I have several comments as to FSIS' 2006 Federal Register Notice, "*Salmonella Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection"*. To fully address the numerous issues contained in such a lengthy document, I have included the particular FSIS reference in quotations, followed by my comments which are delineated by indentation and red type. At the end of my comments I have provided specific information as to the events that occurred in a particular poultry plant from 1998 to 2005 in reference to fecal problems and Salmonella control. My comments are then summarized following this in-plant scenario.

FSIS "will assess each completed *Salmonella* sample set in light of either existing regulatory standards or recently-published baseline study results, as appropriate. FSIS **expects** to take follow-up action, which **may include** scheduling of another sample set or assessing the design and execution of the food safety system, based on how a plant's performance compares to the existing regulatory standard or nationwide baseline results and to the presence of serotypes of Salmonella that are common causes of human illness."

> The highlighted terminology which is well known to us who have worked in the field for FSIS is not specific, and leaves room for changes which may not be brought to the public's attention. Thus, this terminology should be changed to state "FSIS **will** take follow-up action, **that includes** scheduling of another sample set and assessing …."

"To further encourage industry process control efforts, the Agency is providing a new compliance guideline containing information that FSIS has found to be relevant to control of Salmonella, particularly for poultry."

> I applaud the fact that information about Salmonella control will be accessible, especially to the small processors who may have not had access to such information previously; however HACCP was implemented on January 26, 1998 in large plants followed by implementation in subsequent years by smaller plants. Thus, Industry has been aware of and should have dealt with its responsibility to control the Salmonella problem for at least eight years. As HACCP was implemented primarily to shift responsibility for a safe, wholesome food product from FSIS onto Industry, why is FSIS providing a guideline? As such, Industry should be assuming this responsibility, not FSIS.

Food Safety and Inspection Service (FSIS)
Docket No. 04-026N
May 22, 2006
Comment from Christina Dumal, D.V.M.

Background

"FSIS intends to monitor closely the percent positive in verification samples month-by-month over the course of a full calendar year, beginning in 2006. After one year FSIS will evaluate these data, reassess how it reports Salmonella results for each class of products, and consider making additional changes in how it reports and publishes results."

> FSIS should immediately begin posting sample set "A" results by establishment name and number, immediately after the sample set is completed. *Salmonella* positive product is permitted to enter commerce and, as such, the public and further processors are entitled to know what product is contaminated with *Salmonella*. Further, the American taxpayer pays FSIS to collect and analyze these samples, and, as such, is entitled to view the results of such tests. This public information will provide much needed information as well as provide economic incentive for those establishments who continue to produce contaminated product.

"However, establishments that fail the performance standard are scheduled for a follow-up sample set after the establishment takes corrective action (i.e, the ``B," ``C," and ``D" sets) resulting in one or more additional sample sets annually."

> This is true, and except for some specific plant personnel, who may find their jobs in jeopardy, offers little incentive from a public health perspective. What generally happens is the establishment adds an anti microbial wash to the carcass at the end of the evisceration process or at some other strategic location and the origin of the Salmonella problem is never pursued and/or controlled. In reality, failure becomes just an exercise in paperwork exchange (Refer to December 17, 2003 *Salmonella* sample set "A" and "B" failures in the example of the in-plant scenario described at the end of my comments.)

"The Agency has also published aggregate yearly data from ``A" sets, by product class (e.g., steers/heifers, broilers, ground beef) and plant size as defined in the PR/HACCP final rule (large, small, and very small)."

> This aggregate data has been invaluable to ascertain a baseline for product class and plant size, and in the future will provide guidance inasmuch as establishment corrective action implementation remains unchanged. However, if the establishments are permitted to implement corrective actions upon receiving positive results during the sample set testing period, then the aggregate results will be skewed, and comparison between past and current results will not be comparable. Further, what safeguards/consequences are in place should an establishment, upon receiving positive results, implement

corrective actions without informing FSIS personnel? Those of us in the field know that occurrences such as these are not uncommon. In fact, if establishments within the meat and poultry Industry were forthright, conscientious, and responsible then there would not have been a need for the federal government to employ food inspectors in the first place within these privately run plants. Further, if such safeguards are already in place, are the consequences of ignoring them severe enough to prevent such actions? As will be delineated in the in-plant scenario at the end of my comments, corrective actions and retesting are not adequate incentives for an establishment to find and eliminate its *Salmonella* problem.

"FSIS invites interested persons to submit comments on this notice…… All comments submitted in response to this Notice, as well as research and background information used by FSIS in developing this document, will be posted to the regulations.gov Web site."

An end date for posting comments was not listed in the FR Notice. However the FR Notice does state that the described changes will be effective on May 30, 2006. As of May 22, 2006 there weren't any comments posted. When will all comments submitted to FSIS concerning this Notice be publically posted so all can review them? Additionally, is it FSIS' policy that they will respond to these comments presented here today in three years as evidenced by the nine comments that were submitted in 2003 and addressed in this 2006 Notice?

Agency Decisions

1. "The Agency will add results from individual *Salmonella* verification sample tests to reports the Agency regularly makes to meat and poultry establishments that have asked to be informed of various test results.

One concern that needs to be addressed is why the establishment would want these individual test results. What is it that they plan on doing with these results? Do they plan on immediately implementing corrective actions? Will they be required to retain any contaminated product?

The Agency should inform the public as to whether the establishment will be permitted to implement corrective actions during the testing period or will they have to wait until the sample set testing is completed. Further, will the product that has tested positive for *Salmonella* continue to be permitted to enter commerce?

If the establishment is permitted to implement corrective actions during the testing period, then this information must be posted on the Agency's website by establishment name and number. Further, this information should be included in the aggregate information. Also, if the establishment is not permitted to implement corrective actions then what safeguards are in place for those who would do otherwise? If safeguards are in place are the consequences severe enough to deter those establishments who would unwittingly implement corrective actions without adequately informing FSIS personnel? Actions such as this would ultimately skew the aggregate results such that future results would not be comparable to past results.

2. "The Agency will also begin posting quarterly, rather than annually, nationwide *Salmonella* data by product class on the Agency Web site."

The Agency should make individual results public, immediately after completion of the sample set. The results must be posted on the website by establishment name and number.

3. "As soon as possible in 2006, FSIS will issue instructions to inspection program personnel and begin conducting sampling in establishments slaughtering young turkeys."

This testing is indeed overdue. According to an April 15, 2006 article in the Duluth News Tribune, *Salmonella found in state plants' ground turkey,"* over the course of three years there were three Jennie-O turkey plants (Hormel Foods is the parent company) whose *Salmonella* rate was at least 40%. According to the story, these results were obtained through the FOIA. I'm not aware of any FSIS regulations, Directives, or Notices that restricts turkey contaminated with *Salmonella* from entering commerce, thus I must assume that all of this product eventually made its way to consumers, the American Public. This fact does make one wonder if FSIS has set any restrictions for product that is found to be contaminated with *Salmonella*, or will it all be permitted to enter commerce as occurs with poultry?

4. "Each completed sample set result will be recorded in one of three categories in relation to the standard or baseline guideline: "

Category 1
Category 2
Category 3

a. "FSIS data indicate that increased Agency scrutiny through food safety assessments and verification testing leads to improved plant performance in controlling *Salmonella.* (See Fulfilling the Vision: Initiatives in Protecting Public Health,

USDA/FSIS, July 2004;
http://www.fsis.usda.gov/PDF/Fulfilling_the_Vision.pdf
Less frequent sampling of those establishments that have a relatively low percent positive of *Salmonella* samples will free Agency resources for application to establishments that are not performing as well."

What provisions have been made for FSIS' in-plant veterinarians to have access to the establishment's microbiological sampling results? What provisions are in place for FSIS' veterinarians to analyze the establishment's results and to take action should a problem arise? And, as we know, the results obtained by the establishment are not open to public preview so if there is a problem, how will the public be protected? A prime example occurred in 2002 with the ConAgra debacle. In the September 2003 USDA's Office of Inspector General's Audit report, *Food Safety and Inspection Service Oversight of Production Process and Recall at ConAgra Plant (Establishment 969)*, about the incident cited numerous failings on the part of ConAgra and FSIS. However one failing in particular is relevant to FSIS' current Notice concerning Salmonella. The 2003 report stated that ConAgra's microbiological results showed that beef product from the Greenly Colorado plant had been "testing positive for *E. coli* 0157:H7 as early as April 12, 2002 to as late as July 11, 2002." The report further stated that "FSIS policies limited the documents inspectors could review and the enforcements actions they were allowed to take. Under FSIS policy, plants such as ConAgra that performed their own pathogen tests as part of HACCP were exempt from FSIS testing, ant those tests performed apart from HACCP were not directly presented to FSIS for review. None of the tests taken by ConAgra for HACCP purposes in 2001 and 2002 showed the presence of *E. coli* 0157:H7, while at least 63 of the tests taken for non-HACCP purposes in 2002 did. The tests taken for HACCP purposes were on carcasses; the non-HACCP tests were taken on beef trim. Trimmings for meat are used as ingredients in the production of many meat products, including ground beef." The result of this 'shortcoming' was that numerous people were sickened, an enormous amount (but not all) of the product was recalled, and one establishment who purchased trimmings from ConAgra to use in its further processing was put out of business as it was uninformed by ConAgra that these trimmings were indeed testing positive for *E. coli* 0s157:H7.

Further, will those establishments who have relatively low percent positives be required to perform their own testing? If that is the case, will their labs be equal to FSIS' lab standards?

To circumvent any problems in this area, all establishments must be required to test their product for *Salmonella* using approved labs. Further, these results must be available to the in-plant FSIS veterinarian for analysis. Finally, results must be posted in the minutes of the weekly FSIS/plant meetings, and be

available through FOIA requests.

b. "Importantly, establishments in Category 2 and 3 that demonstrate an inability to control for the on-going presence of serotypes of Salmonella known to be associated with common human illness will receive greater attention by FSIS regarding the verification of the establishment's food safety programs."

As in the past those establishments who failed to control their *Salmonella* problem have always received greater attention from FSIS, however greater attention does not equate to a safe or safer product. What consequences will result to those establishments who fail to control their *Salmonella* problem? How many times will they be permitted to fail before their product is not permitted to enter commerce? This problem is further delineated in the in-plant scenario outlined at the end of this document. Adequate consequences and definitive criteria must be established and communicated to all involved. The safety of the consumer is not a convenience of FSIS, it's a mandate.

5. "FSIS is providing a new compliance guideline particularly related to the broiler industry containing information that FSIS has found to be relevant to the control of Salmonella."

Additional ideas for control of any pathogen is laudable, however let's not forget that Industry is ultimately responsible for producing a safe, wholesome product.

Although I believe that all available information should be accessible, I would like to stress that HACCP was implemented eight years ago, on January 26, 1998, in large meat and poultry plants. Thus it would not be unreasonable to expect that the Meat and Poultry Industry has had a significant amount of time to obtain information/studies on this subject. If that is not the case, then one might wonder why they wouldn't have such information. HACCP was implemented in order for these food producers to take responsibility for producing a safe food product. FSIS lacks the resources to fully undertake this responsibility, and thus should not be placed in the position to accept responsibility for food safety within a privately owned Meat/Poultry slaughter and/or processing plant. Further, the American taxpayer must not be left in the position to continually subsidize these privately owned companies. However from my experience working in a large poultry plant, little time, energy, and money has been spent on this crucial area of food safety.

6. "FSIS will also be obtaining more timely *Salmonella* serotype information for each positive test result from its verification program and may intensify testing or scrutiny via a food safety assessment of establishments that produce product with serotypes of epidemiological concern."

It is equally important that adequate consequences, such as retaining *Salmonella* contaminated product be implemented for those establishments who continue to ignore adequate Salmonella control.

7. "…the Agency will be conducting baseline studies for *Salmonella* and other pathogens and indicator organisms among specific product classes."

As previously noted, baseline studies are an invaluable tool in FSIS' mandate to protect the public from contaminated food products. In the past the results have provided a basis to compare improvement or lack thereof concerning bacterial contamination of meat and poultry products However FSIS must remember that implementation of any corrective actions during the testing period can skew future results, making it appear as if there indeed is a decrease in *Salmonella* incidence when in fact, the incidence is masked by the implementation of corrective actions during the testing period. Presently, corrective actions are implemented after the testing period. The sample set "A" was set up to provide a 'picture' of what was occurring within the plant environment during the previous year. If that set failed then the establishment presented corrective actions to FSIS, after which FSIS performed another series of tests, sample set "B', in order to ascertain whether the corrective actions were effective.

The results of these baseline studies must also be posted on the web page by establishment name and number. In addition, if corrective actions are permitted to be undertaken by the establishment or if the product is retained upon the establishment receiving positive results, then these actions should also be listed on the web page by establishment name and number. Finally, appropriate consequences should be in place for those establishments who might implement corrective actions during the testing period without informing FSIS as these actions will skew aggregate results.

8. "The main Agency focus will be on control of Salmonella in slaughter and combined slaughter/processing establishments because these operations have direct control over this pathogen during sanitary dressing and further processing."

The Agency must continue performing random sampling even if it is at a decreased rate in all meat and poultry establishments. All establishments must be required to conduct their own testing using approved labs. The results of such testing must be available to the FSIS in-plant veterinarian for analysis. Further, the results of such testing must be placed in the minutes of the weekly FSIS/plant meeting and be accessible to the public through FOIA requests.

Further Agency Considerations

1. "FSIS intends to monitor the Salmonella percent positive in verification samples by

product class over the course of a full year beginning in July 2006. The Agency's current thinking is that if the percent positive of Salmonella in verification samples over that one-year period for the great majority of establishments (e.g., 90%) in a specific product class is not at or below half the performance standard/baseline guidance level (i.e., Category 1), FSIS will consider whether there are further actions that should be taken to ensure that establishments improve their control of Salmonella and further enhance public health protection.

For example, FSIS would consider actions that would provide an incentive to industry to improve controls for Salmonella. One approach that FSIS has considered and favors is posting on the Agency Web site the ``A'' set result from the completed Salmonella sample sets for each establishment producing that product class, identified by establishment name and number. Publishing the results of these FSIS *Salmonella* analyses, which have been used by the Agency as one component for assessing establishment performance, could serve as a valuable support to an establishment's process control efforts."

All known *Salmonella* positive product is currently permitted to enter commerce. As such, individual results of a sample set must be made available to the public immediately upon completion of sample set testing. These results must be listed by establishment name and number. It is inexcusable for FSIS to wait until some future date to post these results. Industry has been given adequate time in which to resolve this problem. Yet it is presently still unresolved and as it is a real concern to public health , the public should have immediate access to these results.

2. "A study by USDA's Economics Research Service (ERS) has shown that increased public information on food safety performance measures can offer incentives to establishments to invest in process control by helping them realize benefits from their investments, and thus spur industry innovation in food safety (see Food Safety Innovations in the United States: Evidence from the Meat Industry by Elise Golan, Tanya Roberts, Elisabete Salay, Julie Caswell, Michael Ollinger, and Danna Moore, AER-831, USDA/ERS, April 2004; http://www.ers.usda.gov/publications/aer831/ FSIS believes that this study has relevance regarding the Salmonella strategy articulated above relative to publishing establishment-specific information associated with Salmonella control. For example, a further processor of ground product who purchased carcasses from a slaughter operation would not know whether the carcass was produced with the best or worst safety procedures, even though the procedures were in compliance with the minimum regulatory requirements. This situation reduces incentives by manufacturers of the source material (e.g., carcasses) to invest in food safety innovation. By addressing this asymmetry, that is, providing more information about the process control performance of establishments related to Salmonella, FSIS believes it would be providing the appropriate incentive for the meat and poultry slaughter industry to attain consistent,

good control for Salmonella. FSIS is especially interested in receiving comment on this approach to ensuring pathogen reduction in all raw products regulated by FSIS."

As previously stated, this information should be made available immediately to the public by establishment name and number. The informed consumer will avoid those establishments who are producing *Salmonella* positive product, thus providing much needed economic incentive to the establishment. However, to be fair to differing establishments, FSIS must perform unannounced testing in all federally inspected establishments based on the amount of production. It would be unfair and inaccurate to test a poultry plant that slaughters 5000 chickens per day at the same rate as one who slaughters 330,000 chickens per day.

3. "The Agency will also consider other actions, such as modifying its approach to inspection, if widespread industry performance provides a basis for reducing Agency concern about control for pathogens in classes of raw product. For example, the Agency is aware that limits on linespeeds are a concern to both the young poultry slaughter and the hog slaughter industries."

In addition to the contamination issue FSIS must address how the increase in line speed will affect the quality of inspection. Further, FSIS must address the effect of increasing the line speeds on the safety of its workforce as well as plant employees.

Presently, 30 to 35 poultry carcasses are inspected per minute by a FSIS food inspector. Thus, an inspector has less than 2 seconds to inspect the inside and outside of each carcass for numerous defects and diseases. Increasing the line speed would decrease the already scant amount of time that inspectors have to inspect each carcass, and in my opinion increase the possibility that diseases would be missed and enter commerce.

In the summer of 2004 the Jackson FSIS District office was notified of the seriousness of musculoskeletal injuries resulting from the repetitive motion of inspecting large poultry carcasses. In November 2005 the issue was presented to the National Advisory Committee for Meat and Poultry Inspection (NACMPI). In response to my request for this issue to be placed on the agenda, one committee member informed me and I quote "I would suggest to you that the NACMPI is probably not the best forum to raise the issues you describe. Our committee is statutorily charged with providing advice to FSIS on issues presented to the committee by FSIS, and we meet only twice per year. As committee members, we do not suggest nor do we determine what is on the agenda." I have since secured the commitment of another committee member who plans to present this issue at the next meeting. Then on December 7, 2005 this safety issue was presented again in comments to FSIS' proposed rule

change for Turkey line speeds (Docket 04-033P). These comments have yet to be addressed and, as such, are presented here in full::

From Docket 04-033P: The proposed rule's objective is to increase line speeds in establishments that use specific shackles in conjunction with the Bar-cut opening of turkey carcasses. This proposed rule states that the IIC can reduce line speeds when, in his or her judgment, the prescribed inspection procedure can not be adequately performed within the time available because of health conditions of a particular flock or because of other factors. Such factors include the manner in which the birds are being presented to the inspector for inspection and the level of contamination among birds on the line.

This proposed rule states that the preamble to the final NTI system regulations explains that the maximum inspection rates in these regulations were established by work measurement calculations and were based on the amount of time necessary for an inspector to properly perform the correct inspection procedure (50FR 37511). There isn't any mention as to whether or not studies pertaining to the resulting musculoskeletal disorders (MSDs) of those who work on the evisceration line were performed or even considered. According to the January 2005 GAO Report, *Safety in the Meat and Poultry Industry, While Improving Could Be Further Strengthened*, states that some experts believe, for example that faster line speeds increase workers' risk of injury (page 4). Were baseline studies performed as to the safety of those who work on the evisceration line when these initial NTI regulations were proposed? If studies such as these were performed then why are they not mentioned? Who performed these studies, and when were these studies conducted? Where is the documentation for these studies? If indeed these studies were performed then what conclusions were drawn as to the inspectors' and plant employees' safety concerning the effects of this highly repetitive, forceful, and static position job task? Were baseline studies performed to ascertain at what level of repetition and force an inspector could safely sustain these hand motions so as to adequately inspect the turkey carcasses? Although OSHA's proposed Ergonomic rule of 2000 was never enacted, it does provide valuable information. Was this proposed rule reviewed to ascertain what detrimental effects might be encountered by the inspectors and plant employees? The proposed rule states that indeed those who work the evisceration line can perform the work, but it fails to adequately address and assess the cumulative, detrimental effects that this fast-paced task places on those workers.

As there is not any information available concerning the particular hand motions currently employed by FSIS turkey inspectors, I will assume that

this inspection task is performed in a fashion similar to that performed on young chickens (I refer you to pages 15 and 16 of the Employee Development Guide, Revised 1990 and to pages 1 to 3 of the SIS Procedure guide of 1986). For young chicken inspection the inspector is required to use both hands to inspect each carcass. If this is indeed the case, then turkey inspectors currently are required to perform 1050 hand motions per hour for bar-cut opened heavy turkeys (> 16 pounds) and 1350 hand motions per hour for bar-cut opened light turkeys (< 16 pounds). This proposed rule wishes to increase these hand motions by 180 per hour, to 1230 for heavy turkeys and 1530 for light turkeys. Have studies been completed so as to determine what effect this increase in line speed will have on the upper extremities of FSIS inspectors and establishment employees?

The rule states that FSIS may realize benefits because the inspectors would not be required to perform this extra hand motion (required for bar type openings). It further states that the elimination of this extra hand motion may reduce undue fatigue among turkey inspectors. So to put this in perspective, for a bar-cut opening, FSIS inspectors are required to perform 1050 to 1350 hand motions per hour in addition to the aforementioned hand motions. This proposed rule will eliminate this additional hand motion, but will add 180 hand motions per hour, thus increasing hourly hand motions to 1230 to 1530 for heavy and light turkeys, respectively.

The proposed rule further states that no difference was observed in processed turkey attributable to line speed changes during the period of study, or between the test week and the previous week. FSIS concluded that establishment employees and FSIS inspectors are able to perform as well as they did using the slower, regulatory maximum Bar-cut line speeds. Again, what studies were performed to ascertain the effect of this increase in repetition on the upper extremities of those who work on the evisceration line?

FSIS increased line speeds for poultry in the mid 1980s. This increase in line speeds was in addition to the already highly repetitive nature of the assembly line work of the evisceration line. Both FSIS inspectors and establishment employees who work on the evisceration line have been adversely affected. Data from the Bureau of Labor Statistics (BLS) for 1982 through 1993 showed a dramatic increase in total illness cases due to disorders associated with repeated trauma, from 21 % to 63% for all private industry. In 1994 BLS began compiling this data from specific sectors. At that time 65% of all illness cases in the poultry processing and slaughter sector (SIC code 2015) were due to disorders associated with

repeated trauma. In 2000, disorders associated with repeated trauma accounted for 67% of the total illness cases within the poultry processing and slaughter sector. In 2001 data collection again changed within BLS so these particular figures can not be followed. Industry contends that there has been a decrease in these types of injuries. However one must wonder about the validity of this statement upon reviewing the 2005 Wake Forest University study that contends that the number of work-related injuries may be underreported. Additionally the 2005 Human Rights Report, *Blood, Sweat, and Fear*, stated that even OSHA-supported research confirmed assertions that there is substantial underreporting of MSD injuries. According to a May 2004 memo from Dr. Barbara Masters FSIS costs alone for OWCP were 15.9 million in (FY) 2002 and 18.5 million in (FY) 2003 for work-related disorders. A breakdown of the particular injuries was not provided in her memo. Presently there are approximately 11,000 employees in FSIS, with approximately 8700 working daily in poultry and meat plants. Dr. Masters encouraged bringing these injured employees back to work, but there was not any mention of ergonomic changes to facilitate their permanent re-entry. In fact FSIS has not addressed these work-related MSDs in its wellness program nor in its Health and Safety meetings. Presently FSIS employees are ignorant as to the debilitating and potentially disabling effects that increasing line speeds have on the muscles, nerves, tendons, joints, and ligaments of their upper extremities. There is no excuse for these omissions as FSIS was informed of these potential problems as recently as August and October 2004 but has failed to enact any safeguards for its employees.

The proposed rule further states that the IIC can reduce line speeds. Such factors as manner of presentation and contamination were cited as factors that an IIC can use when, in their judgment, the line speeds should be reduced. However, what concrete guidelines are given so that the IIC can make an objective decision, 50 percent of a ten-carcass sample,75 percent? There aren't any. In fact in 1993 Directive 6550.1, Line Speeds for Heavy Young Chickens, was issued and it directs the IIC to reduce line speeds when carcasses are greater than 6 pounds. VIII A of that directive states "IIC's must adjust line speeds as necessary to allow for proper inspection of heavy young chickens." VIII A 2 (Responsibilities of IIC) states "Adjust line speeds according to the weight of the birds." Yet, there was not one IIC in the Jackson Mississippi circuit who could enforce that directive. In March 2004 when the District Manager of Jackson Mississippi was questioned as to how to enforce that directive, the IICs were informed that presentation and disease incidence would have to be considered when reducing the line speed, it could not be based on weight alone. There's nothing in the directive that states that presentation or disease incidence must be considered. In addition there's not any

objective criterion given as to what disease incidence should be used in such an instance. Reduction of line speed using one's judgment is precarious and subjective, and it will be called into question by establishment personnel. From experience it will result in an immediate phone call by plant management to the Front Line Supervisor or the District Office and the line speed will be mandated to be returned to its 'normal' rate.

FSIS will also counter these arguments saying that the presentation tests could be used. Presentation tests are performed by both establishment and FSIS personnel. It is rare indeed for these tests to fail for two reasons. First, in most plants the arranger is stationed adjacent to the inspector so when they see the 'tester' approach, they can easily arrange adequately to pass the twenty carcass test(10 inside errors plus 10 outside errors). After the 'test' is recorded they can easily revert back to inadequately arranging the carcasses. Speaking to plant management at the weekly meetings does little if nothing to alleviate this problem. Second, these presentation tests are generally only performed by FSIS personnel twice a shift. If the FSIS 'test' fails, plant personnel will immediately follow with their own test, and in my experience, the majority of these 'tests' always 'pass'. This holds true for any test preformed by FSIS, such as prechill and post chill tests. In my experience it was rare indeed to ever see plant personnel 'take control' of the line or even of a process unless FSIS threatened to 'tag' the product.

Before this proposed rule is accepted, there are several issues that must be resolved. The first is a baseline must be established at which the inspectors and plant employees can work safely. Criteria must be established as to what rate of repetition and force (weight of carcass) is 'safe' for the FSIS inspector and plant personnel. Next, studies must be conducted to ascertain what effect this increase in line speed will have on their safety? The third issue that must be resolved is at what level of disease incidence/contamination will the IIC be able to reduce line speed. Finally, presentation checks are relatively useless, and need to be re-evaluated. (**End of Docket 04-033P comments)**

In-plant events occurring within a poultry slaughter/further processing plant, 1998 to 2004:

One concern that needs to be squarely addressed at this time, is at what point in time is Industry expected to accept its responsibility to produce a safe, wholesome product? Large plants were mandated to implement HACCP plans and meet *Salmonella* pathogen reduction standards by January 26, 1998. I was

employed by FSIS at that time, being stationed in a large poultry slaughter/processing plant. Subsequent to HACCP implementation, FSIS personnel located within that particular poultry plant worked in earnest to communicate and implement the necessary changes as well as communicate food safety goals to plant management. From 1998 to 2004 we found that it was a continual struggle for plant management to understand and effectively implement HACCP and SSOP food safety standards. In addition to informing plant management verbally of their many non compliances with the regulations, in-plant FSIS personnel wrote an inordinate number of non compliance reports (NRs); many of which were not reviewed by plant management for several weeks or months after being written and presented to plant management.. Further, weekly as well as many daily meetings occurred between me, the IIC, and plant management. During those ensuing years it appeared that all plant management really paid attention to was FSIS personnel tagging of product/rooms and their numerous *Salmonella* sample set failures. In fact, from 1998 to 2004 this particular establishment had two *Salmonella* sample set "A" failures, in 1998 and 2003. Before 1998 the establishment had a serious fecal contamination problem which continued up to 2004. And yet during that same time period they never once stopped their production line; the entire product entered commerce. During that time, FSIS personnel discussed numerous strategies with plant management as to how they might determine the origin and eventual elimination of their *Salmonella* problem. HACCP being the system that it is, and FSIS being the Agency that it is, did not provide any tools for in-plant FSIS personnel to elicit any incentive for plant management to pursue and/or solve their *Salmonella* problem. Nor did plant management take any personal responsibility to solve their problem. Plant management did do several things though in response to their *Salmonella* sample set failures. Initially in the early HACCP days, they scrutinized how FSIS in-plant personnel were collecting the chicken wash samples. When their efforts failed to find fault in the collection of these samples, they began to scrutinize the particular testing method performed on these samples at FSIS' labs. During this time in-plant FSIS personnel split every chicken wash sample that was collected with plant management in order for plant management to perform their own tests for *Salmonella*. When their efforts to undermine FSIS' testing procedure were thwarted, they began providing other excuses for their problem. And, to pass FSIS' Salmonella testing letters with corrective actions were sent to the District Office where they were reviewed, resulting in letters being sent back to the plant, and then another round of testing was undertaken. Ultimately, new anti microbial washes were installed and the tests were passed.

Late in 1997 I was temporarily assigned to a large poultry plant which slaughtered approximately 330, 000 chickens daily. It was quite apparent that this plant had a severe fecal contamination problem as well as severe sanitation

problems. Both issues were discussed extensively with plant management. In 1998 during the first ever FSIS plant specific Salmonella testing, this establishment failed the "A' test. Their corrective actions primarily consisted of the installation of a Sanovia anti microbial wash being used on the carcasses at the end of the evisceration process. The establishment then passed the "B" set of testing. However sanitation and fecal NRs continued to be written and these issues continued to be discussed, but to no avail. On October 6, 1998 I sent a detailed letter to plant management with a copy to the Jackson Mississippi District Office (DO) detailing the seriousness of the fecal contamination problem (123 fecal NRs had been documented since January 1998) only to find out that I did not have any support from the District Office. My letter did result in the DO requesting that I submit weekly 'tracking' reports detailing the establishment's progress. In these reports, I listed the number of weekly fecal NRs, however further action was not requested. To compound this fecal problem, upon the implementation of HACCP, FSIS in-plant personnel became very limited in how they could control intestines entering the chiller system. In September 1998, an area poultry plant won their appeal at the FSIS TECH Center level concerning the 'dumping' of a chiller by FSIS personnel. Upon hearing of this ruling I immediately contacted the TECH Center, and was informed that "for zero tolerance, the finding of a fecal on a carcass is a food safety hazard, however at this time the regulations do not apply to other products, including intestines in the chillers. If intestines are found in the chillers, a non compliance exists and a NR should be written using the 04C procedure code and the trend indicator is economic. Documentation of the NR is very important!! It should include information on the nature and extent of the noncompliance as well as indicating that the presence of intestines found in the chiller represents a lack of process control because of the high likelihood of fecal material being present in the intestines." I was shocked by FSIS' TECH Center response as it was common knowledge that *Salmonella* was carried within the intestine, and yet intestines in the chiller were to be considered a non food safety issue, and coded as an economic problem. I debated this situation adamantly, but to no avail. Further I requested scientific studies to support these economic conclusions, only to receive a formal clarification of this policy from the TECH Center on August 11, 1999; scientific support was never forthcoming.

As the plant also had a serious sanitation problem, the inspectors and I began instead to focus on it. Clearing up this sanitation problem alone took four years, until July 2002, to resolve. The primary problem in this area was that the plant was not permitted to employ an adequate number of sanitation employees, thus the plant was inadequately cleaned. This situation was only able to be resolved at that time due to the extensive documentation (NRs) that we had amassed, and which I finally presented to the vice president of the company, informing him that I would recommend that the plant be shut down if the issue was not dealt

with effectively and immediately. Upon realizing the amount of documentation that I had as well as my resolve in having this problem solved, he immediately permitted the local establishment personnel to hire an adequate number of sanitation crew employees, and the problem was resolved within a relatively short period of time.

The entire time that the FSIS in-plant personnel were observing and documenting the sanitation problems, the fecal contamination problem continued. We continued to document the problem on NRs as well as discuss it weekly with plant management. In addition plant management was informed that *Salmonella* was carried within the intestinal tract, and thus fecal contamination could possibly be associated with *Salmonella* contamination of the product. Little if anything was done by plant management to solve this problem though. In fact, fecal NRs would be written and presented to plant management, only to be held for weeks or months before plant management mounted a response. Generally the numerous NRs which had been written over several days or weeks would be returned in bulk to me, all with the same response. I continued prodding plant management to solve the fecal problem and I warned them that if they continued to ignore their fecal problem, eventually they would fail FSIS' Salmonella test. All that FSIS in-plant personnel could do was to document the problem, and wait for another failed *Salmonella* test. Then on July 25, 2002 FSIS issued Notice 28-02, *Actions to be Taken in Establishments Subject to Salmonella Testing*. This Notice directed the IIC to analyze data generated from inspections findings. In other words we were to analyze the NRs that had been previously issued to the establishment. As a result I completed a 20 page report in which I analyzed each of the areas within the plant. These areas were delineated by a specific code, such as 01B, 01C, 03J, etc, that was used when issuing the NR. As we were in the process of finally getting the sanitation issue resolved, the only other major area of concern was the repetitive fecal contamination problems. A copy of the report was given to the plant. Also by this time the establishment was performing its own in-house *Salmonella* testing and they were very much aware that they had a *Salmonella* problem. And yet, even with their testing and my report, they did little to find a solution to their fecal problem or to find and eliminate the source of their *Salmonella* contamination. During this time they did switch to a different anti microbial wash. This change however was not due to the initial anti microbial wash being ineffective; instead it was a safety issue. During this time the establishment continued to pass FSIS' annual *Salmonella* tests although on October 6, 2002 they did receive an Early Warning Notice. Early Warning Notices are sent to poultry establishments who have greater than 6 *Salmonell*a positive tests. During a course of testing, such as sample set "A, 51 samples are collected by FSIS. A sample set is considered to have failed when 13 out of 51 tests are found to be positive. An Early Warning Notice is sent to the establishment when the over half of the results are positive

for *Salmonella*. In this particular case when the seventh positive result occurred the establishment was notified. In the current system, even upon receiving an Early Warning Notice, the establishment is prevented from implementing corrective actions during the duration of the testing period, and contaminated product is permitted to enter commerce. By March 2003 I had enough data accumulated from 1998 through 2002, using the NRs, to effectively analyze where the highest incidence of fecal problems were within the plant environment. I analyzed the data by evisceration line, shift, contamination time, and attachment of intestinal tract to the carcass. One interesting fact that became quite obvious to me at this time was how few fecal failures were being documented by the fecal plant monitors as compared to the FSIS inspectors. Further, the fecal plant monitors tested approximately four times as many carcasses daily as did the FSIS inspectors. The fecal plant monitors tested 10 carcasses per line per hour whereas the inspectors tested 10 carcasses per line twice daily. Yet, the inspectors were documenting almost all of the fecal contamination problems. Few were documented by the plant itself The HACCP idea is for the plant to monitor and control its own processes which ultimately result in a safe, wholesome product being sent into commerce; FSIS is just there to inspect each carcass and to verify that the establishment is indeed following its stated HACCP and SSOP plans. Upon completion of this report, I was hopeful that once plant management reviewed it, they would understand that a logical, systematic approach might be a useful method by which they could solve their fecal problem and in turn, their *Salmonella* problem. I was also hopeful that the District Office would find the information useful, and provide those of us in-plant with a way to encourage plant management to solve their fecal contamination problem. That was not the case though. On May 13, 2003 a District Early Warning System (DEWS) report was issued for the establishment. At that time DEWS reports were issued when an establishment's non compliance with regulations was greater than 10% for SSOP problems and greater than 8% for HACCP problems. This particular establishment failed in both areas, SSOP and HACCP. As a result of the DEWS report, on May 23, 2003 the District Office finally took action and issued a Notice of Intended Enforcement Action (NOIE) to plant management. The NOIE was issued for an inadequate HACCP plan due to repetitive fecal failures and an inadequate SSOP plan. Throughout the summer of 2003 the problem was addressed through paperwork transmitted between plant management and the DO. Then on October 16, 2003 the case was closed primarily because the Jackson District Manager had abruptly retired in September 2003, and the Acting District Manager wanted a 'clean slate' for the new, incoming District Manger. FSIS began *Salmonella* sample set "A" testing on September 29, 2003. On October 25, 2003 the establishment received an Early Warning Notice from FSIS concerning the *Salmonella* testing results. On December 17, 2003 the establishment was informed that they had failed this

set having 18 positive *Salmonella* results. The plant responded to this failure by submitting more corrective actions to the DO, after which testing for set "B" began. On April 23, 2004 this "B"sample set was completed, and the establishment was notified that they had again failed the set. In July 2004 in response to this failure, the establishment installed yet another different anti microbial washing system, the Tomco hydorchlorous acid system, which was used on the carcasses before the scalding process, before pre chill, in the chiller, as well as added to the water used on the conveyor belts. Subsequently a Food Safety Assessment (FSA) was conducted. As a result of this FSA the DO issued another NOIE to the establishment. Several letters were sent between the DO and the plant and on November 9, 2004 the DO issued a letter of Deferral. The establishment was to remain under deferral until the completion of sample set "C". On October 29, 2004 Sample set "C" was set to begin, but was postponed until December 29, 2004. A follow-up FSA visit occurred on January 25, 2005, and they recommended that the deferral process continue for another 30 days after which if the regulatory requirements had been met then the NOIE should be closed with a Letter of Warning. During this time, I was required to submit bi weekly reports to the DO and FSA team documenting establishment progress or lack thereof. As of February 15, 2005 Salmonella sampling was still underway. I do not know whether or not this particular establishment passed this particular sample set as on February 17, 2005 I was abruptly removed from my position as FSIS stated they could no longer "accommodate my disability". My 'disability" was due to a work-related injury I sustained while giving inspection breaks on large carcasses, resulting in severe tenosynovitis of my left wrist. I could still perform all aspects of my position however as my condition was chronic and severe, I could not give inspection breaks which involved repetitive use of my left hand.

To summarize, the establishment had a fecal contamination problem as early as 1997 and in1998 failed set "A' of the Salmonella testing. They installed an anti microbial wash, and subsequently passed the "B" set of sampling. In September 1998 a local poultry plant won their appeal concerning intestines in the chillers. This issue was adamantly debated between veterinarians in the field and the TECH Center; however the TECH Center's national policy was permitted whereby these intestines which were known to carry fecal material as well as Salmonella were to be coded on NRs as a non food safety problem (04C), using the economic trend. The TECH Center was asked for scientific support of this issue, but none was forthcoming to those stationed in the field. The District Office was alerted to the severe and continuing fecal problems of this particular poultry establishment in October 1998, and did nothing other than to request that weekly 'tracking' reports be sent to the DO. These 'tracking' reports included information on the high number of fecal contamination that was occurring within the establishment. During the next four years in-plant personnel worked in earnest to get the establishment to

resolve their sanitation problem. After four years, finally in 2002, the establishment resolved its sanitation problem by hiring an adequate number of sanitation employees. During this same time frame severe fecal contamination continued. I completed a report about this problem in August 2002. A copy went to both the District Office and to the establishment. Nothing changed. On October 16, 2002 during FSIS' annual *Salmonella* testing, the establishment received an Early Warning Notice, having had at least seven positive *Salmonella* results. In March 2003 I completed an extensive fecal analysis report sending a copy to the District Office and one to the establishment. Nothing changed. On May 13, 2003 FSIS issued a DEWS report to the establishment. DEWS reports are issued when a particular establishment has greater than 10% SSOP failures and/or greater than 8% HACCP failures. In this particular establishment the failures occurred in both the HACCP and SSOP areas. As a result, on May 23, 2003 the DO issued a NOIE to the establishment for repetitive fecal failures and an inadequate SSOP plan. During the summer paperwork passed between the DO and the establishment detailing how the establishment would solve their problems. The case was closed in the fall of 2003 to provide a 'clean slate' for the incoming District Manager. FSIS annual *Salmonella* testing began on September 29, 2003, and the establishment was issued an Early Warning letter on October 25, 2003 for having greater than 6 positive *Salmonella* test results at that point in the testing period. On December 17, 2003 the establishment was informed that they had failed sample set "A". Throughout 2004 there was another paperwork shuffle between the establishment and the DO, followed by another round of testing, sample set "B". The establishment failed sample set "B", and a FSA was initiated. Finally the establishment installed yet another anti microbial wash at various locations throughout the plant. In addition they finally purchased new evisceration equipment for two of the four evisceration lines. Sample set "C' was set to begin on October 29, 2004, but was postponed. The DO issued a Letter of Deferral on November 9, 2004 and the establishment was to remain under deferral until after sample set "C" was completed. Sample set "C" commenced on December 29, 2004. A follow-up visit from the FSA team occurred on January 25, 2005, and they recommended that the deferral continue for 30 more days whereby if the establishment met the regulatory requirements then they would be issued a Letter of Warning. During this entire time, FSIS in-plant personnel verified the establishment's corrective actions and the IIC submitted bi- weekly reports to the DO and FSA team. On February 15, 2005 samples were still being collected for sample set "C", however the final results are unknown to me as I was abruptly removed from my position on February 17, 2005.

From 1998 through 2005 all product known to be contaminated with *Salmonella* entered commerce. During the seven years from the time that the establishment initially failed the *Salmonella* set "A' testing, the establishment

did little to solve their severe fecal contamination problem. FSIS' National Policy enabled Industry to continue putting contaminated product into commerce by allowing intestines to enter the chillers as the consequences of such actions consisted of this situation being documented as an economic problem and not a food safety problem. Both FSIS and the establishment were aware that *Salmonella* was carried within the intestinal tract, and that the fecal contamination would increase the probability that *Salmonella* contamination could be a problem. The establishment finally did begin to perform their own in-house testing for *Salmonella* as a requirement for Russian exports, and were aware that they had a *Salmonella* problem. However even with this knowledge the establishment did virtually nothing to find and eliminate the source of their *Salmonella* contamination. Instead they resorted to changing anti microbial washes and other such corrective actions so as to pass FSIS *Salmonella* tests. Finally, beginning in 2003, FSIS spent an inordinate amount of time and resources in dealing with this particular establishment's continuing Salmonella and fecal contamination problems.

Summary

I have provided this background in order to show what happened and what didn't happen at a particular poultry plant relative to encountering *Salmonella* problems. Plant management was apprised of its fecal contamination problem and the possibility of failing the *Salmonella* testing even before they failed the first test in 1998. Nothing but excuses was given initially. When the plant actually failed their first test, they responded by implementing an anti microbial wash system on the back end of the evisceration process. This allowed them to finally pass the testing. Subsequently fecal contamination continued to be a problem, and was discussed and documented ad nauseum with plant management but to no avail. During this time plant management did begin performing their own in house *Salmonella* testing, and were aware that they still had a *Salmonella* problem. I constantly reviewed their testing results, and continued to urge them to focus on finding the origin of their problem and eliminate it at the source. Little if anything was done to solve their problem though because they did not have any incentive to solve their problem; when they failed a sample set, production continued, all of the product entered commerce and made its way to the consumer. A failed sample set basically resulted in the plant presenting their corrective actions to the District Office, and then they were scheduled to undergo another round of testing. This circular process continued, generally resulting in an anti microbial wash being added to the process. However the real, underlying problem was never resolved. There were no effective consequences to the plant if they failed one of these sample sets, only additional paperwork, and sometimes there would be a change in plant management personnel. So even though plant management was aware

that they had a problem, they did virtually nothing to solve it, and ultimately they failed it again. Again there was a scramble for corrective actions, and when that didn't work, a different anti microbial was installed. They finally passed that test, but again did not pursue any avenues to solve their *Salmonella* problems. Further, part of this ongoing problem is due to Industry being enabled by FSIS' lack of adequate consequences and its National policy concerning documenting intestines in the chillers as a non food safety problem.

This is but one example of how plant management has handled their responsibility or rather lack thereof in ensuring the production of a safe, wholesome food product in the HACCP environment. They have had years in which to deal with this problem, but have done little if anything to explore its origins let alone eliminate it. Instead they continue to solve their problem with the addition of anti microbial washes, doing nothing in the interim, all the while contaminated product enters commerce.

As a result of all that I observed while working in a large poultry plant that had severe fecal contamination problems as well as a *Salmonella* contamination problem, I have several proposals that need to be carefully considered.

First, I propose that all slaughter/processing plants be tested periodically by FSIS, based on production amount, and all testing be unannounced as per regulations. The results of this testing must be immediately posted on FSIS' web site by establishment name and number immediately after completion of said sample set. This should begin in July 2006. This serves two purposes. First, it alerts the public and further processors of contaminated product that has entered commerce and to which they may have come in contact with. The taxpayers pay for FSIS to perform these tests and as such should have access to the results. Second, this will provide a much needed incentive for individual slaughter and processing plants to ultimately clean up and solve their *Salmonella* problems. These results will be monitored closely and those plants that produce *Salmonella* contaminated products will ultimately be shunned as consumers opt for products that are not contaminated.

Second, I propose that all establishments be required to test their own product using an approved lab. Again the amount of testing necessary will be determined by production amount. Results of this testing must be available to FSIS' in-plant veterinarian who will analyze this information and post it in the weekly FSIS/plant meeting minutes. These minutes must be accessible through FOIA requests. The veterinarian must have the appropriate criteria and authority to enact known consequences should the results be positive. All information and steps taken must be documented and available to the establishment and to the public.

Thirdly, I propose that FSIS adequately inform the public of the disposition of product that is known to be contaminated with *Salmonella*. Is this product to be reworked? The public is generally unaware of what occurs when product is re-worked, and needs to be aware of this little known process.

In addition, I propose that FSIS inform the public and Industry as to whether an establishment will be able to implement corrective actions upon receiving positive *Salmonella* results. In the past corrective actions have not been permitted during the testing period as this period was designed to 'get the real picture' of the establishment's current process controls. If the establishment is permitted to obtain these individual sample set results immediately, and if they are permitted to implement corrective actions during the testing period then ultimately this will affect the interpretation of the aggregate results when compared to previous aggregate results. The bottom line is that it will appear that *Salmonella* contamination will have decreased. On the other hand there are those plant management personnel who may undertake the implementation of corrective actions unbeknownst to FSIS personnel once positive *Salmonella* results are obtained in order to 'save' their jobs. This too will result in skewed aggregate results. What measures will be in place to circumvent this problem should it arise? Finally, I propose that if a particular establishment should initiate/implement corrective actions during a sample set testing due to receiving positive *Salmonella* test results that this information should also be posted on the public web site.

Finally, I propose that FSIS review its intestines in the chiller policy as a non food safety issue. If indeed FSIS still contends that intestines in the chiller do not pose a food safety problem, and this fact has been scientifically proven from the appropriate studies being undertaken, then this information must be distributed to FSIS' field personnel.

Respectfully submitted,

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