

I am writing this letter to urge everyone who reads it to take the message to heart and hope that it either provides inspiration to you or challenges you to stand up for what is right. I hope this reaches an audience including many people who do not know who I am. For that reason, I will provide a brief background. I will also warn everyone that there is a significant amount of negativity in this document, but that negativity is followed by a message of hope and guidance, so I urge everyone that begins to read it, read it until the end.

I was a Supervisory Public Health Veterinarian (SPHV) within USDA's Food Safety Inspection Service from 2007 until May 13th, 2011. On that day, I resigned without warning and walked out the door. This surprised many of my closest colleagues who I respected dearly, but more importantly had developed close friendship's with. Many of these close friends called and asked why and why so sudden. When I first came in to the Agency, many of these same co-workers told me I was a "gunner," that I needed to slow down and not take everything to heart. They said if I didn't the Agency would break me and I would leave. In that sense, all of those people were right, I did leave, but the Agency never broke my drive to do what I believed was right. Instead I left due to a variety of factors that I saw that I did not believe were right. I lost all confidence in the leadership of the organization, from the district level on up. I left because I no longer believed in many of the policies that all of us field inspectors were being asked to enforce. Most importantly, I left because I was no longer proud of what I was being asked to do, but instead was embarrassed. I was embarrassed to be using tax-payer money in ways that served no purpose in contributing to the actual Mission of the Agency. I felt guilty enforcing rules, regulations, and policies that served no purpose in contributing to the actual Mission of our Agency and more importantly served no purpose in ensuring that the food products being produced were safe for human consumption. I will go into explicit detail and provide examples of what led me to come to these beliefs. I know not everyone who reads this will agree with everything in it, but if you do, pass it on to everyone you know and more importantly speak out against the policies that do not make sense. I believe a major change is needed within the organization but unfortunately believe we severely lack the leadership needed to make these changes. One person cannot lead change and thus, I ask all of you who read this and believe in what I have to say, take heart and do your part to urge for change. Most importantly, stand up for what you believe and fight for what you think is right instead of just going with what you are being told to do when there is no regulatory or scientific basis behind it. Change doesn't come from people taking the easy road, but instead comes from people who have the courage to stand up for what they believe in. I urge whoever reads this to have the courage to stand up and voice opposition against the policies and procedures that serve no purpose in food safety and instead are just a waste of effort, human resources, and overall just a waste of tax-payer money.

The Mission Statement of the Agency states the following:

The Food Safety and Inspection Service (FSIS) is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's

commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged.

In my view, the Agency has lost focus on its number one mission and that is to ensure that the commercial supply of meat, poultry, and egg products are safe, wholesome, and correctly labeled and packaged. The loss of focus has come from too many competing interests and mandates placed on various levels within the Agency.

Management controls have led to the demise of the most important functions of inspection and that is to ensure the products being produced are done so under sanitary conditions. Instead of using valuable resources where they are needed most, which is in the plants, the Agency continues to waste resources on trivial matters such as management controls. Management controls and target levels of performance have become a complete hindrance and seeing how resources are utilized to meet these is appalling. When a District manager, deputy district manager, Front-line supervisor, and SPHV converge on an establishment all to meet management control targets, it is embarrassing. The plant asks what the occasion is and the response is that the DM is observing the DDM who is observing the FLS who is observing the SPHV who is observing the CSI to ensure the CSI is performing the task correctly. That is taking redundancy to a level that I didn't think could be achieved anywhere. Wow, talk about embarrassing and a waste of tax-payer money, but I am glad we can meet the management control percentages of reviewing by direct observation a certain percentage of IPPS reviews. Sorry, I don't have the exact date on this occurrence, but I am sure one could find it by reviewing when the "Check Box" for review by direct observation was checked by the SPHV, FLS, DDM, and DM for the CSI's IPPS review. That is if AssuranceNet would actually work long enough to check for that information. I hope everyone involved got an outstanding on their performance appraisal that year for meeting Agency targets. I think the American tax-payer deserves more.

Or what about a trip to Hawaii by the DM in fiscal year 2010 in which over-half the District's travel budget was used on this one trip? Was that also to meet management controls? Maybe the public would have been better served by a visit to two of the largest establishments in the country less than 60 miles away from the district office to address and listen to various concerns raised by the in-plant teams of these two plants, one of which had a recent recall traced back to them from foodborne illnesses, but that wouldn't have been as fun as a 3 week trip to Hawaii and Guam on the tax-payers dime. I would like to think there was a legitimate reason for the trip to Hawaii, but actions speak louder than words and from the field, it appeared to be more of a vacation on the tax-payers dime than a meaningful trip centered on food safety. Is this really how people in leadership positions spend tax-payers money? This leads me to question the leadership of the organization. Where is the leadership to change these wasteful programs and policies? When the DM and DDM were driving 60 miles one way and taking a minimum of 2 hours to do so, did anyone think to stop and evaluate what they were doing? Did anyone think to try to put a stop to this practice and send an email up to the masters of Assurance Net and authors of the management control guidelines for reviewing IPPS reviews (See Directive 4430.3 revision 2 dated 2/9/2010, specifics on page 4 for management controls). Once again, tax-payers

money is being spent on this stuff? Really? I walked away from a good paying job but at-least I can hold my head high knowing that I refused to buy into this sort of wasteful spending and did all that I could to make sure that I was doing everything in my power to uphold the ACTUAL mission of the Agency and I am pretty sure all my friends and colleagues that I worked with would vouch for that. What about your peers, would they say the same about you? Can you say the same? I hope so, but more importantly I hope the individuals in leadership positions truly evaluate what they are asking the field force to do and how these trivial tasks to meet target numbers are both a waste of taxpayer money and interfere with the Agency's actual mission.

## **PHIS and Predictive Analytics**

On the Agency's website promoting PHIS, there is a video on predictive analytics. This video discusses the increased functionality of PHIS which has been developed to replace PBIS. PHIS will change how the field force is assigned various tasks, how the results of these tasks are entered, and also allow all data being generated to be inputted into a single program allowing access to all information generated through all levels of the Agency. This will be an improvement, but to think that the data being input will actually result in meaningful predictive analytics functions is crazy. The Data, Analysis, and Integration group is charged to evaluate much of this data and use the data to move towards "Risk-Based Inspection." Once again, in theory, this sounds great and makes for a great promotional piece to tout to the general public and Congress, but in actuality, the change will have little to no impact on the safety of the products being produced at establishments across the country. The Agency leaders will say this is just an opinion with no factual basis, but my experience in a variety of plants and analysis of all this "data" that the Agency creates has little to no correlation to the safety of the products being produced. To demonstrate this, here are a couple of examples.

Less than three weeks ago I received an email from my FLS. The email contained "HATS Data" (Humane Activity Tracking System data) from across the country. This data originated from headquarters in DC and was distributed to all the District Veterinary Medical Specialists (DVMS) across the country. This data is being tracked to ensure that the Agency meets a targeted value of I believe 140 FTE (full-time equivalent hours) monitoring humane handling activities across the country. The Denver DVMS then highlighted the establishments that had less hours recorded than the previous year for the month of March. Two of my establishments had less time entered into the system than the previous year, but that doesn't really matter. First, lets consider how the system tracks the amount of time spent monitoring humane handling activities. Inspectors enter the data into eADRS (electronic animal disposition reporting system database). Inspectors enter the amount of time monitoring each category in 1/4 hour increments for each of 8 categories. An inspector can monitor most of these categories simultaneously, but to enter what was monitored, they can only do so in 1/4 hour increments. Thus, no matter how you enter the data, it isn't accurate. I would venture to guess that most of time the data is completely canned and the CSI's and PHV's just went down the list on a

daily basis and made sure 1/4 hours were entered in various categories. This is the data that headquarters is paying someone a pretty hefty salary to monitor so they can report to congress on whether the 140 FTE's are being met. Are you serious, we are paying someone money to evaluate this canned data and asking the field force to respond when targets aren't met. What a complete waste of tax-payer money and resources! If you think this is only being monitored by the DVMS's and the DAIG group, you are highly mistaken. As the fiscal year of 2010 was winding down, the entire Denver District field force received an email from the District Manager indicating that the country was not on pace to meet the 140 FTE's or whatever the mandate is. The country would have to increase the humane handling activities by 12% to meet this mandate. Are you kidding me! 12% increase based on falsified data to begin with! Are taxpayers really paying for this sort of data analysis by the DAIG group and the people that respond to this data? Rest assured though my friends and colleagues, the increased HAT activities over the last month and a half of FY 2010 meant that the Agency could report that the goals were met as was reported in an email later on by the District Manager. I hope you slept better knowing that the 12% increase was met, I know I did. On a serious side, why do our leaders not recognize the absurdity of these reports and do something to stop them and save the field inspectors from these silly requests.

On another note, every year, USDA has to prepare an accountability report to Congress. In that, various goals from the different Agencies are stated and then reported on. For the report in 2010 ([http://www.ocfo.usda.gov/usdarpt/pdf/2k10\\_USDA\\_PAR\\_11.18.2010\\_508\\_FINAL.pdf](http://www.ocfo.usda.gov/usdarpt/pdf/2k10_USDA_PAR_11.18.2010_508_FINAL.pdf)), FSIS had three goals, listed and analyzed beginning on page 70. One was to reduce the overall public exposure to Salmonella from broiler carcasses, one was to reduce total illnesses from FSIS regulated products, and the last was to increase the overall percentage of establishments with a functional food defense plan. The first two goals were not met, but luckily the third goal was. Maybe if the money that was used to analyze the inaccurate and falsified HATS data would have been spent on resources to ensure the field force had the resources available to them to actually ensure that those broiler carcasses were free of fecal/ingesta material prior to entering the carcass cooler or ensuring that beef, lamb, etc carcasses were free from the same prior to entering carcass washes, the Agency could have met the first two goals. Another failure of management, but as Dilbert says, I know you can do better next time.

Back to predictive analytics and how the Agency is currently promoting the new PHIS functions and how the system will allow the Agency's data can be analyzed as part of a risk based inspection approach. Once again, in concept, this sounds great, but this is not really anything new. In fact, this same analysis was being done by the then called "Data Analysts" in the District Offices around the country. On 3/25/2009, I received an email from the FLS over concerns over "high rates of non-compliance for SSOP operational and pre-operational tasks at several establishments. I need to explain this failure to meet established targets to my superiors" the FLS stated. In the original email from the District Analyst, it was stated that an arbitrary value of greater than or equal to 6% noncompliance had been applied to the SSOP data and the corresponding values are color-highlighted. For the establishment that my FLS was

concerned about, the rates of noncompliance ranged anywhere from 6.7% up to 36.4% noncompliance rates were determined for sanitary operational and pre-operational deficiencies. Following this request, I reviewed all the NR rates for the previous 15 months, I also reviewed trends related to pathogen testing results, sanitary dressing noncompliance reports, and all other data that was available from the system. I have since performed several other reviews of such data and come to the same conclusion each and every time in that there is no correlation between noncompliance reports, sanitary dressing related NR's etc, and the possible safety of the product being produced at the establishment. This is not to say there isn't a link, but rather, the in-plant inspection methodology performed as directed by FSIS directives does not create any meaningful data and PHIS doesn't change any of those methods. What is really alarming is when I sent this same information and conclusions up the supervisory chain, I received no response from anyone other than my direct supervisor who concurred with my analysis. Is that how "leaders" who truly want to address potential food safety concerns or improve the status quo respond? If I owned a business, was paying some to analyze data created in my business to identify trends of concern, and then asked for a report on that data, I would want to know from the people in the field that I asked to respond what they thought! Apparently, that is not what the Agency's goals were, which makes one wonder if the data analysts are just going through the motions to justify their existence!

I don't see how a new computer system (PHIS) is going to correlate to a safer food supply. A computer programs with nearly useless data is not going to correlate to any meaningful predictive analytics functions. The Agency keeps touting a science-based inspection, to back that up, the Agency must start by collecting meaningful scientific data and then analyze that data. The data entered daily by the in-plant inspection team isn't scientific, and by-and large isn't meaningful (refer to discussion above on HATS data). A good step would be to re-allocate the resources used on the salaries of the data analysts to analyze pointless HAT data and re-direct it to meaningful testing programs. By meaningful programs, I do not mean more specific pathogen testing, but instead analyzing finished product (i.e. carcasses, end-product, etc) for indicator organisms which could at-least provide an indication of general sanitary practices within the facility and could be used to validate establishment interventions. Bottom line, predictive analytics could be meaningful, but predictive analytics based on current data collected wouldn't be worth the paper it was printed on.

There is a complete disconnect between the inspection force in the plants and the individuals that are leading the Agency and in charge of providing direction to the local inspection teams. The individuals making the policies and interpreting the policies either have lost the connection to the field or do not want to acknowledge and respond to the concerns that the field inspectors raise. This same comment was made to me by a SCSI (Supervisory Consumer Safety Inspector) who had attended the first PHIS training session. In that session there was a module on sanitary dressing evaluation. The SCSI stated that controversial questions were raised concerning the lack of meaningful direction and authority of the inspectors in the field. This same concern and poor response from the policy development

division was exemplified in the askFSIS question that is attached. When confronted with a problem that I had observed at all three of the very large establishments that I had been assigned to recently, they never addressed any of my concerns. When they did address those concerns, they made false assumptions that it was a performance issue of the in-plant team but when I challenged that portion, all the staff officer stated was, "I apologize." This answer was shared with district office personnel and again, no meaningful response was gained. I discussed it on the phone with the deputy district manager who agreed this was a problem with policy, but again, what is being done to address this? I showed this question to several people across the district and all responded the same way in that the question pretty much sums up the frustrations that each face when assigned at high-speed beef establishments. When one gets the type of meaningless responses from the so-called leaders of the organization, one really starts to question what the Mission of the Agency really is.

### **The HACCP and Food Safety Assessment (FSA) Hoax**

All of the above complaints were minor and contributed little to the reason I suddenly resigned. The single most important factor in my resignation was that I no longer believed in the direction in which the Agency was going. Specifically, I had no confidence and could no longer push the Agency's version of HACCP on the establishments that I was assigned to. I could no longer tolerate the gross waste of tax-payer money being spent on FSA's, some of which lasted 4+ months. Seriously, 4 months to analyze and argue over an establishment's hazard analysis and whether they could support the decisions in a hazard analysis. What a waste of time and money and based on the importance that the Agency's leaders are placing on FSA's it became clear, that those leaders have lost touch with what the Agency's mission really is.

On Page 11 of the PHIS User Guide for Inspectors, it states that "The FSA is the essential component of the Domestic Inspection process." If the FSA is "THE ESSENTIAL" component of inspection and the individuals in leadership positions truly believe this and allocate resources accordingly, the meat products in which FSIS regulates are going to get less safe instead of better. Maybe that is why there was an increase in foodborne illness rates amongst FSIS regulated policies in 2010 compared to 2009 as commented on above. District offices and headquarters seem to be taking the FSA as the the best evaluator of how well a plant is operating. Instead of relying on the inspection team in the plants on a daily basis, they rely on paper generated by an EIAO who often times lacks the experience and training to truly evaluate establishment processes. They are basing major enforcement decisions based on the results obtained by Enforcement, Investigative, and Analysis Officers and from what I have witnessed, this is downright scary. With the direction our leaders seem to be taking with the FSA's it is clear that food safety has become a paper chase that is only detracting from the actual mission of the Agency and wasting millions of tax-payers dollars every year. I have reviewed numerous FSA's conducted and besides a lack of consistency between them, the only thing that I see is a continual focus to document noncompliances based on "paper deficiencies"

that have no impact on the actual product being produced. Is this really how we are spending tax-payer money? I will answer my one question here and say yes it is how tax-payer money is being spent and it is embarrassing. Within the Denver District, it was not uncommon for FSA's to drag on 2-4 months, even at small establishments and yes noncompliances were always found, but the actual food safety significance of most of these was often-times laughable. It was embarrassing to even be a part of exit conferences and have to document the NR's that were recommended. I am sure the public will sleep better knowing that all the plants in the Denver district have indicated their intent to perform direct observation of corrective actions. They can also sleep better knowing that Est. XXXXX received a noncompliance because they forgot to initial a monitoring record created three months ago. What a farce! if the public really knew their return on investment in 99% of the FSA's, there would be a public outcry. It became apparent after reading hundreds of FSA's that the main intent was to ensure that something was documented even though the NR had no food safety significance. So where's the problem with FSA's? The EIAO's (Enforcement, Investigative, Analysis Officers) are just doing as instructed. The problem lies much higher than the ones doing the dirty work in the field and represents more severe problems within the Agency.

Although HACCP may have a place within the regulated industry, the Agency's version of it is nothing but a hoax. The principles of HACCP are important, but the manner in which the Agency is currently evaluating the HACCP programs within the establishments that they regulate is downright embarrassing. Maybe if the Agency would forget about what the actual hazard analysis states and how the hazard analysis is worded and instead focus on the actual principles employed by each establishment, a food safety assessment may be valuable, but until that begins to occur, the manner in which the FSA's are being conducted is nothing but a waste of tax-payer money. In the 3+ years employed by the Agency, I had the opportunity to visit 30+ establishments of a variety of sizes from very small up to very large. I was asked to respond to a variety of problems including significant public health events (i.e. recalls due to foodborne illnesses). All of the focus always came down to the hazard analysis and throughout all establishments, the hazard analysis and interventions were nearly identical. Bottom line, instead of focusing on what mattered, the Agency continues to put a focus on paper and the majority of the FSA's I have reviewed, the FSA wasn't worth the paper was written on. What is truly alarming is this same statement about a FSA not being worth the paper it was written on was made by an official of a foreign government during an export audit! If government officials from a foreign country can see it after briefly reading the content of a single FSA, what the hell are the people in leadership positions in the Agency thinking when they are reviewing these FSA's. They must be seeing something that I'm not. Talk about wanting to crawl under a table and hide all identifiable clothing that tied me to the Agency when that statement was made! The establishment personnel sitting in the audit was relieved; the foreign audit team spent more time critiquing the Agency than the establishments programs. It rang true 2 years ago when the Korean official made the statement and it still rings true today.

So, I urge all of you to critically evaluate the results of all FSA's. Prior to making a decision on whether or not a NR is warranted, ask yourself these questions: What implications will this have on the ACTUAL product? What is the food safety significance of the finding? Why anyone would waste time on paper work NR's with no food safety significance baffles me and this practice needs to stop. The taxpayers and the establishments you are charged to regulate deserve more. Whatever happened to common sense and working together for the common good? Writing NR's for verbiage issues and missing a couple of initials on a record two months ago does nothing to either and is an absolute embarrassment and contributes nothing meaningful towards achieving the Agency's actual mission. The FSA's that I have personally reviewed indicate an Agency more focused on a paper chase than a pathogen chase. An Agency focused on how well an establishment can create a paper trail than what the actual conditions in the plant indicate. It appears that the FSA's are being used to justify jobs but rarely are they serving any other purpose. Why we are paying people 70-80 thousand per year to create 160 page documents that are truly not worth the paper they are written on is beyond me! If the Agency truly wanted to make a difference, they would allocate those resources to put more people in the plant to ensure the product being produced is clean and wholesome. If you share these same thoughts, I urge you to have the courage to challenge all pointless NR's recommended as the results of an FSA. The establishments you regulate in and the public in which you serve deserve better.

To demonstrate the importance being placed on a hazard analysis by the Agency, I have attached a second FSIS question and response that was submitted. In that question, I asked whether or not a very small establishment could support that *E. coli* O157:H7 was not likely to occur without specifically testing for the pathogen. I also asked what the statistical significance of following the compliance guidelines in which the Agency has encouraged of testing 4 times a year using the Agency recommended N60 sampling technique. From the response that was received, it became clear that either these "leaders" either don't get it or don't want to answer any challenging or controversial question. The answer all focused on the hazard analysis, which once again, in theory, and from an ivory tower completed removed from the "actual world" this may make sense, but after spending time in over 30 slaughter plants of various sizes spread out across Colorado, New Mexico, Washington, and Oregon, I found this answer to be unacceptable and indicative of a systemic problem within the Agency. That problem is the Agency's continual focus on paper and not the actual process.

I have had the opportunity to spend a substantial amount of time at some of the largest beef plants within the country. These plants were all part of large corporations that supply over 90% of the beef products consumed in the country. These plants have industry leading science to support all of their interventions. These plants have incredibly intelligent and talented employees overseeing the entire process. These plants do everything within their resources to produce a safe and wholesome product, and do an outstanding job at it. Bottom line, these plants all do an outstanding job of mass producing some of the safest product in the world, yet they still face significant food safety related risks every single day. These plants have all done almost everything imaginable to validate their slaughter



HACCP plans and yet, they still get positives. I cannot believe that the leaders of the Agency truly believe that what they are promoting by requiring small plants to validate their process and test 4 times a year is truly making a difference in the safety of the products that they are producing, so why are we even trying to get them to do so? If these same small plants had the resources to actually validate their processes and test at a statistically significant frequency I would support the Agency's push to recommend (or require by the looks of the Denver District) testing at these facilities; but when the same Agency compliance guidelines recommend that testing at a statistically significant frequency would be cost prohibitive, I refuse to recommend and encourage the plants that I supervise at to follow the Agency compliance guidelines when the results of those tests would be statistically meaningless and the Agency officials that wrote those documents even admit so within the documents!

The entire validation and small plant *E. coli* O157:H7 testing dilemma was discussed during an EIAO conference call in which an Agency leader from the Policy Development Division led. One of the EIAO's raised a great question in that the Agency recommends and encourages these plants to test, but what actual regulatory basis does the Agency intend to use to require them to test. No real answer could be provided by the Agency "leader." The actual testing frequency was also discussed, and it was stated that the Agency recommended at-least quarterly testing in "very small plants," but actually five or six tests would be better. Are you kidding me, at-least 4, but 5 or 6 would really be better!

In the askFSIS question below (attachment #2), I asked for the statistical significance of quarterly testing using the N60 sampling methodology and assuming testing methodology equal to Agency standards. This portion of my question was not answered, but using Agency generated guidance, one can come up with some pretty safe conclusions that testing 4-6 times per year at these plants provides no meaningful scientifically supportable data. Using a prevalence of 0.36% (2007-2009 percentage of FSIS directed *E. coli* O157:H7 testing results), one would expect one sample out of 277 samples to be positive. Extrapolating this out, a very small plant following the Agency's minimum sampling frequency and then increasing sampling during high prevalence seasons and testing 6 times per year, an establishment could expect to have one positive result once every 46 years! Wow, is that worth the time and effort, especially considering if you use the Agency sampling and testing methodology, which has recently come under scrutiny from previous OIG reports and knowing that based on an estimate prevalence of 1%, most of the negative results would be false negatives! I am glad that the Agency recognizes that the small and very small plants due not have the resources to thoroughly validate their processes and test at a high frequency, but why is the Agency then asking them to spend resources on testing when from a scientific standpoint. Long story short, I could no longer enforce these policies in which I did not believe in. I refused to question an establishment's hazard analysis and question there scientific supporting documentation that may not have been perfect and tell them that if they test at the minimum Agency guidelines that they then could support their hazard analysis statement that *E. coli* O157:H7 was not likely to occur in their ground and tenderized product when this same establishment had not had a single *E. coli*

O157:H7 test positive from monthly Agency directed sampling, generic *E. coli* results were all below detectable levels, and had never failed an Agency Salmonella set.

Back to the large plants vs. small plants and how the hazard analysis is important, or the Agency leaders think the hazard analysis is important. As I stated above, I have had the opportunity to review countless hazard analysis' throughout the District in which I was in. All of them stated nearly the same thing although the wording of them could vary greatly from plant to plant. Nearly all of the establishments are using the same interventions and all had scientific support that indicated that the intervention achieved a significant log reduction. The very large plants had conducted validation studies for their interventions. The very small plants usually had little validation data and the small plants were somewhere in between. Of the plants testing for actual pathogens, they all had similar rates of occurrence. So, I ask the "leaders" of the Agency, tell me again why the hazard analysis is so vital to the safety of the product actually being produced? I don't see the importance of the wording of the hazard analysis when the interventions that these plants are using all have scientific support indicating that they are effective, but yet that is exactly what the current FSA's spend countless hours of time focusing on. Once again, the Agency is focusing on a paper chase and paper verification instead of an actual pathogen chase and is wasting millions of tax-payer dollars in the process. If you think I don't have a significant amount of knowledge on the subject or I don't have the data to back what I am saying and this is just my opinion, think again. I have witnessed two significant events at the establishment's in which I was stationed at in which the Agency questioned an establishments process and specifically the parameters and how specific interventions were being utilized cause more of a food safety risk to the consuming public than was present before the Agency intervened. Long story short, the Agency's evaluation of HACCP programs is correct in theory, but doesn't work in the "real world" plant situations. I truly feel pity for all the inspection personnel that are actually drinking this "kool-aid" being pushed by the Agency's leaders but more importantly I apologize on behalf of the countless Agency employees that don't believe in the "kool-aid" known as HACCP to all the plant managers and owners that have to respond to the pointless NR's generated by the "kool-aid" pushers.

### **Where to Go From Here - A Message of Hope and Guidance**

I am sure everyone is tired of reading my negative diatribe and examples above and focusing on the negative will not fix the problems that currently plague the Agency. For that reason I think it is important to plant a seed of hope on how these problems can be changed. As I stated several times above, I have had the opportunity to visit 30+ establishments across Colorado, New Mexico, Washington, and Oregon. This opportunity also gave me the chance to see what is truly important to everyone in the industry and the Agency. Throughout all my travels I noticed one common goal that never wavered and everyone believed in. That goal was the goal to produce a safe, wholesome product and do so in a sanitary manner. Although statements in the hazard analysis, how the hazard analysis was worded, how they monitored the interventions, etc, may have changed, everyone did the

same thing with the only difference being the amount of resources the establishments had to focus on more advanced interventions (i.e. carcass wash cabinets vs. hand sprayers). This observation not only provides me with hope and encouragement, but also should guide each and everyone's daily jobs. Always remember that the establishment that you are at has the same goal and that goal aligns precisely with the Mission statement of the Agency. Therefore, work together, treat the establishment with respect, and more importantly treat them how you would want to be treated if you were in their shoes. One final message for everyone based on your specific position in the Agency.

**For Food Inspectors in the Plant:** Before you consider taking a regulatory control action think about what you want to accomplish by doing so. Don't take actions just because you can, take a RCA only when it is justified and truly warranted. Stopping a production line for condensation where no product is located can be handled in a better way than stopping the line. Remember this, your job gives you the authority, your performance gets you respect. Stopping the production line for every minor problem that has no food safety impact doesn't get you respect, it just demonstrates your authority.

**For CSI's in the Plant:** Before you consider taking a RCA or documenting a noncompliance report, evaluate what you truly want to accomplish by doing so. If it is for rust on a door hinge in a raw product area, or rust on overhead structures where no product is at risk of being involved, handle it in a weekly meeting or plant improvement plan. If it is for a missing a single initial on a monitoring record one time, handle it by talking to a plant supervisor or QA technician first. If it is for wording of a hazard analysis and other verbiage issues, ignore it. NR's take time for both you to write and the plant to answer. Items above only serve to create a paper trail with no food safety significance. Spend that time on more important tasks such as directly observing product handling practices in the fabrication department, observing sanitary dressing practices on the slaughter floor, and ensuring that all establishment interventions are functioning as intended. Answering that NR also only takes time from plant personnel in doing the same thing. If you follow this advice, you will not only gain respect from the establishment you operate in, but will also have a positive impact on the food safety system in the establishment. If not, you are only contributing to the paper chase problems that exist in the Agency.

**For PHV's:** Use your scientific knowledge and the critical thinking and diagnostic skills each and every day. Use these skills to evaluate what truly is important in contributing to the Mission of the Agency. When presented with possible paperwork noncompliances, think about what the actual impact these have on the food safety system. More importantly treat everyone that you supervise fairly and value all of the CSI's and SCSI's input. Although I didn't always agree with their CSI's viewpoint, I always valued their input and perspective. These are the people that go to bat every single day, make sure you always treat them fairly and they will do the same to you. Once again, your job gives you the authority, your actions gain you respect. I hope that my actions as a SPHV gained the CSI's respect for me based on my performance and not my GS-Grade. Respect should always be gained by your

performance and not where you are in the hierarchy of the organization and I hope mine was.

For EIAO's and SEIAO's: When performing or reviewing FSA's, think critically about the actual food safety implications of the NR's or enforcement actions you are recommending. NOIE's based on a hazard analysis generally does nothing to improve the actual food safety processes. Trust me on this one, I have seen the results for such NOIE's. NR's for missing an initial or a single time over a three month period does nothing but make the Agency look ridiculous. Writing a NR over how the establishment words a hazard analysis or whether they identify pathogen presence or pathogen growth is also just as pointless. The documentation of such NR's only takes away from the time the CSI's and in-plant personnel have to spend actually monitoring the production of product. Remember the Agency's mission and that is to ensure that the products being produced are safe and wholesome. A safe product on paper doesn't equate to a safe product on the consumer's shelf. I am sure Brianna Kriefel's family could care less whether the establishment initialed a monitoring record. In case you don't know who Brianna is, Brianna is the little girl that succumbed to *E. coli* O157:H7 over ten years ago from eating lettuce that was contaminated by an intact raw, beef steak. Once again, your job may give you authority, but your performance gets you the respect. Respect isn't gained by the number of NR's or NOIE's you recommend. Recommending NR's for pointless paperwork issues does nothing but destroy the Agency's credibility. Once again, the mission of the Agency is to ensure the production of a safe, wholesome product reaches the consumers, it is not to ensure that the paper behind the process is perfect. Focus on the principles of HACCP and the actual process occurring in the plant and not the minutia of how an establishment words it's hazard analysis and whether a "yes" should actually be a "no." Focusing on the minutia does nothing but destroy the credibility of the Agency.

For DDM's and DM: Listen to the field personnel, they are your number one asset. Actions speak louder than words. Emails can come thanking the field personnel on a daily basis, but if those words aren't followed by actions, those words of gratitude mean nothing. When problems arise, come first to the in-plant personnel. They know the processes in their plants much better than someone that visits every 3-4 years. Furthermore, contrary to what the Agency stated in the PHIS User Guide, the daily performance by the in-plant personnel is the "essential" component of the domestic inspection process. If you lose these people in the minutia, you lose the essential component of the inspection process and in turn put the consumer at risk.

For Headquarter's Officials: Once again, listen to the in-plant personnel, come visit in-plant personnel and seek their input on all new guidance documents prior to issuing them. Discuss the challenges being faced by the in-plant personnel. Lastly, take some of the information above concerning meaningless data to heart and put the wheels in motion to change these. Shift the focus from a paper chase that HACCP has become to a pathogen chase.

Predictive Analytics and the Future of the Agency: As I stated above, I have a tremendous amount of respect for all of the in-plant personnel that I worked with. I

remember a specific conversation that I had with the CSI's at the headquarter plant concerning sanitary dressing. I stated that every time that a carcass reached the final inspection station with hair, fecal, etc; it should be documented somehow and monitored on a continual real-time basis. The two-old time CSI's (Gary and Dave are there first names), said I was crazy and it could never be done. I ask them and I ask the industry leaders, and our Agency leaders now, why not? If our President can monitor an operation on a real-time basis from across the world, why can't establishments and the Agency work together to gather and evaluate process control data on a real-time basis on 100% of the carcasses being produced. Process control cannot be based on random, intermittent monitoring which it is in all large establishments across the country. The large establishments already have computer systems to track the location of each and every carcass throughout the process from the time the animal enters the slaughter floor until it crosses the scale in the fabrication department. In my vision, I see a system where we have more GS-5/7 employees monitoring sanitary dressing and entering results on a computer system for each and every carcass prior to any carcass wash interventions. That data is then in-turn evaluated on a real-time basis by off-line personnel and the establishment. Process targets are created at different points in the process and process control is maintained on 100% of the carcasses being produced and the Agency and the industry work together to ensure that all carcasses are produced with the highest sanitary dressing standards possible. Will my vision be challenging to meet, yes. Is it impossible, I don't think so. I am confident that if we don't have the leadership within the organization to set high goals, we will never get huge results. I know that allocating resources to go towards what I envision would do more to protect public health than the paper chase we are currently on. A paper chase, validation data, testing data, is all good, but it goes against the very principles of HACCP. Validation of interventions is important, but until an intervention such as whole-carcass irradiation enters into the picture, all the other carcass wash system interventions are just band-aids on the actual problems. HACCP wasn't designed to use a band-aid approach. Until resources are allocated to focus on prevention and pre-harvest strategies, HACCP in raw products will never reach it's true potential. And by allocation of resources, I don't mean putting a compliance guideline on the Agency's website. How about using the resources currently being used on the paper chase that the Agency has called HACCP and using those on an increased oversight at the in-plant level coupled with incentives to the industry to develop new and improved technologies aimed to reduce the incoming pathogen load and remove the hide in a sanitary manner.

That's my vision for the Agency and Industry, I am not sure what our leader's vision is, but I am scared by the direction it seems to be going. Every day while at work I recited the prayer listed below. I hope that by taking the action that I did on Friday, May 13th, I was just granted the courage to change the things I can, but it is more likely that I just don't have the wisdom to know the difference! Whatever the case, I will go on living one day at a time and enjoying one moment at a time and taking all challenges and hardships as the pathway to peace and trust that god will make all things right. I hope all of you do the same. I thank all of you that I have had the joy of working with the past 3+ years and hope that you take these words to heart as you continue to fight the good fight in the Agency. Immediately

after I sent my resignation to my FLS and the district office, I received calls from many telling me not to do it, but I am confident I made the correct decision. In my heart I could no longer enforce the policies that I did not believe were right. I leave the Agency with my head held high knowing that I never waived from the values that were instilled in me all my life. Those values of honesty, integrity, and letting my heart lead the way to the pathway that I am supposed to take. I hope when all of you retire or resign, you can say the same. Thanks again for everything, and God Bless, Dr. Travis Nienhueser

God grant me the serenity  
to accept the things I cannot change;  
courage to change the things I can;  
and wisdom to know the difference.

Living one day at a time;  
Enjoying one moment at a time;  
Accepting hardships as the pathway to peace;  
Taking, as He did, this sinful world  
as it is, not as I would have it;  
Trusting that He will make all things right  
if I surrender to His Will;  
That I may be reasonably happy in this life  
and supremely happy with Him  
Forever in the next.  
Amen.

Attachment #1

## Sanitary Dressing

**This incident cannot be reopened or updated. If you need further assistance, please submit a new question by clicking the Ask A Question tab.**

### Communication History

#### **Response PDD Staff Officer via Email**

**01/11/2011 11:32 AM**

No problem. We routinely respond to questions where the underlying issue is performance. I obviously read more into "cat and mouse game" than I should have. For that I apologize.

#### **Customer Travis Nienhueser via CSS Web**

**01/11/2011 10:49 AM**

I received the answer that I expected (as related to NR documentation), but I have to respectfully disagree with the information in regards to having a performance problem. In my first question, I never stated that FSIS Directive provides instruction to shut off the line, call the off-line inspector to the final rail, show the off-line inspector the contamination on the carcass, and notify off-line inspection program personnel when

they believe that an establishment's slaughter or dressing processes are not under control.

FSIS Directive 6420.2 states for on-line inspection activities that when on-line inspection program personnel find feces, ingesta, or milk, they should stop the slaughter line for carcass reexamination and rework by the establishment unless:

i. the establishment has elected to provide a rail-out loop to rail contaminated carcasses off-line for reexamination, trimming, and positioning back on the line for final inspection, and

ii. the IIC has not determined that the establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses.

It also states that when on-line inspection program personnel are to notify off-line inspection program personnel when they believe that:

i. an establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses, or

ii. an establishment's slaughter or dressing processes are not under control (for example, when repeated presentation of contaminated carcasses for postmortem inspection at the rail inspection station indicates failure to control dressing processes).

So, by the directive, when on-line inspection identify a carcass with feces, ingesta, or milk they are directed to stop the slaughter line for carcass reexamination and rework provided that the establishment does not have a rail-out loop. Many of these establishments do not have a rail-out loop and if they do, you still have to stop the line to at least notify an establishment employee of the contamination and that it has to be placed on the out-rail loop. It also directs the on-line inspection personnel to notify off-line inspection personnel when they believe that an establishment's slaughter or dressing procedures are not under control (for example, when repeated presentation of contaminated carcasses for postmortem inspection at the rail inspection indicates failure to control dressing processes). The directive however, does not provide how FSIS on-line inspectors are to notify off-line inspection personnel and what information they are to provide, and thus, most in-plant instructions to on-line inspectors in regards to handling fecal contamination on the final rail are something similar to the following. First couple occurrences of zero-tolerance defects, the on-line inspectors are to stop the line (provided no rail-out loop exists) and have the contamination trimmed off and re-examine the carcass; additionally the inspector is to notify the establishment of what/why the line was stopped or the carcass was railed-out. If the establishment continues to present contaminated carcasses for final rail inspection, the inspector should ask for an off-line inspector (i.e. notify an off-line). So, before the off-line is notified, the on-line inspectors have already alerted the establishment management personnel (area supervisors or the general foreman) that they are seeing excessive contamination. When the inspectors begin notifying establishment management, establishment supervisors usually request to observe what/where/how much



contamination is being observed and thus, by the time the off-line is notified, several examples of contamination are usually present.

Thus, although the directive does not state that the inspectors are to show the off-line the contamination, contaminated pieces are frequently set aside by either FSIS personnel or establishment personnel and thus, both establishment supervisory personnel and off-line personnel verify the type and amount of contamination seen. As stated above, before the off-line is notified, the establishment has already been provided the opportunity to fix the problem's leading to the contamination. The establishment also knows that the off-line will perform a zero-tolerance check when excess contamination is observed by the on-line inspector. Thus, the establishment has already had time to identify and correct the problem and may also have additional personnel present (usually QA's or establishment supervisory personnel will be observing the off-line perform procedures and also will observe all carcasses prior to the zero-tolerance check) prior to the final rail to ensure that no additional zero-tolerance defects are identified. Thus, by the time the off-line is notified, the deficiencies have already been corrected and nothing suggesting a process out of control is seen by the off-line inspector. Besides performing a zero-tolerance check per FSIS Directive 6420.2, this may also lead the off-line to conduct an unscheduled 06D01 procedure by verifying sanitary dressing procedures. Again, though, the establishment is aware of this, and has already corrected the problem and also knows where the off-line is at all times anyway (through closed-circuit cameras) and can communicate with all area supervisors as to where each off-line inspector is. So, the end result is that after following FSIS Directive 6420.2 and also incorporating FSIS Directive 6410.1, no system exists to document the amount and frequency of contamination that is reaching the final rail. In large, high speed establishments, this scenario plays itself out on a daily basis and may occur 2-3 times per shift. Now, I am not saying that many of these establishment's processes are completely out of control and carcasses with 3-4" smears of zero-tolerance defects are a routine occurrence, but to believe that zero-tolerance defects do not reach the final inspection area on a routine basis, would also be false. In the past 3 years, I have been in several high speed establishments and this scenario has played itself out at all of the establishments that I have been at. I have also observed E. coli O157:H7 testing results from these establishments and none of the results indicate processes out of control, but all of the establishments have positives on a regular occurrence with occasional spikes being seen. When these occur, or whenever a traceback investigation or problems arise, in-plant people are asked to review NR's and establishment records to see if any evidence exists that dressing procedure problems existed with the production lot in question. Again, seldom (or never) have I seen a direct correlation between dressing procedure NR's (zero-tolerance or 06D's) and the production lot in question, positive E. coli results, or even indicator organism results. That is not to say there isn't a correlation, but with the systems and directions in place to currently identify and document "process control" meaningful data is seldom generated to link test results to what was actually being observed at the final rail. Sorry for the diatribe, but I do not believe that "performance issues" with the on-line

inspection or off-line inspection do exist as was stated in the original response. With that being said, will the new PHIS system allow off-line personnel to accurately document what was performed throughout the day? (i.e. instead of marking an unscheduled 03J01 as performed, will the inspector be able to include details of why/what/results of determining compliance/noncompliance - i.e. performed an unscheduled 03J01 procedure by conducting a 22 carcass side zero-tolerance check due to excess contamination being observed and reported by the on-line inspector.)

I am sorry for the long response, but I truly believe in what the Agency does, but also believe that there is always ways to improve what and how we do our inspection tasks to provide more meaningful information that can be used to evaluate problems (i.e. E. coli recalls) and help shape future decisions. I have evaluated establishment written programs in several large beef establishments and none have any truly meaningful programs to monitor process control on a continual basis and thus, the only true 100% monitoring of sanitary dressing process control in all of these establishments is our final rail inspectors. Having a system to accurately document and record what is being observed by these inspectors would provide much more meaningful data related to "process control" on the slaughter side than any of the documentation that I have seen from the establishments (all of which base process control on intermittent monitoring of a small percentage of the total carcasses produced).

**Response PDD Staff Officer via Email**

**01/03/2011 12:32 PM**

No, repeated instances of fecal, ingesta, milk found by on-line inspection personnel over the course of a day cannot be documented on a NR to address the problem you describe.

You identify what you call a "cat and mouse game" over the instructions for on-line inspection activities in FSIS Directive 6420.2. The instruction in the directive is for on-line inspection program personnel are to notify off-line inspection program personnel when they believe that an establishment's slaughter or dressing processes are not under control. The instruction is not, shut off the line, call the off-line inspector to the final rail, show the off-line inspector the contamination on the carcass, and notify off-line inspection program personnel when they believe that an establishment's slaughter or dressing processes are not under control, which is what your scenario describes. You also describe how the off-line inspectors very seldom determines that the establishment has lost process control of sanitary dressing.

Based on the information provided, you describe two performance related issues. (1) The on-line inspectors are not performing their duties in accordance with the instructions in the directive when they shut off the line and call the off-line inspector to the final rail to show the off-line inspector the contamination on the carcass. (2) The on-line inspector's determination that the establishment's slaughter or dressing processes is not under control may not be supportable because the off-line inspectors very seldom

determine that the establishment has lost process control of sanitary dressing as a result of the on-line inspector's input. I recommend that you discuss what you call a "cat and mouse game" over the instructions for on-line inspection activities in FSIS Directive 6420.2 with the FLS.

**Auto-Response**

**01/03/2011 11:09 AM**

Your message has been received at the FSIS Policy Development Division (PDD) and is being assigned to a staff specialist for response.

Our goal is to provide an accurate response as quickly as possible—in most instances, this will be within two working days. Some questions, however, require extensive research and will take longer to answer. If the response that you receive does not completely answer your technical concerns, you can telephone PDD for additional discussion at 1-800-233-3935 between the hours of 6:00 a.m. and 5:00 p.m. CT, Monday through Friday. Please refer to the incident number when calling for clarification.

The reference number for your question is 110103-000027.

You may update your incident at [http://askfsis.custhelp.com/cgi-bin/askfsis.cfg/php/enduser/acct\\_login.php?p\\_userid=Travis.Nienhueser@fsis.usda.gov&p\\_next\\_page=myq\\_upd.php&p\\_iid=87292&p\\_created=1294070953](http://askfsis.custhelp.com/cgi-bin/askfsis.cfg/php/enduser/acct_login.php?p_userid=Travis.Nienhueser@fsis.usda.gov&p_next_page=myq_upd.php&p_iid=87292&p_created=1294070953)

Thank you for contacting the FSIS Policy Development Division.

**Customer Travis Nienhueser via CSS Web**

**01/03/2011 11:09 AM**

FSIS Directive 6420.2 provides instructions for both on-line and off-line inspection activities related to zero-tolerance defects observed at the final rail. For on-line inspection, it states that the line inspectors should stop the slaughter line for carcass reexamination and rework by the establishment unless the establishment has a rail-out loop, etc. It later states that if excessive contamination, the on-line inspectors should notify an off-line. For the off-line verification it describes conducting a zero-tolerance check by examining so many sides based on the production volume of the establishment. At large establishments this cat and mouse game plays itself over on a routine basis. On-line inspection find excessive contamination, call for an off-line, show the off-line the contamination, the off-line performs a zero-tolerance check by examining 22 carcass sides which very seldom have any deficiencies. 30 to 45 minutes later, the situation may repeat itself. At the same time, FSIS directive 6410.1 describes procedures to perform sanitary dressing evaluation on a bi-weekly basis (scheduled) or in response to events and thus, besides performing a 22 carcass audit, the off-line inspector will also communicate with establishment management as to potential causes

and observe dressing throughout the process. During this time, the establishment identified and corrected the potential problem that led to the first instance of contamination. While the CSI is tracing the problem of the first event, contamination occurs elsewhere on the carcass from another establishment employee not performing their job correctly, but again, by the time it reaches the final rail and is observed on every 4th/5th carcass, the establishment has also fixed this problem by the time the off-line is notified and the deficiency that caused the second problem, like the first, is never observed by FSIS. FSIS Directive 6410 also describes using a systematic approach and also utilizing establishment and FSIS test results in the determination of compliance. These test results for the product in question will not be available for another 3-4 days from slaughter and often times no correlation exists. The point of this all is that my understanding of the directives above are that both are reactionary in nature and make it difficult to accurately document and record any meaningful information that can be used later on when establishment test results are received. This difficulty combined with the current hindrances faced by on-line inspection to actually observe fecal at high line speeds w/ substantial discoloration seen at many large high speed facilities also further make the current system described in these directives reactionary. So, my question is, can repeated instances of fecal, ingesta, milk found by on-line inspection personnel over the course of a day be documented on a NR even if no deficiency is found when performing sanitary dressing defects and/or off-line zero-tolerance checks? If so, what regulatory citation would be applicable (417.2(c)(4) for zero-tolerance defects or 416.1, 416.14(d) for insanitary condition, also 310.18(a)? If not, any other suggestion or guidance on how to deal with day to day dressings issues that arise in large high speed establishments?

## **Additional Details**

### **Email Address**

[travis.nienhueser@fsis.usda.gov](mailto:travis.nienhueser@fsis.usda.gov)

### **Reference Number**

110103-000027

### **Status**

Solved

### **Created**

01/03/2011 11:09 AM

### **Updated**

01/11/2011 11:32 AM

### **Closed Date**

01/11/2011 11:32 AM

### **Product**

1 General Inspection Policy

### **Category**

1 Slaughter

## **Policy Arena?**

Domestic (U.S.) Only

### **Attachment #2**

## **Communication History**

### **Response RMD Staff Officer via Email**

**05/12/2011 12:14 PM**

Now I want to make clear that my answer in this question is contingent that the establishment is further processing from its own slaughter operations. It is assumed that an establishment would know more about how beef products were produced if they slaughtered the animals themselves versus if they are buying beef from a different company that slaughtered the product.

For me when determining whether the plant can support its decision about O157 in an O3B or O3C plan, I would look at the O3J plant first and see the controls the plant has for O157 in it's slaughter plan and how well they have supported, validated, and implemented those interventions. I would find it difficult for a slaughter process to support that O157 is not likely to occur not matter whether they sample or not.

Now I would look at the history of the slaughter process in combination with the controls in place to then determine whether the establishment can support the decision in their further processing hazard analyses and sampling is part of that but I don't want to give you the impression that it is the only deciding factor. Yes our guidance "recommends" sampling and we always encourage sampling but there is a way that a very small low volume plant could potentially rigorously verify the operational parameters of their interventions and CCPs at slaughter as a way to support their decisions.

I would say, if the plant has validated slaughter interventions and verifies the critical operational parameters, does not have a history of positive samples, fecal failures or

intervention implementation issues, and the quarterly sampling is the only thing you have on the plant as a result of your FSA, I am not sure this issue alone can support an enforcement action. We need to do a comprehensive assessment of the system and not a simple checklist of do you have this, do you have that.....

Now I want to say again for emphasis that if this was a further processor who was purchasing the beef, my answer would be completely different. If the establishment lacked interventions at slaughter or had a history of positive samples, intervention implementation problems, or fecal failures, my answer would be completely different. If this was a larger small plant with considerable volume production or a large plant, my answer would be completely different because the risk goes up.

**Auto-Response**

**05/11/2011 11:10 AM**

Your message has been received at the FSIS Risk & Innovations Management Division (RIMD) and is being assigned to a Staff Specialist for response.

If your issue is pertinent to a particular staff member, please indicate in the text that you would like your inquiry directed to that person.

Our goal is to provide an accurate response, as quickly as possible - in most instances; this will be within two working days. However, Retained Water Protocol submissions will be answered within 30 days and New Technologies notification and protocol submissions will be answered within 60 days.

If the response that you receive does not completely answer your technical concerns, you can telephone RIMD for additional discussion at (301) 504-0884 between the hours of 7:00 a.m. and 4:00 p.m. ET, Monday through Friday. Please refer to the incident number when calling for clarification.

The reference number for your question is 110511-000036.

You may update your incident at

[http://askfsis.custhelp.com/app/account/questions/detail/i\\_id/97420/username/Travis.Nienhueser@fsis.usda.gov](http://askfsis.custhelp.com/app/account/questions/detail/i_id/97420/username/Travis.Nienhueser@fsis.usda.gov)

Thank you for contacting the FSIS, OPPD, Risk & Innovations Management Division (RIMD).

**Customer Travis Nienhueser via CSS Web**

**05/11/2011 11:10 AM**

Can an establishment support that E. coli O157:H7 is not likely to occur in raw ground and blade tenderized products if they do not test for the specific pathogen? If the establishment only uses product from their slaughter HACCP program, can the

establishment use past history from FSIS testing coupled with years of generic E. coli records below detectable levels, etc for support that it is not likely to occur? If not, based on the compliance guidelines a very small plant would be expected (but not required) to test quarterly with increased testing during high prevalence seasons. What statistical significance is quarterly testing providing these operations if they use Agency N60 sampling protocol and assume a prevalence of 1% (assuming they would test trim prior to grinding) when false negative results are expected at a high frequency assuming a 1% prevalence rate in the sampled lot?

## **Additional Details**

### **Email Address**

[travis.nienhueser@fsis.usda.gov](mailto:travis.nienhueser@fsis.usda.gov)

### **Reference Number**

110511-000036

### **Status**

Solved

### **Created**

05/11/2011 11:10 AM

### **Updated**

05/12/2011 12:14 PM

### **Closed Date**

05/12/2011 12:14 PM

### **Product**

1 General Inspection Policy

### **Category**

1 EIAO Methodology

### **Policy Arena?**

Domestic (U.S.) Only