Confessions of an E.coli Terrorist

They say that confession is good for the soul. I've been involved in a series of ugly events since my plant recalled 270 lbs of *E.coli O157:H7* contaminated ground beef in 2002, and now want to admit the embarrassing truth for public review.

I co-owned and managed a USDA-inspected slaughter and processing plant for 34 years in Miles City, Montana. When I sold it in 2005, the business had been in my family for 59 years. The primary reason for its sale was problems emanating from my production of E.coli-laced burger in 2002, the details of which I now desire to confess.

First of all, a description of my meat plant may be helpful. My folks moved to Miles City, Montana the year I was born, 1946, and purchased a very small meat plant. I was the fourth of ten children. After graduating from Montana State University in Bozeman, MT, and stints with Continental Oil and Target Stores, I returned home to take over the plant in 1971. Under Dad's initial guidance, then mine, the plant experienced numerous expansions. Our marketing area in 1946 was limited to our small hometown of Miles City which boasts a population of 10,000. We eventually delivered to numerous communities in eastern Montana. Our sales to full line distribution warehouses allowed our products to be shipped across Montana and into adjoining states. At the peak of our production, we employed seventeen people fulltime, and were a substantial member of our rural community. Besides marketing our products to retail grocery markets, restaurants, and a walk-in retail trade, we also benefitted area ranchers who sold their livestock to us. The highest number of beef we processed in one week was 100 head, so we were a small plant.

Since 1970, our plant has been USDA inspected. USDA meat inspections are performed by its "Food Safety Inspection Service" (FSIS), a term this report will now use.

In January, 2002, the FSIS Inspector at my plant collected a ground beef sample, and sent it to the USDA lab for microbial analysis for *E.coli O157:H7*. It was "Positive" for *E.coli O157:H7*. FSIS CAUGHT ME. When I notified Inspector Dan Ellis (now retired) of the adverse lab results, he immediately replied *"John, I wouldn't worry about it, because it wasn't your meat I sampled last week*". His memory was correct, because the meat he had sampled was Coarse Ground Beef I had purchased from an outside source slaughter provider. Inspector Ellis was a prophet, because after my recall, FSIS quickly finished their investigation, and expeditiously allowed me to resume normal operations after I implemented some minor changes. Interestingly, during a May 3rd meeting with FSIS District Office personnel, the District Office manager told my wife Kathryn and me that Inspector Dan Ellis "*did not have the right to make that statement"*. This report will reveal many agency attempts to obstruct the full truth, not only at my plant, but at small plants nationwide.

Since ours was a small plant, our kill floor was not capable of providing all the meat required to fill special customer orders throughout the year. For example, a large banquet or reunion might require several hundred pounds of prime rib roasts, sirloin steaks, ground beef patties, etc. Filling these orders

necessitated my purchase of meat from outside source slaughter providers to supplement meat originating from our own kill floor.

The suggestion to perform a recall emanated from a telephone conference call initiated by FSIS's 10-member, multi-disciplinary Recall Committee. One topic discussed during the conference call centered on the agency's demand that I implement corrective actions to prevent recurrences. Befuddled, I asked the prestigious committee of the agency's foremost scientific experts what kind of corrective actions I should implement, realizing the meat causing the recall had originated from a source slaughter provider, and as such, I had no control over the wholesomeness of meat arriving at my dock. The recall committee's reaction was……CONTEMPTUOUS SILENCE! I acknowledge that my anger exploded, and I restated the same question, but not so tactfully this time. Finally, one committee member hesitantly suggested that I request a copy of my source slaughter provider's HACCP Plan, which would describe how my provider consistently produces safe meat, free of pathogens. I complied with their request. One document provided me by a supplier was a publication entitled "*The Strongest Chain of Safety*", portions of which will be quoted and discussed later in this report. Quickly, FSIS allowed me to get up and running again. The term "HACCP" is fully explained in Part 2 of this report.

The Recall Notice, released by USDA, made no reference to the fact that the *E.coli O157:H7*-contaminated meat originated from my source supplier plant, not from my plant. I brought up this issue with the agency's Compliance Officer, DuWayne Hansen (now retired). Compliance Officer Hansen stated "*The USDA Legal Department forbids the inspectors to record the origin of the meat*". When I asked Mr. Hansen if he would be willing to document the true origin in his report, he replied "*If I would document the origin of meat being sampled, I'd be walking down the road"*. For the longest time I did not understand the agency's refusal to document source evidence of pathogen-laced meat.

Agency policies at that time mandated an additional 15 consecutive days of subsequent sampling after a recall. Results of these 15 samples would indicate if my production of adulterated meat was merely an isolated incident, or it may have been a frequent occurrence at my plant. I must admit to you that in the midst of these 15 subsequent samples, meat samples taken at my plant on three consecutive days (February 19, 20 & 21, 2002) were all positive for *E.coli O157:H7*. Talk about a consistently filthy plant! The batches of meat which caused these three subsequent *E.coli O157:H7* positives had not been shipped into commerce, as I had quarantined the meat. Since the product had not been shipped into commerce, no recall was required.

I must own up to the fact that prior to the January recall, I did not maintain a grinding log which would have documented all source evidence for every batch of meat put into my grinder. Inspector Ellis and I knew the source meat was Coarse Ground Beef from an outside supplier, but we didn't know from which supplier, production date, batch number, etc. We utilized Coarse Ground Beef from two suppliers, ConAgra & Cargill. Since we didn't know which suppliers' meat had been used for the sample, I offered to provide unopened, intact chubs of Coarse Ground Beef from both suppliers to the FSIS at no charge, for testing at the USDA lab. FSIS blithely dismissed my offer. For the longest time, I was flummoxed by the agency's refusal to test these intact chubs, which would likely have conclusively

proved the true SOURCE of contaminated meat which necessitated my recall. Nineteen months later, in August of 2003, we were finally informed of the reason for FSIS's refusal to accept the unopened chubs from me. Following a 3-day USDA Office of Inspector General (OIG) investigation at my plant in August 2003, the agency's top official in Montana, Dr. Grady Skaggs (now retired) discussed the issue of these chubs with me and three other employees. Dr. Skaggs stated "*The* [FSIS] *Compliance Officer wanted to accept my offer of these chubs at no charge, but the Minneapolis Office said 'Oh no, don't do that, because if you do, ConAgra will sue us'*". When given an opportunity to perform testing which may very well have revealed the true source of E.coli-contaminated meat, FSIS decided not to protect public health, but instead to protect the agency from feared litigation stemming from one of the industry's behemoths.

This dilemma was further explained by a statement from FSIS Inspector Abe Waldner (now retired), who collected a sample on Friday, February 22, 2002. Prior to taking the sample, I suggested to him "*Instead of taking the sample after it comes out of our grinder, why don't you simply open up the bag of Coarse Ground Beef from Brand X and take a sample directly from it? It would be more scientific, and would quickly narrow down the true source of contamination*". He replied *"If I did, I would be guilty of 'conspiring' with the plant to point blame at the big packer*". In other words, science-based and unrestricted evidence gathering by inspectors at the time of sample collection is tantamount to conspiracy, and verboten. Over time, I realized that FSIS's vaunted "*Abundance of Caution*" had morphed into an <u>Abandance</u> of Caution when testing for *E.coli O157:H7.*

Over time, it became obvious to me that FSIS prohibits documentation of source evidence throughout the sampling/testing process, if there is any chance the evidence might possibly implicate one of the industry's biggest players.

My 2002 recall taught me the need to fully document all evidence. Fortunately, we had complete source documentation when the subsequent three consecutive days of positives occurred in February, 2002. When FSIS notified me of the three additional positives, I then reviewed my plethora of evidence, and surprisingly discovered that meat for all three positives emanated from the same outside source provider, from the same production date, and the same batch number at the source provider plant. The box labels from the three boxes remain secure in a bank safety deposit vault.

I'm embarrassed to admit my naiveté, but when I discovered that all three positives emanated from one supplier, and from the same production date and the same grinder batch number, I commented "*Good, now USDA will be forced to change some meat inspection policies*". A full nine years have since passed, and agency policies have changed very little. FSIS has implemented a few minor changes in policies, while adroitly avoiding meaningful changes which would benefit public health, which are described in a subsequent portion of this report.

The USDA lab notified me on Friday, February 22, 2002 that the sample collected on February 19th tested positive for *E.coli O157:H7*. The lab notified me the next day (Saturday) of another positive, and the last positive was communicated to me on Sunday the 24th. I was caught red-handed, with no

gracious exit. I fully anticipated a phalanx of FSIS enforcement officials descending upon my plant on Monday, but strangely, no one appeared, and odder yet, I received no calls from the agency. The agency's disinterest in these three positives was a stark contrast to the blitzkrieg of agency officials who immediately confronted me during the recall. A month later however, FSIS knew that all meat tested on these three subsequent days originated from an outside plant, and not from my kill floor. The agency already knew that the inspector involved had likewise documented all this source evidence, which exonerated my plant. Why is this important? Let's start by defining the nature of *E.coli O157:H7*.

E.coliO157:H7 and *Salmonella* are classified as *"Enteric*" bacteria. By definition, enteric bacteria emanate from within animals' intestines, and by extension are found on manure-covered hides. Enteric bacteria are different from other bacteria such as listeria, which are environmental, meaning they do not have to emanate from within animals' intestines or from manure-covered hides. In contrast, environmental bacteria are somewhat ubiquitous, and can be found anywhere. Since both my plant and my source suppliers slaughter livestock, the *E.coli O157:H7* causing these three lab positives could have emanated from my own kill floor, or from my supplier's kill floor. Therefore, to prove the true SOURCE of this pathogen, enabling corrective actions to be mandated at the truly noncompliant source slaughter plant, copious documentation of all evidence of the source of meat being sampled at the time of sample collection is readily apparent, and should be required in any science-based sampling protocol.

At the time of my January, 2002 recall, my plant was immediately visited by numerous agency officials, who perused all production records at my plant. Therefore, because of three consecutive days of additional lab positives, I was prepared for an avalanche of furious FSIS officials the following Monday, February 25. Strangely, no one came, nor did anyone even call. I smelled a rat. In an attempt to shame FSIS into investigating all evidence, I stayed at work late into that Monday night, and sent an email (at 8:56 pm) to the manager of the FSIS District Office (DO) in Minneapolis, which has jurisdiction over Montana. The email makes reference to the fact that other further processing plants like mine also have on their premises coarse ground beef from the same supplier, with the potential to cause outbreaks. Referring to these other plants, I concluded in my email "*If those plants perform a final grind on that product, and some consumers get sick and/or die, while you and I both know the details spelled out in this email, then ……. ? Both of us should share a cell in Alcatraz".*

Tact is not always my long suit.

Rather than my email shaming the agency to investigate my evidence, FSIS again avoided my plant, and did not send any investigators to my plant the following day, Tuesday, February 26, 2002. So, I stayed at work again late Tuesday, and sent another email to the Minneapolis District Office at 7:35 pm, again inviting them to visit my plant to obtain all evidence. Finally, the agency did send personnel to my plant on Wednesday, perhaps worried that the manager of the District Office loathed the idea of sharing a cell with me at Alcatraz. In retrospect, I realize that my suggestion that the manager of the DO should be incarcerated at Alcatraz earned me the eternal hatred of the agency, a bitterness driving all the agency's subsequent machinations against me.

Agency investigators arrived in force the following day, Wednesday morning, February 27, 2002, and spent several days reviewing my records. FSIS Compliance Officer DuWayne Hansen provided me a signed request, officially requesting that I divulge the name of the meat plant which supplied me the coarse ground beef which had tested positive on three consecutive days the previous week. I was ecstatic to have the legal right to provide the name of the plant, the date of production, and the grinder batch number to Officer Hansen. Why did Officer DuWayne Hansen provide me a signed request? Shouldn't FSIS have the authority to DEMAND all evidence? There is an embarrassing reason for this. In my previously-mentioned email to the manager of the Minneapolis DO on Monday, February 25, I made the following statements:

> "*Since the mere documentation of the origin of trimmings is illegal (I presume) for your inspectors, my release of the same information would also be illegal. I want to fully participate with your staff in addressing the origin of this contaminated meat, but I also know that if I release the information, USDA's legal staff will have my butt in court the next day. Dr. Clark, I want to cooperate with you 100% in this issue, but the USDA legal staff prevents it"*
>
> *Bottom line: before I release to you the information (and I want to), I require signed documentation from the USDA requesting this information, and stating it is legal for me to do so. I'm not gonna sit in jail in return for exposing the source of contaminated meat"*

Armed with all this data, the FSIS officials then retreated to the comfortable confines of the Minneapolis District Office (DO), to determine what actions to orchestrate against this miniscule plant in southeast Montana. The imbroglio which followed is scandalous, and will be revealed in the second installment of this report.

PART #2 DAMN THE EVIDENCE!

Prior to discussing negotiations in the following months between FSIS enforcement officials and my plant, we must describe contemporary FSIS meat inspection policies in existence in 2002, which remain to this day. Faulty agency designs in current meat non-inspection protocol birthed the problems seen at my plant, justifying FSIS's persistent misbehavior.

Subsequent to the Jack in the Box E.coli outbreak in 1993 which sickened hundreds of consumers and killed four, FSIS perceived the need to change its meat inspection system. The old system was incapable of detecting invisible pathogens, such as the newly-emergent *E.coli O157:H7* bacterium responsible for the Jack in the Box outbreak. The previous system was organoleptic in nature, meaning dependence upon the senses, such as sight, smell, and touch. Invisible bacteria such as *E.coli O157:H7* and *Salmonella* cannot be detected via sight, smell and touch. FSIS was aware of a food production system previously authored by Pillsbury in the 1960's designed to produce consistently safe food for NASA and the Army. Pillsbury named its protocol "*Hazard Analysis Critical Control Point*", or HACCP (pronounced "HASS-up"). Pillsbury designed HACCP for foods which were subjected to a "Kill Step", protocol such as full cooking or irradiation which "kills" all bacteria, producing a consistently safe food. Pillsbury built safety into each individual step of food production, initially validating the safety of each step with substantial microbial testing. Subsequently, food plants utilizing Pillsbury-style HACCP have done very little testing, because their products are consistently safe, in stark contrast to FSIS' current demand for increased microbial testing. Why the difference? The reason is that FSIS-style HACCP is not true HACCP, which this report will reveal. Another reason for the difference is that raw meat products produced under FSIS-style HACCP are <u>NOT</u> consistently safe, thereby necessitating increased amounts of microbial testing.

FSIS proudly proclaimed that FSIS-style HACCP would be "*Science Based*", in stark contrast to its previous organoleptic system. When we questioned what the agency meant by "*science based*", the agency stated that sampling for microbiological testing would be required under HACCP. Indeed, in the 56 years of my plant's existence prior to HACCP, neither the agency nor I collected any meat samples for microbial analysis. Upon HACCP's advent, both the agency and I collected dozens of samples, four of which were positive for *E.coli O157:H7* at my plant. Can't argue with lab results.

FSIS perceived potential industry opposition to HACCP, thus had to dangle carrots in front of the industry to obtain voluntary industry acceptance of this dramatic change. During meetings with the industry to roll out USDA-style HACCP, the agency made the following promises:

1. Under HACCP, FSIS would embrace a "*Hands Off*" role in meat inspection. (Personal note: this promise reveals the agency's desire to not inspect meat production lines)

2. Under HACCP, FSIS would voluntarily relinquish its previous command-and-control authority.

3. Under HACCP, FSIS would no longer police the industry, but that the industry was to police itself. (Personal note: this would work quite well, if all humans were honest. What would happen to tax revenues if IRS allowed us to police ourselves?)

4. Each meat & poultry plant could write its own personalized HACCP Plan, and the agency could not dictate what must be in each HACCP Plan. The deceitfulness behind this promise will be fully explained later in this report, which will reveal the widespread extent of corruption within the agency.

Like other plant owners, I was thrilled at the prospect of less FSIS oversight at my plant, having authority to police myself, and to witness FSIS operating in the lack of any policing actions and no command-and-control authority. Sugar plums were dancing in my head. I fully endorsed this deregulated system of non-inspection. Only later did I discover that these promises were furtively intended only for the big plants, while the agency has been fully noncompliant with all four promises at small plants which lack political and economic clout. FSIS has used HACCP to deregulate large plants, while hyper-regulating the small plants. Pretty nifty! The agency has successfully pulled off the ultimate "Bait & Switch" – all under the umbrella of pseudo science.

FSIS-style HACCP was mandated in the agency's "*Pathogen Reduction: HACCP Rule"* in 1996. Large plants implemented HACCP on January 26, 1998. One year later medium-sized plants implemented HACCP, followed by small plants in 2000.

FSIS mandated that every federally-inspected meat & poultry plant implement a HACCP Plan, although FSIS-style HACCP had dramatic differences from Pillsbury's original HACCP system, a well kept secret. (I was not aware of this until 2009, a full seven years after my recall. FSIS has successfully concealed these core differences, even from industry insiders). Although Pillsbury's HACCP regimen required the afore-mentioned kill steps, FSIS-style HACCP does not require kill steps. Therefore, plants producing raw meat & poultry designed HACCP Plans with the absence of kill steps. Plants using Pillsbury-style HACCP Plans easily qualify for deregulation, because (1) safety is built into each step of their production system, and (2) their products have been subjected to a kill step. Such plants truly deserve deregulation. FSIS-style HACCP simply required plants to author a written HACCP Plan, after which they enjoyed the four agency promises listed above. The assumption was that if a plant merely has a written HACCP Plan, all their raw products would be safe, <u>even though they had NOT been subjected to a kill step.</u>

Central to FSIS-style HACCP is the need to document, document, and document, and then document even more: a classic paper chase. USDA-inspected plants now oversee a daily plethora of HACCP paperwork, inundating themselves with paper flow, much of which has <u>zero</u> connection to safe food. HACCP Plans are to say what we do, then we must do what we say. The only way we can prove that we are doing what our HACCP Plans are saying is to cover our derrieres with an abundance of paper flow, which by the way, can be manipulated via falsification. FSIS could care less, as the agency primarily exists to <u>audit</u> paperwork, not <u>inspect</u> meat. Even though a plant's HACCP Plan is professionally written, worthy of a Pulitzer Prize (in science fiction), including scientific references, bells and whistles, it can still

produce contaminated meat. FSIS fails to acknowledge that food safety is not determined by paper flow, 3-ring binders with cutsie stickers and labels, and bulging files. FSIS wisely fails to acknowledge that sanitary production practices (not paperwork) produce safe meat. After HACCP's advent, inspectors dedicated much more time inspecting my paperwork than inspecting my meat production lines. Does that increase your confidence in meat safety? Only if you have been duped by FSIS-style "*science".* Although FSIS-style HACCP was initially described as a Pathogen Chase, it quickly degenerated into a Paper Chase.

Two common statements from FSIS inspectors and veterinarians since HACCP's advent have been:

1. FSIS implemented HACCP primarily to lessen the agency's legal liability in the event of an outbreak, since the agency cannot be held even partially liable for contaminated meat which FSIS hadn't inspected in the first place. As such, it has been recommended that FSIS-style HACCP be renamed HASSLE, as in "*Hazard Analysis Sorta Scientific Liability Evasion".*

2. Much more importantly, FSIS hierarchy covets <u>COMFORT</u> in its dealings with the influential big packers. Comfort is best accomplished via deregulating the large packers, relegating the agency to a "Hands Off" non-involvement role. Since FSIS willingly forfeited its previous policing authority and command-and-control under HACCP, the agency no longer experiences the delicate discomfort involved with attempting enforcement actions against the industry's high volume elite, who now policed themselves. As such, FSIS used HACCP as a Trojan Horse which was disingenuously labeled "*<u>Food Safety"</u>*, but inside the horse was the agency's ultimate objective, which was <u>Deregulation</u> and <u>Agency Comfort.</u>

With this as a background, let's see how the Minneapolis District Office (DO) responded to the fact that my plant had experienced three consecutive days of adverse lab test results for *E.coli O157:H7*, perhaps a unique event in the history of the meat industry. These adverse lab results also provided the agency a golden opportunity to identify the source plant which was grossly noncompliant with E.coli control measures. This incontrovertible evidence would have enabled FSIS to identify the true source, providing justification for swift and effective agency enforcement actions at the <u>Source</u>, to the benefit of public health.

Initially, the DO stated that not only did I have a failure in my HACCP Plan, but that I had multiple failures because of multiple lab positives. Secondly, the DO stated that I must reassess my HACCP Plan, and implement corrective actions to prevent recurrences.

I quickly reminded them that copious documentation of source evidence, compiled in real time both by the inspector and by my own staff provided indisputable evidence that the meat sampled was Coarse Ground Beef I had purchased from one well-documented outside firm. Furthermore, I reminded them that the documentation also proved that the meat sampled at my plant came from a clean grinder, that is, that no other grinds had been performed earlier in the day which could have potentially deposited residual bacteria which might have caused subsequent grinds to be cross contaminated. I also reminded the DO that the samples on all three days were single source grinds, that is, I did not commingle meats

from various sources into one grind. All of this was documented by the inspector who collected the three samples. Open and shut case. Or so I thought. I never claimed to be brilliant, you know. My dad would never tell me jokes on Saturday nights, as he was afraid I'd laugh in church on Sunday. Anyway, as I commenced my HACCP Reassessment, FSIS allowed me to continue to operate, but did not allow me to grind under the USDA Mark of Inspection. My plant could continue operations as before, but could not grind under inspection. Now, try to operate a small meat plant without a grinder!

I wrote numerous HACCP reassessments, all of which were rejected by the DO as being "*inadequate*". These Reassessments were time consuming, costly, and all futile. Before this scenario terminated, the DO rejected fourteen reassessments, ironic when the industry average is one to two reassessments prior to resumption of normal operations. Fourteen rejections would be laughable, except it's not funny……unless you worked at the Minneapolis DO. Perhaps FSIS wasn't as "*Science Based*" as we had been lead to believe. Sometimes, "science" can be stranger than fiction. Please remember that one of the four FSIS pre-HACCP promises was that each plant could write its own HACCP Plan, and that the agency couldn't tell us what must be in our HACCP Plans. Subsequent historical events continue to reveal to small plants systemic agency misbehavior as shown below. When FSIS officials decide to disagree with entries in HACCP Plans, agency officials automatically resort to the following sophistry:

"*Your HACCP Plan has a failure, and is inadequate*"

"*We can't tell you what is inadequate, nor where the failure is, because it's your Plan*"

After small plant owners don't know how to proceed, FSIS concludes:

"*You should consider implementing the following steps".*

This is allegedly merely a "suggestion", mind you.

Then, after the plant implements the agency's suggestions, the agency frequently concludes:

"Your actions are inadequate"

FSIS-style HACCP is a crazy, convoluted mendacious system, which FSIS lifer bureaucrats have ingeniously designed and mastered.

After a few rejections, a remarkable event transpired which has haunted the agency ever since. An agency veterinarian by the name of Dr. Daryl Burden (now deceased) had previously been assigned to a large plant in the Pacific Northwest, where he observed ongoing pathogen problems. When plant management prevented his access to documents, Dr. Burden sent numerous emails to top agency brass in DC, only to be told he must allow the plant to operate as is, he had lost sight of "*The Big Picture*", and reminding him to be a team player. Dr. Burden quickly became a liability to the agency because of his dogged documentation of recurring problems, coupled with the agency's refusal to demand corrective actions at the plant, a benefit of FSIS-style HACCP. The agency's solution to this delicate problem was to reassign Dr. Burden, to remove him from the problem plant. To the agency's eternal regret, FSIS

relocated Dr. Burden to my area, and my plant was one of the first into which he stepped. Dr. Burden unwittingly inherited a gold mine.

Dr. Burden was immediately instructed by the Minneapolis DO to review my most recent Reassessment, and issue a report to the DO whether I was yet in "full compliance". To the horror of the DO, not only did Dr. Burden state that he personally felt that my most recent Reassessment was adequate, but he went far beyond the assignment given to him and revealed that the source meat originated from another plant. Dr. Burden's hand-written statement (I still have the original) included the following statements:

> *"Review of the three consecutive e.coli O157:H7 failures strongly suggest a common source of the contaminant – coarse ground product of a single identified lot received from Est 969"* [ConAgra's plant in Greeley, CO].
>
> *"I recommend acceptance of Est 7679* [my plant] *response and implemented measures, and suggest a follow-up investigation of the source of the product considering the serious public health implications of other possible e.coli O157:H7 adulterated product from the same production lot".*

Inspector Ronald G. Irvine (now retired) hand-wrote "*I concur with the above!",* signed the document, and dated it 3-1-02, 10:00 am. Dr. Burden asked me to fax the letter to the Minneapolis DO, which I did. He left quickly, to drive back to his home in the Black Hills of South Dakota. Before leaving, he asked me how soon he would be out of cell phone range, as he stated that he knew that the DO would be angrily calling him as soon as they read the fax. American consumers, and me in particular, benefitted by Dr. Burden's courageous act to document the truth in writing, a task which the agency had not requested from him. The absence of this one document would have doomed my advocacy to ruination, as I would have been portrayed as a sore loser, unwilling to accept my well-deserved punishment for allegedly introducing adulterants into ground beef.

Now, the cat was out of the bag, and the agency had to devise strategy to recapture the loose feline.

Wouldn't you know it, early the following week Dr. Burden walked into my office, and sheepishly stated "*The District Office wants me to POLITELY ask you if you would return that letter please*". *I stated "It's too late, I've already made dozens of copies and distributed them in many states*", a true response. Dr. Burden punched the air with his fist, smiled with great glee, thanked me, and walked out. This cat wasn't going back into the bag, much to the chagrin of the Minneapolis DO.

The succeeding weeks were filled with more conference calls with DO officials. Of course, calls were typically several of them, versus one of me. Numerous subsequent HACCP reassessments were provided to the DO, all of which (of course) were rejected. I finally concluded that the agency would never grant me the right to grind again, partly because of the Alcatraz invitation, and because of Dr. Burden's letter.

In one telephone discussion with an official at the Minneapolis DO, I made reference to Dr. Burden's letter. I was cautioned "*Mr. Munsell, it would be good for you to never again mention that letter*". The FSIS DO had now resorted to overt suppression of source evidence. So much for "science".

During one telephone conference with Minneapolis DO officials, when I made mention of the letter written & signed by FSIS veterinarian Dr. Daryl Burden & inspector Ronald Irvine, DO personnel responded by stating:

> "*They were not authorized to make that statement"*
>
> *That was just their personal opinion*"

So much for documenting evidence in real time.

The November/December, 2003 issue of Mother Jones magazine included a story which revealed FSIS misdeeds at my plant, and the agency's lack of oversight of the meat industry. One of many highly revealing statements in the article questioned the agency's desire to document all evidence:

> *"Never mind that the local federal inspector had seen the beef go straight from the package into a clean grinder – a USDA spokesman called that testimony 'hearsay'"*

When confronted with well-documented but embarrassing evidence, agency officials blithely dismiss scientific evidence as *"hearsay", "personal opinion*", and then the all-encompassing solution "*the inspector was not allowed to make that statement*". It is unfortunate when well-meaning FSIS inspectors get in trouble for telling the truth. It is also unfortunate that food safety has been entrusted to an agency which prohibits its field force from documenting all evidence without artificial restrictions from the agency itself. As such, consumers continue to be imperiled, justified by FSIS-style deregulated "SCIENCE".

The Mother Jones article included another revealing quote from an agency official:

> "*USDA spokesman Steve Cohen also argues that Munsell never proved the source of the initial E.coli contamination and suggests that he 'got a good deal' on the ConAgra meat"*

When FSIS lacks any logical explanation for its misbehavior, it resorts to slander. The agency insinuates that I knowingly purchased *E.coli O157:H7*-laced meat from ConAgra, simply because I was offered a discounted price. Since the coarse ground beef was frozen, I did purchase it at a discounted price compared to fresh coarse ground beef. But think about it further: Steve Cohen's statement is an official agency admission that FSIS was cognizant that ConAgra was shipping to me coarse ground beef that was adulterated with *E.coli O157:H7* pathogens. (I didn't know it, but FSIS apparently knew). So, how did FSIS respond? It shut down my grinder for four months, while taking no actions at the source originating slaughter plant.

How does FSIS respond when presented incontrovertible evidence of pathogen-laced meat? Answer: it kills the messenger. And later……..consumers.

During one visit of FSIS enforcement officials to my plant, they stated that improper employee hygiene by my employees may very well have been the cause of the three successive days *of E.coli O157:H7* positive samples. I asked them to explain. They stated that one of my employees may have used the rest room, and afterward did not wash his/her hands, potentially leaving human fecal material on their fingers. Then, the employee allegedly went directly to the processing room and ground the meat from which the inspector collected a sample, which was now contaminated with human feces. These officials intentionally ignored the well-known fact that we don't grind meat with bare hands, because the meat is so cold. And, before grinding, employees put on cotton gloves (for warmth), and then cover the cotton gloves with plastic gloves which keep the cotton gloves dry and warm. I was incredulous at their inane suggestion, and replied that if poor employee hygiene was indeed the source of the problem at my plant, then I have an employee carrying a horrific load of pathogens in their intestines, and the employee must either be in the hospital or at the morgue. I suggested that we review my payroll records, to see who had recently been sick. They declined my offer, and never resurrected this argument again. I bring up this issue to reveal how FSIS will fabricate an unlimited number of false accusations designed to provide ingenious theoretical examples of how further processing plants ostensibly introduce pathogens into the food chain. This is done to obfuscate the true source of contamination, thereby insulating the truly noncompliant large source slaughter plant from fecal accountability. Since my recall, numerous other victimized plant owners have told me they've been accused of the same. While *E.coli O157:H7* can indeed be introduced at downstream locations, FSIS should at least provide plausible examples.

My wife Kathy and I drove to Minneapolis to argue our case in person with six DO personnel. We met on Friday, May 3, 2002 from 2:30 – 6:30 pm, a 4-hour exercise in feckless, feeble futility. Although the agency proffered endless "suggestions", none of which were viable, such as the idea of my irradiating my entire product line, four particular agency statements exposed the agency's unethical bias against small plants:

1. When I complained about the mountain of boneless trimmings accumulating in my freezer, which I could not grind, the DO folks told me I could legally sell the trim, but could not grind it myself. I was stunned. FSIS thus unknowingly admitted that my kill floor was NOT the source of my e.coli problem.

2. One of the DO personnel stated that I had not proven that the sampled meat was not from my own kill floor. So much for the copious documentation compiled by the inspector and my staff during those ill-fated three days of sampling. Essentially, DO personnel assumed the unilateral authority to summarily reject all documentation provided by their own field force, and rewrote history from their remote locations. <u>And secondly, since FSIS still contended that my kill floor was the probable source of the problem, why did the agency authorize me to sell trimmings into commerce which originated from my own kill floor</u>? The DO refusal to accept documentation both from its own field force and from me invalidates the agency's original endorsement of copious documentation, a foundational pillar of HACCP. It is interesting to note that ConAgra quickly issued me a full credit for the three batches of meat I destroyed which was produced on

the three consecutive days of *E.coli O157:H7* positives. In the total absence of any negotiations, ConAgra immediately refunded me for all the meat I had to destroy. No questions asked. Although ConAgra quickly granted my request for a credit, which constitutes ConAgra's acknowledgement that their coarse ground beef was tainted, the Minneapolis FSIS DO continued its mantra that I had not proven that the bad meat had not originated from my own kill floor. As such, the Minneapolis DO claimed that it knew more about the scenario that its own inspector, ConAgra and I knew. But as this report will show, the Minneapolis DO cover-up would eventually be unraveled.

3. The manager of the Minneapolis DO stated that FSIS Inspector Dan Ellis was not authorized to state that the meat he sampled at my plant in January, 2002 was Coarse Ground Beef I had purchased from an outside source supplier. This agency admission should boil the blood of all meat consumers. FSIS itself states that its own inspectors are not authorized to admit the truthful origin of contaminated meat. FSIS deprives its employees the right of free speech, or to document unrestricted truth which would benefit public health imperatives. A full revelation of FSIS corrupt practices could make vegetarians out of all of us.

4. As the meeting progressed, and the subject of multiple Reassessments and an equal number of rejections were discussed, while the DO artfully dodged informing me what I needed to do, my wife Kathy finally raised her hands and said with exasperation "*Just tell us what you want us to do".* The FSIS officials responded "*We can't tell you what to do, because it's your own HACCP Plan* (see Promise #4 in Part 1 of this report), *and you can write it the way you want to*". FSIS authorizes plants to write their own individualized HACCP Plans, then the agency rejects the HACCP Plans as being inadequate. However, the agency does not have to explain what is the source of the inadequacy, nor describe changes necessary (in the agency's mind) to resolve the alleged inadequacy. At this point in the meeting, my wife Kathryn stated "*Bottom line: you're just trying to shut us down*". The manager of the DO replied "*<u>Oh no</u>, Mrs. Munsell, we want to help you get up & running, don't we"* as he looked to his assistants, all of whom bobbed their heads in agreement, like puppets on strings. FSIS officials claimed they wanted to get us up and running, but their actions proved otherwise.

Reminds me of an incident in my home kitchen, decades ago. As our family ate supper, we noticed that our cat had a mouse entrapped in its mouth, the only evidence of which was the rodent tail protruding from our cat's teeth. Cats love to torment trapped mice, temporarily placing them within the cat's mouth, throwing the mouse in the air, batting it around, and finally administering the terminal coup de grace. An apt description of how FSIS plays with small plants.

I desperately sought outside assistance, as my inability to personally push for justice with FSIS hit a stone wall. Montana Senators Max Baucus and Conrad Burns, and Representative Denny Rehberg all pleaded on my behalf, to no avail. I joined the National Meat Association (NMA), as I had previously belonged to its predecessor Western States Meat Association fifteen years earlier, and I perceived that its Executive Director Rosemary Mucklow might provide assistance. I also joined the National

Association of Meat Purveyors, and contacted officials within the National Cattlemen Beef Association (NCBA) who might speak some sense into top FSIS officials in DC. Although officials from these groups made contacts on my behalf, all of my HACCP Reassessments continued to be "***Rejected***", with no specific reasons for rejection, nor solutions provided as what would be required by the agency.

To my relief, NMA and NCBA, at their expense, hired a consultant to work with me to bring this imbroglio to a conclusion. The consultant, Dr. Helmut Blume, was uniquely and preeminently qualified to run the gauntlet on my behalf. He had retired from FSIS only five months earlier, where he had served as the manager of the agency's District Office in Salem, Oregon. He was highly respected both in the industry, and in the agency. Dr. Blume flew to Miles City to meet with me, and reviewed my HACCP Plan and related programs. He personally knew the manager of the Minneapolis DO because of his many years in the agency. We agreed that Dr. Blume would contact Minneapolis on my behalf, explain that he was a consultant for me, and jointly work with the Minneapolis DO manager to devise specific actions I needed to implement for the resumption of our grinding operations. I suddenly became optimistic.

Dr. Blume and the Minneapolis DO manager eventually hammered out a number of actions for me to implement to gain the right to resume grinding under USDA inspection auspices. I fully complied with this list, and submitted the finished list to the DO which rejected it as "*inadequate*". Dr. Helmut Blume was shocked, not understanding how the agreement he had with Minneapolis was summarily rejected as "*inadequate*". Dr. Blume suggested that maybe he couldn't help me, and perhaps I didn't want his assistance. I disagreed, stating that he was my only hope. So, Dr. Blume dejectedly offered to contact the Minneapolis DO again, and see if an agreement could be hammered out.

Well, an agreement was made, and Dr. Blume again provided me an itemized list of requirements mandated by the Minneapolis DO, with which I fully complied. After reviewing these corrective actions, the DO concluded that the newest measures were "*inadequate*". Now, the cat (a.k.a. agency corruption) was fully out of the bag. The FSIS District Office in Minneapolis was now engaged in overt corruption, perhaps mandated from top agency officials in DC. Perhaps for the first time, NCBA, NMA, and Helmut Blume perceived the full extent of the agency's corruption at my plant. They also realized that the previous relationships they had developed over the decades with FSIS officials was valueless. Damn the evidence!

Please remember here that FSIS piously proclaims that each plant can write its own HACCP Plan, and that the agency can't dictate what belongs in the HACCP Plan. Actions by the Minneapolis DO provide a new definition for the term "*disingenuous*". But mind you, Minneapolis DO actions were based in "*science*".

When I contacted Dr. Blume with this development, he was incredulous. I suggested to him "*Perhaps now is the time for me to go public*". I fully anticipated Dr. Blume would forcefully disagree, because he was a HACCP advocate, and was loyal to the agency. Nevertheless, after several surprising seconds of hesitation, he defiantly replied "*Give Mickey* [DO manager] *one more chance, then go public*".

During the four months we couldn't grind, we lost many customers. Our competitors referred to us as "*that E.coli plant*" with great success. We came to discover that our customers slowly developed the perception, over four long months, that *E.coli O157:H7* had become pervasive in our plant, potentially cross-contaminating all our other products as well. One angry customer called, and asked "*When did you start trying to kill your customers?*" Sales plummeted. It was an ugly sight to watch our family owned business atrophy.

At that time, my family had owned and managed the business for 56 years, and I readily perceived that I would be the shamed captain as our ship sank into the agency's bottomless abyss of corruption and virtual lack of accountability. But, as is said "*It is darkest just before the dawn*", I did not see the bright light which was around the corner, one which no author could ever devise in his/her wildest imaginations. Just when FSIS was about to tip me over, it was upended itself by what I call divine intervention, which will be revealed in Part Three.

PART 3 COWABUNGA BALDERDASH!

After my grinder had been shut down for four months, ConAgra's plant in Greeley, CO recalled 354,200 pounds of beef products which were potentially contaminated with *E.coli O157:H7* on June 30, 2002. Yes, this is the same plant identified by FSIS's Dr. Daryl Burden in his March 1, 2002 hand-written letter. This is the same letter which the Minneapolis DO cautioned me to never mention again. The chickens had come home to roost. Even USDA was incapable of covering up the truth over a prolonged period. Out of the ostensible goodness of its heart, the Minneapolis DO expeditiously granted me the right to grind again under inspection, subsequent to the ConAgra recall. This was an unexpected act of gracious altruism on the agency's part, because I had not implemented any meaningful corrective actions in the interim to deserve this reprieve. Other events which were totally out of my control had intervened to my benefit, and to the benefit of public health.

Please bear with me, because I must provide embarrassing (to the agency) evidence which reveals exactly why the Minneapolis DO begrudgingly granted me the right to grind again. On or just prior to Monday, July 1, 2002, the agency's #1 official in Montana, Circuit Supervisor Dr. Grady Skaggs explained to me three demands mandated by the Minneapolis DO that I must incorporate into my HACCP Plan, and if I complied with these three demands, the Minneapolis DO would allow me to grind again. My immediate reaction was that the agency had promised the industry that we could write our own HACCP Plans, and that FSIS could not tell plants what must be in our HACCP Plans. Nevertheless, these three agency demands, which were delivered to me by Dr. Grady Skaggs, mandated that I include sampling for *E.coli O157:H7* as a critical control point in my HACCP Plan. The mandate also required that my sampling protocol would separate (for sampling purposes) meat emanating from my own kill floor, distinguished from meat emanating from my processing brand X meat I purchase from outside source slaughter providers. I was agreeable to these agency demands, since my compliance with the demands would allow me to grind again. But, I wanted to document for posterity purposes that my willingness to comply would also document that the agency was mandating these changes. Admission that these three changes were agency <u>mandates</u> was the remaining deal breaker, which the Minneapolis DO wanted to avoid, but I wanted to document. Therefore, I typed a letter on July 1, 2002, explaining my willingness to comply, but also specifying the mandate behind these changes, and I emailed it to Dr. Nathaniel Clark and Roger Kubera at the Minneapolis District Office. How did the DO respond? Roger Kubera, Inspection Coordinator at the DO responded in an email on July 2, 2002 explaining my responsibilities as a plant *owner. Part of his email stated the following:*

> *"I would not see a problem with the proposed recommendations that you are requesting to include in your HACCP plans, along with the supporting documentation. <u>If this is what you want to do</u>"* (emphasis added).

Mr. Kubera quickly cut to the quick, emphasizing that I must <u>want to do</u> these changes, that is, my suggested changes ostensibly originated from my own voluntarily desires, ignoring that my "*desires*"

were merely a repeat of the mandates originating from the District Office. So, we were at a stalemate, attempting to document the origin of these ostensibly "*voluntary*" decisions/mandates.

The next day, Tuesday July 2, 2002, Mr. Kubera called me at 11:11 am, on a conference call in which other unidentified District Office participated as silent witnesses. To make a 10-minute, 1-sided conversation short, I finally interrupted the monologue and suggested to Mr. Kubera that I simply take HIS letter dated the same day (July 2) and write on the bottom "*Dear Roger – This is what I want to do".* Roger was agreeable, and said with that statement we would be able to grind again with no restrictions. I wrote the laughable note on his letter, and faxed the letter to him at 11:31 am that day. We were immediately up and running again.

I must add that only minutes earlier, Mr. Kubera had visited with Dr. Helmut Blume, the recently retired manager of the agency's District Office in Salem, Oregon, who was also acting as my consultant. Neither Dr. Blume nor Mr. Kubera has divulged to me the content of their conversation which transpired minutes before the conversation between Mr. Kubera, his associates, and me. My assumption is that Dr. Blume must have cautioned Mr. Kubera, warning that I was ready to go public, that the ConAgra recall validated my claims of the previous four months, and that the Minneapolis District Office was perilously close to being revealed as intentionally ignoring evidence which revealed the ongoing production of contaminated meat, to the detriment of public health. We may never know.

Anyway, this innocuous, window dressing conclusion to the four months from hell reveals the biased nature of the agency's current meat non-inspection program. My fax to Roger Kubera was a lie. But, a mere lie was the precise missing link allowing me to grind again.

On July 19, 2002, ConAgra's recall was expanded to include a total of 19.1 million pounds. In the weeks that followed the nationwide recall, more than 45 people in 23 states reported illnesses linked to the contaminated ground beef, and one death occurred in Ohio. The recall was necessary because of public health outbreaks which CDC traced back to ConAgra's plant. However, a secret incident also occurred which helped prompt the recall, an incident which USDA has conveniently kept under wraps. Just prior to ConAgra's recall, agency testing of ground beef at Galligan Wholesale Meat Company in Denver, Colorado, another ConAgra customer, also revealed numerous *E.coli O157:H7* positives. Unlike my plant, Galligan Wholesale Meat does not slaughter, depriving FSIS the opportunity to accuse Galligans of introducing the pathogen. Unless of course, Galligan's employees also have the same degree of inadequate personal hygiene as the agency falsely alleged against my employees.

When an initial *E.coli O157:H7* positive was detected in a sample collected by FSIS at Galligan's, the agency subsequently collected more samples as mandated by the agency's 15 sample protocol. Galligans continued to grind ConAgra meat for the agency's follow-up sampling purposes, which in fact became a point of agency contention. FSIS claimed that Galligans should present meat originating from other suppliers as well, not limiting sampling strictly to meat emanating from ConAgra. However, Galligan management eruditely perceived that ConAgra was the true source of the *E.coli O157:H7*, and to prove their point and protect consumers, they continued to present ConAgra product for sampling.

Their perception was correct, which benefitted the consuming public, because the one true source of adulterated meat was indeed discovered. Two additional lab positives were detected from sampling at Galligans, both of which emanated from ConAgra product.

It is imperative to note that FSIS investigators picked up unopened, intact chubs of ConAgra coarse ground beef at Galligans for sampling and testing at USDA labs. FSIS was unwilling to do this at my plant four months earlier, even though I offered the intact chubs to the agency at no charge. Why did FSIS test intact chubs from Galligans, but not from my plant? For one thing, FSIS had been receiving criticism and input from Montana's congressional delegation and numerous individuals on my behalf. Perhaps the agency finally realized that if it intentionally covered up the same evidence at Galligans that it did at my plant, subsequent revelations would provide bad press for the agency. And, the separate CDC investigation of the outbreak was about to reveal the ugly truth, with or without FSIS cooperation. Against its own desires and policies, FSIS reluctantly tested intact chubs from Galligans, not to protect public health, but to protect the agency's public image. The tests were positive for *E.coli O157:H7.*

FSIS did not shut down Galligans' grinder for four months, like the agency did at my plant. Why? Because the Center for Disease Control & Prevention (CDC) in Atlanta, Georgia, simultaneously and unilaterally (with no assistance from FSIS) traced unrelated adulterated meat back to ConAgra, which incidentally was also the source of the three *E.coli O157:H7* positives at Galligans. At the time of my recall, there was no public health outbreak, that is, no sicknesses caused by consumers ingesting my ground beef. Therefore, agency actions at my plant were shielded from public scrutiny, and FSIS chose to stick its head in the sand, circumventing a traceback to the true source of my contaminated meat. Four months later, when Galligans experienced multiple positives and CDC simultaneously traced public health outbreaks back to ConAgra, the agency lost its previous ability to hide its head in the sand.

The USDA Recall Press Release 055-2002, dated July 19, 2002 describing ConAgra's recall included the following statement:

> "*The Centers for Disease Control (CDC) has documented MULTIPLE* (emphasis added) *cases of illness connected to ConAgra beef that was the subject of the June 30 recall".*

Therefore, while Galligans was experiencing multiple lab positives while grinding ConAgra meat products, a public health outbreak was simultaneously occurring. Furthermore, CDC officials had successfully traced the adulterated meat back to ConAgra, an accomplishment which FSIS had ardently avoided. These historical incidents at my plant and at Galligans proved that FSIS hid its head in the sand as long as possible, until critical mass evidence was gifted to the agency from other government entities, forcing tardy FSIS enforcement actions.

Subsequent news media articles suggested that had FSIS responded appropriately to the evidence compiled at my plant the previous February, USDA should have initiated enforcement actions at ConAgra in February, 2002, and required changes which could have prevented the subsequent dozens of sicknesses, one death, and the 19.1 million pound recall. However, such agency involvement would be against the very heart of FSIS-style HACCP, which is deregulation. During my four months of hell,

numerous FSIS personnel reminded me "*Let HACCP Work*". Yes indeed, HACCP did work at my plant and at Galligans, as both plants successfully detected the presence of *E.coli O157:H7* in meat we had purchased from ConAgra. However, HACCP did NOT work at ConAgra, as revealed in the next few paragraphs.

Congress requested that the USDA Office of Inspector General (OIG) investigate the ConAgra recall. OIG investigators visited my plant for three days in August, 2002 to review all my records. OIG also investigated ConAgra, Galligan Wholesale Meat, and FSIS offices in Minneapolis and Denver. One year later, OIG released its investigative report. I am listing several verbatim statements from the OIG report, which reveal the extent of agency complicity at ConAgra prior to the recall.

> "*Data was available to both ConAgra and USDA in the period prior to the recall that indicated that E.coli contamination was becoming a CONTINUOUS PROBLEM* (emphasis added) *at ConAgra".*
>
> "*Although animal feces on product was REPEATEDLY* (emphasis added) *observed during production at ConAgra, USDA took no enforcement action".*
>
> "*USDA did not take enforcement action against ConAgra even though it continued to cite the plant for HACCP violations involving VISIBLE* (emphasis added) *fecal contamination of products".* Personal note: visible contamination is no longer of concern to FSIS, because visible contamination is accomplished via "organoleptic" (sensory) inspection, which has been outlawed by FSIS-style HACCP. The agency now prefers to audit paper flow, absent visual inspection.
>
> "*USDA Inspectors followed policies that effectively limited the documents the inspectors could review and the enforcement actions they were allowed to take*". Personal note: what else should we expect when the agency voluntarily embraced a "*Hands Off*" non-involvement role, while surrendering its previous policing ability and command and control back to the industry? Consumers are reaping what FSIS has sown.
>
> "*USDA should make recall activities more effective by ensuring that ground beef is TRACEABLE* (emphasis added) *from manufacturing to point-of-sale".* Personal note: FSIS opposes tracebacks to the big packers, for reasons delineated later in this report, all of which are linked to the agency's desire for comfort.
>
> "*USDA had reduced its oversight short of what was prudent and necessary for the protection of the consumer*". Personal note: sorry folks, but FSIS-style HACCP was NOT designed to protect consumers, but for the benefit of FSIS and the industry's biggest players.

OIG had previously warned FSIS of the agency's shortcomings in its implementation of HACCP . On June 22, 2000 (two years before ConAgra's recall), USDA's OIG issued a report on FSIS-style HACCP, which included the following statement in its Executive Summary:

"*Because FSIS was uncertain of its HACCP authorities and had not established needed procedures, it HAD REDUCED ITS OVERSIGHT BEYOND WHAT WAS PRUDENT AND NECESSARY FOR THE PROTECTION OF THE CONSUMER* (emphasis added). Personal note: the fact that OIG's wording in its 2000 report is identical to its wording in its 2003 report is not coincidental. It constitutes an embarrassing revelation that FSIS ignored OIG's warning three years earlier. Is OIG ignorant of the fact that FSIS refuses to utilize a "Hands On" role, refuses to police the industry, and has jettisoned its previous command and control authority? Consumer protection had gone the same route as organoleptic inspection…….into the dinosaur archives.

Now that we've seen how USDA's own OIG documented problems within FSIS-style HACCP and recurring problems at ConAgra, let's study ConAgra's public statements about its compliance with HACCP requirements PRIOR to their 19.1 million pound recall. ConAgra produced a document entitled "*The Strongest chain of Safety*" which includes the following statements:

> "*ConAgra Beef Company's multiple hurdle food safety intervention program has been verified through a series of scientific studies conducted by independent research scientists* (emphasis added)*, which began in 1997. Each successive study demonstrated improved results of the log reduction in E.coli bacteria".*
>
> *"Colorado State University has validated that the ConAgra Beef Company multiple hurdle food safety intervention program reduces pathogenic bacteria by 99.9999 percent".*
>
> "*Most importantly, the study* [December 1998 NCBA-supported study conducted by Colorado State University] *resulted in a 6 log or 99.9999 percent reduction in pathogenic bacteria from the live animal to the chilled carcass, virtually sterilizing the carcass. (SOURCE: Bacon et al. (1999) Colorado State University and National Cattlemen's Beef Association)"*
>
> "*ConAgra Beef Company's unparalleled carcass pasteurization program features a series of scientifically proven interventions that result in a 6 log or 99.9999 percent reduction in pathogenic bacteria from live animal to chilled carcass, VIRTUALLY STERILIZING THE CARCASS"* (emphasis added).

Virtually sterilizes carcasses? This claim does not reconcile itself with the OIG statement above which was that "*E.coli contamination was becoming a continuous problem at ConAgra*". As well as another OIG statement above "*Animal feces on product was repeatedly observed during production at ConAgra"*. Educated folks would ask why FSIS took no actions in spite of the presence of repeated observations of fecal-contaminated carcasses. Who is in charge? Who do you think?

So much for independent, third party audits/verifications of the efficacy of a plant's pathogen intervention system. This report would be remiss if it did not explain the tenuous justifications for independent third party verifications and audits. Why has our globe been deceived into thinking that public health now pivots on third party auditors? Frankly, our globe has bought into a dumbed-down, deregulated food production system absent meaningful government oversight. Since government

regulators now loathe "hands on" oversight of food facilities, the void is now filled with independent, allegedly unbiased third party auditors. We ignore the fact that any auditor who issues adverse reports will soon have no work in the industry.

These issues were addressed in a Washington Post article by Lena H. Sun on October 22, 2010, entitled "*Conflicts of interest mar food producers' independent inspection*". Some highly-revealing quotes from the article include the following:

> "*In fact, most food makers, even those with problems, sail through their inspections, said Mansour Samadpour, who owns a food-testing firm that does not perform audits. 'I have not seen a single company that has had an outbreak or recall that didn't have a series of audits with really high scores', he said"*
>
> *"That was the case with Wright County Egg and the Peanut Corp. of America, both linked to recent salmonella-related recalls. Months before the outbreaks, the same inspection firm gave both companies 'superior' food-safety ratings, the highest possible for that type of audit"*
>
> *"Industry experts say that under the best circumstances the audits can be useful. But a key failure is that auditors are typically paid by the companies they are inspecting, creating a conflict of interest for inspectors who might fear they will lose business if they don't give high ratings"*
>
> *"At a congressional hearing last month into the outbreak of salmonella illness that has sickened at 1,800 people, staff investigators revealed that Wright County Egg, one of two Iowa farms at the center of the August egg recall, had received a 'superior' rating from AIB International two months earlier. AIB also gave a 'superior' rating two years ago to Peanut Corp. of America, which federal investigators have accused of knowingly selling peanut products contaminated with salmonella bacteria that sickened hundreds and killed at least nine"*
>
> *"Wright County Egg also has said it is addressing conditions identified by FDA inspectors, who found piles of manure, live mice and dead maggots in company barns. AIB did not inspect the barns".* Personal note: sounds like FSIS, which focuses primarily on paper-flow, not on physical facilities or production lines.

I am tempted to start a new company to provide third party audits. The name of my independent auditing firm would be "*Integrity for Sale, Ltd".* An appropriate motto would be "*We've got whatever you need"*. For the right price, I'll fill your files with an avalanche of scientific reports which portray your HACCP system to be incapable of contaminating food. If the price is right, I'll validate whatever you desire. Furthermore, I'll promise to merely review your paperwork, and refuse to inspect your physical facilities. If you subsequently decide to digress from your plan, disguise your non-compliances via falsification of records. The "Hands Off" agency will never know.

The primary need for third party audits is that FSIS-style HACCP has removed FSIS from its traditional role of inspecting meat. Since FSIS won't inspect meat, someone has to do it. We can't expect the

industry to fully fill the bill, for obvious reasons. In the absence of any meaningful government oversight, we now rely on third party auditors to perform the duties previously handled by FSIS. If the agency were to reassume its previous role of inspecting production lines, we would have no need for outside third party entities.

Likewise, although independent third party experts concluded that ConAgra's highly-heralded "*Multiple Hurdle Pathogen Intervention System*" resulted in a 7-log bacterial reduction, the real truth was that "*Continuous*" and "*Repeated*" adulteration of carcasses with visible fecal material was a recurring occurrence at ConAgra. It is important to note that the USDA OIG report of the ConAgra recall also stated:

> "*USDA inspectors followed policies that effectively limited the documents the inspectors could review and the enforcement actions they were allowed to take*".

Therefore, not only did ConAgra operate with continuous production of fecal-contaminated carcasses, but FSIS itself didn't know if it had any authority to intervene, gratis FSIS-style HACCP. Therefore, FSIS didn't attempt to force ConAgra to implement corrective actions to prevent continuous and repeated fecal contamination of carcasses.

I was amongst the majority of Americans who elected Ronald Reagan, whose espousal of deregulation's benefits created a paradigm shift in how we viewed the need for government regulation, or the lack thereof. Newly emerging, mutating pathogens like *E.coli O157:H7* revealed gaping holes in Reagan's overly rosy deregulatory assumptions. Nevertheless, FSIS remains blindly committed to Reagan's faulty deregulatory claims.

I am as conservative as they get, so my statements appear to be heinous and heretical. However, I am now one of thousands of industry insiders (including FSIS field personnel) who have witnessed first-hand how FSIS has intentionally bastardized meat inspection, thereby imperiling consumers. FSIS-style HACCP has indeed deregulated the largest plants. The Big Four meat packers currently kill 88% of our feedlot-fattened steers and heifers. The risk emanating from these Big Four is substantial, and obvious. Nevertheless, the largest plants are the primary beneficiaries of the agency's "*Hands Off*" non-involvement role. Small plants lack clout, are much easier prey, and are the agency's primary target for enforcement actions. As long as American consumers unconsciously endorse the agency's overt deregulation of the largest plants, while hyper-regulating the small plants (which produce very little), ongoing outbreaks are virtually guaranteed.

Dan Murphy wrote an article on "The Meating Place" entitled "*ConAgra Beef to adopt new anti-bacterial rinsing process*" on May 10, 2002, two months BEFORE ConAgra's 19.1 million pound recall. The article described ConAgra's innovative "*Thermal Organic Rinse Process*", referred to as "TOR". The article stated that TOR provides "*bacteria reduction of 99.99999 percent*", which equates to a 7 log reduction from the live animal to the chilled carcass. Now, what does a 6 log or 7 log reduction mean?

Each log represents a 90% decrease in pathogenic bacteria loads. I'll explain it this way. Let's say there are ten million e.coli bacteria within a specified area on a manure-covered beef hide. How much does this bacteria count diminish with each successive log improvement?

10,000,000 initial bacteria load on live animals

1,000,000 represents a 1 log reduction

100,000 represents a 2 log reduction

10,000 represents a 3 log reduction

1,000 represents a 4 log reduction

100 represents a 5 log reduction

10 represents a 6 log reduction

1 represents a 7 log reduction

Therefore, ConAgra's multiple hurdle pathogen intervention system was allegedly independently validated to reduce bacterial load from 10,000,000 on live animals to 1 or less on the chilled carcass. Indeed, this would justify the claim that ConAgra's system "*virtually sterilizes carcasses"*. However, OIG's investigation of ConAgra revealed "*continuous problems"*, and that "*animal feces on product was repeatedly observed during production at ConAgra"*, as quoted above.

FSIS is now primarily focused on auditing company-generated paperwork, and not inspecting meat production lines. As stated earlier in this report, FSIS stands for Food Safety Inspection Service. It should be changed to FSAS, as in Food Safety Auditing Service. To claim that FSIS "*inspects meat*" constitutes a violation of Truth in Advertising laws.

Referring to ConAgra's claim to a 7-log reduction in pathogens, USDA's OIG essentially said the claim was but cow-a-BUNG-a Balderdash. In other words, leave your manure in the corrals. However, manure did come inside, and cross-contaminated carcasses. Nevertheless, ConAgra claimed that *E.coli O157:H7* on meat was NOT a food safety issue! This statement will be discussed in Part 4.

PART FOUR: E.COLI ARE NOT A FOOD SAFETY ISSUE!

In May, 2005, Dr. Gary Acuff, a microbiologist who heads Texas A & M's animal science department, conducted a closely controlled scientific study on my kill floor. Its purpose was to validate microbial interventions – hot water and lactic acid spray – for the reduction or elimination of enteric pathogens. The study was funded by USDA in an attempt to develop testing technologies viable for small plants to validate the effectiveness of their kill floor interventions. It involved the development of a surrogate isolate green fluorescing protein (GFP) which mimics *E.coli O157:H7*. This indicator organism demonstrated identical thermal and acid resistance to *E.coli O157H7.* On two slaughter days at my plant, the neck regions of each side of beef were intentionally inoculated with either a fresh fecal slurry [from my corrals] or a fecal slurry containing the GFP *E.coli.* Subsequent to inoculation, all carcasses were washed and placed into our chill cooler. Test results revealed that the hot water wash alone on our kill floor reduced the bacteria to an undetectable level, constituting a 4 log reduction. I was astonished that although all carcasses were intentionally inoculated with fresh manure from our corrals, as well as with the surrogate GFP isolate, we nevertheless experienced only a 4 log reduction. Admittedly, I'm no scientist, and I'm greatly surprised that anyone can experience more than a 4-log reduction, let alone a 7-log reduction.

Please note that a hot water wash BY ITSELF reduced all E.coli inoculants to a less-than-detectable level on our kill floor. Ours is a very small, very slow kill floor, in stark contrast to the fast chain-driven kill floors at the huge slaughter behemoths, which truly need all the interventions known to mankind. FSIS simply can't acknowledge that small plants don't need the compendium of costly interventions which are absolutely essential at the high speed plants. Since small plants do not have all these expensive devices, the agency concludes that small plant owners are not fully committed to food safety. Likewise, small plants haven't hired third party auditors and PhD scientific experts to independently validate the efficacy of our HACCP Plans, which of course would cost tens or hundreds of thousands of dollars to effectuate. One central problem within FSIS-style HACCP is that the agency believes a one-size-fits-all HACCP mentality should fit the entire industry. FSIS ardently avoids acknowledging that small plants, with snail-paced speeds, effectively prevent and eliminate pathogen-laced carcasses on the kill floor. FSIS-style HACCP was specifically designed to deregulate the largest plants, and to hyper-regulate small plants. FSIS is allowed to operate this bifurcated system because the agency is accountable to no one.

In September, 2002, ConAgra officials sold 54 percent of the company to private investors. The name was changed to Swift and Company at that time. After the Greeley plant was sold to Swift & Co, did Swift have better lab results? The Denver Post published an article two months later, on November 17, 2002, entitled "*USDA closes Greeley plant*". One statement in the report was:

> "*The Denver Post has learned the government had already cited the plant 19 times since late August for allowing meat to become contaminated with feces",* and that *"three of those violations occurred in the past week".*

The same Denver Post article on November 17, 2002 included the following statement:

"Swift and Co. spokesman Jim Herlihy defended the plant. "This is a regulatory issue", he said. "It is not a food safety issue".

Swift was indeed in a regulatory dilemma with the agency, for ongoing well-deserved reasons. Mr. Herlihy conveniently failed to mention that ongoing production of fecal-contaminated carcasses was the cause of this regulatory issue. At all other plants, when FSIS discovers pathogen-laced meat, the situation is always described as a food safety issue, which Swift attempted to downgrade to a mere "*regulatory issue*". Contrary to Mr. Herlihy's claim, *E.coli O157:H7* is indeed a food safety issue, even when it occurs at a Swift plant.

The same Denver Post article also included this statement:

"The USDA pulled about 15 of its inspectors Friday after finding beef carcasses smeared with feces. Inspectors said they had briefly shut down production several times in the past few weeks because of contamination, each time allowing it to resume when plant officials promised (emphasis added) *violations would not recur".*

FSIS now circumvents initiating enforcement actions based upon an innocuous "*promise"* that violations would cease. When the violations continue, well, another promise is all FSIS requires to back off again. Another premiere example of "*An Abundance of Caution*".

To better understand how FSIS allowed this conundrum to occur, we must briefly study a document issued by FSIS. On February 1, 1998, the agency issued Directive 10,010.1 entitled "*Microbiological Testing Program For Escherichia coli O157:H7 in Raw Ground Beef*". The publication explains that plants could qualify for an exemption from agency sampling of ground beef for *E.coli O157:H7*, provided that the plant met certain qualifications. One qualification was that the meat plant must conduct routine daily testing, and that the plant had not experienced a positive lab test result for the previous six months. The fact that FSIS was not collecting ground beef samples at ConAgra in 2002, but that ConAgra was conducting its own testing reveals that ConAgra qualified for the exemption. But, something doesn't make sense here: since ConAgra had to prove that it had zero lab positives for six consecutive months in order to benefit from this exemption, how could ConAgra later have a "*Continuous Problem*" as documented by OIG?

The Greeley Tribune newspaper printed an article about ConAgra on July 23, 2002, just four days after the expanded recall, which included this statement:

"*They [FSIS investigators] found contaminated meat had been processed at the plant on at least 34 days going back to April 12, said Dan Puzo of the inspection service".*

What happened to the agency's requirement for six months of zero positives? When ConAgra experienced 34 *E.coli O157:H7* positives in 100 days, did the company implement corrective actions to prevent recurrences? If ConAgra did, their corrective actions were woefully inadequate, made possible by the relative absence of any meaningful FSIS oversight. The sheer number of subsequent adverse lab

results at least leads us to think that corrective actions were NOT initiated. How could this happen? Answer: because of the FSIS deregulated HACCP Hoax, by intentional agency design.

To make matters worse, the OIG investigative report stated:

> *"From April 12, 2002 through October 21, 2002, OIG noted at least 115 e.coli positives at the ConAgra plant".*

The agency's unwillingness to confront the known source of E.coli-contaminated meat, in a timely fashion, is not allowed under the FSIS-style deregulated HACCP Hoax , which of course is "*science based*". If FSIS-style HACCP is science based, I am Darth Vader's fairy godmother.

Let's return to Directive 10,010.1 which provided the big packers exemptions from FSIS-conducted sampling & testing. The largest plants implemented HACCP on January 26, 1998. Ironically, FSIS issued Directive 10,010.1 on February 1, 1998, a mere six days later! Quick payback. FSIS used this exemption as a reward to the largest plants for their "cooperation" in voluntarily implementing HACCP. We must remember that under questioning in the mid-90's, FSIS officials stated that the "*scientific basis*" of HACCP centered on microbial testing; nevertheless, the agency discontinued testing for all practical purposes at the largest plants six days after HACCP was implemented. Science itself seemed to be changing.

Directive 10,010.1's exemption of qualified big packers from agency-conducted sampling explains why an official from the Minneapolis DO rejected my offer to provide unopened chubs of ConAgra & Cargill coarse ground beef for agency testing. Rather than sample the intact chubs, and determine the true source of adulterated meat, the agency elected not to test intact chubs of coarse ground beef for fear of litigation. This is but another example of FSIS being paralyzed with fear of litigation emanating from a large packer. Therefore, FSIS places a higher priority on protecting the agency from litigation, than on protecting consumers from unsafe food. When given a golden opportunity at my plant to conclusively determine the true source of contaminated meat, FSIS opted for the more comfortable alternative, which was to eschew litigation with large source originating plants.

The Federal Meat Inspection Act (FMIA) was passed in 1906, enabling the federal government to oversee the meat industry. Less than 100 years later, namely on January 26, 1998, FSIS voluntarily acquiesced its policing authority back to the industry, all in the name of "*Science*". While the FMIA was designed to protect consumers and promote public health, FSIS-style HACCP was designed to promote agency comfort, by deregulating the largest slaughter plants.

Another superlative example of FSIS-style HACCP's evisceration of agency authority was observed during FSIS attempted actions against Nebraska Beef in January, 2003. According to a February 20, 2003 article in Food Chemical News, FSIS wanted to withdraw inspectors because of Nebraska Beef's repeated failure to correct and implement changes in its HACCP plan. Rather than closing the plant in January, 2003, an out-of-court agreement was reached between FSIS and Nebraska Beef. A shocking revelation was made in the Food Chemical News article:

> *"Steven Cohen, spokesman for FSIS, told Food Chemical News earlier this month that the main reason the agency settled with the company was to eliminate the possibility that the plant could continue to operate under allegedly unsanitary conditions during months of litigation".*

Mr. Cohen admitted that even when FSIS inspectors observed ongoing unsanitary conditions at a plant, the agency lacked the authority to pull its inspectors. At the very least, FSIS knows that litigation is guaranteed if the agency were ever audacious enough to foolishly attempt meaningful enforcement actions against a big packer. Mr. Cohen was precisely correct, and I applaud his honesty. Since FSIS voluntarily surrendered its previous policing authority, relinquished its historical command and control power, and aggressively embraced a "Hands Off" non-involvement role, the agency knowingly abdicated its oversight role at the large plants, essentially tying its hands behind its back.

The agency's weakness at Nebraska Beef was embarrassing, and the agency had to save face somehow. Therefore, then-FSIS Administrator Dr. Garry McKee released a statement on January 27, 2003, which attempted to bolster the agency's PR image. The statement referred to the agency's mandate that Nebraska Beef comply with a series of specific requirements, including:

> *"The appointment of a full time employee responsible for overall implementation, monitoring, verification, validation, reassessment, recordkeeping, review* and maintenance of its *Sanitation Performance Standards (SPS), SSOPs and HACCP systems"*

Nebraska Beef, a plant with 1100 employees, did not have adequately trained HACCP personnel. In stark contrast, my little plant with 11 full time employees had four employees who had received official HACCP training in Salt Lake City and Kansas City, all of whom were capable of administering HACCP principles in the absence of the other three. What a difference plant size makes!

The agency's legal battles with Nebraska Beef were not yet done. In a May 8, 2003, article on Meatingplace.com, one statement included:

> "*In two lawsuits filed May 2, Nebraska Beef asked it be absolved of the conditions of the Jan. 24 agreement and alleged USDA's inspection personnel have, and continue to, treat [Nebraska Beef] in an unfair and biased manner by issuing NRs [written violation notices] for conditions that exist in plaintiff's plant while plants similar in structure and operations to plaintiff's plant, in which same conditions also exist, are not issued NRs for the occurrence of those same conditions."*

The May 7, 2003, edition of the Omaha World-Herald also carried the story, which included the following statements:

> *"Nebraska Beef Ltd. asked in a lawsuit against the USDA that it no longer be required to abide by the conditions of a settlement it reached with the agency in January. It filed a second lawsuit against individual inspectors and their supervisors."*

"Since then, Nebraska Beef has received 58 reports of noncompliance of food-safety standards by the USDA. The company cited the reports as evidence of the inspectors' bias."

"They're trying to send a message to the USDA that some people will fight them every step of the way if they try to enforce the law, said [Carol] Tucker Foreman, director of the Consumer Federation of America's Food Policy Institute, which calls for more regulation of the meat industry."

The fact that Nebraska Beef did not have a full-time HACCP trained individual on staff is but one example of a large plant with no HACCP trained employees. I attended an "*Advanced HACCP/Self Auditing for Meat and Poultry Plants*" Workshop in Los Angeles on July 8 &9, 2002, sponsored by the National Meat Association (NMA) and conducted by the HACCP Consulting Group L.L.C. The trainer was Robert A. Savage, President of the HACCP Consulting Group and a highly knowledgeable former FSIS employee. Mr. Savage explained the necessity to sell the HACCP ideal to all employees, and to train several employees at every plant. As an example, he explained how his company had been hired to provide services to a large poultry plant (he didn't divulge its name) which had over 1,000 employees. The poultry plant had originally sent one employee for official training, who then authored a HACCP Plan and related plans for the poultry plant, but did not train anyone else. This trained employee then left the company, and no one else at the company knew how the HACCP Plan should operate. Ironic, that although large plants with over 1,000 employees didn't have employees trained in HACCP, my miniscule plant with 11 employees, four of whom had official training, was so abused by agency officials who had an Alcatraz Axe to grind. Suffice it to say that the agency's treatment of small plants is biased.

Even when large plants have ongoing, recurring problems from fecal-contaminated meat, FSIS acknowledges it is walking on thin ice if it were ever to be stupid enough to attempt any kind of meaningful enforcement actions. In stark contrast, hell hath no fury like FSIS when contaminated meat is discovered at small, downstream further processing plants.

One conclusion, albeit temporary, resulting from the agency's closure of Swift's Greeley plant was that Swift agreed to slow line speeds to settle the fecal matter issue with the agency. This event was discussed in a November 26, 2002 article at Meatingplace.com. The article stated that the plant was closed by FSIS inspectors November 15 following "*repeated violations*" of the zero tolerance standard for fecal matter on carcasses. Why doesn't FSIS quickly intervene when violations are observed, but instead elects to dilly dally until repeated violations occur, or 115 positives are documented? Or, wait for a CDC or local/state epidemiological traceback, which finally forces FSIS into action? Answer: FSIS-style deregulated HACCP mandates the agency's inaction……..at large plants.

At the time of the ConAgra recall, the USDA Under-Secretary for FSIS was Elsa Murano. The July 25, 2002 World-Herald Bureau discussed the ConAgra recall, and included these quotes from then-Under-Secretary Murano:

"Because ConAgra slaughters 5,000 head of cattle and produces about 800,000 pounds of [boneless] trim daily at the Greeley plant, one or several positive E.coli tests on some days wasn't cause for alarm".

"That is not that high a number", Murano said.

I suggest to you that FSIS was incorrect when it falsely accused ConAgra of having failures in its HACCP Plan. Sanitation failures on ConAgra's kill floor created ongoing problems with fecal-contaminated carcasses. These fecal noncompliances did NOT emanated from theoretical design failures within its HACCP Plan. There is a huge distinction to be made here. If you remember nothing else from this report, it is essential you perceive what is occurring here. During the hide removal process on ConAgra's kill floor, ongoing mistakes were being made which were unwittingly depositing fecal material onto beef carcasses, as documented in the OIG report. I contend that any science-based government agency desiring to remedy this problem would intensively scrutinize all kill floor procedures, to determine where the failures were occurring, and fix the problems at the SOURCE, which is the kill floor, not a written HACCP Plan based in theory. FSIS, with all its highly paid PhD's on staff, disagrees with me. FSIS places full faith in written HACCP Plans, which is where the agency focuses its investigative efforts following a recall, an outbreak, or adverse lab results. It is imperative to realize that plants with theoretically inadequate HACCP Plans can still produce safe food (the meat industry did so prior to HACCP), while plants with superlative HACCP Plans (remember the 7 log reduction claim?) can consistently produce *E.coli O157:H7*-contaminated meat. ConAgra's debacle is but one example. Bottom line: wholesome meat does NOT require a pretty HACCP Plan, gaily decked out with alleged third party validations, scientific studies, annual certifications, Certificates of Analysis, ad nauseum. FSIS disagrees.

When introducing its perverted style of HACCP, FSIS took a triangular peg, and forcefully pounded it into a round hole. Likewise, FSIS-style HACCP does not fit into raw meat and poultry reality.

During the last nine years, I have visited with dozens of plant owners who have experienced adverse lab test findings and/or recalls, all of which resulted in investigations by FSIS. These plant owners unanimously agreed that 98% or more of FSIS time dedicated during subsequent investigations was focused on paper flow and written HACCP Plans in the office. Typically, less than 2% of investigative time was spent in an obligatory, perfunctory zip trip around the meat plant. At the end of every investigation, the impacted plant was forced to incorporate additional sentences or paragraphs into their HACCP Plan, implement microbial testing on incoming meat, and perform more paper work. The rationale behind these changes is that if the impacted plant had previously had such procedures in place, the plant would not have experienced its adverse lab test results or the recall. As such, the plant's production of *E.coli O157:H7*-laced meat was allegedly caused by the plant's inadvertent failure to include a written statement in its historical HACCP Plan! If readers chose to only remember one paragraph from this report, let it be this paragraph. FSIS investigators ardently avoid meaningful inspection of production lines at source originating slaughter plants, implying that production lines are NOT the source of bacterial contamination. Instead, FSIS claims that unsafe meat is caused by less-than-

perfect paper flow, or theoretically incomplete HACCP Plans at downstream further processing establishments. Such thinking virtually guarantees ongoing outbreaks and recurring recalls.

The agency's inability or unwillingness to adequately monitor the meat industry is not confined to ConAgra and Nebraska Beef, but is widespread, as discussed in Part 5.

PART 5 DON'T ASK, DON'T TELL ABDICATION

On October 12, 2002, Pilgrim's Pride Corporation, doing business as Wampler Foods Inc., recalled 27.4 million pounds of fresh and frozen ready-to-eat turkey and chicken products potentially contaminated with *Listeria monocytogenes.* The recall was prompted by a product sample taken by FSIS at the facility that tested positive for *Listeria monocytongenes*. Subsequent news articles revealed that USDA-style HACCP thwarted the agency's inspection force from taking meaningful enforcement actions. The FSIS, along with the Centers for Disease Control and Prevention, linked Pilgrim's Pride poultry to a listeria outbreak that caused eight deaths, three miscarriages and 45 more illnesses, mainly in the Northeast.

FSIS officials stated that Pilgrim's Pride knew the listeria bacteria was present at its Pennsylvania poultry plant months before its products were blamed for killing eight people in the summer of 2002. Vincent Erthal, who was a federal inspector for the night shift at the Wampler plant until September of 2002, said the company had found an "*exceedingly high*" number of listeria bacteria in the plant months before the recall. "*This should have been avoided*," Erthal told Reuters. "*The plant knew they had a problem. They dragged their feet"*. Erthal also told Associated Press that he blamed Agricultural inspectors because of their uncertainty over intervention when harmful bacteria were discovered. A December 11, 2002 New York Times article stated "*But the inspector, Vincent Erthal, said inspection officials had failed to crack down on some of the problems in part because of what he and other critics see as confusion and indecision in a new federal system for regulating the nation's food companies".*

Another news report stated that some congressmen were concerned to have learned the plant had conducted its own environmental tests for the deadly bacteria and found positive results but failed to disclose this information to FSIS inspectors at the time of the testing.

Such statements constitute a disturbing trend. News reports after ConAgra's recall also revealed confusion within inspection ranks as to what authority the agency had, and companies' unwillingness to share test results with the agency.

USDA Undersecretary Elsa Murano said Pilgrim's Pride employees had routinely tested for listeria and found "*a spike*" in July and August for its presence. However, the company did not share the information with FSIS because federal regulations did not require companies to test for the bacteria.

A subsequent article in Food Chemical News on January 27, 2003 related how a coalition of public interest groups charged USDA with unfair treatment of an inspector-turned-whistleblower. The article stated in part:

> *"Vincent Erthal has received treatment by senior agriculture officials that unfairly discredits him, could tend to diminish public interest in his allegations, and consequently, unjustly threatens the integrity of honest public debate, the group wrote in a letter to Agriculture Secretary Ann Veneman".*

"The letter says that Erthal repeatedly warned his supervisors of conditions at the facility that lead to the largest recall in history, and on two occasions recommended that FSIS management initiate strong enforcement action".

"The only crime Vince Erthal is guilty of is being a serial truth teller, said Felicia Nestor, food safety coordinator for GAP. The USDA's shameful treatment of him sends a chilling warning signal to all those who might have to weigh whether acting in the public's interest is a career stopper".

The previously-mentioned December 11, 2002, New York Times article also stated:

"Mr. Erthal, 40, who has been a meat inspector for 18 years, said the new rules have a lot of gray areas. He said inspectors were still taught to step in quickly at any sign of direct contamination. But when it comes to broader sanitation problems, he and others said, many inspectors are waiting longer to intervene out of a sense that <u>it is now the company's role to deal with those issues</u> (emphasis added) unless there are repeated failures". (Personal note: we are continually reminded to "Let HACCP Work")

"Rodney Leonard, a former administrator of the inspection service, said the result is a clear 'don't ask, don't tell mandate' that is causing inspectors to miss red flags all over the place". Personal note: how can inspectors ask or tell, when the agency aggressively embraces a "*Hands Off*" non-involvement role, no longer authorized to police the industry or to utilize its previous command and control authority? FSIS-style HACCP has many gray areas.

"Representative Henry A. Waxman, Democrat of California and the ranking minority member on the House Committee on Government Reform, said "I think what we're seeing is a picture of a department that has abdicated its responsibility to protect the public in the area of food safety".

Another New York Times report dated October 10, 2003, continued to reveal systemic problems within FSIS-style HACCP. This article focused on ongoing fecal contamination of carcasses at the Shapiro Packing Company in Augusta, Georgia, which slaughters 1,200 or more cattle each day, with more than 700 employees. The article includes the following statements:

"Government inspectors monitoring the automated processing line at the Shapiro Packing meat plant here over the past three years <u>repeatedly</u> (emphasis added) *discovered sides of beef mottled with cattle manure".*

"According to government inspection reports, on more than 50 days from early 2001 until July, inspectors at the Shapiro Packing plant found feces on carcasses moving down the processing line. Its meat ends up in schools, supermarkets and fast-food restaurants across the country".

"On 11 days the inspectors at the plant even found the manure on numerous carcasses that had already been through special cleansing washes of hot water and acid".

"In the last five months of 2002, inspectors found fecal contamination [on carcasses] about every 12 days".

"This year brought little improvement. Government inspectors found feces on 12 days in the first six months of 2003. But the documents show that the company's own employees discovered far more. In January and May, Shapiro employees found feces on meat about every other day".

"The employees, who spoke on the condition of anonymity, said that some inspectors became frustrated that their superiors appeared to ignore problems that they had carefully detailed in documents called noncompliance reports, which are commonly referred to as N.R.'s Personal note: This is eerily similar to statements found in USDA's OIG' criticism of FSIS lack of oversight at ConAgra in 2002.

What were FSIS responses to the variety of inspector documentations of ongoing fecal contamination of carcasses? The same New York Times article stated:

"In March, a safety officer visited Shapiro's slaughterhouse to monitor its E.coli controls. The officer took no action, even though the documents show that inspectors had already reported fecal and other contamination of meat on 13 days in the first two months of the year".

"Last November the inspectors also found E.coli O157:H7, a dangerous bacterium spread by cattle waste, in hamburger and stopped a shipment waiting to go to public schools from a Shapiro meat-grinding facility. Yet the Department of Agriculture delayed more forceful actions and never did more than threaten to shut the packing plant down".

Recurring examples of FSIS' systemic inaction at source slaughter plants, in spite of ongoing production of fecal-contaminated carcasses, have become commonplace. The agency intentionally relegated itself to the role of a disinterested bystander when it mandated its style of HACCP at all USDA-inspected plants. Furthermore, FSIS kept its inspectors in the dark regarding their authority under the new FSIS-style HACCP. During the mid-late 90's, FSIS officials publicly stated that the agency would train inspectors in HACCP protocol using a "*Just in Time*" methodology. As late as 2002 & 2003, inspectors at my plant kept asking me for HACCP answers, admitting that they had received precious little training yet. Inspectors nationwide were forced to ask plant management for advice on how HACCP is to work, both for the agency and for the industry. Lack of inspector training was discussed on page 10 in the December, 2002 edition of Meat Marketing and Technology (MMT), which interviewed Dr. Garry McKee, the new FSIS Administrator. The discourse went like this:

MMT: "Some point to the inconsistencies in HACCP interpretation between line inspectors and supervisors as evidence that field personnel haven't been trained properly. How do you respond to that"?

McKee: "Inspector training is a serious issue; I don't deny that. More training is scheduled, and one of my top goals is that all inspectors better understand HACCP".

Interestingly, almost five years after the large plants rolled out HACCP, FSIS had not yet adequately trained its inspectors. In many cases, the industry was performing the training.

Six months later, Dr. McKee wrote an article which appeared in the June, 2003 edition of Meat Processing. One of his statements was as follows:

> *"One of our top priorities is to cultivate a highly trained and educated workforce. Funding in our FY 2004 budget now before Congress provides specialized food-safety training to inspectors and other food-safety professionals. In addition, FSIS issued a new directive to its employees that will provide FSIS field personnel with greater understanding and knowledge about their role and responsibilities in safeguarding the American food supply. <u>This is the first set of comprehensive instructions given to inspectors since the inception of HACCP in 1997</u>. (Emphasis added)*

In the mind of FSIS, this is "*just in time*" training. 1997 to 2003 doesn't qualify for "just in time".

Several months later, Dr. McKee made some interesting comments to a conference of agency supervisors in Nashville, TN, on October 27, 2003. Various news articles included the following quotes:

> *"McKee said he is tired of reading articles that quote inspectors as saying they don't have the authority to take action against a plant that's violating its own HACCP plan or FSIS regulations".*
>
> *"Or isn't it likely that something is amiss in a plant that gets a lot of positives for E.coli O157:H7 and that maybe we should do something about it on a system-wide basis? he asked, referring to the repeated positives at the ConAgra plant".*
>
> *"And lately, there have been many illogical and unnecessary failures".*
>
> *"As for reaction from the inspectors, Stan Painter, chairman of the National Joint Council of Food Inspection Locals, said "it all sounds good and wonderful that inspectors have all these rights and authority, but that's not what's happening." Painter said that supervisors "think they're God,", and that they don't want to relinquish any authority to underlings who don't have veterinary degrees. Supervisors think inspectors don't have the knowledge, skills or ability to make decisions, Painter told Food Chemical News."*
>
> *"Painter pointed to the fact that in some plants, inspectors can't call a fecal failure on their own. They have to wait until their supervisors say "this is fecal material", Painter said. If inspectors can't even call fecal material, what action can they take beyond that?"*

One article stated:

> *"The speech….was starkly honest about FSIS gaffes and was filled with admonitions that the inspection force must be more responsible and accountable".*

The November 11, 2003 edition of USA Today made this quote from Dr. McKee's speech:

"Protecting public health is more than filling out forms. It involves taking responsibility, McKee said".

Dr. McKee's tenure as FSIS Administrator was short-lived. My personal perception is that his demand for personal responsibility being more important than filling out forms may have been his agency death knell. FSIS-style HACCP is all about paper work, totally divorced from personal responsibility, which would dictate that recurring instances of fecal-contaminated carcasses should justify agency intervention. FSIS-style HACCP makes no allowance for common sense, or personal responsibility. FSIS-style HACCP also insulates the agency from any accountability, since the deregulated industry can now operate in the relative absence of any meaningful government oversight.

FSIS has changed some policies which now allow agency access to results of company-conducted testing, found in FSIS Notice 54-03 released on December 16, 2003, in FSIS Notice 39-08 released on June 6, 2008, and in FSIS Directive 5000.2, Rev 2 released on December 4, 2008. FSIS Notice 58-10, which was released on October 8, 2010, now requires inspectors to collect supplier information at the time of sample collection. However, these changes have not dramatically reduced the number of outbreaks and recalls.

This report has quoted media articles revealing inadequate agency oversight at ConAgra, Pilgrims Pride, Nebraska Beef and Shapiro Packing in 2002 & 2003. Both FSIS and the industry initiated changes since 2003, which resulted in a diminution of outbreaks and recalls in 2004, 2005, & 2006. The year 2007 brought us back to reality, during which numerous outbreaks and recalls occurred, which have in fact persisted to the present day. Recalls in 2007 through 2011 are numerous, constantly reminding us that FSIS-style HACCP is not the scientific panacea as originally suggested, and direly needs dramatic mid-course corrective actions itself. Following is an incomplete but interesting listing of some of the largest *E.coli* and *Salmonella* recalls we've experienced during the last five years:

June 6, 2007	United Food Groups	5.7 million lbs	*E.coli O157:H7*
Nov 1, 2007	General Mills	3.3 million lbs (Pizza Products)	*E.coli O157:H7*
Nov 3, 2007	Cargill	1,084,384 lbs	*E.coli O157:H7*
Oct 6, 2007	Cargill	845,000 lbs	*E.coli O157:H7*
April 20, 2007	HFX Inc	259,230 lbs	*E.coli O157:H7*
Oct 13, 2007	J & B Meats	173,554 lbs	*E.coli O157:H7*
July 3, 2008	Nebraska Beef	5.3 million lbs	*E.coli O157:H7*
June 25, 2008	The Kroger Co.	1,613,122 lbs	*E.coli O157:H7*
Aug 14, 2008	Nebraska Beef	1.36 million lbs	*E.coli O157:H7*

May 16, 2008	JSM Meat Holdings	345,000 lbs	*E.coli 0157:H7*
January 12, 2008	Rochester Meat Co	188,000 lbs	*E.coli O157:H7*
Aug 6, 2009	Beef Packers	825,769 lbs	*Salmonella*
July 22, 2009	KINGS Soopers	466,236 lbs	*Salmonella*
June 28, 2009	JBS Swift	380,000 lbs	*E.coli O157:H7*
Dec 24, 2009	National Steak	248,000 lbs	*E.coli O157:H7*
May 21, 2009	Valley Meats	95,898 lbs	*E.coli O157:H7*
Jan 18, 2010	Huntington Meat	864,000 lbs	*E.coli O157:H7*
Feb 12, 2010	Huntington Meat	4.9 million lbs	ADULTERATED

(Please see the next paragraph below which describes what is meant by "ADULTERATED" in this unusual situation at Huntington Meat)

Jan 23, 2010	Danielle International	1,263,754 lbs	*Salmonella*
Aug 6, 2010	Valley Meat Co	1 million lbs	*E.coli O157:H7*
April 21, 2010	Beltex Corp	135,000 lbs	*E.coli O157*:H7
April 1, 2011	Jennie-O Turkey	54,960 lbs	*Salmonella*
March 22, 2011	Palmyra Bologna Co	23,000 lbs	*E.coli O157:H7*
March 8, 2011	Creekstone Farms	14,158 lbs	*E.coli O157:H7*
Feb 5, 2011	American Food	3,170 lbs	*E.coli O157:H7*

The afore-mentioned recall dated February 12, 2010 at Huntington Meat Packing was an expansion of its earlier January 18 recall. The initial recall covered 864,000 lbs of beef products which may have been contaminated with *E.coli O157:H7*. Interestingly, the expanded 4.9 million lb recall was not for *E.coli*, but for the classification "*Adulterated"*. A news article in the February 15 edition of "Food Production Daily" provides the following interesting data:

> *"Huntington Meat Packing Inc has recalled a further 4.9 million pounds of meat that was not processed in line with the company's HACCP plan over the course of almost a year, said US authorities"*

"The products are adulterated(emphasis added) because the company made the products under insanitary conditions failing to take the steps it had determined were necessary to produce safe products, said an FSIS statement"

"This evidence shows that the products subject to this recall expansion were produced in a manner that did not follow the establishment's Hazard Analysis and Critical Control Points (HACCP) plan, it added"

It is interesting to note that FSIS concluded that since the company did not fully comply with its HACCP Plan, all product produced during the period of noncompliance was "*Adulterated*" over almost a full year. Even though FSIS inspection personnel were at the plant every day during the noncompliance time frame, the inspection force did not observe any insanitary conditions during the entire year. This lack of adequate agency oversight of alleged long-term insanitary conditions at the plant is not reassuring to public health interests. The agency's allegation of insanitary conditions and recurring "*Adulteration*" of products for almost a full year (occurring directly under the agency's nose) reveals that the primary god FSIS serves is the company's HACCP Plan, demoting the agency to that of an auditor of paperwork, absent any meaningful oversight of meat production lines. This serves as another example that FSIS perceives that unsafe food is produced by noncompliance with written HACCP Plans, and not by insanitary meat production lines. Please note also that Huntington Meat Packing does NOT slaughter, but merely further processes meat purchased from source slaughter providers. Therefore, since FSIS concludes that all meat Huntington produced during the year of noncompliance is "Adulterated", we must conclude that Huntington purchased previously-contaminated meat from its source slaughter providers for almost a full year. I am not aware that the agency initiated any enforcement actions against Huntington's source slaughter providers, but focused all its enforcement actions against Huntington. Not because Huntington introduced adulterants into its meat, but because it did not fully comply with its HACCP Plan. This is a most important distinction, which awkwardly reveals the agency's misguided focus, gratis FSIS-style HACCP.

Huntington's initial recall was for 864,000 lbs of meat possibly adulterated with *E.coli O157:H7*, which Huntington unwittingly purchased from source slaughter providers. In the aftermath of the ensuing extension of the expanded 4.9 million pounds of additional meat, did the agency's intensive investigation ever determine the true slaughter house SOURCE of the pathogen? No. The source of the *E.coli O157:H7* was never determined; therefore, no corrective actions were required at the source, guaranteeing that public health continues to be imperiled.

The majority of *E.coli* and *Salmonella* recalls this century occurred at plants which have been fully compliant with their written HACCP Plans. If this was not the case, FSIS would have mandated expanded recalls in all cases, justified by the plants' noncompliance with their HACCP Plans. Therefore, we must admit that the vast majority of recalls and outbreaks have been caused not by HACCP Plan failures, but because these pesky enteric bacteria continue to circumvent the best of HACCP Plans and furtively escape into the food chain, all caused by sloppy dressing procedures on the kill floor. Admittedly, since Huntington was caught in the act of intentionally not complying with its written HACCP Plan, the plant is

liable for administrative deficiencies and must face agency enforcement actions. However, the agency's "suggestion" to recall an additional 4.9 million pounds of meat only resolved the administrative noncompliance, with limited if any benefit for safe food considerations. But the 4.9 million lb recall expansion certainly provided PR benefits for FSIS. Who cares if the expanded recall has any benefit for consumers?

Four of the above recalls are still in the agency's "Active File", meaning the recalls have not been completed, which would have allowed the recalls to be retired to the agency's archives. The February 12, 2010 recall from Huntington Meat Packing is still active, as is the April 21, 2010 recall from Beltex Corp. Interestingly, both of these recalls are over 13 months old, but have yet to be closed out. Both the March 22, 2011 and the April 1, 2011 recalls are likewise still open.

However, both FSIS and the industry's biggest packers are in full agreement that consumers are THE ULTIMATE THREAT to food safety, and that consumers must step up to the plate and accept responsibility for these ongoing outbreaks. This attitude by FSIS and the industry's biggest players will be described in Part 6.

PART 6 LAZY CONSUMERS!

How does our industry respond to the issues of *E.coli O157:H7*-laced meat, sicknesses and deaths? For one, we demand "*Show me the graves!*" I suggest that our industry suffers a black eye when we ask for a tour of the *E.coli* cemeteries, or claim that several e.coli positives per day at large slaughter plants are not cause for alarm as claimed by the former USDA Under-Secretary Elsa Murano. Try posing these excuses to Stephanie Smith, Michael & Barbara Kowalczyk, Nancy Donley, or hundreds of other impacted families. Our industry is justifiably viewed as callous to consumer interests when our perennial fallback position is to remind consumers that they are ultimately responsible to fully cook our contaminated meat. As such, we immunize ourselves from the responsibility to produce feces-free meat, and mandate that all our ignoramus customers fully cook our invisible manure.

How does FSIS respond to the same issues? At an industry conference in Chicago on September 16 & 17, 2008, the agency clarified its view on *E.coli O157:H7* testing results. In a PowerPoint given by Dr. Daniel Engeljohn from the agency's Policy & Program Development staff, the following interesting statement was given to the conference's participants under the Heading "*FSIS Framework for Event Days*":

> "*2 in 24 or 4 in 98 N60 samples could represent a cluster of positives potentially (emphasis added) evidencing insanitary conditions".*

The term "*Event Day*" is much worse than a bad hair day. To FSIS, an "*Event Day*" signifies that on one day, a plant experiences a high number of food safety violations such that the agency would be justified to initiate enforcement actions against the plant. For simplicity purposes, the agency stated that if 4 out of 98 tests (4.1%) of boneless trimmings were positive for *E.coli O157:H7*, these lab results could "*potentially*" indicate insanitary conditions at the plant. Not a definitive indication of insanitary conditions, only "potentially". Therefore, if only 3 out of 98 tests were adverse, that a mere 3.1% positive ratio would NOT indicate a potentially insanitary condition at the plant

In 1994, FSIS published its "Adulterant Rule", classifying *E.coli O157:H7* in raw ground beef as an adulterant, making the production of meat laced with *E.coli O157:H7* a felony. As a result, plants are less willing to test for the pathogen, even less willing to release results to FSIS. This plight is especially exacerbated at downstream further processing plants. When tests at such downline grinding plants are positive for E.coli O157:H7, true science would dictate that an unrestricted search for the SOURCE of the *E.coli* commence immediately. Unfortunately, the history of FSIS actions in such cases reveal that the investigations commence, and finish, at the further processing plant.

The cause of Public Health will benefit from:

1. Tracebacks to the SOURCE
2. Require the SOURCE to implement corrective actions

3. All non-*O157:H7* Shiga-Toxin producing E.coli (STEC's) should be classified by FSIS in the same category as *O157:H7.* They are all lethal killers. Since CDC statistics show that Salmonella kills ten times more Americans every year than *E.coli O157:H7*, *Salmonella* belongs in the same classification. This will force FSIS to reconsider its ill-designed Zero Tolerance Policy: there is always room for the truth to come forward.

Frankly, we need to develop incentives for all plants, especially slaughter plants, to test for STEC's, and provide all results to FSIS. Adverse lab positives need to be traced back to the one particular step in the production process which failed. Then, slaughter establishments must devise a stratagem to REDUCE such contamination, realizing that full removal of pathogens will probably be impossible, at least in raw meat and poultry. As long as the slaughter plants are transparent with FSIS in their pathogen intervention steps and test results, and continue to experience a gradual trend of improvement in controlling STEC's, FSIS should not charge them with felonies. Granted, slaughter plants must still be held fully responsible for pathogens which slip through the cracks, get shipped into commerce, and cause consumer illnesses.

Therefore, just how beneficial was the agency's classifying E.coli O157:H7 as an "adulterant"? We still experience ongoing outbreaks and recurring recalls. Plants are reluctant to share test results. FSIS still primarily focuses its investigations at the downstream Destination plants, rather than at the Source slaughter plants. Frankly, we can't REGULATE our way to safe food. However, FSIS desires to REGULATE its way to Food Safety, because it no longer wants to INSPECT its way to Food Safety. The issuance of a Regulation is much easier and more comfortable for the agency, compared to intensive inspection of meat production lines. It is interesting to note that Pillsbury's HACCP protocol was always meant to be a voluntary system, for plants which qualify, requiring kill steps. FSIS however mandates that ALL USDA-inspected plants implement FSIS-style HACCP, even those which produce raw meat, which automatically disqualifies them from true HACCP. I've heard no one defend the idea of Zero Tolerance in raw meat and poultry.

If we can indeed mandate or regulate our way to safe food, then FSIS should mandate that all E.coli O157:H7 bacteria be homogenously dispersed throughout a batch of meat prior to sampling, ensuring that the pathogen will be detected in the lab test. This would be impractical and impossible. It does show however that we can't regulate our way to consistently safe food in raw meat and poultry. We need a partnership between the industry and the agency. Sadly, FSIS-style HACCP prevents such a partnership since the agency must be "Hands Off". An (1) open dialogue, (2) true science, (3) transparency, and (4) empowering inspectors to document visible insanitary conditions will be much more successful to promote public health goals than broadly-sweeping agency regulatory actions. None of these 4 exists under FSIS-style HACCP.

The PowerPoint presentation released in Chicago revealed that the agency openly allows E.coli at a level less than 4.1%, and that its Zero Tolerance mandate is history, at least at the big plants. These statistics also reveal that the agency concludes that an "*Event Day*" required for the agency to initiate enforcement actions requires that at least 4.1% of tests are positive for *E.coli 0157:H7*, and that such a

percentage only constitutes a day which "*could potentially*" reveal insanitary conditions. It also means that when *E. coli O157:H7* is detected in only 3.1% or less of tests, that the pathogen really isn't a danger, probably incapable of injuring a consumer, so the agency ignores its presence.

I felt that FSIS was overly kind to the industry when the agency publicly admitted that a 3.1% positive ratio is essentially no cause for concern. So, how did the industry respond to this liberalized agency stance of disinterest? At a FSIS-sponsored public hearing to discuss Tracebacks on March 10, 2010, the American Meat Institute (AMI) provided public comments, which included the following statement:

> *"AMI remains committed that the predetermined number of positive test results to describe a high event period for an establishment, as previously mentioned by FSIS, has no basis"*

Shockingly, AMI is not content with the agency's free gift of 3.1% positives. To add insult to consumer injury, AMI contends that its member plants should have the right to experience more than a 3.1% incidence of positive test results before FSIS has the right to confront the plant's adverse lab findings. As stated earlier, USDA Undersecretary Elsa Murano stated that ConAgra produced 800,000 pounds of boneless trim daily. 3.1% of 800,000 pounds is 24,800 pounds of E.coli-contaminated meat which could be shipped daily from one plant, with tacit FSIS endorsement, with no need for FSIS enforcement action or corrective actions at the plant. "*That is not that high a number*", again quoting Elsa Murano. Once we understand this agency stance, why did FSIS shutter my grinder for four months, over 270 pounds? Why has FSIS initiated aggressive enforcement actions against dozens of other small plants for producing infinitesimally smaller volumes of ground beef? Answer: "*Hands Off*"……for large plants. Size covers a multitude of sins.

Unfortunately, historical agency statements tend to side with AMI's stance. For example, FSIS sent a letter to nine industry associations on March 19, 2010 regarding the need for meat plants to validate the efficacy of their individual HACCP Plans. The letter made several references to the need for downstream further processing plants to test incoming meat (from source slaughter providers) for the presence of pathogens. Examples include:

> "*For example, collecting data on initial* (emphasis added) *and finished product microbial loads using an appropriate indicator to demonstrate a log reduction capability….."* Interpretation: FSIS wants further processing plants to test incoming meat purchased from source slaughter providers, even though the incoming meat bears the official USDA Mark of Inspection, and the meat emanated from a plant with a validated HACCP Plan.
>
> "*These data can be used to demonstrate that a process, as designed, will mitigate to a specified extent a food safety hazard occurring in the raw materials that the establishment typically receives*"(emphasis added). Interpretation: FSIS admits that incoming raw materials which arrive at downstream further processing plants frequently harbor invisible food safety hazards.
>
> *"These* [microbial] *data can be used to determine whether the process is able to reduce the level of pathogens associated with the raw materials received at the establishment*…" (emphasis

added). In repeated admissions, FSIS acknowledges that pathogen-laced meat is being shipped into commerce, destined for downstream further processing plants. What is the solution to this obvious public health danger? Answer: FSIS contends that the downstream destination plants are responsible to (a) detect and (b) remove the invisible pathogens from incoming meat. Why? Because FSIS now allows the source slaughter plants to produce up to 3.1% OR MORE of its meat with pathogens, even adulterants, and the agency refuses to confront the large source slaughter plants with meaningful enforcement actions. The small downstream plants are much easier enforcement prey, and can be easily manipulated. Interestingly, although neither the source slaughter plant nor FSIS were able to (a)detect or (b) remove pathogens at the source, the agency now expects downstream plants to accomplish both of these functions. Another reason for this crazier-than-fiction soap opera is because FSIS proactively embraces its "Hands Off" non-involvement, semi-retirement role at the large source slaughter plants.

The March 19, 2010 Validation Letter also refers to a "*Prudent Establishment*", which is but a continuation of the agency's historical expectations at so-called "*Prudent"* downstream further processing establishments. In a letter issued by Dr. Kenneth Petersen, then-Deputy Assistant Administrator in the agency's Office of Field Operations on June 2, 2003, the following statement is found:

> "*I would expect a* <u>*prudent*</u> (emphasis added*) establishment to have appropriate procedures to determine product acceptability prior to receiving the product*". Interpretation: prudent establishments must maintain full control over the wholesomeness of incoming meat, PRIOR to their reception of the meat. Small downstream plants which are the Destination of meat emanating from SOURCE supplier slaughter plants have virtually NO control over sanitation conditions at their supplier plants.

Bottom line: FSIS openly allows the production of pathogen-laced meat at the large source slaughter provider plants, and now demands that the small, downstream plants sanitize the incoming meat which is already laced with pathogens. FSIS knowingly allows the horses out of the barn, then dedicates agency resources to detect the horses out in commerce somewhere. This ugly fact was publicly debated during litigation between Excel, Sizzler's Restaurant, and the Estate of Brianna Kriefall. Brianna died of *E.coli O157:H7* complications at the age of six, after having eaten at a Sizzler's restaurant. The investigation revealed that the *E.coli* emanated from Beef Tri Tips which the restaurant had purchased from Excel's slaughter plant in Fort Morgan, CO. In a superlative article written of the trial by attorney Denis Stearns, the following statements were made:

> *"The uniform national standards governing the production of raw meat expressly provide that whole-intact meat containing E.coli may be distributed for consumption in interstate commerce. This is because, although pathogenic bacteria (such as E.coli) occurs naturally in the production of meat (and is virtually impossible to avoid), safe food-handling readily destroy the bacteria. Instead of requiring meat producers to do the impossible (by completely eliminating pathogenic*

bacteria), the federal government relies on the end-user to follow safe food-handling practices to avoid the dangers associated with raw meat".

"In short, according to Excel and its Meat Industry cohorts, the federal government affirmatively authorized the distribution of meat contaminated with E.coli O157:H7, and provided that it was the consumer's responsibility to ensure the safety of the meat consumed".

Excel and its meat industry cohorts were precisely correct in its legal claim that *E.coli O157:H7* is virtually impossible to avoid, but they failed to further explain that such impossibility applies only to raw meat and poultry. *E.coli O157:H7* is killed in Pillsbury-style HACCP Plans, because they utilize a Kill Step. USDA-style HACCP does not require a Kill Step; nevertheless, FSIS attempts to qualm consumer concerns by assuring us that all meat and poultry (including RAW) is produced under HACCP's scientific umbrella, so it must be wholesome. By classifying *E.coli O157:H7* as an "adulterant", and disingenuously claiming a "Zero Tolerance" stance against the pathogen, FSIS gives the impression that the agency can regulate the pathogen out of existence…..even in raw meat and poultry. After thirteen years of FSIS-style HACCP, we should be fully cognizant that safety cannot be <u>regulated</u> into meat!

Let me explain this in layman's terms. Excel was correct in its claim that FSIS expressly authorizes the source originating slaughter plants to ship into commerce intact cuts of meat which are surface-contaminated with E.coli 0157:H7. But to explain the implications of this short-sighted agency policy, let's follow the trail of the intact cut of meat, and review what happens to these *E.coli O157:H7* bacteria which are found on the surface of intact meat cuts shipped into commerce by the source originating slaughter plants, with full agency endorsement.

Let's assume a retail meat market purchases beef Top Inside Rounds, which are an intact cut of meat. Let's further assume that *E.coli 0157:H7* bacteria reside on the exterior surface of the intact Top Round cuts. An employee of the meat market opens the vacuum pack bag in which the intact cut of meat is packaged, removes the meat, throws the empty bag away, and places the meat on his/her meat cutting table or power saw for processing. At this point in time, the E.coli bacteria have already cross contaminated the meat cutter's gloves, apron, the cutting table, and the power saw. The meat cutter deftly processes the meat into round steak, round roasts, cube steaks, stew, and the trimmings go into ground beef. A meat wrapper then wraps the pieces, and places the finished product into the meat case. Now, the E.coli have likewise cross contaminated the meat wrapper's gloves and apron, as well as the wrapping station. Unfortunately, the bacteria are now on the meat cutter's knife (blade and handle both), as well as on the power saw when the saw is used. All meat which subsequently comes in contact later that day with the employees' aprons and gloves, knives, the wrapping table, the power saws and cutting tables are highly likely to pick up residual E.coli bacteria. We must ask ourselves: do we now expect both the meat cutter and wrapper to change or sterilize their gloves, aprons, knives, saws, cutting tables, and wrapping station before processing the next item? Realizing that a meat market can process hundreds of meat cuts daily, the inefficiencies required to conduct such sanitizing constitute an impractical alternative.

One FSIS official told me that trimmings (called "bench trim") derived from processing such intact cuts should be "*tanked*", that is, destroyed. Why? In his own words, because the trimmings emanating from intact cuts are "*High Risk*". How can this be? The large source slaughter plants all have FSIS-approved HACCP Plans, have multiple hurdle intervention systems on their kill floors (remember ConAgra's 7-log reduction claim), have validations performed by impartial and independent outside third parties which prove that the HACCP Plans successfully produce consistently safe food, virtually sterilizes carcasses, have a superlative cold chain program, etc etc. Therefore, how can FSIS officials state that bench trimmings emanating from further processing intact cuts from these state-of-the-art, cutting edge, scientifically marvelous slaughter plants be "*High Risk*"? I must interject here that E.coli come from animals' intestines and manure-covered hides. Retail meat markets, restaurants, hospital cafeterias and the majority of USDA-inspected plants do not have intestines or hides on their premises. Therefore, the very act of further processing intact cuts does not INTRODUCE E.coli, a most important distinction. Instead, invisible *E.coli 0157:H7* bacteria arrive at the retail meat market already residing on the exterior of intact cuts, in boneless trimmings and in coarse ground beef. When the cuts are further processed, a veritable chain reaction of cross contamination occurs, which can cross contaminate all product subsequently processed on the equipment later in the day. If indeed the trimmings are "High Risk", as the agency claims, this means the boxed beef is "High Risk" when it arrives at the retail meat market. FSIS contends that the boxed beef laced with *E.coli O157:H7* is wholesome, but that the act of further processing adulterates the meat. It works like this:

FSIS believes that *E.coli O157:H7* residing on the exterior of intact cuts are relatively harmless "*contaminants*". But, during further processing activities, these heretofore harmless bugs somehow supernaturally morph into lethal "*adulterants",* all because of further processing activities. This is the precise legal argument made by Excel and the meat industry in the Sizzlers litigation. We now understand precisely why FSIS sent out its ill-fated "Validation Letter" on March 19, 2010, requiring downstream further processing establishments to test incoming products purchased from the source slaughter plants. We can now understand why the agency contends that bench trimmings derived from processing intact cuts are "*High Risk*". In actuality, ALL meat emanating from high-speed source slaughter plants is high risk, enjoying the agency's full endorsement as these "USDA Inspected and Passed" pathogens course through commerce.

Consumers also purchase intact cuts, such as Rib Eyes, Tenderloin, Sirloin Butts, New York Strips, Briskets, etc to take home. The identical cross contamination scenario is duplicated in thousands of consumer kitchens daily. When the consumer removes the meat from the vacuum bag, and throws the bag into the garbage, drops of contaminated liquid fall to the floor and onto the counter top. Baby Susie crawls by thereafter, innocently placing her hands on the juices (which according to FSIS are harmless), and then puts her hand into her mouth. Consumers have been falsely led to believe that the USDA Mark of Inspection has a connection with safe, sanitary food.

Let's go back to the agency's suggestion that all bench trim should be destroyed. What impact would this agency idea have on my miniscule very small plant? One item we made was a beef steak strip, just like a chicken strip, only made from beef inside top rounds. One 8-hour shift produced 700 pounds of

round steak trimmings, which makes beautifully textured 85% lean ground round. At today's prices, 700 pounds of such ground beef has a value of over $1400, which the agency spokesman says should be destroyed. Well, it would quickly destroy my plant's ability to survive. Is America to blithely destroy good food, all because FSIS allows source slaughter plants to ship into commerce intact cuts of meat which are knowingly contaminated with *E.coli O157:H7?*

At an industry conference in Chicago on Sept 16 & 17, 2008, then-USDA Under Secretary Dr. Richard Raymond was the speaker at the noon luncheon on the 17th. He stated that the agency had conducted a microbial sampling experiment, in which the agency opened twenty-four packages of intact vacuum-packed meat and tested them for *E.coli 0157:H7*. Shockingly, meat in eight of the twenty-four packages tested positive for *E.coli O157:H7*, and six of the eight were loin cuts. Indeed, we can better understand why the agency contends that trimmings emanating from further processing of boxed beef are high risk, whereas the boxed beef itself should be considered high risk. I subsequently have requested FSIS on two occasions to provide me details of this agency experiment, but to date, have received no reply. These details are top secret, and embarrassing, so not available to American citizens. What we don't know won't hurt us.

Authorizing shipment of intact meat into commerce which is surface-contaminated with *E.coli O157:H7* has global repercussions FSIS would rather not confront. Foreign countries desiring to export their meat to America must have HACCP systems "*Equivalent*" to FSIS-style HACCP protocol. Therefore, those countries can ship *E.coli O157:H7*-laced intact meat cuts to America! Case in point: on September 29, 2007, TOPPS Meat Company in Elizabeth, New Jersey, recalled 21.7 million pounds of meat potentially contaminated with *E.coli O157:H7*. TOPPS did not slaughter, but purchased all its meat from outside source slaughter providers. Subsequent investigations revealed that the contaminated meat TOPPS had purchased originated from Ranchers Beef, a Canadian firm. The Ranchers Beef meat was intact beef cuts, classified as "Boxed Sub-Primal Cuts". By FSIS definition, the *E.coli O157:H7* bugs on the surface of these intact cuts were not injurious to public health.

With full endorsement of FSIS and other global food safety agencies, countries can ship to the USA intact cuts of meat which are surface-contaminated with *E.coli O157:H7*. Consumers are paying dearly for this "Free Trade". We now enjoy a global, dumbed down, deregulated, allegedly "science-based" system of "Hands Off" meat non-inspection of raw meat and poultry.

To the agency's credit, it is authoring a greatly modified Validation Letter, a full fourteen months since the issuance of its initial fiasco. It promises to be interesting. If FSIS attempts to trace back to the upstream SOURCE of contamination, the agency will encounter the legal fight of its life.

But let's see what the USDA's own OIG says about "*Prudence*" within FSIS-style HACCP. I previously referred to the Executive Summary of OIG's June, 2000 investigation of the FSIS implementation of HACCP. The Executive Summary states in part:

> *"We [OIG] believe prudent oversight requires FSIS to be aware of all positive test results, generic or otherwise".*

FSIS disagrees. The agency covets comfort, which is accomplished via ignorance of obvious truths, as proven in the OIG investigative report of the ConAgra recall. FSIS prefers to be ignorant of obvious truth at the large, source originating slaughter plants. Because of this, adulterated meat continues to be shipped into commerce, in containers bearing the official USDA Mark of Inspection, from which we continue to experience multiple outbreaks.

This brings into question the value, if any, of the USDA Mark of Inspection which states *"USDA Inspected and Passed Est # xxxx*". For many years I included in my radio and newspaper advertising that my plant was USDA-Inspected, and thought the Mark of Inspection had some marketing value. Since June, 2008, FSIS must be credited with finally acknowledging the limited value of the Mark. In June 2008, the agency sent a PowerPoint presentation to its field force for training purposes. The title of the PowerPoint was "*Prerequisite Programs for E.coli 0157:H7*". The headline on the top of slide 2 of the Powerpoint says "*Basic Principles*". The next sentence stated "*Grinders with prerequisite programs should not rely on the mark of inspection to accept incoming product".* As incredulous as this agency admission is, we must congratulate the agency for its refreshing candor in admitting the Mark of Inspection is valueless.

Subsequently, on January 7, 2009, FSIS issued Notice 05-09. Part II (A) states in part "*An establishment that receives, grinds, or otherwise processes raw beef products cannot conclude that E.coli O157:H7 is not reasonably likely to occur in its production process because the product it receives bears the mark of inspection*". Yet, it can't be otherwise, because the agency aggressively promotes its "Hands Off" non-involvement role under its bastardized version of HACCP.

I have a copy of a cookbook published in 1998 entitled "*America's Favorite Beef Recipes*", compiled by the National Cattlemen's Beef Association. The following statements are found on page 6:

> "*First, the wholesomeness of our meat supply is* <u>*ensured*</u> (emphasis added*) 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* <u>*wholesome*</u> *(*emphasis added*) and accurately labeled"*

I am no prophet, but I predict that we will not see such a claim again, as long as we suffer under the existing corrupted style of FSIS HACCP.

After ConAgra's 19.1 million pound recall in July, 2002, we witnessed a variety of embarrassing revelations as I've delineated above. Once the Minneapolis DO had a change of heart, and allowed me to grind again under the Mark of Inspection, I was seething within because of the agency's overtly corrupt handling of my plant. I was faced with a discomforting dilemma: should I let dead dogs lie, and go on with business, grateful that I was finally able to operate again in the absence of the agency's artificial grinding restrictions against me? Or, should I go public, and hope that a potential public outcry

would force FSIS into greatly modifying its faulty HACCP Hoax, which would result in safer meat products? The risk was obvious: if I revealed it all, FSIS could very well launch unending witch hunts against me, and would certainly be successful in closing me down for tenuous reasons. I lack the staff and financial largesse to tackle this monster of an agency, a veritable David vs Goliath, with little chance of success. But, if I chose to ignore the obvious problems permeating the FSIS-style HACCP Hoax, and consumers continue to be sickened, I would be at least partially responsible for those future sicknesses because of my cowardice to publicly admit the full truth.

What was I to do? I didn't want to lose my business, but I also didn't want to become a silent accomplice to the agency's shielding the large source slaughter plants from accountability. My grand kids came into play here, nudging me in the direction I should go, which will be discussed in Part 7.

PART 7 COVERUPS AREN'T SUSTAINABLE

Back in full swing again, authorized to grind under the Mark of Inspection, I questioned the wisdom of my going public, which would fully reveal the multitude of agency misdeeds. Although my eldest grandchild was but four at the time, I found myself imagining conversations with her on this issue. I defended the position of NOT going public, and in my mind, she argued in favor of my going public. I kept stating (in my mind) "*Hannah, I can't afford to have the agency mad at me, as they will use retaliatory tactics*". She would reply "*Grampa, what's right is right. What's more important: your comfort level with FSIS, or my health*?" This argument went on for several days, and Hannah always won the argument. The turning point was when Hannah stated (in my mind) "*Grampa, they're gonna shut you down anyway, it's just a matter of time. So, what do you have to lose?"* Bingo, the light went on! Without Hannah actually saying a word to me, she caused me to do an about face. There's just something about grandkids. I then knew that if I remained quiet, and more outbreaks occurred, and innocent children continued to die, I'd have a difficult time looking Hannah in the eye. I realized I'd rather lose my business and have my granddaughter's respect and trust, than remain silent and become a secret accomplice with FSIS.

On Thursday morning, July 18, 2002, I started calling around, speaking to anyone I could find in the media, to tell my story. I knew it would be a hard sell, because who in their right mind would ever believe that FSIS adroitly avoids tracebacks to the SOURCE? The very idea that the agency was not willing to test potentially adulterated meat for E.coli seemed outlandish. Through an unusual set of circumstances, a representative of NBC Nightly News with Tom Brokaw quickly contacted me, somewhat incredulous with my claims. After a lengthy visit, they asked if I would allow their film crew on my premises, and would I be willing to be interviewed. I agreed, and immediately sent word everywhere that the NBC crew was coming, and to be watching for a future evening news story focused on agency misdeeds at my plant.

The next agency action was very interesting. Since I immediately announced the upcoming NBC revelation, I had the foreboding fear of immediate agency retaliation. Yet, the agency had become suddenly quiet, which was disconcerting. Like the lull before the storm. On Friday, July 26, 2002, the FSIS Office of Field Operations hq's in DC sent an email to all of their District Office Managers. The email referenced *"Here is a summary of the procedures that were agreed upon at the conference call earlier this week"*. The operative sentence was the following:

> "*At the time the* [ground meat] *sample is taken, 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".*

I was immediately provided a copy of this by Dr. Daryl Burden, the same courageous agency veterinarian who hand-wrote the letter exposing Est 969 (ConAgra) as the source of the three positives at my plant. Since my recall, I had been unsuccessfully pressing the agency to document all source

evidence at the time of sample collection, but with zero success. Is it possible that the agency made this procedural change in advance of the embarrassing NBC revelation? You be the judge.

On August 1, 2002, exactly two weeks after I went public, Tom Brokaw broke the story. The news clip showed the now-infamous letter from Dr. Burden, as well as footage taken at my plant, and an interview with USDA Under-Secretary Elsa Murano who stated that agency investigators were sent to ConAgra, but could find no product to test. Think of it! Indeed, there was no product remaining at ConAgra from the same date which produced the hot meat at my plant for three consecutive days, because it had already been shipped into commerce! The appropriate agency action would have been to "suggest" (aka "demand") a recall of all coarse ground beef from the one day of production involved. The very top management at FSIS concluded that no problem existed because they could find no meat at ConAgra from the one day of production. The problem was not hot meat ensconced at ConAgra, but at multiple locations throughout the country which were performing final grinds on the pathogen-laced meat. As we know, FSIS closed down my grinder for four months, but ConAgra's grinder never stopped. What a difference plant size makes!

One unanticipated result of the NBC revelation was the multiple dozens of unsolicited emails, telephone calls, and letters I received from total strangers throughout the country. Some were other plant owners, but many were FSIS employees: inspectors and veterinarians, both currently employed and retired. These folks related similarly scandalous scenarios implemented by FSIS from coast-to-coast. My next admission is that I had been totally wrong! During the four months the agency abused me, I wondered why FSIS targeted my solitary plant for its unethical enforcement actions, thinking such behavior was targeted exclusively at me, and that my plant was unique. I was quickly informed by this unsolicited influx of evidence from total strangers that the agency revels in conducting such witch hunts at small plants across this continent, that my plant was indeed not unique. Now if one or two strangers had called with such evidence, I'd tend to disbelieve their disturbing stories. However, all these folks told the same story, lending credibility to their revelations.

After the July 26 email from FSIS hq's in Washington DC to all DO managers, inspectors commenced documenting evidence which should have been part & parcel of agency HACCP procedures since day 1 of HACCP, since HACCP is ostensibly based in science. But, I can see why the agency waited to change this procedure until faced with an embarrassing NBC revelation: how can FSIS employees document unrestricted evidence after the agency promised to utilize a "Hands Off" non-involvement role, and would no longer police the industry? Two inspectors subsequently documented this evidence at my plant, and provided me copies, which I still have. When the Minneapolis DO found out such source evidence was being documented at my plant, E.coli hit the fan! The DO angrily demanded to know who created this "*rogue form*" on which source evidence was being compiled at my plant. Although FSIS headquarters in Washington, DC, demanded that such evidence be compiled at the time of sample collection, the Minneapolis DO went ballistic when informed that inspectors were indeed documenting such evidence at my plant. The DO preferred to keep its head in the sand. But the ultimate question here is who is the head of the snake? Someone from the DO, or from DC?

A couple months later, I heard rumblings that the Minneapolis DO was discreetly instructing its inspectors to discontinue documenting source evidence at the time of sample collection. The issue took on a "hot potato" leprosy: no one wanted to discuss it, and evaded any reference to what was happening. And, the inspection force really did not know official agency policy because the agency was not issuing any written statements on this issue, intelligently creating no paper trail. I wanted to know what was happening behind closed doors at the DO.

At a joint FSIS/industry meeting in Great Falls, Montana, on Saturday, October 5, 2002, the manager of the Minneapolis DO took his turn responding to industry questions. So I described to him the uncertainty faced by his field force, not knowing if they were to document source evidence at the time of sample collection, or wait until lab results were returned. His reply, which was made in front of the crowd, and no one in the agency has ever attempted to deny, was as follows:

> "*For legal reasons, the agency has decided that sample evidence is not to be collected until after lab results have been released".*

The agency did not fear litigation emanating from small plants. In less than two months, the procedural change which benefitted public health had been rescinded. But, we must acknowledge that the NBC Nightly News revelation was now old, dismissed to the archives. The agency was no longer in the media cross hairs, free again to orchestrate intentional obfuscation of the full truth.

I should explain why source documentation in real time benefits public health. Let's say a plant like mine (which slaughters and processes) is scheduled for the inspector to collect a sample of ground beef for microbial analysis at a USDA lab. Let's say my plant ground meat which originated from my own kill floor, and the USDA lab concludes that it is positive for *E.coli O157:H7*. When the adverse lab result is communicated to the agency inspector, who then notifies me, I could falsely claim that the meat emanated from one of my source slaughter providers. Since several days have now transpired since the sample was collected, the trail of evidence has turned cold, and the inspector has no way of unilaterally validating the accuracy of my claim as to the source of the sampled meat. Agency-mandated delays in documenting all evidence provide an opportunity for unethical plant operators to intentionally lie about the source of the hot meat. On the flip side of the coin, when the USDA lab concludes that the sample was contaminated, FSIS assumes the right to accuse the plant of using its own previously contaminated meat, because no records were kept of the true source of the meat at the time of sample collection, even though the meat may have been purchased from an outside supplier. The agency's refusal to document all evidence at the time of sample collection creates opportunities for both the agency and the meat plant to make false claims and accusations. It also intentionally obfuscates evidence which would prove where the meat was contaminated.

Then-Montana Senator Conrad Burns had been intimately involved in pressuring the agency to utilize appropriate actions at my firm in 2002. Senator Burns called for a Senate Field Hearing in Billings, Montana on December 11, 2002 to discuss "*Food Safety Recall Procedures*". The panelists included Mr. William C. Smith, FSIS Assistant Administrator in the agency's Office of Field Operations (OFO), me, and

two others. OFO has full authority over agency actions in the field, including agency actions against my firm. During the Hearing, I stated that on "*the day that a sample is taken, it is my contention that both the inspector and the plant management should work together and fully document all that information…..*" Senator Burns then asked Mr. Bill Smith for his response. Two of Mr. Smith's responses in the transcript were candidly revealing. On page 39 of the transcript, Mr. Smith had this response:

> "*We'd be collecting an awful lot of information when it would be – we could have inspectors doing more important things".*

More important things than doing what? Answer: documenting the full truth.

On page 40 of the transcript, Mr. Smith further explained agency opposition to documenting source evidence at the time of sample collection with this statement:

> "*…because a number of packers would also be very upset about us* [FSIS] *collecting information on negative findings"*

I suggest to you that collecting evidence of contaminated meat should be the responsibility of FSIS, but the agency disagrees with me. Yes indeed, FSIS is paralyzed with fear of litigation emanating from the big packers if the agency were ever audacious enough to document source evidence about the pathogen levels in meat originating from these big packers. Now it is easier to understand why the Minneapolis District Office refused to accept my offer of unopened, intact chubs of Coarse Ground Beef for sampling at USDA labs, concerned that "*ConAgra would sue us*" as previously described. As such, Mr. Smith admits that FSIS is more concerned with placating the big packers, than protecting and promoting public health.

A most interesting exchange occurred immediately after the closure of this Hearing. My wife Kathryn approached William Smith, and stated:

> *"I just want you to know that what you have done to this man* [John Munsell] *is absolutely disgraceful. Over and over and over he rewrote his HACCP Plan 14 times, and every time you rejected it".*

William Smith replied:

> *"We have a small plant outreach center in Washington, DC, and John should have contacted them to help him with his reassessments".*

My wife responded:

> *"Yes, and he was told not to contact her, because she is married to you".*

A visibly upset Mr. Smith angrily demanded:

> "*I'd like to know who told you <u>THAT</u>!"*

Who is "*she*", at the small plant outreach center? "*She*" is none other than Mary Cutshall, who just happens to be married to Mr. William C. Smith. It is true that at one time I had considered contacting Mary, but an agency employee (who shall remain unnamed) privately confided in me that I should NOT contact Mary because of the obvious conflict of interest, explaining that if I would contact Mary Cutshall for help, she could pass on my comments to her husband.

Senator Burn's involvement didn't end there. During a chance meeting at the Minneapolis airport in December 2003 (one year after the Hearing), Senator Burns and I discussed the state of agency activities against my plant. Senator Burns stated that he had recently been at a social gathering, where he had visited with Ann Veneman, who at the time was the USDA Secretary. Senator Burns brought up the issue of agency behavior at my plant, to which Secretary Veneman replied:

"We mishandled that from day one"

It's a shame that one branch of USDA (FSIS) conducts itself so shamelessly that even the USDA Secretary was cognizant of details. Amazingly, the agency has yet to learn its lesson, as FSIS continues to perpetrate similar misdeeds at small plants nationwide, as revealed to me by dozens of agency employees and other plant owners. This report is not focused on agency misbehavior at my plant, but on systemic agency violations of its public trust and abdication of its congressional mandate to inspect meat and protect public health. FSIS-style HACCP is all about agency comfort and deregulation of the agency's closest ally, namely, the big packers. As William Smith testified at the Senate Field Hearing, a number of packers would be upset if the agency were to collect information on lab results which prove the existence of contaminated meat emanating from the large source slaughter providers.

It is imperative that I state my endorsement of agency field force, both inspectors and veterinarians. These dedicated folks want to do what is right, desiring to document problems in the field, and frequently report sanitation problems to supervisors who are regularly prohibited from initiating meaningful enforcement actions……at the SOURCE slaughter plants. More than one field employee has told me that HACCP has indeed removed command and control from inspectors. They immediately add that command and control has been effectively transferred to and is alive and well at the District Offices and in Washington, DC. As such, agency bureaucrats have effectively eviscerated field force of any authority, having transferred all authority to FSIS headquarters. Agency lifer bureaucrats have centralized all decision making into headquarters offices, denying online inspection personnel the authority they need when they observe ongoing fecal sanitation problems. Admittedly, there is an occasional inspector who misuses authority and victimizes plant management. But overall, the agency's field inspection force is reputable; nevertheless, it has been demoted to an inferior status by intentional agency design, another fatality from the FSIS-style HACCP Hoax.

Another incident also opened my line of communications with dozens of total strangers, resulting from a lawsuit filed on my behalf by the Government Accountability Project (GAP) against FSIS in October, 2004. The lawsuit had two goals: force FSIS to initiate long-overdue changes in its corrupted HACCP program, and to reimburse my company for financial losses caused by the agency's misdeeds. Once the

litigation was announced, I again received dozens of unsolicited communications from many total strangers, both from within the industry and from within inspection ranks. Interestingly, they all described the same story of FSIS insulating the source slaughter plants from accountability nationwide, the agency's prohibition against its own inspection force to take meaningful actions when witnessing ongoing fecal sanitation problems against the source slaughter plants, and targeting small plants with unjustified enforcement actions. While plant management and inspectors alike swore me to secrecy, they nevertheless educated me on the ubiquitous nature of the agency's pervasive departure from common sense meat inspection protocol, while dedicating an inordinate amount of time to monitoring paperwork flow.

Another result of my going public was the agency's perception of the value of its protocol which required 15 additional samples subsequent to the detection of E.coli-contaminated meat at meat plants. You may recall that this valuable scientific tool had conclusively proven the SOURCE of adulterated meat both at my plant, and at Galligans in Denver, Colorado, in the first half of 2002. In fact, the protocol was TOO successful, an embarrassing hot potato for which FSIS wanted to avoid any future recurrences. So, how did FSIS change or improve this protocol? Answer: the protocol was totally rescinded! FSIS published Notice 11-03 on April 18, 2003, less than one year after ConAgra's 19.1 million pound recall, and eight months after the NBC revelation. The rescission was quietly snuck in, with no fanfare, a furtive attempt to hide this agency misdeed. Part II (A) 6 of Notice 11-03 includes this statement:

"Section VI, E. 2. Of FSIS Directive 10,010.1 is revoked"

The implications of this statement are substantial. When adulterated meat is detected, the agency desires to skillfully avoid accumulation of additional microbial evidence which could result in (should mandate) a successful traceback to a large source slaughter provider. In order to insulate the large source slaughter plants, the agency disbanded this fifteen sample policy which had caused the agency so much grief in early 2002.

In all fairness, it must be acknowledged that five years later, FSIS reintroduced a subsequent protocol allowing a diminished amount of follow-up sampling. On October 30, 2008, FSIS issued Notice 79-08 entitled "*Multiple Follow-Up Sampling After FSIS Positive Escherichia coli (E.coli) 0157:H7 Results".* According to this Notice, inspection program personnel are to collect 8 samples for low volume establishments (establishments that produce less than 1,000 pounds per day of product in question), or 16 for all other establishments. This Notice 79-08 expired on November 1, 2009, and its provisions have been incorporated into Directive 10,010.1. The Directive allows for additional scheduling of sampling if it is deemed appropriate. FSIS has not defined what plant conditions would be deemed "appropriate" to justify additional sampling.

Since FSIS now allows plants to write their own HACCP Plans, FSIS has jettisoned its previous national standards which had previously provided a solid foundation from which to establish plant production protocol. After all, since FSIS now embraces a "Hands Off" non-involvement role, and cannot police plants, FSIS claims it cannot establish national standards. However, the agency regularly rejects HACCP

Plans because of alleged inadequacies within the Plans, without revealing (a) the alleged inadequacy or (b) the solution to the inadequacy. Under HACCP, each plant can author its own standards, providing it has scientific justification for such decisions. A problem this creates is that plants utilize commonly accepted scientific findings in writing their HACCP Plans, but FSIS bureaucrats regularly reject the adequacy of the particular scientific study in one plant, while accepting the study in other similar plants. Let me give you an example.

Prior to HACCP's advent, FSIS mandated that plants maintain their processing rooms at a 50 degree F temperature or less, to control the growth of bacteria. If temperatures exceeded 50 degrees, then the plant had to perform a mid-shift cleanup within four hours of the temperature exceeding 50 degrees. Cold temperatures greatly retard pathogen growth. So, when I wrote my HACCP Plan, I unilaterally reduced the temperature of my processing room to 45 degrees as a food safety measure. Some FSIS inspection personnel objected to this change. For several weeks, I played pure hell with these agency folks, who threatened enforcement actions against me for implementing this common sense improvement in my production procedures. Furthermore, this agency argument against me contradicts the earlier FSIS promise that plants could write their own HACCP Plans, and the agency can't tell plants what must be in their HACCP Plans. I'll explain how this crazy situation played itself out in Part 8.

PART EIGHT I WAS LIVING A LIE

FSIS' justification for denying me the right to lower my temperature to 45 degrees was based on the belief that since I didn't have a copy of an approved scientific study in my files which proves that a 45 degree temperature was acceptable, I couldn't implement a lower temperature. However, if I increased it to 50 degrees, FSIS would find no fault. In other words, plant management can't make any decision to change operations until they can find a scientific study which validates the efficacy of every specific decision. Attempts to convince the agency to re-implement National Standards to provide "safe harbors" to plants as they establish meat production protocol have been totally fruitless. Instead, in the absence of common sense national standards (a benefit of deregulated HACCP), FSIS can badger and intimidate small plants. Mind you, the agency doesn't provide answers, but merely rejects numerous common sense decisions plants make, only to hagride plant owners to the point that the owners close the doors and walk away to circumvent this senseless scenario. Please don't get me wrong here: although the vast majority of inspectors believes the agency desires to close down small plants, I disagree. My perception is that FSIS could care less if small plants continue to exist. Instead, FSIS wants to be relieved of the responsibility of providing inspection services to small plants. The best way to accomplish this is to torment and harass small plant owners, especially with worry and dread, until the owner gets so exasperated s/he walks away. Another win for public health! No, another win for an agency which only wants to provide deregulated service to the largest plants. Not only would the agency's payroll budget decrease, but the agency would no longer have to worry about its thousands of inspectors revealing details of the agency's failed HACCP theory to the public. Much easier to micro manage a smaller work force.

A comparison of the relative number of agency enforcement actions at small plants versus large plants is easily seen by comparing the number of Noncompliance Records (NR's) at some large plants versus small plants in 2010. Through a recent Freedom of Information Act request, FSIS provided me the number of NR's at various large plants in America. At the following three companies, I eliminated the "outliers", that is, the highest and lowest figures, some of which were way above or below the average of the other plants:

Tyson	14 Plants	114 Average
Cargill	7 Plants	71 Average
Smithfield Packing	3 Plants	53 Average

Both National Beef and Seaboard Foods have only three plants each, so I did not eliminate any outliers.

National Beef	3 Plants	87 Average

Seaboard Foods	3 Plants	43 Average

With the exception of Seaboard Farms' bacon plants, the large plants listed above kill thousands of beef, pork or chicken daily, yet they average only 43 – 114 NR's annually.

The number of NR's issued at two small plants in Montana in 2010 provide us food for thought. FSIS assessed 158 NR's at Ranchland Packing in Butte, Montana, and 115 at Stillwater Packing in Columbus, Montana. In four Meatingplace blogs in January through March, 2011, former USDA Under-Secretary for food safety Dr. Richard Raymond discussed agency behavior at these two Montana plants, generating a record number of Meatingplace responses. Following Dr. Raymond's embarrassing revelations, FSIS immediately decreased the number of NR's at these two small Montana plants by over 50 percent. The agency also retroactively rescinded many NR's which had been closed out in 2010 at the two plants.

Please refer to page 28 in Part 4 of this report, which revealed that Nebraska Beef filed litigation against FSIS because Nebraska Beef had been assessed 58 NR's, which constituted evidence of the inspectors' bias as claimed in the litigation. If Nebraska Beef, with 1100 employees, is justified in filing a bias claim against FSIS because of 53 NR's over four months, should a small plant with only twelve employees which receives 158 NR's in twelve months be likewise justified? However, FSIS has no concerns over well-deserved litigation potentially stemming from small plants, because the small plants lack the political clout and financing to challenge the agency. Small plants are much easier enforcement prey.

The volume at these two Montana plants is incredibly small, and their kill floor speed is negligible. These two plants have not invested millions of dollars to determine how they can remove visible fecal on the kill floor, because the production lines moves so slowly workers readily observe and quickly remove any contaminant. Likewise, their HACCP Plans lack the multitude of independent third party scientific theories which the biggest plants proudly parade. The kill floors at these two small plants lack the steam pasteurization interventions employed at the high speed plants, because the small plants don't need the intervention.

Back to my 50 degree temperature problem with FSIS. At the time the agency was hassling me on this issue, FSIS just didn't seem to have copies of any scientific articles available to assist small plant ignoramuses like me. The agency was fully cognizant of a number of temperature-related articles, but wouldn't divulge them. Much more fun to watch plant owners squirm and sweat blood! When the agency created the position of Consumer Safety Officers (CSO's), the agency instructed the CSO's to make such scientific demands, but to NOT provide copies of the required scientific articles. How do I know this? Because dozens of agency employees have related this imbroglio to me. Other plant owners relate the same sad tale. Admittedly, when the agency morphed CSO's into Enforcement, Investigation & Analysis Officers (EIAO's), the agency did an about-face, and instructed the EIAO's to proactively provide copies of such articles, or at least links required to access the articles. So, for several weeks the agency threatened enforcement actions against me for lowering my processing room temperature five

degrees, and I steadfastly resisted to go back up to 50 degrees. For some unknown reason, the agency let this scenario suddenly disappear, never to resurrect it again. One of the few battles I won. Perhaps the agency knew that their position on this was so grossly incompetent and egregious, FSIS wanted to avoid a PR debacle if it ever went public.

Do you perceive now what FSIS-style HACCP had devolved to? Instead of inspecting meat production lines, agency personnel were busy beavers inspecting written HACCP Plans, and ensuring that plants had an abundance of bullet-proof scientific articles justifying every decision appearing in the plant's HACCP Plan. Who cares if pathogen-laced meat was flowing down the production lines? FSIS now prefers to closely inspect the theoretical bases of all company decisions, dedicating precious time to audit all company-generated paper flow and its library of scientific articles. Who cares about actual meat production lines? As long as the written HACCP Plan appears to be in order, FSIS assumes that all meat produced at the plant must be safe.

A superlative example of how this plays out is the aftermath of FSIS' issuance of a Federal Register Notice on October 7, 2002. The notice required all meat plants to reassess their HACCP Plans to determine if *E.coli 0157:H7* was a Hazard Likely To Occur. As a result of our recall, and our experiencing four lab positives for *E.coli O157:H7*, I had already determined that *E.coli O157:H7* was indeed a hazard likely to occur, and had taken numerous steps to address this hazard. These changes had already been dictated by the Minneapolis DO during the four months of disputations in early 2002.

In 2003, FSIS sent their CSO's (Consumer Safety Officials, allegedly the ultimate HACCP experts) into the field to determine if all plants were compliant with the agency's demand to reassess their HACCP Plans to determine if *E.coli O157:H7* was a Hazard Likely To Occur. Two CSO's visited my plant on September 15 – 18, 2003, not only to ensure my compliance, but also to review all details of my HACCP Plan. One of the CSO's was already intensely familiar with my HACCP Plan, as he was the primary agency spokesperson for the Minneapolis District Office (DO) during the four months of negotiations the DO had with me in early 2002. These were the four months during which the DO prohibited me from grinding under the USDA Mark of Inspection.

Some incredible agency demands were made of me during the four days the two CSO's were at my plant. When they arrived, my "Raw Ground" HACCP Plan had six CCP's to prevent E.coli contamination of products. CCP means "Critical Control Point". CCP's are used at points in the production line where we could intervene to prevent, eliminate or reduce pathogens to an undetectable level. This report previously referred to consultant Dr. Helmut Blume, who provided services to my plant in 2002 to resolve my problems with the Minneapolis office. Dr. Blume thought that it was totally unnecessary for me to have six CCP's in my "Raw Ground" plan, as six CCP's was a dramatic overkill. Many others in the industry agreed. However, since the Minneapolis DO had "*suggested*" (aka MANDATED) these six CCP's during our four months from hell, I quickly implemented them into my HACCP Plan. When the CSO's visited with me in September 2003, they also agreed that not only should I not have these six CCP's, but also stated that all six should be removed! For some reason which will never be revealed, the Minneapolis DO did an abrupt about face on my HACCP Plan. Apparently, science had changed (for the umpteenth time). This scenario again reveals that the agency is noncompliant with its previous promise

that plants could write their own HACCP Plans, and that the agency can't tell plants what must be in their HACCP Plans. When agency EIAO's and other touring officials tell small plant owners to jump, we ask "*How high*?" Refusal to play this game enables agency officials to conduct a witch hunt at the plant, and the agency always wins. I stayed late at work on September 17, 2003, and made pencil changes which removed all six CCP's, to fully comply with their "***suggestions***". Upon their return to my plant on September 18, 2003, they asked what CCP I then intended to use as a replacement for the six which were removed. I replied that I was not aware of any which would be appropriate. One CSO then suggested that I list Salmonella as a Hazard Likely To Occur, and to control it with temperature. I complied with his "***suggestion***", and I now had but one CCP. And please remember that the six CCP's which were removed had originally been implemented because of mandates from the Minneapolis DO. Now, fifteen months later, at the insistence of the newest agency visitors at my plant, I deleted all six CCP's, and replaced them with one CCP, the details of which were mandated by these two CSO's. Whatever happened to the agency promise that each plant could write its own HACCP Plan, and that FSIS couldn't tell plants what must be in their HACCP Plans?

At the same time, the two CSO's stated that it was inappropriate of me to list *E.coli O157:H7* as a "Hazard Likely To Occur". I disagreed, stating that my plant had already experienced a recall for *E.coli*-contaminated meat, and had experienced four adverse lab reports which revealed *E.coli O157:H7* at my plant. I stated that if there was one plant in the country which should have concluded that *E.coli O157:H7* was a Hazard Likely To Occur, it was MY plant. The two CSO's disagreed, yet again denying me the right to author my own HACCP Plan.

Plants across the country already knew that if they disagreed with CSO suggestions, the plants were almost guaranteed to be issued a NOIE (Notice of Intended Enforcement) from the agency. A NOIE is an agency warning to a plant, stating that if the alleged violation was not resolved within 72 hours, the agency could withdraw inspectors from the plants, essentially closing the plant. Because of this historical fact, I submitted to all "***suggestions***" from the CSO's, and implemented their demands. Therefore, when the CSO's demanded that it was inappropriate for me to list *E.coli O157:H7* as a Hazard Likely To Occur at my plant, I fully complied. Although I had never experienced a positive sample of Salmonella at my plant, these two CSO's demanded that I must conclude that Salmonella is a Hazard Likely To Occur at my plant. Conversely, although I had already experienced one *E.coli O157:H7* recall and four adverse lab tests for *E.coli* at my plant, these two CSO's demanded that I no longer list *E.coli O157:H7* as a Hazard Likely To Occur. I have to question if this craziness was being dictated from top FSIS officials in DC, but only the two CSO's can answer that question. Regardless of the source of this agency misbehavior, it again shows that FSIS personnel regularly mandate what must be in individual plant's HACCP Plans, but only at small plants. And, that their mandates are typically inconsistent with and contradictory to previous agency mandates. Science continually evolves!

My wife Kathryn participated in one of these meetings with the two CSO's. Kathryn discussed constantly changing, contradictory and conflicting demands from each new FSIS visitor to my plant, all of whom mandated changes to my HACCP Plan, while criticizing changes I had previously initiated at the demand of previous agency employees. Exasperated, Kathryn finally asked "*Who is in charge here?*" After a long

hesitation, one CSO admitted "*Well……..no one*". This CSO response reveals a central failure in FSIS-style HACCP: FSIS lacks consistent standards, energizing each new FSIS visitor to unilaterally require whatever subjective bias s/he has, even though the newest mandate is diametrically opposed to all previous agency requirements. Plants' decisions must be scientifically supportable, but agency decisions do not.

During and immediately after this four-day session with these two CSO's, I maintained copious records of all events which transpired during the four days. Hopefully these records will be subpoenaed in a future court proceeding, where the agency and their two CSO's can provide their side of the story.

Another interesting agency action at my plant occurred during another CSO visit to my plant on March 13, 2002. During this visit, FSIS personnel saw a pistol in the file where my HACCP Plan was kept locked. As I unlocked the file and removed the HACCP Plan, the pistol could be seen. This pistol is used to shoot buffalo, and I kept it locked up for safe keeping purposes. The following week, Dr. Daryl Burden came to my plant again, and in his own words, stated that the agency had commenced a "*Violence in the Workplace*" inquiry against me. I was incredulous, and asked for an explanation. Dr. Burden stated that since I kept the pistol in the same drawer as my HACCP Plan, that agency personnel allegedly felt intimidated by the pistol. The inquiry was concerned that I was subtly implying that if agency personnel asked to view my HACCP Plan, they might be looking down a pistol barrel instead. I immediately relocated the pistol into another locked file. Dr. Burden interviewed all pertinent agency field force, who essentially laughed in his face, and admitted that they did not feel threatened in the slightest. Dr. Burden's response to this alleged Violence in the Workplace inquiry included the following statement on March 22, 2002:

> *"I have never witnessed anything at Est 7679 which could at all be considered threatening or intimidating by the management, nor have I been able to find any record of such concerns in the past"*

This is but another example of FSIS concocting trumped-up charges against "rebellious" plant owners who attempt to stand up for their rights with FSIS.

Ask any small plant owner in America, who will admit that an agency official (CSO, EIAO, Front Line Supervisor, etc) arrives at their plant, and "*<u>suggests</u>*" that numerous changes be made in the plant's HACCP Plan. Any attempt to object results in agency-sanctioned harassment and retaliation. Therefore, we've all learned to implement whatever the agency mandates/suggests. Six weeks later, another agency official arrives, reviews the recently-changed HACCP Plan, and requires that the recent changes be rescinded, and replaced with "*suggestions*" from the newest agency visitor. If the "*suggestions*" are not implemented, Noncompliance Reports and NOIE's are guaranteed. So, we implement the "*suggestions*", regardless of how frivolous. Subsequently, another agency employee shows up at our door, reviews our HACCP Plan (not the production line), and thoroughly repudiates the most recent agency-mandated changes, and mandates/suggests an alternative protocol.

And think about it folks. As FSIS continues this façade, this shell game of ever-changing HACCP changes (most of which have zero connection to food safety), the agency continues to endorse the right of the large source slaughter plants to ship into commerce intact cuts of meat whose surfaces are liberally

laced with *E.coli O157:H7.* Remember, FSIS states that intact cuts of meat which are surface-contaminated with *E.coli* are NOT adulterated. Therefore, even if the agency successfully shutters all small plants, ongoing outbreaks and recurring recalls continue. Well FSIS, who will you blame this time?

I implemented HACCP in January, 2000, a true believer in HACCP protocol. But as time went on, I witnessed serious discrepancies in the way that FSIS responded to issues in the field. I slowly came to realize that I was living a lie, but couldn't put my finger on the true source of the lie. I simply could not identify what was happening right before my eyes, it was so deceptive. It wasn't until August of 2009 that I was informed of the origin of the lie: FSIS-style HACCP is not true HACCP! Suddenly, all of the agency's behavior made sense. I am no longer living the lie. Just as my understanding the enormous differences of FSIS-style HACCP compared to Pillsbury HACCP has enabled me to connect the dots to explain our ongoing outbreaks, my goal is that this report will enable all Americans to connect the dots revealing the agency's intentional bastardization of scientific principles. This shell game has allowed the agency to abdicate its legislative mandate to protect public health, and to use pseudo science at its justification.

FSIS sowed the seeds of outright deception when it authored its faulty version of HACCP. Consumers are now reaping repetitive outbreaks caused by the agency's unscientific policies.

This agency-sponsored conundrum also reveals the need for effective tracebacks to the SOURCE, instead of focusing agency investigations and enforcement actions at the downstream DESTINATION plants which unwittingly purchase meat which was previously contaminated with invisible pathogens. Historical agency actions continue to reveal that the agency overtly prevents tracebacks to the true SOURCE of contamination, via intentional obfuscation of source evidence at the time of sample collection. The agency's insulation of source plants from accountability virtually guarantees ongoing outbreaks and recurring recalls. Here we are, a full thirteen years since the largest plants implemented HACCP, and we continue to experience a spate of ongoing outbreaks and recurring recalls. For consumers' sakes, FSIS must be forced to remove its head from the sand.

FDA & FSIS jointly hosted a public hearing on Traceback Protocol on December 9 & 10, 2009, meetings which went all day, both days. One statement made by Jerold Mande, the FSIS Deputy Under Secretary of Food Safety, was as follows:

> "*We* [FSIS] *often don't have all the information we need to protect public health".*

Finally, an admission by a high-ranking FSIS official that agency traceback protocol is inadequate.

Not to be outdone by this two-day joint venture with FDA, FSIS was the sole host of a subsequent Traceback Hearing in DC on March 10, 2010. In stark contrast with the FDA Hearing, this FSIS Hearing was completed in three and a half hours. One of the audience participants who stepped up to the audience microphone with a statement was Scott Goltry, the Vice President for Food Safety and Inspection Services at the American Meat Institute (AMI). While AMI membership is open to meat

plants of all sizes, AMI primarily represents the interests of larger plants. One of Mr. Goltry's comments was as follows:

> "*Except in the case of high event periods, AMI is unaware if a change to the trace back follow up sample procedure would have a significant improvement to public health".*

In other words, improving trace back protocol would not benefit consumers. AMI concludes that definitive determinations of the true SOURCE of contamination, and agency enforcement actions at the SOURCE, would provide no additional benefits for public health purposes. Instead, let's just continue to assess full responsibility against the downstream further processors which unwittingly purchase previously contaminated meat, and maintain the agency's current practice of insulating the source originating slaughter plant from accountability.

To the agency's credit, it issued Notice 58-03 on October 8, 2010, entitled *"Collecting Supplier Information At The Time Of Sample Collection For Escherichia coli (E. coli) 0157:H7 In Raw Ground Beef Products And Bench Trim"*. Sound familiar? This is the same protocol which the agency demanded in the afore-mentioned Email from FSIS headquarters in Washington, DC, on July 26, 2002, days before NBC News carried my story. It's the same protocol which FSIS rescinded two months later, "*for legal reasons*", as stated by an agency official. If FSIS utilizes a truly science-based meat inspection system, the agency would have demanded copious source documentation from day one of HACCP's advent. Even when I had high school and college lab classes 40 plus years ago, we were taught the obvious need to document in real time all evidence to describe the ingredients which went into our lab project. FSIS disagreed, until Notice 58-10 was released. After numerous, embarrassing, and painful outbreaks and recalls, FSIS is more willing to document source slaughter evidence.

Is there a need for tracebacks? Consider this: between January 1, 2009 and November 30, 2010, FSIS-conducted testing resulted in 64 positives for *E.coli O157:H7*. Of these 64 positives, 29 were from plants that did not slaughter and used only one source in the tested lot. Nearly 50 percent should have been easily traced to the source, but were not. FSIS-style HACCP prohibits tracebacks to the true source. Tracing back to the true source, and then forcing the true source to implement meaningful corrective actions to prevent recurrences would greatly benefit public health, in spite of opposition from FSIS & AMI. In fact, the idea of "Prevention" is at the top of the priorities shared by the agency's new Under Secretary for Food Safety, Dr. Elisabeth Hagen, and the agency's Administrator Al Almanza. To their credit, they have proactively embraced Prevention as a means of promoting public health imperatives. Theirs is an unpopular and dangerous position, diametrically opposed to the agency's historical primary focus on "Corrective Actions" since HACCP's advent in 1998. Prior to the current focus on Prevention, FSIS has been content to require corrective actions at downstream further processing plants, ignoring the need for Prevention at the Source.

FSIS is currently launching a dynamic data analytics system called the Public Health Information System (PHIS), developed as part of the agency's effort to collect, consolidate and analyze data. The FSIS website makes the following statements about PHIS:

"*It will integrate and automate our paper-based business processes – often found to be inefficient, time-consuming and limiting – into one comprehensive and fully automated data-driven inspection system. PHIS will significantly improve the way FSIS detects and responds to foodborne hazards."*

"PHIS will enable FSIS to respond more quickly when threats are realized."

Only time will tell if PHIS will reveal when the agency unethically targets individual plants for unusually high numbers of NR's. If so, the agency's inappropriate actions against these two small Montana plants would be red flagged for the world to observe. A central issue within PHIS is whether FSIS officials will continue to enjoy carte blanche authority to perform such targeting, or will PHIS require accountability for all agency employees.

One feature being designed into PHIS, in proposal form now, would require inspectors to document onto their laptops source information whenever the inspector collects meat for microbial analysis at USDA labs. If implemented as proposed, the following data be documented for the source slaughter provider for the meat being sampled at the time of sample collection:

Name and Establishment number of supplier

Establishment Phone Number

Establishment contact

Name, Title, Email, & Fax #

Supplier lot #

Production dates

Name of beef components used in implicated products

Amount of lot

Previous agency data collection efforts have indeed collected statistics, which have not always forced the agency to initiate meaningful enforcement actions, or even beneficial conversations with impacted meat establishments. An example is the agency's STEPS system, which represents "System Tracking E.coli Positive Suppliers". Whenever a plant experiences an *E.coli O157:H7* positive lab sample, or a recall for *E.coli*-contaminated meat, FSIS personnel have accumulated a list of all the source slaughter suppliers from which the impacted plant has purchased its products. All these suppliers are entered onto the STEPS data system as a "potential" supplier of the contaminated meat which caused the pathogen problem at the plant in question. Over time, if one source slaughter provider's name would reappear many times on STEPS, FSIS could then consider initiating some actions at the slaughter plant,

such as a Food Safety Assessment (FSA), or an increased incidence of agency-conducted microbial sampling.

In a July 2008 STEPS Reporting of "*Suppliers Identified 3 or More Times*" since FY 02, the highest reporting six plants were as follows, ranked by number of hits:

Nebraska Beef, Ltd.	Est 19336	21
Beef Products, Inc.	Est 19872	15
Moyer Packing Co.	Est 1311	15
Greater Omaha Packing Co.	Est 960A	13
Farmland Nat'l Beef Pk., Co.	Est 208A	10
Gibbon Packing	Est 5511	10

Questions I have which stem from data on this report can only be answered definitively by FSIS bureaucrats in Washington, DC. One question is a potential connection between Nebraska Beef's 21 appearances in STEPS in July 2008, and Nebraska Beef's two recalls in July and August, 2008, as reported on page 35 of this report. I'd like to know what types of communications or enforcement actions, if any, were initiated by the agency with or against Nebraska Beef once the company's name appeared on STEPS ten times, let alone 21 times. FSIS cannot claim that the two recalls (found on page 36 of this report) were the agency's actions, because the two Recall News Releases both mentioned that the recalls were due to a foodborne illness outbreak which on August 8, 2008 included 31 cases in 12 states and Canada.

FSIS continues to develop its technology allowing inspectors with lap tops to accumulate reams of statistics. The real question which remains to be answered however is agency willingness to respond appropriately when gifted incontrovertible evidence which reveals that a source slaughter plant is shipping meat into commerce which is laced with enteric pathogens. It appears that STEPS data has not generated meaningful agency response. Will PHIS suffer the same fate? Will FSIS bureaucrats have the ability to manipulate numbers in the PHIS data base? Or to unilaterally remove discomforting statistics? In order to maintain the agency's semi-retirement comfort level, will FSIS be able to discredit embarrassing PHIS entries by inspectors by stating that the entries are but "*personal opinion*" or "*hearsay*"? Will the agency destroy damaging evidence by claiming that *"The inspector had no right to make that statement*"? Past agency behavior gives us little reason for confidence.

The mere accumulation of damaging data is valueless if FSIS is unwilling to act on it.

Another question I would pose to FSIS is what authority the agency has to initiate enforcement actions, even when in possession of damaging microbial evidence which proves that a source slaughter plant has

shipped into commerce meat laced with enteric pathogens. FSIS sold its version of HACCP to the industry with the four promises listed on pages 6 & 7 of this report. The agency promised that it would no longer "*Police*" the industry, that it would be forced into a "*Hands Off*" non-involvement role, and that it would voluntarily disband its previous "*Command and Control*" authority. If we believe that FSIS can be held true to these promises, the agency has intentionally eviscerated itself of any meaningful authority in the industry. So, will the agency comply with all its promises, or be noncompliant? FSIS must publicly decide: is its primary goal to promote agency comfort with the large plants, or to promote and protect public health?

Many articles have been written this century about the agency's cozy "*revolving door*" relationship with the big packers and their national associations. While the two partners continue to share employees, we can't accuse them of illegal associations, but the conflict of interest is obvious.

Poking holes in FSIS-style HACCP is easy, as agency misdeeds and inaction have provided us limitless fodder. More difficult however is clearly defined changes which should be implemented to promote public health concerns. Part 9 will provide numerous suggestions for long overdue changes.

PART 9 WHAT CAN WE DO WITH THIS "SCIENTIFIC" MESS?

The primary focus of this report is the bigger picture, which is the current style of meat non-inspection concocted by FSIS. The agency's deregulated scheme was conceived in deceit, spawning inevitable and ongoing outbreaks.

True science is constant, such as 2 + 2 = 4. Or, water is two parts hydrogen, one part oxygen. In stark contrast, FSIS-style pseudo science is constantly changing, being newly defined by each new agency official who visits a plant and requires that earlier "scientific" mandates required by previous agency officials be rescinded. As such, inspectors properly define FSIS-style HACCP as "Hardly Anyone Comprehends Current Policies". FSIS-style HACCP is truly incomprehensible for its remarkable inconsistencies, and lack of common sense. Not only is FSIS-style HACCP non-scientific, it is also nonsensical, and imperils public health.

I frequently ask myself if this entire story is too bizarre to be true. Can the agency which considers itself America's premier public health agency actually be involved in insulating the source from accountability? Does the agency truly avoid tracebacks to the source? Is it possible that FSIS bureaucrats deny field inspectors the right to document unrestricted evidence of visible fecal contamination? Is it possible that FSIS-style "*science*" is actually nonsense, and non-science? Incredible allegations. You be the judge.

Nevertheless, whether we can agree or not on all the evidence this report has revealed, we at least must seriously contemplate how the agency's current deregulated system of meat non-inspection can be improved. We can agree on that. I'd like to pose ideas for all Americans to consider.

When FSIS designed its perverted style of HACCP fantasy, the agency totally discarded organoleptic inspection. FSIS essentially threw out the baby with the bathwater, to obtain agency comfort. When the time comes when FSIS or another agency modifies the current FSIS-style HACCP protocol, it is imperative that sensory perceptions be re-implemented as an acceptable complementary meat inspection partner. FSIS currently considers the organoleptic detection of VISIBLE fecal material on carcasses to be faulty, constituting "non-scientific" observations. We now know that plants with 7-log pathogen reduction interventions regularly fail to resolve VISIBLE fecal. FSIS must allow its inspectors to again use their senses, including common sense.

FSIS did not accidentally blunder into its failed deregulated policies, which were intentionally designed in the 90's. The agency hoped against hope that deregulation would actually benefit the public: the same hope which drove deregulation of the investment & banking industries, for which we are still paying a price. Since FSIS placed more focus on hope than on science, the agency essentially painted itself into a corner, from which it is attempting to extricate itself and still save face.

To understand how FSIS-style HACCP was imposed on America, we need to understand how FSIS overruled recommendations from its own National Advisory Committee on Microbiological Criteria for

Food (NACMCF). We slipped into the FSIS-style HACCP at least in part because of an over-reaction by the Clinton administration to the Jack-In-The-Box *E.coli O157:H7* outbreak. This outbreak peaked in the middle of January, 1993, just as the Clinton administration was being inaugurated. Its over-reaction is epitomized by the *E.coli O157:H7* in ground beef adulterant rule, published in 1994, and by the Pathogen Reduction: HACCP Rule, published in 1996.

The latter Rule was developed with initial input in 1994 from the NACMCF, which was co-chaired by the USDA's FSIS Administrator and FDA's CFSAN Director. Broad parameters of a potential Rule were discussed. Strong resistance to the idea of *Salmonella* performance standards for monitoring process and sanitation controls was expressed by several Committee members representing academia and the food industry. They argued that process controls could be much more effectively developed, validated and verified by the use of a microbiological indicator test such as the aerobic plate count.

After several initial meetings on this topic, NACMCF quite unexpectedly went dark for about one year. When encountering the FSIS Administrator at a professional meeting in 1995, one of the Committee members mentioned above asked why there had been no meetings for one year, as the Committee had previously met regularly, as often as eight times in one year, since its formation in 1988. The Administrator explained that NACMCF meetings were open to the public; FSIS wanted to develop its final rule without public discussion or input. Upon parting the Administrator cheerfully said "*We are changing HACCP, and there is nothing you can do about it".*

We need to remember: FSIS unilaterally changed Pillsbury-style HACCP. This is a fundamental point, which FSIS has successfully kept under wraps.

So much for transparency in government processes. With its cavalier blocking of public input, FSIS had also blocked input from some of the best scientists and food safety professionals in the country, including those most knowledgeable about true HACCP and food safety management. The meat and poultry industries and the American taxpayers have been burdened ever since with dysfunctional regulatory procedures which are counterproductive to their claimed missions of enhancing food safety and protecting the public health.

If FSIS decides to change course, and protect consumers rather than protect the source slaughter plants, the agency must require source slaughter plants to validate the safety of meat shipped into commerce from these source plants. The slaughter plants and FSIS alike should commence a large number of microbial tests of boneless trimmings, intact boxed beef cuts, and carcasses at all source slaughter plants. All FSIS test results must be posted on the agency website in real time, realizing the tests were financed via taxpayer dollars. Results of plant-conducted tests must be provided to inspectors and vets in real time, but would otherwise be considered proprietary. These lab results will quickly reveal to the agency, and to the consuming public, the true source(s) of contaminated meat. This is but step one, and step two will be a daunting task.

Step two would require that FSIS implement efficacious enforcement actions at the SOURCE, requiring the source slaughter plants to implement truly meaningful corrective actions to prevent recurrences. Admittedly, such actions would create gross discomfort for an agency which has been asleep at the wheel, and would impose production problems for the high-speed source slaughter plants. We must give credit to these source plants for already investing multiple millions into the development and implementation of various interventions which have diminished the incidence of pathogens. However, necessity is the mother of invention. JFK announced in his inaugural address in 1961 that he wanted a man on the moon by the end of the century. Although the task was arduous and gargantuan, Neil Armstrong walked on the moon in the summer of 1969, and we were all glued to our televisions. Likewise, development of additional interventions at the source will be difficult, time consuming, expensive, and won't be accomplished overnight. But it has to be done. We'll never have zero pathogens, but I've not heard anyone claim that improvements are either unnecessary or impossible. Until the source is required to clean up its act, ongoing outbreaks and recurring recalls are virtually guaranteed. And, the nation's focus will be glued on FSIS and the industry, expecting improvements.

My perception is that the vast majority of Americans agree with the previous paragraph. However, the agency's pre-HACCP promises to the meat industry effectively stymie increased FSIS oversight of meat production lines. FSIS loathes a "Hands On" involvement at the large source slaughter plants, avoids policing the large plants, and revels in circumventing its previous command and control authority at the powerful largest source slaughter plants, many of which are now multinational behemoths which enjoy enormous political and economic clout. Therefore, the first step is to rewrite and redesign the agency's theoretical HACCP Hoax, to prevent recurrences of outbreaks. A major mid-course directional change is required, akin to FSIS reassessing its own failed HACCP Plan. However, neither FSIS nor the big packers would approve of such improvements, which leads to my next suggestion.

FSIS will never voluntarily implement the steps referred to in the previous paragraph. I propose that FSIS be disbanded, and its previous duties assigned to a newly formed agency which indeed desires to inspect meat, not satisfied with a cursory window dressing audit of paper flow. FDA is not the agency for this. While FDA professionally oversees medicines and medical devices, it has neither interest in nor practical experience with inspecting food facilities. Recent illness outbreaks associated with lettuce, peanut butter, cookie dough, eggs, etc have educated this country that FDA's nonchalant "reviews" of plants once every six years or so is woefully inadequate. The new agency must embrace a "Hands On" role, willing to police the industry, and be empowered with command and control authority.

The new agency must be divorced from, and totally independent of USDA, because of a conflict of interest. USDA promotes global sales of USA's agricultural products, a noble cause which deserves our continued support. When food safety issues arise which potentially threaten our exports, USDA must place priority on exports, not on food safety. This conflict must be removed, giving food safety even footing with our export activities.

A somewhat similar scenario is transpiring in China. In the April 27, 2011 edition of "*Global Times*", which is printed in Beijing, the issue of pigs dying from diseases and subsequently delivered to slaughter

plants was discussed. An estimated 20 to 30 million dead and diseased pigs enter the food chain each year in China. In recent years, cases of factories processing long-dead pigs have been found in many cities in China. Two quotes from the article include:

> *"Sang Liwei, a lawyer who helped revise the Food Safety Law, said that the core problems in this pork safety issue lie in the lack of supervision from relevant* [government] *departments, and suggested building a strict accountability system for government officials"*.
>
> "*In China, officials from* [government] *departments that failed to supervise the quality and safety of food normally received administrative penalties such as being transferred to other posts or removal from the post. That is not enough. Their criminal liabilities should be investigated too, Sang said to the Global Times, adding that only when the cost of crime was increased would people be more cautious".*

We should be cognizant of the fact that under the global HACCP umbrella, protein from China and other countries can be shipped to the USA once those countries have ostensibly "*proven*" their inspection systems are equivalent to our. Personally, I prefer domestically-produced pork. The situation in America is somewhat different than in China, in that FSIS inspectors want to take action when observing ongoing fecal sanitation non-compliances, but FSIS avoids initiating meaningful enforcement actions at the source slaughter plants. Upton Sinclair's "*The Jungle*" focused on problems in the meat industry, but this report is focusing on problems in deregulated government non-inspection policies, such as the above Beijing article reports.

Simultaneously, it is imperative that protections for plant owners be implemented which provide expedited legal recourse when FSIS employees attempt to exceed their authorities. Truly meaningful legal recourse must be easily accessed by plant owners who are faced with inappropriate and illegal harassment, interference, intimidation and/or retaliation from ill-meaning agency employees. FSIS Directive 4735.7 was designed to provide owners such protections. However, we've had more than one example of agency cover-ups of inappropriate agency activities in Montana, even after plant owners utilized their privileges described in Directive 4735.7, which is inadequate. Directive 4735.7 also requires major modifications.

As a new agency is developed, regulations must prohibit its future employees from taking jobs within the industry for six years after departure from the agency. Currently, we are facing a dilemma entitled "*Agency Capture*", in which the agency has been captured and controlled by the very industry supposedly being regulated.

Pillsbury's original HACCP protocol is indeed science based, and provides obvious value to any industry. Meat & poultry plants fully compliant with Pillsbury HACCP principles (including a kill step) truly produce consistently safe food, and qualify for deregulation. Plants producing raw meat and poultry cannot produce consistently safe products; thus, do not qualify for agency deregulation. Requiring Pillsbury concepts such as hazard analyses, development of CCP's, utilizing pre-requisite programs, good

manufacturing practices, SOP's etc is commendable, and should be retained. If the meat & poultry plant successfully produces consistently safe products, such plants should qualify for deregulation. Plants producing fully cooked jerky, ham, precooked chicken, beef & pork for example should qualify for deregulation only after validating the safety of their products via substantial microbial testing at every step of their production process. After qualification, a decreased incidence of ongoing plant microbial test results may be implemented, results of which must be provided to agency personnel in real time. And, the agency itself must collect a specified number of microbial samples at various stages within the production line, at decreased intervals the frequency of which is predicated on historical lab results.

Meat and poultry plants utilizing kill steps, and whose lab tests are consistently negative for the presence of pathogens, qualify for deregulation. Plants producing raw meat and poultry, such as my plant and ConAgra's plant in Greeley, Colorado do NOT qualify for deregulation. These plants require a much higher degree of regulatory oversight, including a meaningful "Hands On" role by FSIS. Admittedly, this would involve two levels of FSIS scrutiny, which would NOT constitute an impossible burden. Admittedly, this would create an UNCOMFORTABLE burden to the agency to embrace a meaningful presence at the largest slaughter plants. We must remind ourselves that FSIS employees are paid via taxpayer dollars to protect public health, NOT to protect packer profit or promote agency comfort.

NASA confidently sends astronauts into space with food produced under Pillsbury-style HACCP protocol. Pillsbury-style HACCP is true HACCP, while FSIS-style HACCP is a bastardized imposter. FSIS-style HACCP is akin to cobbling together four flat tires, a chassis, a dilapidated motor, a folding lawn chair, and visqueen for a windshield and calling it a Mercedes.

We all remember the unfortunate incident when a returning Space Shuttle disintegrated upon re-entering the earth's atmosphere, showering toxic debris over numerous east Texas counties. This horrific accident resulted in an intensive NASA investigation, scouring every square foot in those east Texas counties looking for clues which could reveal the cause of the accident. If FSIS investigators had been in charge of the investigation, the agency would have concluded that the accident had been caused by inadequate air quality control standards in those counties. FSIS would also have required those counties to implement corrective actions to prevent recurrences. I agree, this is absurd! However, it is no less absurd than the agency's continued insistence on blaming downstream further processing plants for the presence of *E.coli O157:H7* and *Salmonella* which arrives at their docks (in containers bearing the official USDA Mark of Inspection).

All microbial sampling protocol must be specifically designed in part to allow tracebacks to the true source of contamination. Whenever possible, samples should be collected from single source products, not commingled. Ground beef samples should be collected from a clean grinder. All sampling, regardless of who collects it, must include thorough documentation of all evidence in real time to describe the meat being sampled. Public health cannot allow any artificial restrictions of evidence compilation such as FSIS has traditionally employed. Traceback protocol must be fully developed before the new agency takes power, not thirteen years later such as FSIS is now attempting. Since agency

sampling is funded by taxpayer dollars, all agency lab results must be posted on the agency's website in real time, with unrestricted taxpayer access.

A resurrection of the agency's previous 15 sample protocol subsequent to the detection of *E.coli O157:H7* is essential at all plants, regardless of size. And, these 15 samples must be collected on 15 consecutive days, or over a longer period at small plants which do not grind every day.

All tests, whether by the agency or the industry, must be completed, that is, to either a confirmed positive or confirmed negative finding. Artificial termination of tests must no longer be countenanced. All documentation of FSIS-collected samples must be jointly signed by the agency inspector and a plant employee at the time of sample collection: this would deny FSIS the opportunity to falsely charge an innocent plant if the lab test comes back positive, and deny the grinder the opportunity to deny personal responsibility.

Sampling of finished products does have SOME public health benefits. However, if the sample is collected from unknown sources, or a large variety of sources, the ability to subsequently implement meaningful and targeted corrective actions at the true source are limited. Therefore, testing should primarily be focused as close to the source originating slaughterhouse origin as possible.

Whistleblower protection must be guaranteed for agency employees who blow the whistle on agency corruption.

FSIS-style HACCP has deregulated the largest plants, while hyper-regulating small plants, many out of existence. Much of this is caused by the lack of national standards. A new agency must implement national standards, allowing plants of all sizes to utilize scientific findings in the absence of irrational and ever-changing subjective demands from every new agency official visiting a small plant. Small plants constitute 93% of all USDA-inspected plants, but produce only 10% of our domestic meat. Large plants constitute only 7% of USDA-inspected plants, but produce 90% of our domestic meat supply. If the new agency prefers to NOT inspect small plants, fine! All funds previously used by FSIS for small plant oversight should then be given to the states to oversee small plant operations. States are much more efficient that the bloated USDA/FSIS overlapping bureaucracy, as states have fewer levels of wasteful hierarchical administrators. Let's not allow FSIS to continue its current deception, by which it claims to desire to assist small plants, while simultaneously harassing and intimidating small plants. For this to work, liberalized Interstate Shipment rights must be given to state-inspected plants, with NO federal oversight, which would sabotage interstate shipment before it commences.

The vast majority of FSIS Field Force with whom I have visited across America fully agrees that FSIS desires to shut down small plants. I somewhat disagree. My perception is that FSIS simply desires to be set free from small plants. As such, FSIS could care less if the plants close down or stay in business; it's just that the agency no longer wants to be responsible for small plants. I believe the agency would fully embrace the idea of all small plants going under State Inspection, or become custom exempt, as long as

the agency is relieved of the burden of inspecting small plants. Think of the budgetary savings which would accrue to the agency.

Anyone who endorses FSIS-style HACCP becomes an unwitting saboteur of public health.

FSIS will refuse to see the hand writing on the wall (i.e., FSIS-style HACCP is a Hoax), until the agency's back is up against the wall. We're getting close.

Nixon had his Watergate, Clinton his Monicagate, and FSIS is experiencing its HACCPgate. However, FSIS can't fire Archibald Cox.

Force the Source, Don't Destroy the Destination.

Sleep well tonight. FSIS is.

Oh what a tangled web we weave,
When at first we intend to deceive.

Submitted by John W. Munsell, Manager
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