THE TRACE BACK BILL

USDA's Meat Inspection System, administered by Food Safety Inspection Service (FSIS), is driven by the commonly shared goal to produce Safe Food. FSIS regularly tests meat for enteric bacteria such as E.coli and Salmonella, pathogens which by definition emanate from within animal intestines. Whenever contaminated meat is discovered, Corrective Action to prevent recurrences is required. Meaningful Corrective Action cannot be accomplished unless the TRUE ORIGIN of contamination can be identified. The purpose of this Traceback Bill is to require changes in FSIS microbiological sampling procedures which will in most cases provide an expedited and scientifically accurate determination of the TRUE ORIGIN of contaminated meat originating from enteric bacteria. Such a determination will then allow FSIS to require Corrective Action at the source of contamination. This will directly benefit public health, promote the goal of Safe Food, and protect innocent further processing plants from liability for pathogens introduced at upstream supplier slaughter establishments.

The Traceback Bill is composed of four common sense, science-based suggested changes in existing FSIS microbiological sampling protocol for enteric bacteria.

1. Whenever USDA/FSIS personnel collect meat samples for agency microbiological testing for E.coli 0157:H7 and Salmonella, the agency employee must document the original source(s) of the meat being sampled. Such evidence gathering must be done at the time the sample is collected.
2. Evidentiary documentation must be jointly signed by (a) the FSIS employee who collects the sample, and (b) a representative of the plant where the sampling is being conducted.
3. Whenever the sample is determined to be "Positive" for E.coli 0157:H7 or Salmonella, FSIS must conduct an immediate and unrestricted Traceback investigation to the true origin of contamination and implement enforcement actions at the originating slaughter establishment.
4. FSIS must reinstitute its previous "15 Sample Protocol". This protocol requires FSIS to collect an additional 15 consecutive daily samples of ground beef at any plant where initial testing produced an E.coli 0157:H7 lab positive.

Furthermore, FSIS is placing a higher emphasis on tracing positive samples of raw ground beef back to the slaughter establishment from which the contaminated meat was obtained. FSIS issued two Notices discussing this issue: Notices 17-07 and 18-07, both dated 3/1/07. These two Notices made several statements, such as:

From Notice 17-07:

> "*FSIS will begin performing routine follow-up sampling* ***at the slaughter establishments*** (emphasis added)……..*that provided the beef…..…that tested positive for Escherichia coli* (E.coli) *0157:H7 by FSIS*".
>
> "*As part of it's more risk-based sampling program for E.coli 0157:H7, FSIS will begin* ***tracing*** (emphasis added) *positive samples of raw ground beef back to the establishment that* ***slaughtered*** (emphasis added) *the animal. This follow-up sampling, in conjunction with routine sampling of beef manufacturing trimmings addressed in a separate FSIS Notice, is the first step towards developing a more* ***risk-based*** (emphasis added) s*ampling program for E.coli 0157:H7 in raw beef*".

From Notice 18-07:

> *"On March 19, 2007, inspection program personnel will begin routine verification sampling of beef manufacturing trimmings intended for use in raw ground beef or beef patty products* ***at the slaughter establishments*** (emphasis added*) that produced those trimmings".*
>
> *"This routine sampling of beef manufacturing trimmings, in conjunction with follow-up sampling addressed in a separate notice, is the first step towards developing a more* ***risk-based*** *(*emphasis added*) sampling program for E.coli 0157:H7 in raw ground beef and raw beef patty components".*

These watershed agency Notices publicly reveal the agency's new and improved thinking in two areas:

1. A truly **risk-based** sampling program must commence where enteric pathogens originate, namely, the slaughter plants. FSIS acknowledges that the **risk** of enteric pathogens occurs at the originating slaughter establishment, not at downline further processing plants or retail meat markets.
2. FSIS will commence **tracing** enteric pathogens back to the true origins of contamination, which are slaughter plants.

These agency pronouncements do indeed constitute a common sense first step in protecting public health from food borne outbreaks. In the absence of appropriate implementation protocol however, the required subsequent steps will be circumvented and the goal of safe food will continue to be conveniently avoided while slaughter plants are insulated from accountability for producing contaminated meat.

POLICY CHANGE NUMBER ONE

Whenever USDA/FSIS personnel collect meat samples for agency microbiological testing for E.coli 0157:H7 or Salmonella, the agency employee must record the original sources(s) of the meat being sampled. Such evidence gathering must be done at the time the sample is collected.

BACKGROUND INFORMATION

FSIS Directive 10,010.1, Revision 1, dated March 31, 2004 describes agency sampling protocol for E.coli 0157:H7. Furthermore, FSIS Notice 17-07 dated 3-1-07 describes "*Follow-up sampling of certain raw ground beef products after an FSIS verification samples tests positive for E.coli 0157:H7"*. Existing protocol imposes an unnecessary delay in the accumulation of evidence necessary to scientifically and expeditiously determine the true origin of contamination discovered in E.coli 0157:H7 adulterated meat. For the purposes of this discussion, we will call the day of sampling to be "Day 1".

Day 1: FSIS employee collects sample, and ships to USDA lab via next-day-air.

Day 2: USDA lab receives sample, and commences lab procedures.

Day 3: USDA lab produces initial conclusion, which will either be "Negative", or "Potential Positive". If potential positive, the lab will subject the sample to additional confirmatory testing.

Day 4: USDA lab produces another conclusion, which will either be "Confirmed Negative", or "Presumptive Positive". If presumptive positive, the lab will commence further testing for a final determination.

Day 5: USDA lab produces final results, which will be either "Confirmed Positive" or "Confirmed Negative".

Part III (A) 1 in Directive 10,010.1, Revision 1 describes actions required by FSIS on Day 4, when the sample is declared to be "Presumptive Positive". It states "*Because most Presumptive Positives are eventually confirmed, the contact person in the District where the establishment is located needs to immediately inform the establishment that the sample is a Presumptive Positive. At the same time, the District contact person also informs the establishment management that if the results are confirmed positive, FSIS will collect the following information regarding the suppliers of the source materials used in the production of the product….."* See Attachment A.

Directive 10,010.1 Revision 1, Part III (B) 1 explains what FSIS is to do on Day 5 if the sample is declared to be "Confirmed Positive" for E.coli 0157:H7. It states "*When a sample is confirmed positive, inspection program personnel collect from the establishment the information in Part III, A* (see preceding paragraph). See Attachment B.

When FSIS personnel are forced to wait until Day 5 to obtain source information on meat sampled back on Day 1, obvious potential problems occur which seriously question the scientific foundation of the sampling/testing protocol. First of all, FSIS lacks the ability to validate the accuracy of source information provided by the plant on Day 5, since the trail of evidence has turned cold. Because of the 4 day delay, plants are given the opportunity to provide misleading and falsified evidence. If the plant is a combination slaughter and processing facility, the positive sample may have emanated from the plant's own kill floor. If such a plant desires to minimize agency enforcement actions as a result of the "Confirmed Positive" finding, the plant has an unrestricted opportunity to claim that the meat emanated from an outside slaughter supplying facility, and the agency would have no way to prove or disprove plant-provided "evidence".

Secondly, and just as importantly, the lack of verifiable source evidence affords FSIS the opportunity to readily assign exclusive responsibility to the smaller receiving plants rather than confronting the originating slaughter establishment. This biased practice violates the underlying scientific precepts upon which HACCP was designed. This unnecessary scenario gives FSIS the right to accuse the innocent further processing plant of having a "failure" in its HACCP plan, and require a HACCP reassessment. In some cases, the further processing plant may have used meat emanating from its own slaughter floor, and would indeed be guilty of experiencing a failure. However, an increasing number of plants drop slaughter operations every year, electing to strictly perform further processing activities. Therefore, every year a higher percentage of inspected establishments solely perform further processing activities. Nevertheless, these plants which now do no slaughter operations are still assessed with exclusive responsibility for the presence of E.coli 0157:H7 and Salmonella, both of which are ENTERIC bacteria.

Biased and unscientifically justified FSIS actions are obvious. The implication is that the non-slaughter facility is guilty of introducing enteric bacteria into the product, even though the agency agrees that enteric pathogens emanate from sloppy kill floor dressing procedures. At the very least, FSIS expects these further processing plants to purify previously contaminated meat from these invisible enteric pathogens. Some chemical treatments such as acidified calcium sulfite, sodium chlorite and citric acid, as well as Senova applications have been invented which are effective interventions against enteric pathogens. The substantial capital outlay required for such interventions make such treatments financially impossible for most small plants.

Further complicating this scenario is the foundational HACCP belief that when problems do occur, establishments must implement corrective action to prevent recurrences. Since E.coli emanates from kill floor activities, down line further processing plants which perform no slaughter activities cannot perform corrective action to prevent recurrences except for the chemical interventions previously mentioned, or fully cook or irradiate the previously contaminated product. The vast majority of meat products are sold raw, eliminating the first option. Irradiation is extremely expensive, and most of the very large plants do not irradiate, for a variety of reasons, one of which is that consumers don't want irradiated meat. Furthermore, consumers rightly perceive that they should not have

to eat irradiated manure. The ultimate responsibility to prevent E.coli outbreaks rests with kill floor dressing procedures, not with further processing plants to remove invisible bacteria from previously contaminated meat, and not with consumers to fully cook someone else's adulteration.

Furthermore, the ultimate irony is that non-slaughter plants merely further process meat which arrives at their docks in containers bearing the official USDA Mark of Inspection which states "*USDA Inspected and Passed*", which formerly had a direct connection to wholesomeness and food safety. One of USDA's closest allies, the National Cattlemen Beef Association (NCBA) made the following statement in its 1998 publication entitled "America's Favorite Beef Recipes". In a page 6 section entitled "Meat Inspection" the following statement is made:

> *First, the wholesomeness of our meat supply is **ensured** by meat inspection conducted by the U.S. Department of Agriculture (USDA). All meat that is sold must, by law, pass inspection. Inspection provides assurance that all meat sold is **wholesome** and accurately labeled". (Emphasis added).* See Attachment C.

In recent years, USDA has avoided making any direct relationship between the Mark of Inspection and product wholesomeness. This historical fact is caused by the fact that the agency's self-designated official role under HACCP-style meat inspection is "Hands Off", while mandating that the plants police themselves. This means the final product is not USDA inspected, although the official USDA Mark of Inspection claims that it is. Under HACCP, FSIS no longer "inspects" meat, but merely audits paperwork. The USDA Mark of Inspection states "*USDA Inspected & Passed Est. # 9999*". Passed perhaps, but not inspected.

When non-slaughter plants have experienced E.coli 0157:H7 and Salmonella lab positives in recent years, and have asked FSIS officials for ideas on how the plant can implement effective corrective actions, the agency typically suggests that the plant discontinue purchasing meat from the supplier involved, and purchase only from other suppliers. This implausible suggestion cannot emanate from a truly science-based meat inspection program. First of all, this idea releases FSIS from the discomfort involved in common sense enforcement actions at the source slaughter plant where the contamination truly occurred. Since no effective corrective actions are being required at the true origin of contamination, recurring production of contaminated meat is virtually guaranteed while the agency allows the source slaughter plant to continue operations as is. Secondly, industry consolidation this past decade has minimized the number of source plants from which further processing plants can purchase. Thirdly, if further processing plants are prohibited from purchasing from any large slaughter plant which has experienced Salmonella or E.coli 0157:H7 positives and/or recalls, small plants would have no suppliers left from whom to purchase. Fourth, this FSIS suggestion is a tacit admission that the agency is cognizant of faulty slaughter procedures at the source slaughter plant; nevertheless, the agency fails to take enforcement actions at the slaughter establishment where the contamination occurred.

In 2002, FSIS endorsed the common sense protocol of documenting all source evidence when sampling ground beef for E.coli 0157:H7 *"at the time the sample is taken"*. On July 26, 2002 Cheryl Hicks, Program Manager in the FSIS Office of Field Operations sent an email to all District Office Managers to confirm procedure changes previously discussed in a conference call on July 23. A copy of the email can be seen in Attachment D. The primary focus of Cheryl Hicks' email states *"At the time the sample is taken (emphasis added), the IIC will obtain from the establishment, the name, point of contact, and phone number for the establishments supplying the source materials for the lot of ground beef being sampled"*. Cheryl Hicks' email established a precedent which establishes erudite logic justifying immediate real-time documentation of all source materials being sampled for lab analysis. On October 5, 2002 one of the FSIS District Office Managers who had received the July 26 email publicly stated that this procedure change had been rescinded "*for legal reasons*". Public health imperatives should override agency-perceived "legal reasons" which have effectively insulated noncompliant source slaughter plants from accountability for their production of contaminated meat.

(Please note: Attachment D also includes two subsequent emails sent by FSIS Minneapolis District Office Management to field staff with instructions to "*immediately implement*" these changes in sampling protocol).

FSIS testing for Salmonella is described in FSIS Notice 36-06, dated June 29, 2006. It is entitled *"Reporting of Salmonella Sampling Results"*. While there are numerous substantive differences in agency procedures between sampling for Salmonella compared to E.coli, The Traceback Bill addresses the common necessity for agency sampling protocol to include documentation of source slaughter plant evidence at the time of sample collection.

On Thursday, February 23, 2006 FSIS announced a comprehensive initiative to reduce the presence of salmonella in raw meat and poultry products. Under this initiative, FSIS will now provide results of its salmonella performance standard testing to establishments as soon as they become available on a sample-by-sample basis. The goal is to enable establishments to more readily identify and respond to *needed process control in the slaughter-dressing operation* (italics added). Currently, establishments receive results only after the entire sample set is completed, a delay which denies plants access to test results which would enable expedited corrective actions. If FSIS had previously been willing to disclose test results in a more timely fashion, plants could have more quickly initiated corrective action to produce safer food, directly benefiting public health.

The new FSIS salmonella initiative perfectly compliments The Traceback Bill in two vital areas:

1. The initiative correctly identifies the need for improved process control in the slaughter/dressing operation, i.e. the kill floor. The agency hereby admits that the origin of salmonella, and by extension E.coli 0157:H7 is the kill floor, not the down line further processing plants which unwittingly purchase previously

contaminated meat. This was common knowledge long before the Supreme Beef litigation, and simply makes common sense.

2. The initiative shows agency commitment to provide test results back to the affected plants in a more timely fashion, which will enable corrective actions to be implemented more expeditiously, directly benefiting consumers. Documenting the origin of meat being sampled <u>at the time of sampling</u> provides the same benefit.

FSIS would do well to emulate APHIS procedures mandated when collecting brain stem samples for BSE testing. The fourth Performance Objective required by APHIS is as follows:

> *"Provide documentation that identifies the origin of each animal from which a sample was collected……"*
>
> This requirement reveals that APHIS properly perceives the need for scientific documentation in real time; FSIS must do the same.

This discussion of tracebacks to originating slaughter establishments is not new. The May 2000 NACMPI meeting included a discussion between Philip Derfler (FSIS/OPPED) and Rosemary Mucklow of the National Meat Association. Mr. Derfler admitted that FSIS had not conducted any tracebacks of the eleven positives discovered in the agency's surveillance system since January 1st of 2000. In the **<u>seven</u>** intervening years since this NACMPI meeting, FSIS has progressed very little in its Traceback efforts. No progress will be made until the agency allows adequate scientific documentation of all evidence in real time.

It is interesting that FSIS mandates that source origination information be collected at the time of sample collection, <u>but only on **imported** meat</u>, excluding domestic meat from the same requirements. This biased policy is described in FSIS Notice 29-05, dated 5-12-05 entitled "Collecting and Reporting Information On Foreign Suppliers Of Source Materials For Raw Ground Beef Products Found E.Coli 0157:H7 Positive". See Attachment E. Notice 29-05 includes the following statements:

> *<u>At the time of sample collection</u> (emphasis added), when source material is identified as being from a foreign establishment, inspection program personnel should collect as much of the following information as possible and e-mail it to the District Office (DO):*
>
> 1. *country of origin (source material)*
> 2. *foreign establishment number*
> 3. *U.S. import establishment number (stamped on shipping cartons)*
> 4. *whether the sampled raw ground beef product was from a sole source or from multiple sources;*
> 5. *description of the imported product (e.g., beef trim or coarse ground product);*

6. *date the imported product entered the country (obtained from shipping documents)*
7. *health certificate number (found on the health certificate accompanying the imported product);*
8. *shipping marks (see information on the shipping mark in the note below);*
9. *bar coding and any other information that identifies the product's date of production.*
10. *U.S. grinder establishment that produced the sampled product.*

Six of the ten items listed above are specifically **excluded** from agency documentation which accompanies meat samples originating from **domestic** product. Item numbers 1, 2, 4, 5, 8 and 9 are conspicuously absent from FSIS mandated paperwork protocol when the sampled product is of USA origin. Since HACCP is science based, true science would mandate identical protocol for all sampling activities, regardless of country of origin. Consumers deserve safe food, regardless of its origin. Forbidding complete documentation of the origin of domestic meat being sampled constitutes an inappropriate constraint, which deftly circumvents the scientific method. The message conveyed here is that FSIS considers imported pathogens to be more lethal than domestic pathogens.

The reasons to immediately document the true origin of meat being sampled are numerous and compelling. The laudable goals of protecting public health and production of safe food are best accomplished via immediate documentation of source evidence of all sampled meat. Immediate declaration of the true source of contaminated meat, coupled with agency enforcement actions at the noncompliant slaughter establishment can only be accomplished by a thorough and scientific paper trail which leaves no stone unturned. Existing agency sampling policies declare many evidentiary stones sacred, restricted, and off limits. However, if FSIS is sincerely committed to public health, the agency must allow unrestricted access to all evidence, which insulates no plant from accountability.

POLICY CHANGE NUMBER TWO

Evidentiary documentation must be jointly signed by (a) the FSIS employee who collects the sample, and (b) a representative of the plant where the sampling is being conducted.

BACKGROUND INFORMATION

HACCP (Hazard Analysis Critical Control Point) is the meat inspection system currently being used by USDA/FSIS. It was originally developed in the 1960's by Pillsbury as a scientific way to produce food for NASA, food which could be guaranteed to be wholesome. The HACCP concept was initially sold to the meat industry, consumers and the general public by USDA in the 1990's as being similarly "*science based*". The

scientific foundation of HACCP was claimed to be superior to the previous organoleptic meat inspection method primarily because HACCP would ostensibly introduce a substantial increase of microbiological testing, which was used very little pre-HACCP. Since FSIS hung its hat on microbiological testing as the scientific foundation of HACCP, the agency needs to ensure that all aspects of testing meet every definition of science, while demanding copious documentation of each component of testing protocol.

Another foundational premise of HACCP was the need for plants to document, document, document. Even today, a common criticism of HACCP is that too much emphasis is placed on intensive scrutiny of written records, and too little focus on the production of meat; in other words, a paper chase. Inspection personnel dedicate much more time to reviewing paperwork than they do monitoring production lines and inspecting meat products, truly a "Hands Off" FSIS involvement in the deregulated meat inspection environment under HACCP methodologies.

Scientific protocol echoes HACCP's original theoretical underpinnings. True science mandates copious, thorough and immediate documentation of all pertinent data surrounding scientific experiments, which in this case is microbiological testing of meat. Scientific microbial testing must by definition include not only the timely compiling of all data in an unrestricted fashion, but must also have witnesses to verify the accuracy of every step in the scientific process. An example of this is FSIS' mandate to the industry regarding the required steps plant personnel must follow during daily verification activities. Plant verification steps are (a) records check, (b) direct observation, and/or (c) thermometer calibrations. FSIS believes that when plants perform paperwork functions, the actions by one monitoring person are inadequate, and must be supplemented by a follow up verification step as described in a, b, or c. With the exception of very small plants, the verification step is performed by someone other than the monitor. In stark contrast, whenever FSIS collects a ground beef sample for pathogen testing, FSIS allows such a sensitive procedure with potentially serious results to be conducted by one individual without a separate verification activity. The scientific method must by definition require standardized protocol.

HACCP ideals consist of substantial record sharing between FSIS and plants. Access to records has increased, rather than decreased. As an example, FSIS Notice 54-03 dated 12-16-03 makes the following statement under II Background: *"Given these regulatory requirements, the results of any testing and of any monitoring activities that are performed by the establishment may have an impact on the establishment's hazard analysis, whether or not such testing or monitoring is incorporated into an actual HACCP plan, referenced in a HACCP plan, or considered as separate activities. Therefore, records of these activities are subject to FSIS review and are to be available to FSIS personnel"*. Please see Attachment F. Furthermore, recent statements by FSIS officials that they desire to "*partner*" with the industry indicates a desire to share more information, rather than to work separately.

Joint signing of sample test forms would constitute laudable, common sense and scientific "partnering" by the regulator as well as the industry, in an attempt to prevent

confusion or unnecessary delay in attempting to identify the true origin of contaminated meat. If the sample is determined to be positive, both sides would have already agreed to the origin(s) of the sampled meat, enabling an immediate investigation to the true source of the pathogen-laced meat. Only then would the noncompliant slaughter plant be identified, as well as required to implement corrective actions with no undue delay. Neither the agency nor the packer has anything to lose by joint documentation. The goals of public health, corrective action, as well as the production of Safe Food would all benefit, with no liability to FSIS or the meat plant except the need for impeccably documenting the full truth in a timely fashion.

Disputes over the accuracy of sampling/testing evidence would be eliminated, since both sides originally agreed to the accuracy of all data which was compiled when the sample was originally collected. Very little, if any additional time would be required to initially document the origin(s) of sampled meat. Currently, when disagreements arise over such evidence, the dispute can extend for several days with no definitive resolution. This unnecessary waste of time would be totally eliminated via joint documentation. This voluntary partnership is essential for smoothly functioning sampling/corrective action activities.

A statement commonly heard is that HACCP has created a meat inspection system which clearly delineates the limited and minimized authority given to Inspectors. This strategy was designed to prevent the agency from having any meaningful oversight or direct monitoring of meat production activities, while empowering the industry to "police themselves" in the relative absence of FSIS involvement. Therefore, the suggestion in The Traceback Bill to conduct joint evidence gathering during sampling might be depicted as an assault at "the very heart of HACCP". Conversely, the heart of HACCP was originally designed to promote the production of Safe Food. When the true origin of contaminated meat cannot be determined, meaningful corrective action at the **source** plant where contamination occurred cannot be accomplished, virtually guaranteeing multiple recurrences. This directly threatens the goal of Safe Food.

USDA's Office of Inspector General (OIG) issued a report on January 10, 2006 which was critical of Grain Inspection, Packers and Stockyards Administration's (GIPSA) management and oversight of the Packers and Stockyards Programs. GIPSA's failures to adequately document and track pertinent data are hauntingly similar to FSIS's failures in the same areas. The OIG report included the following criticisms of GIPSA:

> "In addition, records in the **tracking** (emphasis added**)** system were not complete because there were no procedures for **validating the accuracy** (emphasis added) and completeness of information recorded".
>
> "P&SP's inability to accurately and completely **track** (emphasis added) its inventory of investigations limited the scope of our work".

> "P&SP also needs to implement procedures for recording data in the agency's **tracking system** (emphasis added) and for **validating the accuracy** (emphasis added) and completeness of the information recorded".

The unwillingness of a variety of USDA departments to adequately document and verify the accuracy of evidence compiled may now be systemic within the agency. Since the agency proclaims its procedures are "science based", the agency must commence incorporating truly scientific protocol in all its activities. The four policy changes found within "The Traceback Bill" represent a watershed change to use truly science based protocol in meat inspection and production..

USDA/FSIS repeatedly states that HACCP is a living scientific process, constantly changing to respond to changes in scientific thinking as well as new technologies and processes available to the industry. HACCP is thereby flexible enough to make such a minor change in sampling protocol which will have far-reaching positive results.

Creating or maintaining sampling protocol which intentionally obfuscates the true origin of contaminated meat, or delays the opportunity to implement corrective action to protect public health is not scientific, and needs to be changed. Joint documentation would eliminate both of these unnecessary dilemmas.

POLICY CHANGE NUMBER THREE

Whenever the sample is determined to be Positive for E.coli 0157:H7 or Salmonella, FSIS must conduct an immediate and unrestricted Traceback investigation to the true origin of contamination and implement enforcement actions at the originating slaughter establishment.

Numerous FSIS publications make references to the agency's commitment to and endorsement of Tracebacks and Trace Forwards. For example, FSIS issued a "*Guidance for Beef Grinders to Better Protect Public Health*" in March of 1998. See Attachment G. This agency document makes twenty-one references to the need for "*tracebacks, trace forwards, tracing, traceability, tracking, and trace"*.

In December, 1998 issued an updated version of the agency's "*Guidance for Beef Grinders to Better Protect Public Health"*. See Attachment H. The revised edition details the need for "*….recordkeeping controls designed to ensure the safety and traceability of their products*…" The new Guidance document makes 17 references to records, recordkeeping, and recording. It also makes 21 references to traceback, tracking, traceability, trace, and trace forward. It is noteworthy that FSIS' revised Guidance document includes a substantially increased focus on Traceback and recordkeeping activities than the original Guidance document. This highlights the agency's full

endorsement of Traceback activities, predicated on copious record keeping. Realizing the agency's official public stance on these two issues, FSIS current insistence that source origination data be precluded from agency documents at the time of sampling is puzzling.

In April 2002 the agency produced a document entitled *"FSIS Security Guidelines for Food Processors"* to assist plants to strengthen their biosecurity protection. On page 6 of the document the following statement is made under the heading "Slaughter and Processing Security": *"A validated procedure should be in place to ensure the trace-back and trace-forward of all raw materials and finished products"*. See Attachment I.

Since 9/11, the specter of terrorist contamination of our food supply has reminded both the industry and FSIS of the need to redouble their efforts to not only protect our meat products, but also to be able to investigate the origin of any outbreaks. The same concern exists with the threat of BSE to our animal herds. Both USDA and livestock producers are dedicating substantial time and finances to develop a National Animal Identification System (NAIS). This system is being designed to enable a complete Traceback of any BSE positive animal within two days to its original place of birth, as well as document all changes in ownership and locations the animal experienced in its lifetime. The universal trend within the livestock industry, as well as USDA oversight, is to design science-based monitoring systems to identify all potential hazards at all points within the agricultural production and processing continuum. Unfortunately, existing FSIS sampling protocol for enteric pathogens such as Salmonella and E.coli 0157:H7 is inadequate to timely identify the <u>true origin</u> of meat being sampled.

Expedited trace backs to the true origin of E.coli contaminated meat can only be accomplished by FSIS requiring copious and thorough documentation of source origination data <u>at the time the sample is collected</u> by FSIS. If legitimate trace backs to the source of contamination are not possible, corrective action cannot be accomplished, to the detriment of public health.

Existing forms utilized by FSIS personnel when collecting samples require the name of the grinding plant where the sample is taken, but have no provision for recording the name(s) of the source plant(s) where the meat was originally slaughtered. Therefore, in the event of lab positives, the Traceback starts and stops at the same location, which is the down line, further processing grinding plant, which more often than not performs no slaughter operations. The obvious result of this short circuited Traceback is that the plant which introduced the contaminant is insulated from performing corrective action, virtually guaranteeing recurrences of pathogen-laced meat. Simultaneously, the down line further processing plant (which does no slaughter) is charged with having a "failure" in its HACCP plan, is required to conduct a complete HACCP reassessment, and must prove that subsequent corrective actions have been taken which ostensibly will prevent recurrences.

USDA/FSIS has a rich history endorsing the efficacy of Tracebacks. In contrast, existing FSIS sampling procedures are inadequate to allow Tracebacks, and must be changed to not only allow expedited and accurate Tracebacks, but <u>mandate</u> Tracebacks.

Former USDA Inspector General Roger Viadero has reminded the agency and the industry that food tracing is a tenet of the Bioterrorism Act of 2002. He stated that by law, all entities involved in the production, distribution or sale of food products in the U.S. must be able to track their products – and all components thereof – two steps back and one step forward in the supply chain. FSIS unwillingness to track back even one step makes the agency intentionally noncompliant with the Bioterrorism Act of 2002.

POLICY CHANGE NUMBER FOUR

FSIS must reinstitute its previous "15 Sample Protocol". This protocol requires FSIS to collect an additional 15 consecutive daily samples of ground beef at any plant where initial testing produced an E.coli 0157:H7 lab positive.

FSIS at one time utilized a common sense policy in which the agency conducted 15 subsequent tests for E.coli 0157:H7 when an earlier test was declared to be positive for E.coli 0157:H7. The primary purpose of the subsequent testing was to determine if the one positive was an isolated incident, or did the one positive reflect ongoing failures at an out-of-compliance plant. Another purpose was to protect public health, preventing adulterated food from entering the food distribution chain. This protocol worked very well, as the following scenarios prove.

In January 2002, a USDA inspected plant experienced one positive test result for E.coli 0157:H7. During the subsequent 15 sample protocol, three more positives occurred. Both the plant management and the USDA Inspector documented that all 3 positives emanated from the same slaughter supplying establishment, same production date and batch number. Copious documentation, as required by HACCP, accurately defined the true source of product contamination. The documentation also proved that the three samples all emanated from single source materials, and was not a commingled product from several sources.

Five months later, another plant experienced a positive, resulting in the subsequent 15 sample protocol. The subsequent testing produced two additional positives. This plant also documented the origin of meat being ground and tested, and discovered that both subsequent positives originated from one supplier. Interestingly, its supplier was the same source plant which produced the 3 subsequent positives five months earlier at the previously mentioned plant. All five subsequent positives were copiously documented to be single source grinds, not from commingled grindings. The validated evidence did eventually result in a traceback to the source plant, resulting in a 19 million pound recall from the one supplying slaughter establishment..

In these two incidents, had the "15 Sample Protocol" not been in place, contaminated meat in commerce would not have been detected. Furthermore, the true source plant for

contamination would very likely not have been identified, nor would effective corrective action have been accomplished at the true origin of contamination. The 19 million pound recall was a public embarrassment to both the agency and the plant involved, and the humiliation was exacerbated by a subsequent OIG investigative report one year later. However, subsequent required nationwide changes to the HACCP system resulted in improved meat production methods nationwide and a decreased incidence of consumer sicknesses as reported by the CDC in Atlanta, Georgia.

Perhaps because the 15 sample protocol worked **too** well, FSIS rescinded the protocol on April 18, 2003 via FSIS Notice # 11-03, a mere ten months after the protocol proved its value for public health purposes. Part III (A) 6 of Notice # 11-03 stated "*Section VI. E. 2 of FSIS Directive 10,010.1 is revoked"*. Please see Attachment J.

However, FSIS still retains the 15 sample protocol subsequent to the discovery of a positive E.coli 0157:H7 sample when the sampled meat emanates from **foreign** meat. FSIS Directive 10,010.1, Revision 1 dated 3-31-04 provides the details in Part XI (D) which states the following:

> *"If FSIS finds raw ground beef product collected at an import inspection establishment positive for E.coli 0157:H7, does FSIS conduct follow-up sampling of product from the foreign establishment?"* The Directive provides the following answer: *"Positive samples from imported products result in an intensified level of sampling of subsequent shipments from the foreign establishment. An intensified level of sampling is automatically generated by the AIIS for the next 15 consecutive shipments of product from the foreign establishment presented at port-of-entry anywhere in the United States"*. See Attachment K.

The United States maintains equivalency agreements with foreign trading partners which are authorized to ship meat into our country. Foreign countries must have meat inspection/production protocol at least equal to our domestic HACCP program in order to qualify for shipping to the USA. Since USDA/FSIS has classified these foreign plants to be "equal to" domestic plants, science would dictate that FSIS would utilize equivalent follow-up sampling protocol in the event of positive lab findings, regardless of the national origin of the meat producing the positive lab tests. Since contaminated meat originating from foreign plants is subjected to a subsequent 15-sample protocol, domestic plants experiencing positive samples should likewise experience an identical follow-up 15 test protocol. If safe food and public health are the primary goals of HACCP, standardized follow-up sampling protocol must be a scientific necessity, and domestic meat must also be subjected to an intensified level of sampling. True science would not afford biased and preferential treatment to domestic meat.

See conclusions on next page.

CONCLUSIONS

The Jack-In-The-Box outbreak in 1993 pressured FSIS to implement a different type of meat inspection system. FSIS introduced HACCP as a superior science based improvement to the previous organoleptic (sensory) meat inspection methods, and hurriedly ushered HACCP into practice in a knee-jerk reaction that lacked adequate advance planning. HACCP was originally designed for fully cooked, ready-to-eat food for NASA astronauts. The application of HACCP to raw meats has presented numerous challenges, which are still being addressed and resolved to this day. Fortunately, mid-stream corrections to HACCP philosophy have been possible since HACCP is a living, ever changing organism flexible enough to accommodate required common sense changes.

HACCP, by FSIS definition, must therefore meet all criteria defined by the scientific method. The dictionary defines "scientific method" as follows: "*The systematic procedure for scientific investigation, generally involving the observation of phenomena, the formulation of a hypothesis concerning the phenomena, experimentation to test the hypothesis, and a conclusion that validates or modifies the hypothesis*". Current agency documentation protocol during sampling procedures miserably fails to meet scientific standards. In fact, the intentional obfuscation of source origination evidence guarantees that subsequent investigations will be thwarted, a direct contravention of the scientific method. A truly science based microbiological sampling program must include unrestricted and unbiased access to all evidence. This requires copious real time documentation of facts which would then allow (in fact mandate) an accurate and expedited Traceback investigation when contaminated meat is detected. Current agency sampling protocol utilizes procrustean methods which determine in advance that the down line grinding plant is solely responsible for the presence of pathogens detected via lab test results. Such pre-conceived conclusions totally lack a scientific basis.

Consumers have the right to expect that the premier public health agency in America is willing to utilize the same sampling/Traceback scientific methods for domestic meat as it uses for imported meat. Standardized and unbiased scientific protocol must be a foundational HACCP premise.

When the space shuttle disintegrated on February 1, 2003 upon reentering the earth's atmosphere, NASA conducted an intensive investigation to determine the cause of the disaster, hoping to prevent recurrences. NASA investigators combed the countryside in numerous east Texas counties looking for toxic debris which could have held clues to the cause of the accident. If NASA investigators had been forced to utilize the same scientific rationale required of FSIS while investigating incidents of E.coli 0157:H7 and Salmonella positives, NASA would have concluded that the east Texas counties were guilty of multiple "failures" in their air quality control programs. NASA would also have mandated the counties conduct reassessments of their failed air quality control programs, and implement corrective actions to prevent recurrences. Admittedly, such absurd

actions would not be scientifically justified. Similarly, current FSIS insistence that down line further processing grinding plants be held responsible for meat previously contaminated with enteric pathogens is equally absurd and unjustified by any scientific standards. Whether the detected pathogen is E.coli 0157:H7 or Salmonella, public health interests are best served by a scientific determination of the TRUE SOURCE of the contamination.

Corrective action which effectively prevents recurring production of pathogen-laced meat must by necessity by conducted at the TRUE SOURCE of contamination, not at the down line further processing grinding plants which unwittingly and legally purchase previously contaminated meat. This major improvement can only be accomplished via FSIS modifying its existing paperwork protocol used when conducting product sampling procedures. This would be a simple and easily accomplished procedural change requiring minimal additional payroll costs or training. The twin goals of protecting public health and production of safe food can be greatly aided by FSIS voluntarily implementing these rudimentary changes.

FSIS' December 1998 release of its "Guidance for Beef Grinders to Better Protect Public Health" includes a revealing statement on page one. It states "*Putting aside any **legal considerations*** (emphasis added), *it is essential that grinding operators assume that they are responsible for their products until the products' end use*". In stark contrast, FSIS must assume responsibility to aggressively pursue the detection of the true origin of contamination, which can only be accomplished by a proactive commitment to a copiously thorough sampling documentation system. Realizing that small, further processing grinding operators have little control over pathogens in their product, except for full cooking and irradiation processes, FSIS must implement basic changes mandating that responsibility be ethically placed at the true origin of contamination. FSIS insistence that down line further processing grinding plants assume responsibility for another plants' contaminated meat reveals a callous disregard for public health and the free enterprise system. Public health must not be imperiled by "*legal considerations*".

FSIS published Docket No. 04-006P, FDMS Docket Number FSIS-2005-0028, RIN: 0583-AD10 on March 6, 2006 on the USDA Website. On page 4 is found the following statement: *"FSIS is **responsible*** (emphasis added) *for ensuring that meat and poultry products are safe, wholesome, and accurately labeled"*. This constitutes an official admission by FSIS that the agency shares responsibility in detecting meat which is not wholesome, and to prevent its shipment into commerce. It also serves as further proof that down line grinding plants should not be held solely responsible for products further processed and ground at the plants, when the source materials emanated from large slaughter plants, materials which arrived at the grinding plants in shipping containers bearing the official USDA Mark of Inspection. When this occurs, FSIS is guilty of failing to **ENSURE** the wholesomeness of meat being produced under inspection and shipped into commerce. HACCP should not immunize FSIS from responsibility or accountability.

The common good of a democratic society is best promoted only when responsibility is placed on those entities where improvement is necessary. Legitimate, innocent businesses must not be victimized by officially sanctioned, biased policies which threaten honest businesses and imperil public health. FSIS persistence in mandating currently inadequate sampling procedures which prevent tracebacks is socially irresponsible, scientifically unjustified, and flagrantly unconscionable.

FSIS has released a plethora of agency documents which officially endorse the usefulness of Tracebacks to the origin of contamination. Now is time for FSIS to pay more than lip service to Tracebacks. The health of a nation, and victimized plants, is at stake.

ATTACHMENTS

Attachment A:	Page 5 of Directive 10,010.1, Revision 1. Part III (A) 1
Attachment B:	Page 6 of Directive 10,010.1, Revision 1. Part III (B) 1
Attachment C:	Page 6 of NCBA Cookbook entitled "America's Favorite Beef Recipes", printed in 1998.
Attachment D:	July 26, 2002 email from Cheryl A. Hicks, FSIS Program Manager to all FSIS District Office Managers. Includes two subsequent emails from Minneapolis FSIS management on July 31, 2002 and August 8, 2002.
Attachment E:	FSIS Notice 29-05, dated 5-12-05, entitled "Collecting And Reporting Information On Foreign Suppliers Of Source Materials For Raw Ground Beef Products Found E.Coli 0157:H7 Positive"
Attachment F:	FSIS Notice 54-03 dated 12-16-03 entitled "Review of Establishment Data by Inspection Program Personnel"
Attachment G:	"Guidance for Beef Grinders to Better Protect Public Health", issued by Food Safety and Inspection Service in March 1998.
Attachment H:	FSIS December 1998 publication entitled "Guidance for Beef Grinders to Better Protect Public Health".
Attachment I:	FSIS Security Guidelines for Food Processors, April 2002
Attachment J:	FSIS Notice 11-03, dated 4-18-03, entitled "Update to FSIS Directive 10,010.1, Microbiological Testing Program for Escherichia Coli 0157:H7 in Raw Ground Beef".
Attachment K:	Page 20 of FSIS Directive 10,010.1, Revision 1, dated 3-31-04.
Attachment Y:	Incidence of Food Borne Illnesses in US: CDC data
Attachment Z:	FSIS Form 10,210-3 which accompanies lab samples