## **AFFIDAVIT**

My name is Felicia Nestor. I am submitting this statement freely and voluntarily, without any threats, inducements or coercion, to Tom Devine, my counsel at the Government Accountability Project (GAP) because I have become alarmed by two major developments within USDA's Food Safety Inspection Service (FSIS) which threaten food safety. One involves the agency's refusal to correct problems with its policies for the control of tissues which carry high risk for the transmission of Mad Cow disease (called "specified risk materials" or "SRMs"). The policy inadequacies are guaranteeing that these potentially dangerous tissues are entering the food supply. The other involves the veil of secrecy with which the agency is shrouding meat and poultry production and inspection.

I am a graduate of Georgetown Law School and a member in good standing of the New York State Bar. I worked as Food Safety Director for the Government Accountability Project from 1995 until 2004. During my tenure at GAP, I facilitated public disclosures by FSIS meat and poultry inspectors, members of the American Federation of Government Employees-National Joint Council of Food Inspection Locals (AFGE-NJC), regarding their concerns about policies, enforcement problems or other issues hindering FSIS inspection programs in effect at the time of the disclosures. I have been instrumental in the public release of information gained from confidential and published disclosures by approximately one thousand (1000) whistleblowers about the activities of FSIS and associated meat inspection programs. I presently am employed as an independent food safety consultant, and with the help of Public Citizen, a national non-profit consumer advocacy organization, I am continuing my work with whistleblowers nationwide working in federally-inspected meat and poultry plants.

#### 1. BACKGROUND

The regulations and policies that exist on paper rarely match exactly what goes on in meat plants. Over the years, I have depended on FSIS inspectors to describe how production and inspection actually occur, and the degree of variation that is allowed before FSIS managers will consider a violation of the regulations significant enough to trigger enforcement activity. Sometimes there are regional, local, or even individual plant modifications of these standards. Sometimes these variations are so extreme as to make the official regulation a mere formality. Only eyewitnesses can actually describe the degree to which government policies on paper correspond to procedures in the plants – and the degree to which USDA reports actually reflect the extent of violations in any plant.

Beginning in late December 2003, when the first BSE-positive cow in the United States was announced, the agency implemented a number of new regulations to address the newly recognized threat. One of the most important was a ban on "specified risk materials" (SRMs) from the human food supply. SRMs are the tissues in cattle which are most likely to transmit the disease if an animal is infected with BSE. Many tissues that are allowed for human consumption when they come from young animals are designated as SRMs, and therefore

prohibited for human consumption if they come from an older animal; therefore, a correct age determination of each animal is critical to proper enforcement of the regulation.

The agency bases most of its reassurances about the continued safety of US beef on the claim that all SRMs are being removed. But inspectors on the frontlines, the ones who inspect every beef carcass that carries the USDA seal of approval, have revealed that USDA's policy is not ensuring that age determinations, which are made by plant employees, are being done correctly and therefore SRMs are slipping unnoticed into the human food supply.

Agency officials in Washington were first notified of whistleblower inspectors' claims on December 8, 2004. Since that time FSIS has not taken any steps to change a failed policy that continues to threaten public health. Instead it has maintained a campaign of harassment against the union chairman who first notified headquarters official William (Bill) Smith of the problem.

The only meaningful action by Mr. Smith, who oversees USDA's inspection operations in the field, has been to threaten and place the messenger under investigation.

## USDA'S RESPONSE TO FIRST BSE CASE IN U.S.

On December 23, 2003 a case of BSE was confirmed in an animal that had been slaughtered in Moses Lake, Washington. Because of the tremendous public health significance and the sizable trade implications of the disease finding, the agency had to take immediate action to reassure the public that the U.S. beef supply was safe. The next day, USDA Secretary Veneman announced on national television that "this cow had given birth, and that it had not been able to get up since then." Officials publicly claimed that the agency's discovery of this animal proved that the USDA surveillance program, which focused on "downer" animals (those that cannot walk), had worked to protect the public.

But within a few weeks of the announcement, I supervised a GAP investigation which uncovered evidence that directly contradicted the official agency position, including information that the agency was aware the index cow was not a downer. If the animal was not a downer, the new no-downer rule would be much less significant, if not virtually meaningless. As a result of GAP's investigation, Congressmen Tom Davis (R-VA) and Henry Waxman (D-CA) sent a letter of inquiry on February 17, 2004 to Secretary Veneman about the condition of the index cow and the sampling protocol at the index plant. USDA's Office of Inspector General (IG) also investigated the discovery of the index cow and reported to a congressional committee in July 2004. The IG cited evidence on both sides of the issue but did not come to any conclusion in its report about whether the index cow could have been considered a downer. It was therefore clear that USDA had provided premature, if not false assurances to the public when it did not have sufficient evidence to conclude that the index cow was a downer.

Within days of the December discovery, USDA responded with immediate policy changes including a ban on "downer" cattle from the human food supply, asserting that they were acting out of an "abundance of caution." Along with the downer ban, FSIS announced

several other prohibitions and restrictions on December 30, 2003, which were made effective on January 12, 2004. They included:

- Product Holding FSIS inspectors would no longer mark cattle chosen for BSE testing as "inspected and passed" until confirmation is received by FSIS and the plant that the cattle have, in fact, tested negative for BSE. This requirement mandates the plant involved retain, or "hold," the carcass until such time that the sample had proved negative. The rapid testing protocol enacted following this change, including shipping time to one of the approved labs, would result in holding the carcass for two to three days before meat from that carcass is considered "inspected and passed" and is permitted to enter commerce.
- Advanced Meat Recovery AMR machines remove small pieces of meat from animals' bones which is used in ground products. Sometimes the machines also crush bones, bone marrow, or nerve tissues into the AMR product, and the resulting product had been considered "mislabeled" by the agency because it does not conform to the definition of meat. With this publication, FSIS declared that skulls and vertebral columns of cattle 30 months of age or older were not acceptable as human food and if they were used in an AMR machine, the resulting product would be considered adulterated, which would carry more significant sanctions than mislabeled product.
- Air-Injection Stunning FSIS banned the practice of air-injection stunning to ensure that portions of the brain are not dislocated into the tissues of the carcass as a consequence of using this technology for stunning cattle during the slaughter process.
- Specified Risk Material FSIS declared that skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle 30 months of age or older and the small intestine and tonsils of all cattle are specified risk materials that are prohibited in the human food supply.

#### IS USDA NOW PROVIDING FALSE REASSURANCES ABOUT SRM REMOVAL?

Of all of these regulatory changes, SRM removal has been repeatedly affirmed as the most important. Soon after the regulations were announced, USDA assembled an international scientific review panel to review the department's actions pertaining to BSE. In February 2004, the panel said "the removal of the specified risk materials from the animals from the food supply was the single most important action [USDA] took to protect public health in our human population."

The statement has been repeated numerous times by government and industry personnel and figured prominently in many media articles. USDA's Undersecretary for Food Safety Elsa Murano repeated this statement to Congress in March 2004 when testifying before the House Agriculture Appropriation Subcommittee about FSIS' 2005 budget request. USDA Secretary Veneman and Jim Hodges, President of the American Meat Institute Foundation, both reiterated the same statement at the Joint Hearing of the House Government Reform Committee and House Agriculture Committee on July 14, 2004.

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<sup>&</sup>lt;sup>1</sup> Transcript of Remarks From Technical Briefing on BSE and Related Issues With Agriculture Secretary Ann M. Veneman and USDA Chief Veterinary Officer Dr. Ron DeHaven. March 15, 2004. http://editorials.arrivenet.com/gov/article.php/2686.html

Other agencies responsible for BSE-prevention also cite the SRM ban as the primary prevention against the transmission of the disease to humans. USDA's Animal and Plant Health Inspection Service (APHIS), the agency in charge of the BSE surveillance program, has emphasized that USDA's testing for the disease is not designed to keep positive animals out of the food supply because the SRM removal policy is intended to ensure that infective tissues do not enter the human food supply. In December, 2003, Ronald DeHaven, APHIS Administrator said, "By removing the specified risk materials from animals [over] 30 months of age [Note the emphasis on age-related SRMs], we have done the single most important thing that we can do to protect human health." When a possible second BSE cow was discovered in November 2004, Andrea Morgan, Associate Deputy Administrator of APHIS said, "USDA remains confident in the safety of the U.S. beef supply. Our ban on specified risk materials from the human food chain provides the protection to public health, should another case of BSE ever be detected in the United States.

But it appears that the agency may again be issuing false reassurances about its controls for BSE. Whistleblowers have described a system that is structurally incapable of preventing and in fact, is concealing when SRMs from enter the human food supply.

#### 2. SRMS ARE NOT BEING PROPERLY REMOVED FROM THE FOOD SUPPLY

SRM removal occurs in the context of the general meat and poultry regulations of FSIS. The written policies for SRM describe how SRM removal *should* work. Whistleblowers' information shows why it is not working.

#### BASICS OF FSIS REGULATION

In each plant, basic food safety, sanitation and other activities necessary to meet the regulations are performed by employees in four distinct roles: company employees, FSIS Public Health Veterinarians (PHVs), FSIS Off-line Inspectors and FSIS On-line inspectors. (FSIS PHVs and Off-line Inspectors perform many of the same functions with respect to SRMs, and will be considered together, under the category "Off-line Personnel," except where otherwise indicated.) The regulatory program used in FSIS-inspected meat and poultry plants is called the Hazard Analysis Critical Control Point program, or HACCP.

<u>Basic Company Responsibilities</u> - Each company is responsible for assessing food safety hazards which are likely to occur, devise a "HACCP plan" to address them, and implement and monitor the execution of the plan by company employees. The plant also must devise a Sanitation Standard Operating Procedure (SSOP) to address sanitation issues that could affect

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<sup>&</sup>lt;sup>2</sup> Technical Briefing and Webcast with U.S. Government Officials on BSE Case. December 31, 2003. http://www.usda.gov/news/releases/2003/12/0456.htm

 $<sup>^3</sup>$  Statement by Andrea Morgan, Associate Deputy Administrator , Animal and Plant Health Inspection Service, USDA, November, 18, 2004, Release No. 0501.04, http://www.usda.gov/wps/portal/!ut/p/\_s.7\_0\_A/7\_0\_1OB/.cmd/ad/.ar/sa.retrievecontent/.c/6\_2\_1UH/.ce/7\_2\_5J M/.p/5\_2\_4TQ/.d/2/\_th/J\_2\_9D/\_s.7\_0\_A/7\_0\_1OB?PC\_7\_2\_5JM\_contentid=2004%2F11%2F0501.xml&PC\_7\_2\_5JM\_navtype=RT&PC\_7\_2\_5JM\_parentnav=LATEST\_RELEASES&PC\_7\_2\_5JM\_navid=NEWS\_RELE ASE#7\_2\_5JM

the wholesomeness of its products, implement and monitor the execution of the SSOP by company employees. The plant may also perform other activities so that its products meet regulations, but it does not have to have formal written plans or monitor these activities.

<u>Basic On-line Inspection Responsibilities</u> - Prior to the slaughter of the animals, on-line inspectors in some plants observe the behavior of live animals to identify those acting abnormally. This is called ante-mortem inspection. (In other plants, the PHVs perform this initial function themselves.) This is the stage at which a symptomatic mad cow could be spotted and prevented from entering the food supply. Those acting abnormally will be further examined by a PHV and may be kept from the food supply.

All apparently normal animals enter the slaughter facility, are killed and then are subject to a second, post-mortem, government inspection during which on-line inspectors are supposed to examine the carcass, head, and viscera of each animal to look for symptoms of disease and contamination. In the small plants, all of this may take place in the same room, with the animal in a stationary position. In the larger slaughter plants, up to nearly 400 animals per hour will be slaughtered and hung on a moving chain to be carried through the "disassembly" process. On-line inspectors are positioned at fixed stations along this line to examine each head, viscera, and carcass. These inspectors rotate between the three inspection stations several times throughout the day in order to maintain a fresh perspective. There are a few conditions for which on-line inspectors are authorized to take action. For instance, in theory they are authorized to require plant employees to conduct further decontamination activities when they spot fecal contamination on a carcass. With respect to most pathology, however, their instruction is only to separate "normal" from "abnormal," not to identify specific diseases or conditions. They are required to call most conditions to the attention of off-line inspectors or veterinarians, so that these supervisors can make a final determination. Off-line inspectors can make some dispositions on contamination that on-line inspectors are not allowed to make; veterinarians make all pathology dispositions.

On-line inspectors performing duties at the Head Inspection Station perform a number of examinations to complete an inspection of the head. (The on-line head inspection station is very pertinent for proper SRM removal because this is the stage at which the government *could* check the age of every animal). The inspectors assigned to this station are expected to perform checks of the eight (8) lymph nodes in the head, palpate the tongue, make an incision in the cheeks to check for disease indicators that could affect the rest of the carcass, and check the eyes for disease indicators. They also check for contamination and to see if there are too many "knock-holes" in the head which would indicate inhumane slaughter. Inspectors at this station may have less than thirty seconds to perform all of these examinations.

In most slaughterhouses, one chain carries the animal heads alongside the chain bearing the carcasses until they are given corresponding marks; this will enable either part to be located if later examination indicates that the whole animal or parts should be condemned. If the on-line inspectors detect anything that appears to be abnormal with respect to pathology they are to identify the carcass so that plant employees can "rail out" or sidetrack the suspicious head or both carcass and head for further evaluation by the PHV. Depending on what pathology is observed, one or both may be condemned.

Basic Off-line Inspection Responsibilities - The PHV performs pathology examinations for suspect conditions on any animals "railed out" or otherwise segregated (for instance, during ante-mortem inspection) by government employees. PHVs also supervise the inspection activities of all of the FSIS inspectors assigned to the plant and make the final determination regarding the acceptability of product produced by the plant when such product has been challenged by FSIS staff. If the carcass and associated products make it beyond the "final rail" inspection process, that product will end up in the food chain for public consumption.

Off-line inspectors on the slaughter floor typically have had more years with the agency than the on-line inspectors. Their primary responsibility is to perform HACCP-related "verification" procedures and verification is the primary inspection methodology under HACCP. After the initial on-line inspection of the carcasses for pathology and gross contamination, all other meat processing activities will only be regulated through spot checks, called verification, by the government. Most products become eligible for the government seal of approval not because they have actually been inspected by government inspectors, but because inspectors have *verified* that the establishment was conforming to its own HACCP and SSOP plans while producing the product. In contrast to on-line inspectors, who look at the parts of every carcass that are subject to inspection, processes can be so numerous and/or complex that it is impossible for off-line inspectors to check all parts of all processes on a daily basis, and inspectors are instructed to spot-check using several different methodologies.

Verification has been the subject of many FSIS materials and training, as it is an integral part of the overall HACCP concept. The design of a plant's HACCP plan (that is, which production points in the plant are classified as likely hazards, and what procedures are designated as critical control points for controlling those hazards) sets the parameters for what FSIS inspectors are entitled to verify. This has been a source of confusion and variation from plant to plant since HACCP went into effect, and also the subject of broad-based criticism by consumer groups as well as government reviewers. <sup>4</sup>

An agency directive on Verification, from May 21, 2003, says:

If the establishment has a separate HACCP plan for each of the products in the same processing category, the CSI [FSIS inspector] needs to have a method of verifying that the regulatory requirements are met in all of the HACCP plans at some frequency.

Yet inspectors have told me that there is no official form to make records of their verification activities, which would enable them or other off-line inspectors to ensure that no parts of the process are being missed altogether; when they have devised forms to enable such in-plant coordination they have been ordered to stop using "bootleg" forms.

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<sup>&</sup>lt;sup>4</sup> United States Department of Agriculture/Office of Inspector General. "Food Safety and Inspection Service: HACCP Implementation." Report No. 24001-3-At. June 2000.

United States General Accounting Office. "Meat and Poultry. Better USDA Oversight and Enforcement of Safety Rules Needed to Reduce Risk of Foodborne Illnesses." GAO-02-902. August 2002.

The Oxford Desk Dictionary and Thesaurus defines "verify" as "establish the truth or correctness of by examination," but in this context, it should not be understood to mean that every aspect of a company process that has been verified by FSIS has been found to be working correctly, or even that it has been specifically looked at. On any given day, other parts of the process might have been inspected instead, and over time, a particular task may be routinely neglected. Since the agency prohibits the recording of what specific verification inspections have actually been done, there are no records to demonstrate that all aspects of company processes are being checked on a regular basis.

During the slaughtering process, beef carcasses and parts are subject to a combination of the comprehensive "carcass-by-carcass" on-line inspection and hit-or-miss "verification," depending on the particular condition in question. For example, on-line inspectors check every carcass for fecal contamination. But the age determinations governing which tissues must be removed as SRMs are only subject to verification.

Off-line personnel (either the Off-line Inspector or the PHV) are responsible for the issuance of Noncompliance Records (NR's), the agency methodology for documenting a condition or product that is not in compliance with the applicable agency regulation. When a plant repeats a violation, subsequent NRs trace the numbers of accumulated NR's already issued for related violations. This protocol was supposed to provide a visible, readily accessible indicator on the face of the NR that the facility's corrective actions for a given problem were ineffective.

Off-line personnel may only document violations they witness themselves. When on-line personnel witness a violation for which they do not have authority to act, they must call for the off-line personnel to come to the area to take action. The off-line personnel must observe the noncompliance themselves and may not document a violation solely on the word of the on-line inspector, so if the plant corrects the problem in the interim and the noncompliance is not still occurring when the off-line arrives to the area, there will be no government documentation of it.

For several hours of each day, off-line inspectors and PHVs in the larger plants must take over individual inspector's positions "on the line" to provide relief breaks for these on-line inspectors. They also must do this when there are not enough on-line inspectors in a plant due to illnesses or vacancies. While covering these positions they are unable to perform any HACCP-related verification tasks. When off-line personnel are on the line, the agency functionally demotes them to acting only in the role of on-line inspectors and prohibits them from writing an NR about violations they see while working in that position, *even after* they return to their off-line position. This is very significant because it means that there are no documentary records of violations that have occurred during significant periods of time.

In order to estimate how significant these "black-out" periods are, I asked agency officials during a meeting between consumer group representatives and FSIS administrators, to estimate what portion of the day the off-line personnel must fill-in on the line. Agency officials were unable even to estimate and no specific records are kept. Agency officials cited some records that could provide a partial estimate, but even this analysis is not being done.

There is no excuse for this ignorance. A record of the hours that off-line personnel spend on the line could, very easily, be kept on the nationwide computerized inspection database that would enable Congress and agency administrators to evaluate the impact that short-staffing and prolonged vacancies in on-line positions is having on food safety.

# <u>SRM REMOVAL – THE THEORY</u>

On January 12, 2004, the agency issued FSIS Notice 5-04, Interim Guidance for Non-Ambulatory Disabled Cattle and Age Determination. This notice reads, in part:

#### II. BACKGROUND

...Although cattle of any age must have the tonsils and entire small intestine disposed of as inedible, cattle 30 months of age and older have additional specified risk materials (SRMs) that also may contain the BSE agent in cattle infected with the disease. [These include the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia.] These SRMs must be disposed of as inedible.

IV. D. [FSIS will] consider cattle to be 30 months and older when the examination of the dentition of the animal shows that at least one of the second set of permanent incisors has erupted.

Company Responsibility for SRM - Companies are responsible for how age determinations will be made and how SRMs will be removed and segregated, and to ensure that any cross-contamination from SRMs is addressed. On January 23, 2004, the agency issued FSIS Notice 9-04, Verification Instructions for the Interim Final Rule Regarding Specified Risk Materials (SRMs) in Cattle. This notice reads, in part:

...establishments that slaughter cattle and establishments that process the carcasses or parts of cattle shall develop, implement, and maintain written procedures that are incorporated into their HACCP plan, or in their Sanitation SOP or other prerequisite program for the removal, segregation, and disposal of SRMs.

On January 9, 2004, the agency had issued FSIS Notice 4-04, Awareness Meeting Regarding New Regulations That Prohibit Non-Ambulatory Disabled Cattle and the Use of Certain Materials From Cattle for Human Food. This notice directed FSIS inspection program personnel to inform plant management of the new requirements and conduct follow-up meetings "to ensure that the establishment understands what is required under the new regulations." This notice reads, in part:

### Has the establishment addressed:

...How it will determine age of cattle, such as by records or dentition?

How it will segregate cattle 30 months of age and older from cattle younger than 30

months?

How it is removing, segregating, and disposing of SRMs to ensure that there is no cross-contamination with edible product? (NOTE: For example, the vertebral columns from cattle 30 months of age and older do not have to be removed during the slaughter operation. However, if they are not removed in the slaughter operation, procedures must be put in place to ensure that the vertebral columns are adequately identified as being from cattle 30 months of age and older and the documentation transfers with the vertebral columns until they are appropriately disposed of as inedible.)

On January 12, 2004, the agency issued BSE-related FSIS Notice 5-04, which clarified that plants could use documentation (birth certificates, cattle passports, etc) to demonstrate the age of animals. However, if documentation were not available the government would verify age using a dental examination.

There may be some plants that slaughter exclusively younger or older animals, but most plants will at least periodically have a mix, and therefore need to have an established procedure to pin down the age of individual animals. Until a national animal identification system is in place (which USDA officials have indicated is not likely until 2009 at the earliest), dentition checks will play a critical role in determining cattle age.

Age determination using the dentition method necessarily takes place near the beginning of the disassembly process when the head and carcass are still in close proximity so that both can be marked before they are separated. SRM removal does not necessarily occur at this beginning stage and often will occur later in the lengthy disassembly process. Even when all SRM removal takes place in the slaughter plant, the slaughter line can be extremely long and winds through several different rooms. A correct age determination and marking of the carcass parts is essential so all industry and government personnel throughout the rest of the process are on notice to treat the parts of the carcass appropriately. Only correct age markings adequately notify all subsequent workers on the line that extreme precautions must be taken so that dangerous tissues do not infiltrate the food supply.

There are less than 700 US plants that slaughter any cattle but FSIS estimates that nearly 3, 400 total, which perform other regulated functions like processing, engage in commerce with SRMs. Mistakes in any of the slaughter plants could go on to impact the safety of products in many plants and food service facilities. The distribution pattern for the BSE-infected cow discovered in 2003, which was slaughtered at a very small facility, provides a good example – meat from the one cow reportedly went to 578 establishments in at least 8 states and Guam and led to the recall of 38, 000 pounds of products due to potential cross-contamination.

<u>Off-line Personnel Responsibility for SRM</u> - On January 14, 2004, the agency issued FSIS Notice 7-04, Questions and Answers for FSIS Notice 4-04 Regarding BSE Regulations. This notice defined the responsibilities of FSIS personnel for verification of the prohibitions upon SRM entering the food chain. This notice reads, in part:

Question: Who is responsible for the verification of these procedures?

**Answer:** The off-line inspection personnel will verify the implementation of the procedures

On January 23, 2004, the agency issued FSIS Notice 9-04 "Verification instructions for the interim final rule regarding specified risk materials (SRMs) in cattle," which describes in detail the actions that inspection personnel should take to prohibit SRMs from entering the food chain. This notice reads in part:

# IV. VERIFICATION PROCEDURES FOR INSPECTION PROGRAM PERSONNEL

...Inspection program personnel are to perform the verification activities related to SRM removal in conjunction with the other food safety concerns by reviewing records (e.g., looking at HACCP monitoring records), observing plant employees performing procedures (e.g., observing plant employee performing a dentition examination), or by conducting hands-on inspection verification procedures (e.g., verify adequacy of Sanitation SOP procedures).

<u>On-line Personnel Responsibility for SRMs</u> - FSIS Notice 7-04, referenced above also identifies the responsibilities of on-line inspection personnel. It reads, in part:

## C. Post-mortem on-line verification duties

#### Head and Carcass inspection:

- 1. When on-line inspection program personnel perform individual carcass or head inspection and observe visible (readily identifiable) SRMs on edible portions of the product, the establishment may recondition the entire carcass or head by knife trimming.
- 2. On-line inspection program personnel are to notify the VMO or, if unavailable, other off-line inspection program personnel when there is evidence that an establishment's SRM control program is ineffective (for example, when repeated presentation of contaminated heads or carcasses for post-mortem inspection at the rail and head inspection station indicates failure to control SRM contamination).

This notice only instructs on-line inspectors to check that no SRMs such as pieces of spinal chord or brain matter are present on meat. There is no mention of checking the animal's age. On-line inspectors already closely examining *each* head for this and other conditions are in an excellent position to check each head for the incisors which indicate an animal over 30 months old; this would indicate whether plant employees have correctly identified and marked the heads and carcasses of all older animals. Although the agency says that any inspector who finds an age determination mistake must prohibit SRMs from entering the food supply, it is unlikely that most on-line inspectors will make the original finding because, not only are on-line inspectors not instructed to check age determinations, the agency

has decided and repeatedly makes clear that it is not their job. During the January 27, 2005 meeting between representatives from consumer groups and FSIS administrators, Pierson and Masters, confirmed that it was not the job of on-line inspectors to do dentition examinations to check for proper age determinations.

#### SRM REMOVAL – THE REALITY IN THE FIELD

Whistleblower Disclosures - Understandably, implementation of new regulations and policies may encounter unforeseen difficulties that prevent achieving identified goals. By late summer 2004, I began to hear from inspectors in mechanized slaughter plants that the official BSE procedures mandated by the agency were not working to keep dangerous SRMs from getting into the food supply. I spoke with inspectors from three plants in two different parts of the country who told me about specific instances when on-line inspectors went above and beyond their assigned duties, checked plant employees' age determinations and found that cattle over 30 months old had not been marked. The unmarked heads and carcasses were proceeding into other production areas to be processed as if they were younger animals, which could result in SRMs entering the human food supply. On-line inspectors had used the dentition method to determine the cattle's age. In all cases, they notified the off-line personnel, who confirmed their findings. In all cases, the plant was required to take effective corrective actions to ensure that known SRMs did not enter the food supply. In at least two of the cases, an NR was written.

In all cases, the on-line inspectors pointed out to off-line personnel that age determinations were not being done correctly by plant employees and expressed their concerns that violations could be occurring frequently. They asked or suggested that the online inspectors be instructed to check every head. In all cases they were told that it was not their job. They were not forbidden, however, from doing the check or reprimanded for having done it and found the problems.

Unidentified older carcasses pose additional danger when the bones are used in AMR machines. Many of the larger plants have AMR machines. Although the new regulations prohibit the use of skulls and vertebral columns of animals older than 30 months old from being used in AMR, if an over 30-month carcass leaves the slaughter floor unmarked, that public health rule will be meaningless, with no way of preventing bones from entering any AMR process to which they are sent.

On-line inspectors from the plants who originally informed me of the SRM problems said they were fairly certain that the plants they worked in had been cited for AMR violations within the previous two years. This is not surprising since the agency's own studies have previously and recently identified significant rates of non-compliance with AMR restrictions. I also heard from two inspectors in two different parts of the country that when working at the Viscera Inspection Station they were unable to keep plant employees from sending kidneys and hearts from older animals into production streams where only organs from the younger animals should have been sent (to comply with export requirements.) Once the unmarked

organs were separated from the older carcasses there was no way that on-line inspectors could prove that they had come from the older animals. Since off-line personnel must not make decisions without seeing violations themselves, the off-line inspectors were unable to prevent the organs from continuing into production. These organs are not considered SRMs in the U.S. but are prohibited from export to Mexico. The Export Requirements for Mexico dated September 13, 2004 read, in part

# A. Eligible Products

1. Fresh/frozen meat and meat products with the exception of beef and beef products. However, boneless beef and boneless beef products including tripe, trimmings, heart, kidneys, lips, diaphragm, tongue and cheek meat derived from animals less than 30 months of age and produced under an approved Agricultural Marketing Service (AMS) Beef Export Verification (BEV) program for Mexico are eligible for export.

One of the whistleblowers asked FSIS supervisors numerous times if there were something else that could be done to prevent the export of prohibited products, but was told it was the company's responsibility to make sure that export requirements were met, not FSIS'. The other whistleblower also complained that prohibited products were being sent into production areas where products were being packed for export and was told, "Mind your own business."

It became clear from the whistleblowers that these occurrences were not flukes. They were the result of inadequate agency policies and institutional impediments which hinder both company and government employees in their responsibilities to see that SRMs do not reach the public. In 2005 other whistleblowers have continued to tell me of older animals not being correctly marked, and being prevented from entering the food supply only because an on-line inspector went above and beyond his or her assigned tasks, checked the head, found the age determination procedure was not followed correctly, and called off-line personnel to take action. Problems with products destined for export also continue.

<u>Institutional Impediments: Companies</u> - Institutional impediments which decrease industry effectiveness in removing the SRMs include the lack of government training or certification requirements for industry workers, difficult working conditions, high rates of worker turnover, and the inherent conflict of interest when industry regulates itself.

First, there is no government requirement that plant workers be trained about the public health significance of SRMs, or even which tissues constitute SRMs. As a rule, that means that the plant can attempt to meet the regulation in any way it chooses, e.g. it could train workers about which tissues must be removed but it is not required to inform them why proper removal is important. Workers may be ignorant of the danger to public health that results if even slight mistakes are made. There are no requirements for minimum qualifications established by FSIS regarding the skill and training of the plant personnel performing the age determination of cattle at the slaughter facilities. There is no government testing of industry employees responsible for performing these tasks or for those employees who monitor them. Among government employees, in contrast, only the veterinarian is

considered qualified and is given the authority to definitively determine the age of cattle and enforce this part of the regulation.

A recent study by Kansas State University<sup>5</sup> reported on data from 7 firms which represent "more than 60 percent of 2003 beef slaughter and were sufficiently diverse to represent a reasonable cross section of the beef packing industry." The study found that:

Some [firms] train only those [employees] directly affected by the rules (e.g., dentition personnel), while others train all plant employees. . . . One firm was using a formal ongoing training program to review and evaluate employee performance. However, in most cases, ongoing training expenses were not reported. <sup>6</sup>

Despite the public health significance of thorough SRM removal, government expectations of industry self-monitoring activities are surprisingly minimal. The "information collection and recordkeeping requirements" for this activity were estimated by FSIS to be "about five minutes a day developing an average of nine monitoring records, which includes documentation of any corrective actions taken, and an additional two minutes a day to file each record."

The second impediment to company effectiveness is the working condition of most company employees. In 2004, Human Rights Watch reported in "BLOOD, SWEAT, and FEAR. Workers' Rights in U.S. Meat and Poultry Plants" that industry workers have few employment rights, can be fired at will and are aware that they are, by and large, fungible and easily replaced. Turnover rates exceed 100 percent per year at some companies. Workers, especially the many undocumented employees who make up a sizable portion of staff at large beef plants, are so fearful of the company's ability to fire them or their family members that they neglect to seek compensation for on-the-job injuries. It would be unreasonable to expect those workers to resist pressure from production managers and protect consumers from the risk from Mad Cow disease and SRMs, if they are even aware of these dangers.

Finally, the inherent conflict of interest for companies between food safety and profits, which has always existed in the industry, has become more significant for consumers in the last decade since the agency implemented HACCP. Industry conflict of interest is also especially problematic with respect to keeping BSE out of the food supply in this HACCP environment.

The agency maintains that under the HACCP inspection system companies are now more "responsible" for food safety. Often this means an honor system where the government does not hold those companies that pose the greatest risk *more* accountable for food safety, but less. In reality, the firms are on their own, to an unprecedented degree.

<sup>&</sup>lt;sup>5</sup> Kansas State University. "The Economic Impact of BSE on the U.S. Beef Industry: Product Value Losses, Regulatory Costs, and Consumer Reactions." April 2005.

<sup>&</sup>lt;sup>6</sup> Kansas State University. page 37.

<sup>&</sup>lt;sup>7</sup> 69 Fed. Reg 7, 1872 (January 12, 2004)

The agency's treatment of products contaminated with E. coli O157:H7 provides an important example. E. coli O157:H7 is a pathogen which can contaminate meat during the slaughter of cattle. It is found in the intestinal tract and spreads through fecal contamination on hides or when the intestines are punctured through improper slaughtering procedures. Analysis of the agency's E. coli testing policies by the Office of Inspector General after a massive recall of ground beef in 2002, shows that until the recall, the agency held the very small companies who bought beef from the much-larger ConAgra company accountable for the microbial conditions of the products they got from the industry giant. OIG further reported that FSIS ordered inspectors in the ConAgra plant to ignore repeated signs of trouble there. (Figures provided in the IG report show that ConAgra produced nearly four times as much beef product in one day as the two spotlighted companies receiving its contaminated products, together produced in one year.) The agency also actively resisted using its regulatory authority at the large processor to protect consumers even after it found proof of contamination in ConAgra's products at one of the small plants. The agency instead focused numerous resources and all enforcement activities at the two small plants that had received contaminated beef from ConAgra. Agency officials also retaliated against one plant owner<sup>9</sup> and ridiculed the other for suggesting that the agency should hold the original contaminator accountable:

It is the [receiving] establishment's responsibility under the regulations to address the source of the food safety hazard.... It does not appear that this company is trying to do this, but instead to point fingers at other companies [ConAgra] not meeting their responsibilities...."

This paradigm shift, under which it is not the government but the industry's responsibility to hold other upstream violators accountable, now governs U.S. inspection of meat and poultry products. The IG report demonstrates that under the current inspection regime, the government expects the buck to stop with smaller processors, not government regulators, to hold conflict-of-interest at the big packing companies in check.

There are also characteristics specific to the BSE problem that magnify typical conflict-of-interest concerns. In general, each expense (e.g. to train workers or invest in food safety technologies) and each production delay that could improve food safety (e.g. to slow linespeeds so that workers have enough time to remove contamination) is directly weighed against profits. However, profits also can be threatened by inadequate attention to food safety. Indeed, the industry often has argued with respect to microbial contamination that the possible financial consequences to a company from a food poisoning outbreak create enough incentive to ensure that companies will decide all judgment calls in favor of consumer protection. They assert that companies will spend money to take food safety precautions on a day-to-day basis in order to avoid the potentially higher cost of being sued if a customer gets sick or loss of market share if the company is associated with an outbreak. However, the

<sup>&</sup>lt;sup>8</sup> Food Safety and Inspection Service Oversight of Production Process and Recall at ConAgra Plant (Establishment 969). USDA/OIG Great Plains Region Audit Report. Report No. 24601-2-KC. September 2003

<sup>&</sup>lt;sup>9</sup> "Shielding the Giant: USDA's 'Don't Look, Don't Know' Policy for Beef Inspection." Tom Devine. Government Accountability Project. June, 2003.

<sup>&</sup>lt;sup>10</sup> *Id.* USDA/OIG. p 46.

government's own economic studies demonstrate that, because the source of contamination which causes a foodborne illness is rarely identified, market incentives to incur extra food safety costs are actually weak (although not entirely non-existent) and do not lead to increased company attention to consumer safety.

If pure market incentives are inadequate to prevent the industry from gambling with consumers' lives when they *might* be held accountable for selling pathogen-tainted food, then the economic incentives will be nil when the contaminant is BSE. In the absence of effective regulation it would be reasonable to expect companies to cut corners. Any establishment could assess the risk of possible BSE contamination from cattle coming into the slaughterhouses as extremely low, following the leadership of the American Meat Institute which states there is an "infinitesimal incidence of BSE in North America." According to one industry attorney, most of his clients do not control SRMs as food safety hazards that are likely to occur, because they rely on the various other regulations that are in place for animal feed, surveillance, and other pre-slaughter programs. (Several whistleblowers have said that USDA supervisors also have justified less stringent approaches to BSE testing or precautions based on this assumption.)

Additionally, there is no comparable risk of getting caught for negligently allowing SRMs or tissues from a BSE-positive animal to enter the food supply, as now exists relative to pathogens. In contrast, where microbial tests are available and have been widely used by the agency and industry to detect contamination post-production, to date no production-based test for BSE tissues or SRMs has been developed. Once the animals leave the slaughter floor there is no chance of negligent company procedures being detected by using a test further along in the process. Intermediary merchants who might receive negligently handled beef will have no way of testing for SRMs. Consequent illnesses also will not be an indicator of negligent practices within a particular company because the incubation period for BSE is theorized to be between 10 and 40 years. <sup>12</sup> In the event a consumer does contract the human form of mad cow disease it will be impossible using current science to link that illness to any particular beef company.

Because there are virtually no incentives for a company to incur costs to protect consumers by preventing SRMs from entering the food supply, company activities to protect consumers from BSE should not be relied upon. Because of the extreme inherent conflict-of-interest with respect to BSE, it is unreasonable to expect that companies will spend any more than is required to meet the minimum government regulations pertaining to BSE. Companies may spend as little as possible to train and monitor the workers tasked with performing age determinations and company production managers may actually even pressure workers, who have very little ability to affect company practices, to cut corners on BSE protections like stringent age determinations and careful SRM removal. Since I began working with inspectors 10 years ago, I've heard many times of company workers, even those responsible for quality assurance and food safety programs in companies, who are so reluctant to risk

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<sup>&</sup>lt;sup>11</sup> Footnote 798 in Thomas O. McGarity with Frank Ackerman, Center for Progressive Regulation, "Flimsy Firewalls: The Continuing Triumph of Efficiency Over Safety in Regulating Mad Cow Disease Risks." July 22, 2004. http://www.progressiveregulation.org/articles/mad\_cow\_report.pdf at 103.

<sup>&</sup>lt;sup>12</sup> Personal communication – Dr. Michael Hansen, Consumers Union, May 10, 2005.

angering the production management that instead of confronting offending company employees, they routinely and secretly notify government inspectors about violations of the regulations, on the hope that they will take the required action to protect the public.

<u>Institutional Impediment: FSIS Off-line Personnel</u> - During my investigation, frontline personnel in different parts of the country explained the weaknesses of off-line verifications for protecting the public from age-specific SRMs. The impediments to veterinarians and off-line inspectors' effectiveness in ensuring that SRMs are removed are company autonomy in designing HACCP plans, little or no agency standards for performing verifications of SRMs, and excessive workloads that preclude off-line personnel from doing adequate verifications.

First, off-line verification is limited by how a plant designs its HACCP plan because this determines what will be verified. As mentioned above, the new BSE regulations required that plants reassess their HACCP plans and devise specific controls for SRMs. At one end of the spectrum a plant could establish age determination as a Critical Control Point in its HACCP plan, which would allow maximum government oversight of the age determinations, and subject the plant to NRs, corrective action, and possible re-evaluation of the plant's HACCP plan in the case of noncompliance. At the other end of the spectrum, the plant could avoid this level of government scrutiny by claiming that contamination with age-specific SRMs was unlikely because the plant had included removal of SRMs from older animals in a pre-requisite program.

The Center for Responsive Politics analyzed USDA regulation of SRMs and found that pre-requisite programs "do not require FSIS approval, do not establish and monitor quantitative limits for the risky material in meat products, require little documentation, have a high tolerance for failure, allow companies to shift responsibility to downstream processors who may not have sufficient expertise or resources to do the job, and are ultimately not very likely to attain the much flaunted "zero-tolerance" goal that FSIS established in its regulations."<sup>13</sup>

Not surprisingly, the Center found through numerous interviews with industry representatives that "virtually all of the establishments subject to the January 2004 regulations are addressing SRMs in their Sanitation SOPs and prerequisite programs, rather than by amending their HACCP plans to establish scientifically monitored critical limits at critical control points." <sup>14</sup>

Second, consistent with problems identified earlier, there is little if any agency guidance on the frequency with which off-line verifications for age determination or SRMs should be performed. Prior to HACCP inspection, the inspectors' assignments sheets instructed them to perform very specific inspection tasks – there were over 400 of them. Inspectors would record that each task was or was not performed and whether the plant's performance was acceptable or not. Under HACCP, there are less than 40 verification activities, and they are

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<sup>&</sup>lt;sup>13</sup> McGarity, supra at 97.

<sup>&</sup>lt;sup>14</sup> McGarity, supra at 102.

much less specifically defined. Consequently, off-line personnel have much more discretion and their recorded reports of verifications activities similarly are more generalized.

Under the current system, the assigned task will only be to verify the plant's HACCP plan – there is no specific inspection task to check SRMs or age determinations. It is entirely up to the off-line personnel when and if to check these as opposed to other parts of the HACCP plan, whenever this assignment is given. An off-line inspector in a larger plant confirmed that there are more possible verifications than he could perform on any given day, due to time constraints and that the agency has issued no notice which indicates that age determination and other SRM issues should be a top or any priority. Although inspectors are instructed to ensure that all parts of the process eventually are verified, the agency does not mandate that inspectors record specifically what individual parts of the process they verified, how they verified it, or how many times, if at all, they verified it on any given day. Therefore, neither the other inspectors in the plant, nor the agency will have records to determine or report the extent to which age determination verifications are actually being done. When consumer groups met with FSIS administrators on January 27, 2005, the agency confirmed that there were no identifiable frequencies with which verifications for age determination were done.

On April 22, 2005, I called FSIS' Tech Center, <sup>15</sup> asked about verification for SRMs and was told:

- The inspection code to trigger an agency verification of a company's SRM controls would be 03J. This would also refer to company control of other food safety hazards like fecal and ingesta contamination. When inspectors are assigned an 03J task, they might decide to check the SRMs or they might decide to check these other controls instead.
- Inspectors might get an 03J code one or more times, or not at all, on any given day.
- While inspectors always have the option of performing a verification when they are concerned, in larger plants they cannot perform a verification of all aspects of a company's production system every day, due to time constraints.

As a result, to say that off-line personnel verified that a company's HACCP plan was working on any particular day does not indicate that the age determination activity was reviewed at all by the government, let alone that it was operating as it should.

Finally, inspectors in the larger plants have been reporting for years that the off-line personnel routinely "cover the line" for two or more hours per day. At the April 25, 2005 meeting with FSIS administrators, consumer representatives were told that off-line personnel do have to fill in for on-line inspectors to give breaks and when there are vacancies. We were also told that there are no records kept of how frequently they do this or for how long.

Institutional Impediments: FSIS On-line Inspectors - On-line inspectors currently do not have an official agency role in ensuring that age determinations made by company employees

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<sup>&</sup>lt;sup>15</sup> "The TSC serves as the Agency's center for technical assistance, advice, and guidance regarding the implementation of national policies, programs, systems, and procedures including implementation of the farm-to-table food safety strategy within a HACCP framework." http://www.fsis.usda.gov/OFO/TSC/

are correct. The agency claims this is irrelevant and that any inspector who finds an age determination error must act to protect the public. This argument misleads the public because it implies that, despite impediments under the current policy, inspectors will spot the problems. It ignores the following facts about on-line inspection as it occurs in plants today:

- Given the line speeds that the agency allows at large plants, on-line inspectors have less than a half a minute to perform all of their examinations. A whistleblower told me that approximately only 10-15% of on-line inspectors he knows ever perform dentition checks, perhaps for this reason. Deputy Under Secretary Pierson told a meeting of consumer representatives on January 27, 2005 that if the agency added an age verification task, one of the other head inspection tasks would have to be dropped. He would not consider a change in line speed policies that would allow this examination to be added.
- The agency does not distribute information about age determination to on-line inspectors or instructions for how to perform this examination, so even more senior on-line inspectors might be uninformed about how do it, even if they were inclined to do more than their assigned tasks. The Tech Center expert I spoke with on April 22, 2005 said that "inspectors would know how to check every head" but one inspector told me that he did an informal survey of on-line inspectors and found that 70% of them were not aware of how a dentition examination to determine age is performed.
- The on-line inspector position is the entry-level position for FSIS inspection jobs. While many inspectors work as on-line inspectors for years, many if not most on-line inspectors in large plants are newly hired employees. These inspectors are probationary for one year and during this period are getting on-the-job training. They are busy learning and being evaluated as they perform the numerous examinations of the head, carcass and parts of the animals and it is unlikely that they would perform optional examinations, even if they knew about them. Since checking company age determinations is not an official on-line task, it is also unlikely that they will see any other inspectors performing these examinations.

Finally, when off-line personnel are covering on-line positions there is a double impediment to thorough enforcement of the age-related SRM ban. First, because they are in the role of on-line inspectors, they are not required to check the age determinations. Second, when on-line inspectors find an age determination violation, they call for an off-line inspector who then documents the problem; but if an off-line inspector finds a problem while performing on-line tasks, they cannot call anyone else to document the problem and they are prohibited from ever documenting it, even after they go back to their off-line role.

## 3. USDA'S RESPONSE TO WHISTLEBLOWER DISCLOSURES

SRM removal was a cornerstone of USDA's response to the U.S. discovery of BSE and has been USDA's linchpin for maintaining confidence in the safety of the U.S. beef supply. Credible evidence that SRM removal regulation is not working might shake that confidence and lead to pressure for other actions to protect the public. In other countries with more

extensive discoveries of BSE, governments had to enact much more extensive measures than SRM removal to regain consumer confidence.

"Across Europe, all OTM [over thirty months] cattle that enter the food chain are tested for BSE before they are released from the abattoir. In France the test is carried out for cattle older than 24 months, although this is seen as more of a reassurance to consumers than a strong scientifically based measure." . . . [In the UK,] British ministers decided that meat from both home-killed and imported animals aged over 30 months old at slaughter should be prevented from being sold for human consumption altogether. . . .In Britain, consumers were genuinely worried that they might be exposed to meat from animals that might contain detectable levels of BSE infectivity. The OTM rule helped restore public confidence at the expense, to a degree, of the beef industry. It is also relevant that, due to consumer concerns, retailers and caterers were in any case refusing to sell meat from animals over 30 months of age." <sup>16</sup>

While it is unlikely that there would be a public call for a ban on all OTM cattle, a universal testing requirement and other more stringent testing programs have already been proposed in this country. New "rapid tests" which can return a result within 24-36 hours now make it possible to test animals and get a result before the meat is allowed into commerce. Japan tests all animals at slaughter. The Japanese government has kept its border closed to U.S. beef because each animal here is not tested prior to the meat being released for food.

Some U.S. meat companies (most notably Creekstone) wanted to respond to the concerns of Japanese customers by testing every animal but it became immediately clear that USDA was loathe to consider it. USDA issued a blanket prohibition of any company testing using a law from the early 1900's and based on the premise that testing every animal would mislead consumers into thinking that animals testing negative were necessarily safe to eat. This truisim hardly means that we should not test and catch all possible, positive animals from entering the food supply.

The SRM removal regulation is the most frequent reason the agency advances for why each animal need not be tested. The clear implication is that it would not even matter if meat from positive animals enters the food supply since all of the infective tissues are removed. It should be noted that USDA does not use a similar argument to hinder pathogen testing of meat and poultry, and for good reason – easily available microbial testing would enable skeptics to immediately call such a bluff.

#### THE SIGNIFICANCE OF THE DISCLOSURES

Eyewitness accounts from inspectors on the slaughter floor are indispensable in understanding whether SRM policies are working because there is no other reliable gauge:

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<sup>&</sup>lt;sup>16</sup> "What BSE Means for Beef Processors: Testing, traceback, and a transformed industry: Hard lessons from the European experience" Chris Harris. Meat Processing. February 2004. www.meatnews.com

- There are no tests that consumers, downstream processors, or the government can use to test for SRMs once meat leaves the slaughter floor,
- There are no government records specifically concerning age determination or SRM verifications,
- The agency has created a double whammy, "see-no-evil, speak-no-evil" policy by declaring (1) that no government documentation of violations will be made based solely on the observations of on-line inspectors, the only eyewitnesses always on the "frontline" of the slaughter floor, and (2) when offline personnel are covering on-line positions, they cannot record violations they see once they are back in their off-line role,
- The agency has not issued a top-priority or required-frequency-forverification memo to off-line personnel to mandate even an identifiable minimum level of government oversight.

From a historical perspective, the months of April through September are typically those with the highest number of cattle slaughtered across the nation. Accordingly, it is reasonable to expect to see an increase in the number of animals older than 30 months presented for slaughter and thus, because many tissues are SRMs only if they are from these older animals, an increase in the likelihood of more SRMs being presented in the slaughter process at this time.

Beginning in August 2004 and continuing through the rest of the year, I received information, described in detail in the previous section, from FSIS Inspectors assigned to federally inspected slaughter facilities. In all cases, on-line inspectors were unable to prevent SRMs (as defined by U.S. regulations and Export Requirements) from entering the food chain. They reported violations to off-line personnel who took action and documented the violations only when they were able to independently confirm the problem. On-line inspectors' requests for adequate authority to prevent any more SRMs from entering the food supply were denied and inspectors were told to accept the limitations created by agency policies.

Over several months, I had repeated conversations with the whistleblowers in order to ensure that I thoroughly understood the issue and was able to see that these were recurring problems. I heard separate confirming accounts of specific situations and acquired several NRs that confirmed the details of some disclosures. I also received a sworn affidavit from one of the whistleblowers.

After having their concerns repeatedly ignored within the chain of command, and fearing for consumer safety, the whistleblowers wanted me to get the information to lawmakers who would take a second look. At the same time, they were extremely frightened of retaliation and wanted to make sure that nothing I did would identify them. I promised them that I would not reveal any identifying information to anyone without getting their permission first.

#### UNION CHAIRMAN INFORMED OF INSPECTOR CONCERNS

I approached Charles Painter, chairman of the National Joint Council of Food Inspection Locals, and advised him of the information I had learned from the inspectors and the other evidence confirming it. I also informed him of their fear of retaliation and told him that I could not reveal their identities or locations.

Painter suggested that he first go to the agency with the information first. Over the past ten years I have seen the effectiveness of joint union/management efforts fluctuate. At times, the agency has been willing to learn from its experts on the frontlines and has made adjustments to policies. In most cases, however, the agency has ignored them only to read the same criticisms and concerns in subsequent USDA's Office of Inspector General and GAO reports. The agency often tries to ignore these as well. I was not optimistic, but Barb Masters had recently become the FSIS Acting Administrator. Inspectors I had spoken with respected her and felt they could work with her, and I thought that Painter's idea was based on new found optimism which might turn out to be warranted. I also hoped that corrective action by the agency officials might be expedited by a desire not to subject the issue to public debate.

Based on my report, on December 8, 2004 Charles Painter authored a letter to the Assistant Administrator for Field Operations, Bill Smith, informing him of whistleblowers' allegations. (See http://www.citizen.org/documents/NJCletter-12-8-04.pdf for full text of the letter.)

#### Painter asked Bill Smith to:

- empower on-line inspectors to review all age determinations made by the dentition method performed by plant employees;
- authorize and assign inspectors to enforce the export requirements of foreign countries;

Painter reiterated that the Union was very concerned about the violations and issues he was reporting and asked that he be provided a formal response by December 17, 2004. Neither Smith nor anyone else from the agency responded or even acknowledged receipt of the letter.

#### PUBLIC RELEASE OF LETTER

On December 20, 2004, following the agency's failure to respond to Painter's letter, Public Citizen released a copy of it and a copy of a letter of concern it had written to Dr. Pierson, to the news media. The agency immediately began reassuring the public, without having any proof for its claims. Steve Cohen, spokesman for the USDA FSIS was quoted when responding to media inquiries as saying, "Parts that are defined as SRMs are being removed and being disposed of according to regulations implemented in January 2004." <sup>17</sup>

 $<sup>^{\</sup>rm 17}$  "US Meat Plants Violating Mad Cow Rules – Inspectors" Randy Fabi. Reuters. December 20, 2004.

In response to inquiries publicized by MSNBC on December 23, 2004, Steve Cohen noted that the on-line inspectors were not supposed to check ages themselves and continued to state that age verifications were "being done correctly," noting that plants follow a written plan for determining ages.

One inspector, on condition of anonymity, provided a statement to MSNBC stating that at the plant where the inspector was assigned, unless the supervisors personally witnessed a violation, they were instructed to ignore the on-line inspectors' claims. The inspector continued, "I am concerned that under current policies federal inspectors cannot prevent these potentially dangerous products from carrying the USDA 'inspected and passed' seal." 18

On December 23, 2004 Public Citizen submitted a Freedom of Information Act request for NRs pertaining to SRM violations, and received an acknowledgement of the request on December 30. On February 2, 2005 Janice Carpenter, of the FOIA staff, told Public Citizen's Patty Lovera that the agency had to request information from the 15 District Offices and that there was a difficulty fulfilling the request because of the agency's recordkeeping procedures. In early March, Lovera agreed to narrow the request. On April 6, 2005, the agency sent a letter stating that it was still working on the request. To date, Public Citizen has received no responsive materials.

## **FSIS RETALIATION**

On December 23 2004, an FSIS Compliance Officer (CO) arrived unannounced at Painters' home and told him to provide the CO with all related documents and the names of the inspectors providing Painter with information concerning SRMs entering the food supply. Painter informed the CO that he had no documents, that he had intentionally not sought to learn the identities of the inspectors involved because of previous instances when the agency had sought to persecute whistleblowers, and that therefore he could not identify specific plants or inspectors. Without explaining the agency's previous silence and inaction, the CO indicated that concerns about whistleblower confidentiality were now irrelevant because the public health concerns were so significant. Painter reiterated that he had no knowledge of the identities of whistleblowers or the locations of the plants where violations had taken place but informed the CO that NRs had been written when allowed by agency policy and that the agency could and should review those NRs.

On December 28, 2004, Kristie Kelm, Chief of the FSIS Employee Relations Branch, formally notified Painter that he was being investigated for misconduct. The email says, in part:

"This office recently received a request for a formal investigation to be conducted jointly by the Office of Program Evaluation, Enforcement and Review and the Labor and Employee Relations Division. This investigation is concerning allegations raised by the National Joint Council of Food Inspection Locals in a letter dated December 8, 2004, claiming that current Food Safety and Inspection

<sup>&</sup>lt;sup>18</sup> "One Year After Mad Cow, Questions Linger: Loopholes Remain in Government's Food Safety Efforts" Jon Bonne. MSNBC. December 23, 2004. http://www.msnbc.msn.com/id/6742730/

Service cattle inspections fail to conform to USDA regulations, resulting in risk material making it into the human food supply and alleged violations of export requirements.

As a result of these allegations, on December 23, 2004 you were informally interviewed in an effort by the Agency to address these serious allegations. You failed and refused to identify or provide the information to substantiate the allegations by identifying plants, inspectors, or incidents which you alleged to have occurred.

Based on the information received, this office will be conducting a formal personnel misconduct investigation. Mr. Painter, please be reminded that USDA employees are obligated to give information to authorized representatives of the Department when called upon if the inquiry relates to official matters and the information is obtained in the course of employment or as a result of relationships incident to USDA employment. . .

In order to facilitate the timeliness of the investigation and due to the serious allegations of food safety you have raised, the investigation will commence the week of January 3, 2004..."

#### FALSE AND MISLEADING PUBLIC STATEMENTS

On December 28, 2004, FSIS spokesperson Matt Baun provided the following response to the Food Chemical News, in response to its inquiries about Painter's allegations:

FSIS is confident that BSE regulations are being effectively enforced. Nevertheless, FSIS believes that all charges must be fully examined and has launched an investigation into these charges. Towards this end, we have queried Mr. Painter but he has failed and refused to provide specific details about the allegations. Therefore, we are pursuing information and evidence associated with the allegations by conducting a formal investigation. The BSE regulations that FSIS has issued provide clear and specific direction to plants regarding their responsibilities to have written plans and procedures in place to identify the age of cattle and ensure the removal of SRMs. Public Health Veterinarians, who are assigned to every slaughter plant in the country, perform antemortem and postmortem inspection on every animal. These highly trained FSIS veterinarians and Consumer Safety Inspectors are specifically assigned the responsibility for verification of the development, implementation and maintenance of plant control procedures for the removal, segregation and disposition of SRM's. This includes age determination, which in most instances is accomplished through verification of birth or other records.....In the absence of documentation; dentition is used to determine age. Because the permanent incisors of cattle erupt between 24 and 30 months of age, FSIS relies solely on its Public Health Veterinarians to make age determination on cattle in the absence of other valid

records. These highly trained individuals are fully authorized to take immediate regulatory enforcement actions in the event of noncompliance." <sup>19</sup>

The statement issued to FCN is false and misleading in several aspects. First, the issue of Painter's supposed non-cooperation not only is false, but serves as a smokescreen to disguise USDA's own inaction on the reports by scapegoating the inspector messengers. As Painter told the CO, there are NRs in the agency's own files which apparently have been gathering dust. Rather than read the documents, USDA chose to say it was his fault for not verbally summarizing records he had never seen. Painter also told the investigators to call me because he knew I had the information they were trying to get from him. But no one from FSIS ever contacted me, despite the agency's professed sense of urgency.

Second, PHVs do not normally perform antemortem and postmortem inspections on every animal slaughtered. In fact, according to one whistleblower, PHVs routinely perform ante and postmortem inspections on only approximately one-tenth of one percent (.1%) of the cattle slaughtered in the plant where s/he works. Additionally, the statement implies that the age determination of cattle without age verification documents is made only by "highly trained FSIS Public Health Veterinarians." This also is false. By FSIS policy and directive, the age determination of cattle is solely the responsibility of the plant personnel, none of whom are highly trained PHVs. This was later admitted by the agency.

#### AGENCY QUESTIONS MR. PAINTER

On January 6, 2005, the agency interviewed Painter in Washington D.C. for over three hours. During the interview, the agency again pressured Painter to turn over the locations of plants where SRM violations were occurring. Painter reiterated that he did not know the locations and again urged the agency to look for the NRs in its own database. The agency official responded that they had looked for NRs but couldn't find any. He repeatedly said they could gain the most detailed possible information by contacting me. They did not even try.

## AGENCY QUESTIONS NJC PRESIDENTS

On January 11, 2005, the agency summoned the seven NJC Regional Council Presidents to Washington D.C. to question them about Painter's December 8, 2004 letter, incurring plane fare, hotel and per diem expenses. I learned later that the agency questioned the Regional Presidents about Painter; about whether or not any of the Regional Presidents had spoken with Painter regarding the issues; whether they knew Felicia Nestor and/or anyone at Public Citizen; whether and when any of the Presidents had spoken with me or Public Citizen staff, and what the subject of those conversations were. Significantly, the agency did not ask the Regional Presidents whether they were aware of any SRM violations occurring in their regions.

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 $<sup>^{19}</sup>$  "FSIS Admits to ID Problems in Some Plants, Say Consumer Groups" Carole Sugarman, Food Chemical News, January 4, 2005.

#### FSIS INTERVIEWS PAINTER AGAIN

After meeting with the seven regional council Presidents, the agency summoned Painter to another interview. There were several irregularities with the agency's scheduling of the meeting, which interfered with Painter's duties as the chairman of the NJC. These also prevented him from attending necessary training that the agency was aware had been scheduled and paid for many months before. This interview took place on January 18, 2005. I am not aware of any public health modifications implemented by the agency subsequent to this interview.

On January 26, a letter from 19 consumer, farm, and health groups was sent to USDA, expressing their concern about the apparent retaliation against Painter. The groups urged the agency to end the investigation and to direct agency resources for steps necessary to establish an environment inside FSIS that encourages employees to disclose issues of waste, fraud, or threats to public health.

(See http://www.citizen.org/cmep/foodsafety/madcow/articles.cfm?ID=12883 for full text of the letter.)

#### CONSUMER REPRESENTATIVES MEET WITH AGENCY

On January 27, 2005, I attended a regularly scheduled Safe Food Coalition meeting with Dr. Merle Pierson, Acting Under Secretary for Food Safety, and Barb Masters, Acting Administrator for FSIS. This meeting afforded me the opportunity to challenge agency management regarding the false statements released by Matt Baun almost one month before. When the issue of the false statement that "PHVs perform antemortem and postmortem inspection on every animal," was discussed, agency management readily admitted that Baun's statement was not correct. Officials promised that steps would be taken to see that the misstatement was not repeated. When I argued that some damage had already been done and asked that they issue a correction, Masters committed to notifying me when the agency publicly released a correction to the statement.

During the meeting, the issues brought forth by Painter were discussed. Responding to the expressed concern that SRMs could be entering the food supply, Pierson stated that the likelihood of a BSE-positive animal entering a slaughterhouse is very small and that the agency did not have reason to believe that additional SRMs were entering the food supply. He exlained that FSIS just wanted to make sure those SRMs already present in the slaughter process were identified, segregated and disposed of properly.

When Pierson was challenged on whether or how the agency would change the verification procedures to ensure SRMs were not entering the food supply, he responded that the agency would continue to rely on the procedures and practices of plant employees. Either he or Barb Masters added that, throughout the agency, some PHVs were positioned to perform age verification "frequently." But this was not defined and I am unaware of any changes which might be implemented.

When I asked the agency if it had looked in its NR database and found any evidence of SRM violations, Barb Masters stated that the agency routinely looks at the data and that they had always been aware of some "low level of non-compliance" with the SRM regulations. She said that when the Painter disclosures became known, the agency reviewed the NRs again and found some based largely on PHV verification, a smaller number based on off-line inspector verification and an even smaller number based on findings by on-line inspectors. This would mean that the agency had to have at least six NRs for violations of the SRM regulations but she did not state how many there were. Neither did they explain why they had decided to investigate Painter when they had NRs to substantiate his claims.

When challenged whether or not the agency would allow the on-line inspectors to begin checking the age of the heads via the dentition method, Pierson avoided answering directly. Eventually, he responded to the repeated question by informing the attendees that the on-line inspector's job was difficult; and that they were dedicated but were already pushed as far as they could be with the inspection tasks that need to be performed in the allotted time frame. He reiterated that if the on-line inspectors were to perform the age verification checks on the head, they would have to forego other inspection tasks. When I suggested that linespeeds could be slowed, Pierson and Masters were silent. The message was clear, the agency was not going to authorize the on-line inspectors to check the age of the cattle and was not going to make any substantive changes to the age verification process. They were going to continue to rely upon the plant determination of cattle age.

#### AGENCY FAILS TO ISSUE CORRECTION

On February 4, 2005 Ms. Tara Balsley from FSIS' Congressional and Public Affairs office sent me an email, which reads in part:

*Below please find the clarification to the statement that was requested.* 

In the course of the meeting, Dr. Pierson and Dr. Masters clarified the statement, "Public Health Veterinarians, who are assigned to every slaughter plant in America, perform ante mortem and postmortem inspection on every animal."

To be more precise, the statement should read, "Public Health Veterinarians, who are assigned to every slaughter plant in America, perform or verify ante mortem and postmortem inspection on every animal."

I contacted Ms. Balsley and asked whether the "clarification" would be posted on the agency's website and was told that the agency had decided, instead, just to send the clarification to reporters who had received the original language. When I expressed concerns, Ms. Balsley sent the following reply:

I double checked with our media staff. Everyone who received the original language was provided with the clarification language.

On February 7, 2005 Food Chemical News published the following:

"... The consumer groups meeting with Pierson and Masters (see main story) were also peeved over a statement issued by FSIS that said agency veterinarians perform ante mortem and postmortem inspection on every animal. Not true, they said.

In the course of the meeting, according to FSIS spokesman Steven Cohen, the statement was clarified. To be more precise, Cohen said, the statement should read, "Public Health Veterinarians, who are assigned to every slaughter plant in America, perform or verify ante mortem and postmortem inspection on every animal." <sup>20</sup>

Since then I have spoken with four other reporters who routinely cover USDA and meat inspection issues, none of whom were sent the clarification. One sent me the original misleading statement s/he originally received from the agency. The others were uncertain whether they had ever received the original statement.

When I complained at a subsequent meeting between the agency and consumer representatives that the agency reneged on its promise to post a correction, the agency suggested that I should send the copy of Ms. Balsley's email to reporters. I objected that I did not have the list of reporters whom had received the original statement and that it should not be incumbent upon me to guess at the scope and specific outlets of the agency's published falsehoods. They refused to do any more. Since that meeting, I have spoken with at least one reporter who said that the original statement might have dissuaded them from covering the initial story.

#### USDA'S INSPECTOR GENERAL

On April 26, 2005 I met with Keith Arnold, who is directing the Office of Inspector General's audit of BSE-related issues, and Assistant Special Agent William Busby, of OIG's investigation unit, to discuss the evidence I had obtained on SRM violations and my involvement with Painter. I was represented by Tom Devine, Legal Director for the Government Accountability Project, for this meeting, which occurred in GAP's office. I shared as much information as I was able to without compromising the whistleblowers' identities or locations. It is my current plan to continue to provide the OIG with as much information as possible in order to ensure that this inadequate policy is thoroughly investigated and exposed.

## 4. IMPACT OF RETALIATION ON WHISTLEBLOWERS

Above and beyond the immediate danger created by the unreliable SRM policy, I am equally if not more concerned by FSIS' campaign of harassment against Painter. Its effect, if not its intent, is to intimidate all inspectors and other agency employees, nationwide. This is

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 $<sup>^{20}</sup>$  "FSIS Admits to ID problems in some plants, say consumer groups." Food Chemical News. Feb 7, 2005, p. 26

preventing subsequent truth-telling by these potential eyewitnesses to ongoing food safety threats including a mad cow reform that is not genuine.

When I first began working on these issues over ten years ago, I was immediately struck by the powerful chilling effect that one well-publicized retaliatory act against a whistleblower would have on other potential whistleblowers thousands of miles away and years later. These frontline eyewitnesses were concerned for the public, including family and friends, and felt compelled to get their information to someone who could correct the problem but were terrified to come forward. And yet they were the ones who could most accurately describe ongoing failings of agency policies and most rapidly sound the alarm about new threats to the safety of our meat and poultry.

FSIS' campaign of harassment and intimidation, therefore, threatens one of the primary consumer protection mechanisms, which has an extensive and demonstrable record of success in improving food safety systems at FSIS. A whistleblowing disclosure can restore public health protections immediately and significantly. In one instance, FSIS administrators allowed a company to sell excessive levels of diseased chicken meat to the School Lunch program for eight weeks, according to the agency's own records. During that time the plant met the 1.7% acceptable disease rate on only two days; the disease rate on the remaining days was as high as nearly-20%. Forty-eight hours after the whistleblowers' public disclosure there was a drop in the rate of diseased carcasses going into the School Lunch program, FSIS sent a top official to gain control at the plant and within the week, the violation rate had dropped dramatically with the plant meeting the standard twice as often as it violating it.

Whistleblowers' disclosures were also the prime impetus for five of the eight major reviews since 1999 of FSIS' new inspection program published by major governmental reviewing agencies. Willing witnesses on the frontlines also provided detailed information about problems with agency policies to government auditors for two more of the eight reviews. All of these reviews recommended changes in FSIS policy that were essential to improve food safety, a number of those recommendations have been implemented, and some unnecessary illnesses and deaths have been avoided.

Would FSIS have made the necessary improvements without these reviews? It is possible, but very unlikely. In most if not all cases, whistleblowers didn't go public until they first tried to work within the chain of command only to have the agency repeatedly deny that any problems existed.

The agency has never made it easy on the truth-tellers – the threat of retaliation seems ineradicable. To protect whistleblowers and to encourage eyewitnesses to continue to come forward with the truth, I have defended whistleblowers when the agency retaliated against them, organized campaigns of consumer support for particular whistleblowers and their issues, and interrupted agency retaliation in several instances by reminding officials of legal rights in the First Amendment and the Whistleblower Protection Act. Encouraging disclosures in this threatening environment, while at the same time providing as much protection for the whistleblowers, is a tightrope walk. I've tried to develop strategies to maximize and expedite the transformation of the hard truth into necessary change while

minimizing whistleblowers' exposure to retaliation. For example, using a 'safety-in-numbers' strategy in 1999, I surveyed over 500 inspectors about the major problems with the inspection system so that many could remain completely anonymous while providing detailed reports of what they saw on their jobs everyday.

## 5. CONCLUSION

Consumers cannot write this off as a labor-management issue that will have little effect on them. Let there be no confusion. Through passive resistance, vague and misleading public statements, and active harassment of whistleblowers, the agency has made a practice of keeping the public in the dark. In all previous instances, what was actually happening in the nation's slaughter and processing plants was a departure from the official food safety policies as described in agency publications and as reported by agency officials, and without the whistleblowers, unnecessary food safety threats would have persisted much longer. Consumers have been the primary beneficiaries of this public-spirited commitment to tell the truth and U.S. consumer groups have repeatedly rallied in support of the whistleblowers because they recognize that the public is indebted to these brave and conscientious men and women.

I am very concerned because since the agency began its retaliatory campaign against Painter, inspectors have become even less willing to blow the whistle on obvious public health threats. For example, agency supervisors have recently told inspectors throughout the country that plants are allowed to produce meat and poultry products even when inspectors are not on duty. This contravenes a longstanding government policy and could result in government approval and the sale of deadly products reflecting informal deregulation. In at least three areas of the country, inspectors have asked for this new instruction in writing and have been repeatedly refused. When I've asked inspectors if they'd be willing to discuss this with consumer representatives, the media or Congress, the answer has been the same – "No, not after what the agency is doing to Painter."

Such reticence to come forward is unprecedented in the 10 years that I've worked on food safety issues. I'm worried that if this trend towards silence amongst whistleblowers in meat and poultry plants continues, it will be deadly for consumers. Listening to the "cops on the beat", who are in the plants every day, can help us improve food safety and save lives. The agency must not be allowed to silence those trying to enforce food safety regulations who can pinpoint the policies that are preventing them from doing so.

# **6. RECOMMENDATIONS**

Until a national system for animal identification is in place, which is not likely to be for several more years, the determination of cattle age is going to be done by people. Proper age determination is critical for the proper removal of SRMs. It is too important to be left solely to the industry, which has an economic incentive to find animals to be younger than 30 months. Therefore:

- FSIS on-line inspectors need the authority to check each age determination made by plant employees. Specifically, checking the age determination should not be left to a verification process, but made part of the tasks a line inspector performs on every carcass. FSIS must ensure that on-line inspectors have adequate training to properly perform this task, and that linespeeds are sufficiently slow to allow enough time to do this and other head inspection tasks.
- FSIS off-line inspectors must have authority to take action based solely on reports by on-line inspectors about any SRM violations. Off-line inspectors should also be required to write up any violations they see while covering an online position.
- FSIS must immediately bring its investigation of Charles Painter, Chairman of the National Joint Council of Food Inspection Locals, to a conclusion. The agency should also publicly explain which of the points he raised in his letter have been confirmed, and if they continue to claim that his concerns are "unsubstantiated," they must offer specific documentation to support this.
- FSIS should respond to Public Citizen's FOIA request for records documenting violations of SRM policies immediately, so that the extent of this problem can be assessed.
- FSIS should immediately address their flawed system for documenting HACCP verification, by documenting which verifications are actually performed on each shift. Additionally, they must start documenting which verifications are not performed and why.

I have read the above statement consisting of 30 typewritten pages. I have been given the opportunity to make additions and/or corrections. It is true and correct to the best of my knowledge.

Executed on

Felicia Nestor

Subscribed and sworn to before me

this will day of and .

Notary Public

OFELIA M. GUTTERREZ

My Commission expires of the Public State of New Jersey