alone and may approach \$300 million annually with the implementation of ground beef testing.

AMI will provide a comprehensive cost analysis in its written comments, but it should be readily apparent to the agency that a most complete cost analysis should be conducted to assure compliance with Executor Order 13563. But, given the many questions surrounding both its potential effectiveness and its cost, implementation should be delayed until a more thorough analysis is conducted and more is known.

Finally FSIS and the consuming public can be assured that a new regulatory policy is not a prerequisite for controlling Non-O157 STEC. Existing industry practices are controlling all STEC, not *E. coli* O157:H7. For the past several years, the AMI Foundation has documented to peer reviewed research that the microbial interventions used to control *E. coli* O157 are equally effective for controlling other STEC and existing microbial monitoring program that target *E. coli* ... can be used as a reliable indicator of process control for STEC. Even the agency said that controls already in place should be effective in controlling non-O157 STEC—

G. DiNapoli

Jim, I'm going to have to ask you to wrap it up, please.

J. Hodges

Yes, I will. The illnesses associated with this strain have not primarily been due to contamination of beef and it's not clear if there is a reduction

in illness. In very plain terms implementing the policy is premature and AMI strongly urges FSIS to delay the arbitrary implementation date until a thorough understanding of the policy's implications can be assessed. Thank you.

G. DiNapoli Thank you, Jim. I just want to reiterate that we have 29 commenters, so we're going to try to keep it closer to three minutes. I'm sorry, everybody, but this is something we have to do here. Our caller I believe is Barry Carpenter with the National Meat Association. Barry, you can go ahead.

B. Carpenter Thank you for the opportunity to comment at this public meeting. I'll focus on six areas of concern. First, testing: a major concern of our members is the accuracy and availability of reliable rapid testing, including test kits. Although industry experiences and related information is limited, there's evidence that many of the existing methodologies are resulting in up to 20% conducted positives, which is much higher than the 2% estimate in the notice. Even if this green positive rate is only 2%, this represents at least a doubling of beef trim that will need to be diverted.

We are greatly concerned that these higher resulted positive levels, many of which are false positives, will cause slaughter processors to reduce or eliminate screening of beef trim to avoid the financial loss incurred by diverting to cooking or otherwise the movement of product in the normal beef trim market. When this happens, certificates of analysis will not be available for downstream beef processors. This will force the downstream processors to either get out of the business or maybe implement their own interventions and validations to conduct that they have taken... to conclude they have taken adequate steps to assure a hazard is not likely to occur. This is especially concerning for small processors that lack the market power to demand testing.

It would be very helpful for FSIS to vet the available test kits to determine the rate of false positives in advance of implementation. This first would avoid the need for callous EIAOs and callous FSAs to identify lack of adequacy in test kits being utilized by individual establishments.

Regulatory framework: it's essential the FSIS maintain the same regulatory framework and related procedures for the six STECs listed in the notice as currently exist for *E. coli* O157. Although not clear in the notice, we assume all the current policy and guide materials which have been provided by FSIS that provide a preliminary basis for many of the

programs and protocols uses by industry will continue to be applicable for these additional STECs.

Issues, such as how (inaudible) determined are presumptive and positive results are defined, applicability of current agency documents that are used and accepted as support for design in food safety program, purchase specifications and various sample protocols and many others are of key importance. Further, it's important that results from non FSIS laboratories be treated identically to how they are in the case O157.

The final issue will make these points very clear so all the processors know what they can expect. As far as HACCP reassessment, the requirements to reassess HACCP plan, SSOP or other prerequisites when the first stage screen potential positive is found, it's very likely it will result in ongoing reassessment that will not add value to the process. Since the presence of STEC and EAEs does not indicate the product contains an adulterant, it seems inappropriate for the agency to conduct... conclude that the establishment is not adequately addressing hazards are likely to occur.

In fact or organism may provide the STEC and another organism may provide the EAE in its initial screening. Directly this early screening as it indicates a presence of an unforeseen hazard seems to go well beyond what we would consider a reasonable position for the agency, particularly as it relates to industry testing.

Regarding imported products, I ask the agency also confirm exactly how imported product testing will be handled to assure equivalency. Though we appreciate this clarification that FSIS has provided us at this point, we are interested— (inaudible, line cuts off.)

Moderator

Our next question will come from the line of Tony Corbo from Food and Water Watch.

T. Corbo

Thank you, very much and thank you for the agency to hold this conference call on this very important issue. We agree with the agency's proposed change in policy and urge that the March 5, 2012 implementation date be maintained. We based our decision on a number of reasons. First, FSIS has been looking at this issue since at least 2007. It held a very well attended public meeting in October of that year where not only domestic public health officials, but public health officials from

the international community also attended and presented very good testimony on the problems associated with these STECs.

The Centers for Disease Control has become concerned with the number of outbreaks associated with these strains of *E. coli*. While not all of the outbreaks have been directly attributed to meat products, the vectors for these strains of *E. coli* are animal based, so the agency needs to tighten its vigilance on these strains.

We've already had one outbreak in this country associated with ground beef products involving one of these strains, so the agency needs to develop a preventive policy to mitigate future outbreaks associated with these strains of *E. coli* from occurring in the future. The agency along with its sister agency, the Agricultural Research Service, have exercised due diligence in developing testing methodologies to detect these stains of *E. coli*.

Our trading partners also need to be fully apprised of this new policy. It should be made crystal clear to them that their continued equivalency status with the United States hinges on compliance with the new policy.

And lastly we would highly recommend that the agency's outreach office develop a training program for very small plant operators who would be subject to this new policy, so that they fully understand what is expected of them under the revised guidelines. We will submit more detailed comments on December 21<sup>st</sup>. I want to thank you for your time.

G. DiNapoli

Thank you, Tony, I appreciate your comments. Our next caller is Scott Allen from NCBA.

S. Allen

Beef Safety Committee and board member of NCBA, National Cattlemen's Beef Association. NCBA appreciates the opportunity to provide comments at today's public meeting. As a cattle producer I support the establishment of realistic food safety objectives designed to protect the public health to the maximum extent possible. These objectives must be based on science, have a strong research foundation and focus on industry application.

I'm concerned that the agency decision to declare six additional strains of Non-O157 STEC as adulterants. There's a lot of knowledge that needs to be gathered, so we can better understand and close the knowledge gap related to these organisms to further protect public health. The science

world of Non-O157 STEC is a relatively new one, unlike the knowledge base we currently have on O157, which took decades to build. There's a lot of information that neither the agency nor industry knows about these pathogens.

What is the calculated food safety risk of these organisms for food products non-limited to beef? What (inaudible) genes are active in these organisms that segregate them from others to invoke human illness? Additionally the standard microbial testing of these organisms developed by ARS and the agency has its challenges the least of which is the time to result. Therefore more rapid methods are essential for the industry to screen product. Today this rapid technology is still in the development and validation stages. The industry needs time for these to develop and the time to validate in-plant different systems to determine which will fit facility practices.

The notice makes reference to HACCP plan reassessments, but how often that is to be done relative to Non-O157 STEC testing is unclear. Just as important as closing the research knowledge gap is the need for the agency to conduct microbiological baseline survey on beef carcasses. The *Federal Register* states that FSIS intends to perform this nationwide survey in late 2011. NCBA encourages the agency to conduct the carcass baseline when prevalence and human illness are typically higher, which would be in the summer rather than in the winter.

The microbiological baseline that is a true representation will also help the industry evaluate testing methods, as well as interventions for those Non-O157 STEC. NCBA would also like to suggest that when the agency designs the carcass baseline to make it comprehensive to include trim and ground samples. FSIS requiring product testing before true baseline is conducted will have unintended consequences for all stakeholders. The government is requiring the industry to take informed actions pertaining to Non-O157 STEC without having the data to support or direct those actions.

In closing, NCBA strongly encourages the agency to reevaluate the effective date of March 5, 2012. In order for the industry to make informed decisions, we need informed data. We request that the agency conduct a baseline survey before the agency begins the routine sampling program to include Non-O157 STEC. Once the government and industry has this information, it will allow all stakeholders to make informed decisions.

As a father and a grandfather and cattleman, food safety will remain a top priority for my and my fellow beef producers. This commitment also includes preventing food borne illnesses to further protect the public health. I appreciate the opportunity to offer comments and look forward to responding with more detail in written comments. Thank you.

G. DiNapoli Thank you, Todd, we appreciate it. Our next commenter is Chris Waldrop with the Consumer Federation of America.

C. Waldrop Thank you again for the opportunity to comment on the agency's determination that six additional serotypes of Shiga toxin-producing *E. coli* should be considered adulterants in raw intact, raw beef products and product components. We will be providing additional written comments in the coming weeks.

CFA strongly supports this determination by the agency. We believe it is an appropriate preventive public health approach and will result in improved food safety and benefits to consumers and public health. These strains are a growing public health problem. The CDC has noted that illnesses caused by the other pathogenic forms of *E. coli* caused more illnesses than *E. coli* O157:H7 in 2010. The big six strains that FSIS are focused cause approximately 70% to 95% of all Non-O157 STEC infections in the U.S. So again, FSIS is taking a preventive approach to addressing this growing problem.

CFA strongly urges FSIS to implement its policy as intended in early March of next year. Summer is the high prevalent season for *E. coli* so beginning implementation in the months prior to summer would allow for the greatest impact on public health during the high prevalent season. The agency was deliberate in its approach to this issue and industry and trading partners will have had sufficient time to prepare for the new policy change, so there's no reason to delay the implementation past the March date.

FSIS has indicated that the agency will expand its application testing program to eventually include testing of ground beef products for STECs as laboratory capacity expands. CFA agrees with this and urges the agency to follow through with this intention. We thank you again for the opportunity to comment and we'll be submitting written comments before the December deadline. Thank you.

G. DiNapoli Our next caller is Ann Wells with the North American Meat Processors.

A. Wells NAMP represents small to medium sized meat processing facilities throughout North America, including Canada and Mexico, as well as the U.S. Our members are further processors of non intact products, such as ground beef and mechanically tenderized steaks.

We wanted to first comment that the agency has asked for comments on the impact of the new rule on small businesses and has stated that the document does not impose significant negative impact on a significant number of small or very small businesses. We do not believe that FSIS has information available to make these statements. The new policy may have significant negative impacts on small businesses in the areas of increased cost of raw materials, increased costs associated with sampling, holding and diverting products, as well as the time cost and resources needed to validate and verify current systems that are affected in controlling the six additional STEC strains. We are also concerned about the requirement to reassess HACCP plans when a screen test is positive and the resources that will be needed to meet this requirement.

Second, the agency should delay implementation of the rule until the major questions and issues surrounding the policy can be resolved. This includes baseline data on both carcasses and trim and the development of accurate rapid and validated test methods available to the industry.

As an organization representing processors across North America, we are also concerned that the new policy does not interrupt trade and that adequate time is given to work with the foreign countries whose products U.S. processors import. We know many of our major trading partners have the same concerns regarding commercially available validated test methods, baseline data and the implementation timeframe.

Finally, we are concerned about the disconnect between draft risk profile and the information presented in the *Federal Register* notice. The risk profile leaves more questions than answers, including prevalence in cattle and ground beef and the virulence of the organism. The conclusion of the draft risk profile seem to be that more information and data needs to be collected before a course of action can be determined. FSIS' independent peer reviewers even question the strength of the evidence presented in the risk profile for drawing conclusions regarding actual risk expressly in what they refer to as the crude nature of currently available diagnostic methods.

That concludes our comments today and we will be submitting more detail in written comments. Thank you.

G. DiNapoli

Our next caller is Chris Parker from the Embassy of Australia.

C. Parker

Thank you very much. The Australian government welcomes the opportunity to provide comments on the United States of America's proposal in relation to the testing for Shiga toxin-producing *E. coli* in certain raw beef products. STEC other than *E. coli* O517:H7 are not considered a major public health concern within Australia and the FSIS published risk profile concerns the majority of Non-O157 STEC infections are attributed to non-based food sources. Australia therefore questions whether testing for these serotypes is scientifically justified, particularly as baseline studies have not been completed in U.S.

Australia believes that an implementation date cannot be established until the test methods get finalized, are tested under field conditions, proven to be reliable and are generally available. Australia is also concerned about the establishment of rules around the early screening stages of the current test method when the testing methodology not yet finalized or tested under field conditions or the relevance presumptive results to the process is unknown.

Testing for these organisms in Australia will rely on commercially available test kits, which have not yet been validated against the FSIS method. Australia therefore requests that FSIS consider postponing the proposed implementation date March 5, 2012 to allow the finalization of test methods and adequate time for implementation of testing. Australia believes that the regulatory action should be limited to concerned positives whilst controlling the movement of presumptive positive lots until the concerned result is known or the product is disposed of. We further know that large volumes of product are expected to be held pending confirmatory tests. Thank you very much.

G. DiNapoli

Thank you very much for your comment. Next is Ian Jensen from Meat & Livestock Australia.

I. Jensen

Good morning. Meat & Livestock Australia represents the Australian red meat industry. As Chris Parker has said, the FSIS policy on testing will result in a number of changes for the Australian industry. Both our commercial customers and our regulator will expect analysis of every lot

of product using the necessary equivalent to the FSIS method. Australian exporters and laboratories are unable to obtain data on the validation of these commercial test systems against the FSIS methods. We believe that that's largely because the FSIS method cannot be conducted outside an FSIS laboratory due to the use of in-house reagents in that method.

In Australia there also appears to be indefinite waits for equipment and/or kits, depending on the supplier involved. Furthermore, no comparative data are available to guide meat processors on the selection of suitable test systems and laboratories therefore have little choice in methods. We're looking for guidance from FSIS on how the industry can verify that they comply with FSIS expectations prior to March 5, 2012 under these circumstances. Thank you.

G. DiNapoli

Thank you, Ian. The moderator was going to make instructions.

Moderator

Our next comment will come from the line of Melissa Hubert from Neogen.

M. Hubert

A number of agency documents including the notice for this meeting specify that six O groups as adulterants. It's our understanding that in reality to be an adulterant a sample must contain a single cell that contains one of the name O group markets in addition to both STEC and EAE. We assume that the agency has talked about O groups as adulterants in an attempt to simplify the issue for stakeholders and the American public. However in doing so, we feel that the agency has confused many stakeholders including some members of the industry and possibly FSIS in-plant personnel with regard to the true intent of this proposed regulation.

A larger concern is the provision for process reassessment in the event that a sample yields a positive result for STEC and EAE. An unintended consequence of this provision is it will serve to discourage some companies from testing for STEC and EAE. This will undoubtedly lead to use of imprecise methods for this important testing requirement, which in turn renders the proposed regulation not nearly as strong a safeguard of public health as the agency had intended. Thank you.

G. DiNapoli

Our next caller is Laurie Bryant with the Meat Importers Council of America.

L. Bryant

Thank you very much for the opportunity to participate and provide comments today. MICA represents the U.S. industry that imports fresh chilled and frozen beef imported into the United States. Our members include importers and known users of imported beef, as well as packers and exporters in supplying countries. We will submit more detailed written comments on the *Federal Register* notice, but we wanted to take the opportunity to draw attention to some significant concerns we have regarding this rule and its impact on imported beef.

First and foremost my members are committed to producing and providing safe and wholesome products. MICA is very concerned about the impact of this policy will have on beef imports as it provides yet another impairment to overseas suppliers and discourages exports to the U.S. market.

(Inaudible) our most important reason the introduction of testing imports for O517 in 2008 was a contributing factor in the decline of beef imports in the last two years. Therefore before any further impairments are imposed on imports, it must be justified by a sound science-based risk analysis and evidence that there is a real danger to public health from these STECs. This is not only important for the U.S. economy but also mandated by the WTO agreement on symmetry and private symmetry measures, which require (inaudible) and food safety rules be based on sound science and on reasonable and transparent risk assessment.

It is MICA's view and we believe it to be supported by the draft risk profile, that the determination of these other six STECs to be adulterants in non intact raw beef products and product components is not justified by the data and is premature in its introduction. As noted in the draft risk profile the data relating to the incidence of these STECs in beef is limited at best and there's even less evidence that these have been demonstrated to result in serious illness through the consumption of beef products.

To our knowledge only one document that the outbreak involving three individuals has been attributed to Non-O157 in ground beef. If there are other outbreaks that need to be associated with Non-O157 STEC in ground beef, that information should be provided for public review.

The difficulty anticipating for these STECs and the unavailability of validated methods and test kits has preventing supplying countries to be able to determine whether these STECs occur with cattle and more

importantly the (inaudible). While commercial kits have been developed, it's not been possible validating against the FSIS standard because the FSIS kits and methodology was not made available until November 4, 2011. It was the publication of the methodology, some of the reagents required by FSIS method are not commercially available, and so validation is still not possible.

Because of the absence of validated test kits (inaudible) based on studies that do not exist in the U.S. or in supplying countries. It will take some time to complete. Without these baseline studies and the little evidence that these STECs are truly health issues in supplying countries, it would seem to suggest that the initial premise has to be that these are not (inaudible) likely to occur and equivalent agreements should be predicated on that basis until they're proven otherwise.

At the very least the date of implementation must be delayed to ensure availability of the test kits and to allow the industry both here and in supplying countries to put in place the systems that will enable implementation of the required tests and to carry out baseline studies to determine whether these STECs actually pose an issue for the domestic and/or imported products.

While we agree that testing should only be required on products in cattle slaughterhouse the date this policy is implemented, MICA believes there's a further justification for delaying the date in which the implementation is to ensure that test kits have been available to all meat packers for at least three months prior to implementation, so they have the opportunity to meet their customer demands for test product that result from the implementation of this policy. Again, we thank you for the opportunity to provide comments.

G. DiNapoli We appreciate your comment. Before we go back, I'd like to open up the line of Barry Carpenter, Barry, if you're still on the line and, Donna, if he's still on the line, we'd like to get him back on. We had inadvertently earlier cut off his line. Can we make that happen, please?

Moderator Mr. Carpenter, please go ahead, your line is open.

B. Carpenter Thank you for the opportunity to finish my comments. I appreciate that. On imported product, I think that's been covered. Baseline study for trim, the notice includes a baseline state for beef carcasses. We believe a baseline study for trim would be much more meaningful. Obviously it

would be logical to conduct the baseline study to determine the prevalence of these six pathogens before implementing regulatory sampling and testing. However this approach is not possible. At a minimum a baseline study should be done concurrently or even be used as a means to schedule the regulatory sampling rather than doing it randomly.

The actual prevalence data from this study could assist the agency in its determination of whether or not to expand testing to ground product as well as the value of continuing testing of beef trim. As far as costs of implementation the National Meat Association has worked closely with the Beef Industry Food Safety Committee to project the costs of implementing the requirements of this notice. Although I'm not prepared today to present the results of this assessment, it's fair to say the costs are considerably greater than those outlined in the notice. These costs will be included in our written comments.

Finally, there are numerous unanswered questions and unknown outcomes that need to be addressed before this notice is implemented. Specifically, failure to resolve the concerns regarding testing, regulatory framework ahead of the assessment will result in a significant disruption in the supply chain including access to beef trim, (inaudible) availability and product pricing. As the agency considers an effective date of implementing this notice, it is critical that these issues are addressed, so that the government, the industry and consumers can experience a seamless transition as it collectively strives for lower risk of food borne illnesses. Thank you and we'll be submitting more detailed comments in writing.

G. DiNapoli

Thank you, Barry. Our next caller is Pat Buck from the Center for Foodborne, Illness Research and Prevention.

P. Buck

Hello, this is Patricia Buck from the Center for Foodborne, Illness Research and Prevention. First of all, I want to thank you for holding this very important teleconference. As you know, CFI has been advocating for the testing of Non-O157 since 2007, so, yes, we support FSIS' proposal to test for Non-O157:H7 STEC for biological testing program. We believe it is a primary objective for FSIS to determine the occurrence of deadline pathogens in its products and then design effective strategies to control and monitor them.

According to the CDC 2010 Foodnet data, the Non-O015 STEC strain exceeded those cases involving *E. coli* O157. While the United States has been successful in lowering the burden of O157, which we're very grateful

for, we now need to learn more about the other Non-O157 STEC strains. Currently while many believe that the Non-O157's can be treated in a similar fashion to the O157's, FSIS does not have quantified data to support that assumption.

In addition there is good reason to test for the Non-O157's, but especially given their potential impact on health and when considering they're escalating occurrence, new information about these strains may provide us with better perspectives on control and prevention.

CFI believes that past year's outbreak in Germany points to the perils that lack of knowledge can generate. We see no reason for FSIS to delay its new policy slated to start in February of 2012. There is abundant evidence that a public health threat does exist, especially with regards to children and elders and we encourage FSIS to move forward with its new Non-O157:H7 STEC testing into its current microbiological testing program.

We will submit a more in depth set of comments before the December 21 deadline and we very much appreciate the opportunity to make these comments. Thank you.

G. DiNapoli

Thank you, Pat, we appreciate that. Our next caller is Dean Danilson from Tyson.

D. Danilson

Good day. I'm Dean Danilson and I'm employed at Tyson Foods as Vice President of Food Safety and Quality. I have worked in the beef industry for over two decades. As I prepared for this meeting, I'm reminded how much the beef industry has improved in the last 15 years in the food safety arena. It's not the same industry it was ten years ago or even five years ago. We have continued to significantly advance our food safety management systems and are committed to doing so in the future.

I appreciate the opportunity to provide comment to this meeting. Specifically, I focus my comments on the question or terms used of ordinary, typical or traditional cooking as was portrayed in the recent FSIS STEC implementation documents and draft risk profile. I believe these terms of ordinary, typical or traditional are a step backwards from the hard work that FSIS, consumers and the beef industry have conducted in advancement of consumer education and research.

Recently USDA partnered with the Ad Council to develop public service announcements that address the four key components for ensuring food

safety. They are clean, cooked, chill and separate. These education programs were not created arbitrarily or without scientific substance, but were mindfully developed and based in sound science. The safe handling and labeling along with the partnership for food safety message points commonly refers consumers to properly or thoroughly cook meat and poultry products. This proper or thorough cooking method is the temperature necessary to kill pathogens of particular concern in a particular product.

I submit that the terms ordinary, typical or traditional are not a supportable concept to be introduced into this debate and perhaps may even further confuse and confound the issue of proper cooking in the minds of consumers, industry researchers and regulators. This terminology used is a disservice to those to the work that has been done to address proper food preparation over many years. At issue is the definition of what is meant by ordinary, typical or traditional.

The use of a variety of terms sends mixed messages and will add confusion especially as the safety of the meat and poultry supply is the first priority for all of us. When beef is cooked thoroughly to 160°F it effectively destroys pathogenic bacteria, not just *E. coli* O157:H7 or the other six Shiga toxins *E. coli* that's issued in this notice. This would be the same for a commercial food processing operation or for a consumer that cooks their ground beef products to 160°F.

Research presented at the 2011 International Association of Food Protection annual meeting demonstrated that the same cooking temperatures needed to destroy O157:H7 are effective against the six Shiga toxin-producing *E. coli* mentioned in the notice. The research has been preformed in a variety of institutions, including the U.S. Department of Agriculture's own Agriculture Research Service. This research should have been considered in this notice.

As STEC's response to cooking is the same as O157:H7, then that is what should be stated, cook thoroughly to 160°F, rather than advance a new and unknown cooking instruction concepts such as ordinary, typical or traditional to the food safety curriculum.

I respectfully submit that FSIS should consider removal of this language of ordinary, typical or traditional cooking as it is misleading and inaccurate, thank you.

G. DiNapoli Thank you, Dean, we appreciate that. Our next caller is Joe Harris of Southwest Meat.

J. Harris Good afternoon. I'm speaking on behalf of the membership of the Southwest Meat Association. We represent meat and poultry processors across the United States. We appreciate the opportunity to offer these comments on the agency's plan to implement its new policy regarding the Non-O157 STEC.

First, as a general matter, we remain disappointed that the agency has again chosen to develop and implement new policy without the benefit of a rulemaking process with appropriate notice and comment. Outside of the rulemaking process, the agency is under no requirement to respond to our comments or any other comments that are submitted through this meeting or other forums.

Regarding the current plan policy implementation, we have the following concerns. We believe the agency has dramatically underestimated the cost of compliance for the beef industry, especially the smaller firms. Based upon the contents of the notice and in the comments of FSIS officials in recent public settings, the agency apparently will mandate another round of HACCP reassessments to address the six Non-O157 STEC's. This is despite the fact that the agency has repeatedly asserted its belief that the practices currently in place to control O157:H7 are effective in controlling these other six Non-O157 STEC's.

We find these mandated re-assessments to be redundant and over-burdensome on the industry. The past experience also tells us that with required round of re-assessment will come agency field personnel expectations of additional control measures to be implemented by establishments.

We're concerned that there are not testing methodologies widely available that have been thoroughly field tested and validated in a plant environment nor has the agency itself thoroughly validated its own methodologies in the current beef production system.

Finally because of the considerable gaps in knowledge and the need to field test testing methodologies, we strongly FSIS to delay implementation of the new policy long enough to allow the technology development to catch up. We appreciate the opportunity to submit these comments and we will be submitting more detailed comments in writing. Thanks.

G. DiNapoli Thank you, Joe. Our next caller is Britney Livingston with the Canadian Meat Council.

B. Reid Brian Reid is going to take that role for her. Is that ok? Thank you, my comments will be brief. We support AMI and NMA in their efforts. We also see a need to educate consumers. We should spend more money at an education level. We're going to build in a false sense of security by expanding the current STECs. We also in Canada, we are confused with the science based approach. We would be hopeful if you'd be willing to explain how you approached this one on the science based. We will be supplying more written detail from the Canadian Meat Council by its experts.

The other request that we would have in the country where we don't see the six STECs as critical as are viewed in the United States, we would like to be exempted from products that we import from Canada into the United States from testing for these six STECs. Thank you.

G. DiNapoli Thank you very much. Our next caller is Caroline Smith-DeWaal.

C. Smith-DeWaal Good afternoon. CSPI represents the Center for Science in the Public Interest. We represent 900,000 consumers, both in the U.S. and Canada. CSPI supports FSIS' efforts to address emerging pathogens in the products that it regulates, including these six strains of Non-O157:H7 STEC. We think that the agency's action raises the broader issue of the need for a systematic method for identifying and prioritizing emerging pathogens that may be coming through the meat supply and sickening consumers either in the U.S. or in other countries.

We recommend that FSIS consider a process that continually reviews outbreak and illness data. This type of ongoing process would make the FSIS approach to these pathogens much more proactive than it is today. We believe that FSIS should give the industry clear advice once emerging pathogens are identified on how they should integrate these hazards into their HACCP systems, i.e. when the hazards are considered reasonably likely to occur and in what products.

The current discussion on the need for and access to microbial test kits and test methods is a very important one. We urge FSIS to proceed as rapidly as possible to implement effective controls on emerging pathogens in the meat supply, including these six strains of *E. coli*. Thank you.

- G. DiNapoli Thank you, Caroline. Donna, I believe you have some more instructions for the callers.
- Moderator Our next caller will come from the line of Jamie Collier from (inaudible) of New Zealand.
- J. Collier Thank you. (Inaudible) is the (inaudible) authority related to domestic production and export of all food from New Zealand. We're concerned that the determination of the six STECs as adulterants is not adequately supported by a robust risk assessment and it has a very real potential to significantly disrupt trade. The inability to currently do comparative method validation and the lack of a baseline survey causes us significant concern as to how we can implement the new measure in a scientifically robust way, which will have a positive impact on food safety.
- While (inaudible) will continue to conduct its own research into these pathogens, New Zealand is concerned the entire measure as currently proposed, has the potential to significantly disrupt trade without an appropriate justification. New Zealand has formally requested suspension of all components of this notice until further information is collected and evaluated. In the interim, (inaudible) intends to continue to work cooperatively with the Food Safety and Inspection Service as we always have done to ensure our respective systems meet each other's required level of human health protection.
- More detailed comments have been submitted by the New Zealand government. Thank you.
- G. DiNapoli Thank you. We did not anticipate finishing quite yet. If you'd like to make a public comment at this point, please follow the instructions that Donna gave us earlier and we'll wait a little bit to see if we have any more folks who get on our queue here. So go ahead and do that for us and we'll wait for some more comments here just for a bit.
- Moderator We do have a comment coming from the line of Marian Unielll from (inaudible)
- Marian Thank you, good afternoon. My name is Marian, I'm calling on behalf of the Bavarian government of (inaudible). We would like to take the opportunity for giving the time ... some of our comments. We will be

providing some written comments with the *Federal Register* notice before December 21<sup>st</sup>.

Basically our concern is detecting method that FSIS has approved because (inaudible) since November 2011. We're not sure if what the particulars would be for verification testing in our government in our country. So we would be expecting some information some further information from FSIS during the further weeks.

G. DiNapoli Thank you, Marian. Are there any more callers coming in?

Moderator We have no additional callers in queue.

G. DiNapoli Okay, we can try for one more.

Moderator Or if you have a question or are you taking questions as well?

G. DiNapoli We're not taking questions, but we can clarify anything. So if someone wants to have Dr. Engeljohn clarify anything that would be fine.

Moderator Okay.

G. DiNapoli Okay, we'll go ahead and I'll hand it over to Dr. Daniel Engeljohn for the closing, thank you very much.

Dr. Engeljohn Thanks, everyone, for your comments. As I had mentioned at the beginning of the call, the agency will be taking these comments, plus all those that we receive in writing. We will be issuing a *Federal Register* notice that will be in response to all the comments that we've received. So as we would typically do, we would categorize the comments into like groupings and prepare responses that we believe would fully address the comments that are raised. The intention then would be as well to provide any update to the agency's plan for implementing the policy, whether or not there's any change to that.

But in particular the agency would identify when it will be broadening the policy for the FSIS verification testing that we would incur. So in any case you should expect a follow-up *Federal Register* notice that will be responsive to all the comments we received orally today, as well as in writing through December 21<sup>st</sup>. We will articulate more completely our implementation plans.

We have already posted on the Web page a couple of *AskFSIS* questions and answers for which we believe it was important to provide some clarity or at least some clarification to some of the comments or questions that we were getting, so that commenters would be better informed about the expectations of the agency. We'll continue to assess the comments to see whether or not we need to provide any immediate clarification that would be helpful.

In any case, the agency will be following up with what other guidance we can be pulling together related to small and very small plants as well as our compliance expectations. I do know that on the call today there were questions raised about the policies for O157:H7 and how they might relate to the Non-O157 STEC policies. And as a rule all the existing policies that the agency has in place for O157:H7 should be considered applicable to the Non-O157 STEC policy. So issues related to what we test for, how much we test for, when we test, how we record, enforcement actions, what we issued for guidance. Until we have data to suggest that we should view our policies differently, we're starting with the assumption that our policies and expectations with regards to controls would be applicable to the Non-O157 STEC.

I think with that, I'll close. Again, you have until December 21<sup>st</sup> to get your comments into FSIS. For those of you who are not familiar with the commenting process, if you locate the *Federal Register* document that announced this public meeting today or the *Federal Register* notice from September 20 that announced the original policy, there are instructions in that document with regards to how you can submit comments. And that would be through the federal e-rulemaking portal, which is at [www.regulations.gov](http://www.regulations.gov). Follow the instructions there for our policies related to docket number FSIS-2010-0023 and then your comments will be posted there. They are also available for viewing by the public on the FSIS Web page. Any related documents associated with this policy are also associated on the FSIS regulation page.

And for those of you who have access to Washington DC and to our docket room here, you also can have access to all of the written comments and the administrative record that's available for public viewing in one setting. And you can make an appointment to view that information as well.

So with that, I thank you and we'll close the call.

Moderator

Ladies and gentlemen, that does conclude our conference for today. We thank you for your participation and for using AT&T Executive Teleconference Service. You may now disconnect.