

A REVIEW OF THE USDA'S EXPANDED BSE CATTLE SURVEILLANCE PROGRAM

JOINT HEARING BEFORE THE COMMITTEE ON GOVERNMENT REFORM AND THE COMMITTEE ON AGRICULTURE HOUSE OF REPRESENTATIVES ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

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A REVIEW OF THE USDA'S EXPANDED BSE CATTLE SURVEILLANCE PROGRAM

WEDNESDAY, JULY 14, 2004

HOUSE OF REPRESENTATIVES, COMMITTEE ON GOVERNMENT REFORM, JOINT WITH THE COMMITTEE ON AGRICULTURE,

Washington, DC.

The committees met, pursuant to notice, at 10:05 a.m., in room 2154, Rayburn House Office Building, Hon. Tom Davis of Virginia (chairman of the Committee on Government Reform) presiding.

Present from the Committee on Government Reform: Representatives Tom Davis of Virginia, McHugh, Ose, Lewis, Putnam, Duncan, Murphy, Waxman, Maloney, Cummings, Kucinich, Davis of Illinois, Tierney, Van Hollen, Ruppertsberger, Norton, and McCollum.

Present from the Committee on Agriculture: Goodlatte, Smith of Michigan, Lucas of Oklahoma, Moran of Kansas, Jenkins, Gutknecht, Ose, Hayes, Osborne, Rehberg, Putnam, Burns, Rogers, and Neugebauer.

Staff present from the Committee on Government Reform: David Marin, deputy staff director and communications director; Jennifer Safavian, chief counsel for oversight and investigations; Anne Marie Turner, counsel; Robert Borden, counsel and parliamentarian; Drew Crockett, deputy director of communications; Susie Schulte, professional staff member; Teresa Austin, chief clerk; Sarah Dorsie, deputy clerk; Allyson Blandford, office manager; Leneal Scott, computer systems manager; Phil Barnett, minority staff director; Kristin Amerling, minority deputy chief counsel; Karen Lightfoot, minority communications director and senior policy advisor; Anna Laitin, minority communications and policy assistant; Josh Sharfstein, minority professional staff member; Earley Green, minority chief clerk; Jean Gosa, minority assistant clerk; Cecelia Morton, minority office manager; and Naomi Seiler, minority staff assistant.

Staff present from the Committee on Agriculture: William E. O'Conner, Jr., majority staff director; Brent Gattis, deputy chief of staff; John Goldberg, professional staff; Elizabeth Parker, professional staff; Pamilyn Miller, staff director, Subcommittee on Livestock and Horticulture; Pete Thomson, senior professional staff; Callista Gingrich, chief clerk; Andy Johnson, minority professional staff; and Lisa Kelley, minority professional staff.

Chairman TOM DAVIS. Good morning. A quorum being present, the Committee on Government Reform will come to order. I want to welcome the members of the Committee on Agriculture today,

and we look forward to today's joint hearing on USDA's expanded BSE Cattle Surveillance Program

I am going to recognize Mr. Goodlatte as soon as he arrives, but since he hasn't arrived yet, I will go ahead with my statement, because we have the Secretary of Agriculture waiting and we want to get down to questions.

On December 23, 2003, USDA announced for the first time that a cow in the United States had tested positive for bovine spongiform encephalopathy [BSE] and more commonly known as "mad cow disease." Most Americans are familiar with mad cow disease as a result of the European epidemic that hit its peak in 1993.

As the committee charged with overseeing the Federal Government Reform began oversight of USDA's former mad cow surveillance system and an investigation into USDA's handling of the situation surrounding the discovering of the BSE-infected cow.

During the initial stages of this investigation, the committee was presented with information raising significant questions about the validity of USDA's statements regarding its BSE surveillance system.

The committee was repeatedly told USDA's BSE surveillance program focused on only the high-risk cattle populations where mad cow disease is most likely to be found. The committee was assured that only downer cattle and cattle suffering from central nervous system symptoms were submitted to the Animal and Plant Health Inspection Services [APHIS] and tested for mad cow disease.

Information obtained by the committee from USDA confirmed that not only were downer and CNS symptomatic cattle tested for BSE, but ambulatory samples were accepted by APHIS and tested for mad cow disease. Specifically, the facility that slaughtered the BSE-infected cow had submitted ambulatory samples for BSE surveillance with the knowledge and approval of APHIS officials working in Washington State. In addition, USDA's Office of Inspector General has completed an investigative report that states ambulatory samples were a part of USDA's mad cow surveillance program. These findings heightened the committee's concern that USDA lacked internal controls over its BSE surveillance program and the agencies within USDA, as well as over communications between USDA's field staff and officials in Washington.

The miscommunication within USDA was highlighted in May at Lone Star Beef Processors in Texas. Again, due to confusion over proper protocols, a cow diagnosed with central nervous system symptoms was not tested for mad cow disease. As a result, USDA acknowledged a disconnect between APHIS and the Food Safety and Inspection Services [FSIS] field staff and officials. The committee was encouraged by the renewed commitment between APHIS and FSIS to rectify the situation and ensure the two entities develop a closer working relationship throughout the BSE surveillance system.

Seven days after the announcement of the BSE-infected cow last December, Secretary Ann Veneman implemented additional safeguards to protect the human food supply from mad cow disease, including a ban on downer cattle, which were previously approved for

human consumption. USDA also prohibited the presence of specific risk material in human food. In addition, Secretary Veneman requested the International Review Subcommittee of the Foreign Animal and Poultry Disease Advisory Committee to review USDA's response to the BSE-infected cow and make recommendations to USDA's existing policy on BSE surveillance. These steps, along with the FDA feed ban in place since 1997, illustrate the Federal Government's commitment to the protection of the American food supply.

On March 15, the committee was pleased to learn that USDA was expanding its BSE surveillance program and planning to incorporate several of the International Review Subcommittee's recommendations, including a minimum 1-year effort to better ascertain the presence of BSE in the United States. USDA will now sample as many adult cattle from the high-risk population as possible in the 12- to 18-month timeframe, as well as a random sampling and testing of 20,000 apparently healthy cattle aged 30 months and older.

The expanded BSE surveillance plan reached full implementation on June 1 of this year. The expanded plan is an enormous step in assessing whether BSE is actually present in the U.S. cattle population and, if so, at what level. We are here today to discuss the expanded surveillance plan, its implementation, and receive feedback as to how the initial stages are working. We expect small hiccups, as this is a massive undertaking for the USDA. However, given the proactive measures our Government has taken since 1997, I am confident that we will not be faced with the same mad cow epidemic that plagued Europe.

The Committee on Government Reform will continue to conduct oversight of USDA's BSE surveillance program as it moves forward. I want to thank the committee's ranking member, Henry Waxman, for his efforts on USDA oversight, and Chairman Goodlatte of the Committee of Agriculture for holding this joint hearing, and also the ranking member, Charlie Stenholm. I would also like to thank our witnesses for their participation today, and look forward to their testimony. And I especially want to thank the Department of Agriculture Secretary, Ann Veneman, for her participation leading up to this hearing and for her presence here today.

I will recognize Mr. Waxman, and then we will go to Mr. Goodlatte.

[The prepared statement of Chairman Tom Davis follows:]

Statement of Chairman Tom Davis
Committee on Government Reform
Joint Hearing with Committee on Agriculture
“A Review of USDA’s Expanded BSE Cattle
Surveillance Program”
July 14, 2004

Good morning, a quorum being present, the Committee on Government Reform will come to order. I would like to welcome the Members of the Committee on Agriculture. I look forward to today’s joint hearing on USDA’s Expanded BSE Cattle Surveillance Program.

On December 23, 2003, USDA announced for the first time that a cow in the United States had tested positive for Bovine Spongiform Encephalopathy, also referred to as BSE, and more commonly known as “mad cow disease.” Most Americans are familiar with mad cow disease as a result of the European epidemic that hit its peak in 1993.

As the Committee charged with overseeing the Federal Government, Government Reform began oversight of USDA’s former mad cow surveillance system and an investigation into USDA’s handling of the situation surrounding the discovery of the BSE-infected cow. During the initial stages of this investigation, the Committee was presented with information raising significant questions about the validity of USDA’s statements regarding its BSE surveillance program.

The Committee was repeatedly told USDA's BSE surveillance program focused on only the high-risk cattle populations where mad cow disease is most likely to be found. The Committee was assured that ONLY downer cattle and cattle suffering from central nervous system symptoms were submitted to the Animal and Plant Health Inspection Service, APHIS, and tested for mad cow disease.

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sampling and testing of 20,000 apparently healthy cattle aged 30 months and older.

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The Committee on Government Reform will continue to conduct oversight of USDA's BSE surveillance program moves forward. I would like to thank the Committee's Ranking Member, Henry Waxman, for his efforts on USDA oversight and Chairman Goodlatte and the Committee on Agriculture for holding this joint hearing. I would also like to thank our witnesses for their participation today, and look forward to their testimony. I would especially like to thank USDA Secretary Ann Veneman for her participation.

Mr. WAXMAN. Thank you, Chairman Davis. And I want to thank Chairman Goodlatte and Ranking Member Stenholm for holding this joint oversight hearing today. Oversight is critically important for the functioning of Government agencies, and I commend both of you and all of you for rising to that responsibility today.

Since the first case of mad cow disease was identified last December, the administration has sought to assure and reassure the American public and our trading partners. Numerous administration officials have promoted U.S. beef as safe and endorsed the effectiveness of steps being taken to contain the potential problem. I am concerned, however, that the desire to reassure is trumping the obligation to tell the truth.

In an interview on Good Morning America, just after announcing the first detected case, USDA Secretary Ann Veneman assured the public that "we are taking every step that we possibly can to protect the country from BSE." Yet, at the time there were many steps that USDA had not yet taken, including banning downer cattle and high-risk materials, such as brain and spinal cord, from the food supply.

Even now the administration is retreating from several important measures to protect against mad cow disease. Six months ago the Associate Commissioner of the Food and Drug Administration, Dr. Lester Crawford, testified before Congress that his agency would act swiftly to close loopholes that allow cattle to be fed to other cattle. Since this is the way mad cow disease is spread, closing these loopholes is important. But last week, 6 months after the original announcement, FDA revealed that these changes are no longer imminent. In fact, they could be delayed for years.

In another example, Secretary Veneman assured the public last December that the detection of mad cow disease proved the surveillance system was working. She and other USDA officials have claimed that the mad cow was a downer and had been detected through mad cow surveillance that targeted downers. Yet, we have learned that, contrary to the Secretary's account, at least five eyewitnesses saw the cow walk or stand on the day of slaughter. At least four USDA officials knew that the facility that slaughtered the cow was testing ambulatory cattle, a departure from USDA testing policy. What the Secretary described as evidence of the program's success may be more accurately described as a stroke of luck.

This hearing will focus on the Department's new surveillance program for mad cow disease. In the next 12 to 18 months, USDA will attempt to test over 250,000 high-risk cattle, as well as 20,000 healthy adult cattle. The results of this survey are critically important to understanding the extent of mad cow disease in the United States. But today we are going to hear from the Inspector General at the U.S. Department of Agriculture about serious problems with this program.

USDA claims the new surveillance program will be able to detect mad cow disease even if there are as few as five infected cows in the whole country. Yet the Inspector General found that this assurance is false. USDA relies upon the assumption that the entire risk of mad cow disease is confined to the 1 percent of the cattle popu-

lation who exhibit signs of injury or illness, but mad cow disease can occur in cows that appear to be completely healthy.

The Inspector General also found that USDA is failing to test many animals at the highest risk for mad cow disease, those that actually exhibit symptoms of brain disease. So far in this fiscal year, over 100 cattle have been condemned at slaughter because they show signs of brain disorders. But less than half of these have been tested for mad cow disease. As many as 17 untested cattle were adult cattle with symptoms of brain disorders, the group at the highest risk of testing positive.

In a five-State survey of cows sent to State labs for rabies testing, only 16 percent of rabies negative samples were sent to USDA for testing, even though this is also a high-risk group.

In addition, the Inspector General has found that mad cow data collection is flawed with erratic reporting that often lacks key information. The inspector general has concluded that these and other problems, if not corrected, may negatively impact the effectiveness of USDA's overall BSE surveillance program, impair its ability to perform risk assessments and program evaluations, and reduce the credibility of any assertion regarding the prevalence of BSE in the United States.

It is essential that the administration correct these deficiencies in its surveillance efforts. If USDA fails to act, consumer confidence will plummet and our trading partners will not open their borders.

We all share a common objective: ensuring that our food supply remains safe and free from any signs of mad cow disease. I look forward to working with my colleagues and the distinguished witnesses today as we strive to attain that goal.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Henry A. Waxman follows:]

**Statement of
Rep. Henry A. Waxman, Ranking Minority Member
Committee on Government Reform
Hearing on
A Review of USDA's Expanded BSE Cattle Surveillance
Program**

July 14, 2004

Thank you Chairman Davis, Chairman Goodlatte, and Ranking Member Stenholm for holding this joint oversight hearing today.

When one party controls the Administration and both Houses of Congress, there is a natural inclination not to conduct oversight or ask tough questions. But oversight is critically important for the function of government agencies. I commend you for rising to that responsibility today.

Since the first case of mad cow disease was identified last December, the Administration has sought to reassure the American public and our trading partners. Numerous Administration officials have promoted U.S. beef as safe and endorsed the effectiveness of steps being taken to contain any potential problem.

I am concerned, however, that the desire to reassure is trumping the obligation to tell the truth.

In an interview on Good Morning America just after announcing the first detected case, USDA Secretary Ann Veneman assured the public that “[w]e are taking every step that we possibly can to protect the country from BSE.” Yet at the time, there were many key steps that USDA had *not* yet taken, including banning “downer” cattle and high-risk materials (such as brain and spinal cord) from the food supply.

Even now, the Administration is retreating from several important measures to protect against mad cow disease. Six months ago, the associate Commissioner of the Food and Drug Administration, Dr. Lester Crawford, testified before Congress that his agency would act swiftly to close loopholes that allow cattle to be fed to other cattle. Since this is the way mad cow disease is spread, closing these loopholes is important. But last week, six months after the original announcement, FDA revealed that these changes are no longer imminent. In fact, they could be delayed for years.

In another example, Secretary Veneman assured the public last December that the detection of mad cow disease proved the surveillance system was working. She and other USDA officials have claimed that the mad cow was a downer and had been detected through mad cow surveillance that targeted downers.

Yet we have since learned that contrary to the Secretary's account, at least five eyewitnesses saw the cow walk or stand on the day of slaughter. At least four USDA officials knew that the facility that slaughtered the cow was testing ambulatory cattle, a departure from USDA's testing policy. What the Secretary described as evidence of the program's success may be more accurately described as a stroke of luck.

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Yet the Inspector General found that that this assurance is false. USDA relies upon the assumption that the entire risk of mad cow disease is confined to the 1% of the cattle population who exhibit signs of injury or illness. But mad cow disease can occur in cows that appear to be completely healthy.

The Inspector General also found that USDA is failing to test many animals at the *highest* risk for mad cow: those that actually exhibit symptoms of brain disease. So far in this fiscal year, over 100 cattle have been condemned at slaughter because they show signs of brain disorders, but less than half of these have been tested for mad cow disease. As many as 17 untested cattle were adult cattle with symptoms of brain disorders, the group at highest risk of testing positive.

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The Inspector General has concluded that these and other problems, if not corrected, may “negatively impact the effectiveness of USDA’s overall BSE surveillance program, impair its ability to perform risk assessments and program evaluations, and reduce the credibility of any assertion regarding the prevalence of BSE in the United States.”

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We all share a common objective: ensuring that our food supply remains safe and free of any signs of mad cow disease. I look forward to working with my colleagues and the distinguished witnesses testifying today as we strive to attain this goal.

Chairman TOM DAVIS. Thank you very much.

It is now our pleasure to recognize the distinguished chairman of the Agriculture Committee, Mr. Goodlatte.

Chairman GOODLATTE. I would like to thank the chairman and ranking member of the Government Reform Committee for agreeing to conduct this hearing jointly with the Committee on Agriculture. The cooperation demonstrated in planning this hearing is a testament to the professionalism of our two staffs and an acknowledgment of the importance of this topic.

As I am sure the Secretary of Agriculture can attest, the Agriculture Committee has been rigorous in our oversight of the Department's BSE surveillance programs and determined to ensure that we are learning what we need to know about our Nation's cattle herd.

While our interest in the surveillance program goes back many years, we redoubled our efforts when the first BSE-positive cow was reported in Canada on May 20 of last year. Since that date, we have conducted literally dozens and dozens of meetings, conference calls, and briefings with the scientific and management personnel of the USDA's Animal and Plant Health Inspection Service [APHIS]. This year, the committee has had a hearing and two executive sessions with USDA. These conversations have explored the operational details of the previous BSE surveillance program and contributed to the development of the current expanded BSE surveillance program. As the implementation of the program proceeds, the Agriculture Committee will continue its oversight activities with the goal of ensuring the highest quality outcome.

It is important for people to understand that the Nation's cattle herd is not a static, homogenous collection of animals; it is a huge herd, at over 100 million animals, that is spread over a vast nation. There is a broad array of operations: cow calf producers, dairymen, replacement heifers, cattle feed lots, breeding herds, show animals, veal calf production, and auction houses that range from a few head to tens of thousands. This diverse herd is located in every State of the Union. For example, there are cattle bred and born in Hawaii that are eventually shipped to California for feeding and slaughter.

Additionally, this herd is constantly on the move. First there is the normal buying and selling of everything from individual animals to lots of thousands. Each year, 35 million head of cattle go to market, which means there are 35 million animals leaving the herd and 35 million entering the herd. Over a million live animals are imported from Mexico each year.

The Department of Agriculture's expanded BSE surveillance program is intended to take a snapshot of what is going on in this herd. The surveillance is not intended or designed to be a BSE preventative. While not a direct protection measure itself, it will continue to contribute to the policy process determining our BSE defenses. The results of these tests will help shape how we maintain or modify the protective firewalls already in place, which include import bans on live cattle and certain ruminant products, feed bans prohibiting the feeding of most mammalian protein to cattle and other ruminants, and exclusion of high-risk materials and high-risk animals in our food supply.

When the cow was found in Washington last December, the Department was already in the process of greatly expanding the surveillance plan. In developing the new surveillance program, USDA asked the Harvard University Center of Risk Analysis to evaluate their risk analysis on BSE in the United States, had an international scientific review panel review our plan for BSE, and utilized information gleaned from the international standard setting body for animal health, the OIE. In addition, rapid screening tests had to be evaluated and the necessary labs set up, and arrangements had to be made with many segments of the beef production and rendering systems to ensure we could collect the large volume of tests the program demands. Even the process of announcing suspicious results in a way that does not needlessly roil commodity markets has to be contended with.

It has been a tremendous undertaking, and not without its ups and downs. On June 1, the expanded program began. There is less than 6 weeks experience with the new testing program, which is on schedule but has not even had a chance to ramp up to a pace that will ensure 268,500 tests in a year.

Today's hearing is not the beginning of the Agriculture Committee's oversight of this program, and it will not be the end. I can assure my colleagues, the Inspector General and the Secretary, that we will continue our close watch of the program, and we have never been shy in suggesting how it can be improved.

Again, I would like to thank the chairman and ranking member of the Government Reform Committee, as well as my colleague and ranking member of my committee, Congressman Stenholm, for working so cooperatively to put together this hearing. I look forward to today's testimony and to hearing the questions and answers about USDA's expanded surveillance program.

It is now my pleasure to recognize the ranking member of the House Committee on Agriculture, the gentleman from Texas, Mr. Stenholm.

Mr. STENHOLM. Thank you, Mr. Chairman. And I thank the chairman and ranking member of the Government Reform Committee for joining the House Agriculture Committee today in the conduct of a very important oversight hearing.

I also want to thank Secretary Veneman for being present today, demonstrating the seriousness with which the Department of Agriculture has been and is addressing the issue of BSE. Obviously, this is an important and timely issue, and I am pleased we will have an opportunity to conduct some essential oversight this morning.

The question of how best to deal with BSE surveillance has been considered by the House Agriculture Committee for many months. In fact, for years prior to the identification of that single BSE-positive animal in Washington State, the U.S. agriculture community, USDA, and the House Agriculture Committee have been considering how best to protect the BSE-free status of our domestic cattle herd. The continued safety of our beef supply is a testament to the success of these cooperative efforts over the years.

Now, in response to the identification of BSE in a Canadian-born cow in Washington State, USDA has further expanded their surveillance efforts. As noted, USDA has begun to expand their sur-

veillance to sample as many as 260,000 animals in the next 12 to 18 months. It is important for us to help USDA to be successful in this work, and I hope this is the spirit in which we will go forward during this hearing.

There are legitimate questions, however, about the manner in which USDA is going forward with this good work. Concerns about risk communication, sample selection, geographic distribution, and testing protocols have all been raised. I look forward to the testimony and discussions we will have this morning, and the light they will shed on this important issue on how USDA is addressing these concerns.

U.S. livestock producers are justifiably proud of the quality and safety of our domestic beef supply. Certainly, we will continue to maintain the ruminant feeding ban and removal of risk materials that together protect consumers from potential BSE exposure, should it ever occur in our domestically-produced cattle herd. In addition, I know that we will all want to move forward working together to get the best possible information about the state of that resource. That is what this expanded surveillance program is all about, getting accurate information about the state of our cattle herd with regard to BSE. So I look forward to learning more about the ways that this hearing will advance that effort and aid USDA in that work.

Again, I want to thank all Members and witnesses who are participating this morning. I look forward to an informative and helpful hearing.

Chairman TOM DAVIS. Thank you.

Let me ask unanimous consent that opening statements by other Members be submitted for the record. I ask unanimous consent that the statements by the Center for Progressive Regulation and the Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America be submitted for the record of this hearing. Hearing no objection, so ordered.

We move to our first panel of witnesses. We have the Honorable Ann Veneman, the Secretary of the U.S. Department of Agriculture. Secretary Veneman will provide the committee with an update of how the expanded BSE surveillance program is being implemented and the new written protocols that are in place for the plan. Dr. Ron DeHaven, the Administrator of the Animal and Plant Health Inspection Service, and Dr. Keith Collins, Chief Economist for the USDA, accompany Secretary Veneman to answer questions.

It is our policy that we swear in all witnesses before they testify, so if you would rise with me and raise your right hands.

[Witnesses sworn.]

Chairman TOM DAVIS. Secretary Veneman, thank you very much for being with us. You can proceed with your statement. Your entire statement is in the record, so you can move to sum it up. We have a light there that turns orange after 4 minutes, red after 5, but take what time you need; this is an important program. We are pleased to see it moving underway and appreciate your being proactive in this area.

STATEMENT OF ANN M. VENEMAN, SECRETARY, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY RON DEHAVEN, ADMINISTRATOR, ANIMAL AND PLANT INSPECTION SERVICE, AND KEITH COLLINS, CHIEF ECONOMIST

Secretary VENEMAN. Thank you, Chairman Davis and Chairman Goodlatte, and Ranking Members Waxman and Stenholm, and members of the committee. It is an honor to be with you today to discuss our ongoing activities to protect public health and enhance our food and animal safety systems against BSE.

As indicated, I am accompanied today by Dr. Ron DeHaven, our APHIS Administrator, and Dr. Keith Collins, our Chief Economist. You will also hear from USDA's Inspector General today, whose office has made many recommendations to strengthen the Department's ongoing efforts with regard to BSE.

The U.S. Department of Agriculture works to protect public health by ensuring the safety and wholesomeness of the Nation's commercial supply of meat, poultry, and egg products. We take this enormous responsibility very seriously. In addition, USDA works to protect animal and plant health, and we take that responsibility just as seriously.

My testimony today will focus on the implementation of our enhanced BSE surveillance plan, which we announced in March, to collect the data needed to establish a baseline from which prevalence can be determined. However, before I begin, I would like to provide some background as well as a brief review of the actions the Department has taken since the December 23 find of BSE in the United States.

BSE was discovered in England in 1986, and since then more than 180,000 cases have been confirmed in cattle worldwide. USDA immediately began to study the disease in order to prevent its introduction to the United States or to prevent the widespread epidemic that we have seen in Europe. USDA developed a response plan that has been strengthened over the past 15 years as the scientific evidence and body of knowledge regarding BSE has evolved.

In 1989, the United States implemented an import ban, which was extended in 1997 and again in 2000, on live cattle and other ruminants and certain ruminant products from countries at high risk of BSE. In 1997, the Food and Drug Administration banned most mammalian proteins in the use of animal feeds given to cattle and other ruminants to prevent spread of the disease should it occur in the United States.

USDA began a surveillance program in 1990, and for the past 11 years has met or exceeded international standards as outlined by the OIE, the World Organization for Animal Health, which is the internationally recognized forum for the development and review of standards, guidelines, and recommendations on animal health. In fiscal years 2002 and 2003, we significantly increased BSE surveillance levels with approximately 20,000 animals tested each year.

In 1998, USDA asked the Harvard Center for Risk Analysis to investigate the risk of BSE in the United States. In 2001, its report noted that, because of the actions taken over the past 15 years, the risk of BSE becoming a widespread epidemic in the United States was extremely low.

As you know, on December 23 we announced the discovery of a single case of BSE in Washington State in a dairy cow whose birth predated the 1997 feed ban. On December 30, just 1 week after the find, we announced further actions to protect public health. These included: an immediate ban on non-ambulatory, disabled, or what we call downer cattle from going into the food chain; a “test and hold” policy, which mandates that meat from cattle tested for BSE cannot enter into the food chain until test results have come back negative; a requirement to remove specified risk materials, or what is referred to as SRMs, which can carry the infectivity from the food supply in order to protect public health; further limitations on the use of advanced meat recovery systems; a ban on the use of mechanically separated beef from the human food supply; and a ban on air-injection stunning.

These new food safety protections were officially released in the form of an interim final rule less than 2 weeks later, and which became effective immediately.

In addition, we announced the expedited implementation of a national verifiable animal identification system. Our goals are to achieve uniformity, consistency, and efficiency across the national ID system.

Also on December 30, I announced that an international panel of experts would review our response and offer areas for potential enhancement. The International Review Team convened in January and provided recommendations on specified risk material removal, slaughter methods, surveillance design and approaches, feed restrictions, feed manufacturing and sales, traceability enhancements, and other areas that could provide meaningful additional public or animal health benefits.

The team’s report confirmed the results of the epidemiological investigation, as well as USDA’s actions announced on December 30 to further protect human health. In briefing me on the report, Dr. Kihm, the chairman of the team, described the SRM removal as the single most important action to protect public health.

They recommended a strengthened surveillance program to test cattle older than 30 months in the high-risk population, suggesting this could be done in a 1-year program. According to the report, surveillance systems targeting high-risk animals have been shown to be the most efficient way to identify BSE cases. In addition, the report said that testing of all cattle slaughtered for human consumption was unjustified in terms of protecting human and animal health.

USDA drafted an enhanced surveillance plan designed to meet the objectives outlined by the International Review Team. In developing the specifics of the plan, USDA worked with the OIE.

The current OIE standards provide criteria for establishing the BSE risk status of a country or zone based on risk assessment identifying all potential factors for BSE occurrence. For animal surveillance, the OIE recommends targeted sampling of cattle that display clinical signs compatible with BSE and cattle that have died or been killed for reasons other than routine slaughter. According to the OIE, surveillance should focus primarily on cattle over 30 months of age in these higher risk categories. As I mentioned, the

United States has met or exceeded the international guidelines for BSE surveillance in cattle since 1993.

USDA determined that at least 268,500 samples would be collected from the high-risk population of animals. The approach assumes BSE-positive cattle would be contained in the high-risk population. Sampling efforts were therefore biased toward this population in order to test as many of these animals as possible.

The surveillance plan was reviewed by the International Review Team and the Harvard Center for Risk Analysis. In a letter, Dr. Kihm, the chairman of the International Team, stated, "On behalf of the entire subcommittee, I would like to congratulate you on this plan. All members of the subcommittee responded with positive comments, agreeing that the plan is comprehensive, scientifically based, and addresses the most important points regarding BSE surveillance in animals."

The comments of the Harvard Center for Risk Analysis were also supportive. "In summary," wrote Joshua Cohen and George Gray, "we agree with USDA's focus on testing high-risk cattle." They noted that USDA faces a challenge in drawing conclusions from its testing program for the prevalence of BSE in normal cattle populations. They suggested alternative approaches for consideration. USDA intends to continue consulting with them, as well as others, as we collect the data.

As noted in the International Review Team's report, experience in Europe has shown that testing high-risk cattle is the most efficient way to identify if BSE is present in the cattle population. USDA's enhanced program is designed to collect the majority of samples from the following categories: cattle exhibiting signs of a central nervous system disorder; non-ambulatory disabled cattle; cattle exhibiting signs of other diseases or conditions that may be associated with BSE, such as rabies or emaciation; and older cattle that die on the farm for unexplained reasons.

Test samples are coming from farms, slaughter facilities, rendering facilities, livestock auctions, veterinary clinics, veterinary diagnostic laboratories, and public health laboratories. Early data indicate that we are getting a representative mix of samples from these locations, and they do suggest that we can achieve at least 268,500 samples from the targeted population.

This enhanced plan was made public and posted on the USDA Web site on March 15. In just 2½ months following that announcement, USDA undertook extensive efforts to implement what amounts to a broad, new surveillance program. I would add that our BSE response and surveillance plans have proceeded simultaneously with APHIS responses to other major animal and plant disease issues. These include avian influenza, exotic Newcastle disease, soybean rust, and sudden oak death. Each one of these has also required a substantial commitment of APHIS program staff and management attention.

Between mid-March and June 1, APHIS took steps to build the infrastructure for the surveillance plan. These included licensing of rapid tests, setting up a national laboratory network, testing and certification of laboratories, equipping the staff and holding training sessions, drafting contractual documents, compiling a field manual, building an incident command structure, coordinating

with interagency partners, and collaborating with States, which are key to the success of this program.

USDA's enhanced BSE surveillance efforts would not be possible without additional testing alternatives and increased laboratory capacity to handle the volume of samples submitted as part of the program. To support this component, USDA has issued licenses or permits for five rapid BSE test kits. In addition, 12 public laboratories strategically located across the country have been approved by USDA to support the surveillance program. These laboratories are all part of an existing network of State and Federal laboratories that assist APHIS with animal disease testing as needed.

Because of their geographically dispersed locations, the laboratories have reduced the distance samples need to travel and are thus helping ensure a rapid turnaround time between sample submission and screening. Any inconclusive results on a screening test identified by one of these laboratories must be confirmed at USDA's National Veterinary Service Laboratory in Ames, IA. The NVSL, as that laboratory is referred to, remains the national reference lab for BSE. The reporting and confirmation requirement by USDA is also providing appropriate and timely release of information regarding the screening results. As we have throughout our response to BSE, we need to carefully balance our responsibility to share information with the public with our responsibility to do so in a way that does not inappropriately affect markets.

Throughout the planning and implementation of this plan, we have continued to strengthen the program based on our own analysis, as well as suggestions received by others.

To handle day-to-day management of implementation, APHIS set up National and Regional Command Teams based on the Incident Command Structure, headquartered at the APHIS state-of-the-art operations center in Riverdale, MD. These teams are charged with making sure that all aspects of the surveillance program, sample collection, operational activities and training, are meeting the goals and performance standards on both a local and a national level.

To ensure interagency coordination, these teams include USDA's Food Safety and Inspection Service, as well as State and regional animal health experts. In addition, we are coordinating closely with the Food and Drug Administration and other State partners who have been extremely helpful in providing their counsel regarding implementation.

We have implemented new policies to ensure objectivity of sample selection. For example, under new directives, samples are being taken from animals with signs of central nervous system [CNS] disorders regardless of age, and all ante-mortem condemned cattle—except for veal calves that do not show signs of CNS—will be sampled. Field staff have been instructed, when in doubt, take a sample.

USDA is also working on a broad plan of outreach activities to help ensure that we are receiving all possible samples. A detailed instruction manual has been sent to the field staff involved in sample collection.

We continue activities to inform producers, slaughter facilities, renderers, and affiliated industries about our surveillance goals,

and to encourage reporting of suspect or targeted cattle on the farm or elsewhere.

Not surprisingly, given the scope of the task, our efforts continue to evolve in order to ensure the successful implementation of such an extensive undertaking. Our activities will include additional work with the Office of the Inspector General.

The OIG has provided recommendations to enhance the program and raised a number of issues that continue to merit attention, such as assuring adequate performance measures and management reports to monitor the effectiveness of the surveillance system and the need for consistency across multiple labs and IT systems.

APHIS is also expediting its work with our Chief Information Officer to strengthen the system to track and report testing data.

USDA agencies are also working together to set up and conduct a quality assurance audit system. Our Agricultural Marketing Service will begin a nationwide evaluation of the APHIS enhanced BSE surveillance program, beginning tomorrow, at APHIS headquarters and proceeding to regional and State offices later this month. This assessment process will be ongoing.

In addition to our specific activities on the surveillance plan, USDA, in partnership with other Federal agencies, is taking additional actions to strengthen our safeguards against BSE.

Last Friday USDA and the Department of Health and Human Services issued an Advance Notice of Proposed Rulemaking to solicit public comment on the International Review Team's recommendations, as well as other related areas that have not already been acted upon.

On Monday of this week USDA scientists met with a group of interagency partners to discuss prion science research needs. And, finally, the Department continues to work with the Harvard Center for Risk Analysis to update its risk assessment and evaluate USDA's BSE response.

In conclusion, we remain committed to continually addressing ways to enhance our systems and improve implementation.

Our surveillance plan may find additional BSE-positive animals. Notwithstanding, the United States has strong safeguards in place to protect public health. Removal of SRMs from the food supply ensures that the highest risk materials are not entering the food chain. By continuing the coordination between USDA and other Federal, State and local agencies, and by enhancing our science-based policies and working with our employees and stakeholders, we are confident that we can continue to provide consumers in the United States with a safe supply of meat, poultry, and egg products.

Mr. Chairmen and ranking members, we appreciate the opportunity to inform you and the committee's members of USDA's ongoing BSE surveillance activities. We recognize that there are many different ideas and different opinions about how we can achieve the most robust system possible to guard against BSE. I look forward to the opportunity to discuss these issues that the hearing affords us, and I appreciate the opportunity to be here, and we are pleased to take your questions.

[The prepared statement of Secretary Veneman follows:]

TESTIMONY OF ANN M. VENEMAN

Chairman Davis, Chairman Goodlatte, Mr. Waxman, Mr. Stenholm, and members of the committees, it is an honor to be with you today to discuss the ongoing activities to protect public health and enhance our food and animal safety systems against Bovine Spongiform Encephalopathy (BSE).

Joining me at the table today is Dr. Ron DeHaven, our point person on BSE who until recently, served as USDA's Chief Veterinary Officer. He currently serves as the Administrator of the Animal and Plant Health Inspection Service (APHIS). Also with us is Dr. Keith Collins, USDA's Chief Economist. He has been involved with several BSE-related issues from a policy perspective. Both are here to assist in answering any questions you may have.

Later you will hear testimony from USDA's Inspector General, Phyllis Fong, whose office has made many recommendations to strengthen the Department's ongoing efforts with regard to BSE. The Office of Inspector General (OIG) has reviewed a number of issues, and it has provided suggestions on USDA's BSE programs.

The U.S. Department of Agriculture works to protect public health by ensuring the safety and wholesomeness of the Nation's commercial supply of meat, poultry and egg products. We take this enormous responsibility very seriously. In addition, USDA works to protect animal and plant health, and we take that responsibility just as seriously.

As requested by the July 6 letter from Chairman Davis and Chairman Goodlatte, my testimony today will focus on the implementation of our enhanced BSE surveillance plan, which we announced in March. The purpose of this plan is to collect the data needed to establish a baseline from which prevalence can be determined.

However, before I begin, I would like to provide some background, as well as a brief review of the actions the Department has taken since the December 23 find of BSE in the United States. A more detailed background is contained in the attached materials.

BSE was discovered in England in 1986, and since then, more than 180,000 cases have been confirmed in cattle worldwide. In 1986, USDA immediately began to study the disease in order to prevent its introduction to the United States or to prevent the widespread epidemic that we have seen in Europe. USDA developed a response plan that has been strengthened over the past 15 years as the scientific evidence and body of knowledge regarding BSE has evolved.

In 1989, the United States implemented an import ban, which was extended in 1997 and again in 2000, on live cattle and other ruminants and certain ruminant products from countries at high risk of BSE. In 1997, the Food and Drug Administration banned most mammalian proteins in the use of animal feeds given to cattle and other ruminants to prevent spread of the disease should it occur in the United States.

USDA began a surveillance program in 1990, and for the past 11 years has met or exceeded international standards as outlined by the Office of International Epizootics (OIE), or the World Organization for Animal Health. The OIE is the internationally recognized forum for the development and review of standards, guidelines and recommendations on animal health. USDA's surveillance program has targeted the high-risk population in accordance with the OIE recommendations. In fiscal years 2002 and 2003, BSE surveillance levels increased significantly, with approximately 20,000 animals tested in each year. Before December 23, 2003, we had plans to double that number for fiscal year 2004.

These actions were designed to prevent the introduction of BSE or its spread, should it be introduced in this country. The United States has long been committed to addressing the potential risk of BSE and these programs were strengthened over the years as more was learned about this disease.

In 1998, USDA asked the Harvard Center for Risk Analysis to investigate the risk of BSE in the United States. In 2001, their report was released. It noted that, because of the actions taken over the past 15 years, the risk of BSE becoming a widespread epidemic in the United States was extremely low.

As you know, on December 23, 2003, we announced the discovery of a single case of BSE in Washington State in a dairy cow whose birth predated the 1997 feed ban. On December 30, just 1 week after that find, we announced further actions to protect public health.

These included:

- An immediate ban on non-ambulatory disabled (downer) cattle from going into the food chain;
- A "test and hold" policy, which mandates that meat from cattle tested for BSE cannot enter into the food chain until test results come back negative;

- A requirement to remove specified risk materials (SRMs), which can carry the infectivity, from the food supply in order to protect public health;¹
- Enhanced requirements on the use of advanced meat recovery systems. Product produced using advanced meat recovery cannot contain spinal cord or dorsal root ganglia;
- A ban on the use of mechanically separated beef from the human food supply;
- And a ban on air-injection stunning.

These new food safety protections were officially released in the form of an interim final rule less than 2 weeks later.

In addition, we announced the expedited implementation of a national verifiable animal identification system. Our goals are to achieve uniformity, consistency and efficiency across the national ID system.

INTERNATIONAL GUIDANCE

Also, on December 30, I announced that an international panel of experts would review our response actions and offer areas for potential enhancement. The International Review Team, as it came to be known, convened in January. They were asked to evaluate the prevention and response actions taken to date and provide recommendations on specified risk material (SRM) removal, slaughter methods, surveillance design and approaches, feed restrictions, feed manufacturing and sales, traceability enhancements, and other areas that could provide meaningful additional public or animal health benefits.

The International Review Team's report confirmed the epidemiological investigation as well as USDA's actions announced on December 30 to further protect human health. In briefing me on the report, Dr. Uhli Kihm, the chairman of the team, described the SRM removal as the single most important action to protect public health.

The International Review Team recommended a strengthened surveillance program to test cattle older than 30 months in the high-risk population. They suggested this could be done in a "1-year program." According to the report, surveillance systems targeting high-risk animals have been shown to be the most efficient way to identify BSE cases. In addition, the report said the "testing of all cattle slaughtered for human consumption (was) unjustified in terms of protecting human and animal health." It was also recommended that USDA strongly consider testing a sample of healthy slaughter cattle over 30 months old to support the overall surveillance system.

ENHANCED BSE SURVEILLANCE

After receiving these recommendations, USDA drafted an enhanced surveillance plan designed to meet the objectives outlined by the International Review Team. In developing the specifics of the plan, USDA worked with the OIE.

The current OIE standards provide criteria for establishing the BSE risk status of a country or zone, based on a risk assessment identifying all potential factors for BSE occurrence. For animal surveillance, the OIE recommends targeted sampling of cattle that display clinical signs compatible with BSE and cattle that have died or been killed for reasons other than routine slaughter. According to the OIE, surveillance should focus primarily on cattle over 30 months of age in these highest risk categories. As I mentioned, the United States has met or exceeded the international guidelines for BSE surveillance in cattle since 1993.

The enhanced surveillance plan focuses on testing as many high-risk cattle as possible. To develop a sampling plan with a high level of detecting BSE, USDA determined that at least 268,500 samples would be collected from the high-risk population of animals. The approach assumed BSE positive cattle would be contained in the high-risk population. Sampling efforts are therefore biased toward this population in order to provide the most efficient method of detecting the disease. In addition to testing the high-risk cattle, USDA will also test 20,000 healthy-appearing, older animals sent to slaughter.

The surveillance plan was reviewed by the International Review Team and the Harvard Center for Risk Analysis. Dr. Ulrich Kihm, the chairman of the international team, stated: "On behalf of the entire subcommittee, I would like to con-

¹ SRMs are defined as skull, brain, spinal cord, eyes, trigeminal ganglia, vertebral column (except the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum), as well as the dorsal root ganglia of animals 30 months and older and the tonsils and distal ileum of all animals. To ensure that the distal ileum is appropriately removed, the removal of the entire small intestine is required.

gratulate you on this plan. All members of the subcommittee responded with positive comments, agreeing that the plan is comprehensive, scientifically based, and addresses the most important points regarding BSE surveillance in animals.”

The comments of the Harvard Center for Risk Analysis also were supportive. “In summary,” wrote Joshua Cohen and George Gray, “we agree with USDA’s focus on testing high risk cattle.” They noted that USDA faces a challenge in drawing conclusions from its testing program for the prevalence of BSE in the normal cattle populations. They suggested alternative approaches for consideration. USDA intends to continue consulting with them, as well as others, as we collect the data.

As noted in the International Review Team’s report, experience in Europe has shown that testing high-risk cattle is the most efficient way to identify if BSE is present in the cattle population. USDA’s enhanced program is designed to collect the majority of samples from the following categories:

- Cattle exhibiting signs of a central nervous system disorder;
- Non-ambulatory disabled cattle;
- Cattle exhibiting signs of other diseases or conditions that may be associated with BSE, such as rabies or emaciation; and
- Older cattle that die on the farm for unexplained reasons.

Test samples are coming from farms, slaughter facilities, rendering facilities, livestock auctions, veterinary clinics, veterinary diagnostic laboratories, and public health laboratories. Early data indicate that we are getting a representative mix of samples from these locations, and suggest that we can achieve at least 268,500 samples from the targeted population.

Details of this enhanced plan were made public and posted on the USDA Web site on March 15. In just 2½ months following that announcement, USDA undertook extensive efforts to implement what amounts to a broad, new surveillance program. I would add that our BSE response and surveillance plans have proceeded simultaneously with APHIS responses to other major animal and plant disease issues. These include avian influenza, exotic Newcastle disease, soybean rust and sudden oak death. Each one of these has also required a substantial commitment of APHIS program staff and management attention.

Between mid-March and June 1, APHIS took steps to build the infrastructure for the surveillance plan. These included licensing of rapid tests, setting up a national laboratory network, testing and certification of labs, equipping the staff and holding training sessions, drafting contractual documents, compiling a field manual, building an incident command structure, coordinating with interagency partners, and collaborating with states, which are key to the success of this program.

Expanding the infrastructure to test as many higher risk cattle as possible is a difficult and complex task. The size and geographical scope of the industry presents many challenges. The cattle populations in each state vary tremendously, as do the industry and the concentration points for collecting samples. To address these challenges, we established sampling targets for each state and region.

USDA’s enhanced BSE surveillance effort would not be possible without additional testing alternatives and increased laboratory capacity to handle the volume of samples submitted as part of the program. To support this component, USDA has issued licenses or permits for five rapid BSE test kits. In addition, 12 public laboratories strategically located across the country have been approved by USDA to support the surveillance program. These laboratories are all part of an existing network of state and Federal labs that assist APHIS with animal-disease testing as needed.

Because of their geographically dispersed locations, the laboratories have reduced the distances samples need to travel, and are thus helping ensure a rapid turnaround time between sample submission and screening. Any inconclusive results on a screening test identified by one of these laboratories must be confirmed at USDA’s National Veterinary Services Laboratory in Ames, IA. NVSL remains the national reference lab for BSE. This reporting and confirmation requirement by USDA is also providing appropriate and timely release of information regarding screening results. As we have throughout our response to BSE, we need to carefully balance our responsibility to share information with the public and our cooperators with our responsibility to do so in a way that does not inappropriately affect economic or international trade markets.

Throughout the planning and implementation of this plan, we have continued to strengthen the program based on our own analysis, as well as suggestions received by others.

To handle day-to-day management of implementation, APHIS set up National and Regional Command Teams based on the Incident Command Structure, headquartered at the APHIS state-of-the-art operations center in Riverdale, MD. These teams are charged with making sure that all aspects of the surveillance pro-

gram—sample collection, operational activities, and training—are meeting goals and performance standards on both a local and national level.

To ensure interagency coordination, these teams include USDA's Food Safety and Inspection Service, as well as State and regional animal-health experts. In addition, we are coordinating closely with the Food and Drug Administration and other state partners, who have been extremely helpful in providing their counsel regarding implementation.

We have implemented new policies to ensure objectivity in sample selection. For example, under new directives, samples are being taken from animals with signs of central nervous system (CNS) disorders, regardless of age, and all ante-mortem condemned cattle (except for veal calves that do not show signs of CNS disorders.) Field staff have been instructed, when in doubt, take a sample.

USDA is also working on a broad plan of outreach activities to help ensure we are receiving all possible samples. A detailed instruction manual has been sent to field staff involved in sample collection. This guide is designed to be a "living" document, which will be modified as necessary, based on feedback from headquarters and field personnel, to ensure smooth operations and continued coordination with all involved.

We continue activities to inform producers, slaughter facilities, renderers and affiliated industries about our surveillance goals, and to encourage reporting of suspect or targeted cattle on the farm or elsewhere. These activities include public service announcements, advertisements in trade publications, and presentations to veterinary schools, agricultural colleges, and local farm organizations. In addition, materials will be available on our Web site for livestock markets, animal health technicians and veterinarians.

Not surprisingly, given the scope of the task, our efforts continue to evolve in order to assure the successful implementation of such an extensive undertaking. Our activities will include additional work with the Office of Inspector General.

The OIG has provided recommendations to enhance the program, and raised a number of issues that continue to merit attention, such as assuring adequate performance measures and management reports to monitor the effectiveness of the surveillance system, and the need for consistency across multiple labs and IT systems. We look forward to continuing to work with the OIG to appropriately implement these recommendations.

APHIS is expediting its work with our Chief Information Officer to strengthen the system to track and report testing data. APHIS will be field-testing new software applications, which should improve the integrity and speed of the data collection process.

USDA agencies are also working together to set up and conduct a quality assurance audit system. Our Agricultural Marketing Service (AMS) will begin a nationwide evaluation of the APHIS enhanced BSE surveillance program, beginning tomorrow, July 15, at APHIS headquarters and proceeding to regional and state offices later this month. Over a 4- to 6-week period, AMS will conduct onsite assessments of random locations where surveillance activities occur, with a report issued within 4 weeks afterward. These assessments will be on-going.

In addition to our specific activities on the surveillance plan, USDA, in partnership with other Federal agencies, is taking additional actions to strengthen our safeguards against BSE.

Last Friday USDA and the Department of Health and Human Services issued an Advance Notice of Proposed Rulemaking (ANPR) to solicit public comment on the international review team's recommendations as well as other related areas that have not already been acted on.

On Monday of this week USDA scientists met with a group of interagency partners to discuss prion science research needs. And finally, the Department continues to work with the Harvard Center for Risk Analysis to update its risk assessment and evaluate USDA's BSE response.

CONCLUSION

In conclusion, we remain committed to continually addressing ways to enhance our systems and improve implementation of our efforts.

Our surveillance plan may find additional BSE-positive animals. Notwithstanding, the United States has strong safeguards in place to protect public health. Removal of SRMs from the food supply ensures that the highest-risk materials are not entering the food chain. By continuing the coordination between USDA and other Federal, state, and local agencies, and by enhancing our science-based policies and working with our employees and stakeholders, we are confident that we can con-

tinue to provide consumers in the United States with a safe supply of meat, poultry, and egg products.

Chairman DAVIS, Chairman Goodlatte, Mr. Waxman, and Mr. Stenholm, we appreciate the opportunity to inform you and the committee's members of USDA's ongoing BSE surveillance activities. We recognize there are many different ideas and opinions about how we can achieve the most robust system possible to guard against BSE. I look forward to the opportunity to discuss these issues that this hearing affords us. We would be pleased to take any questions you have at this time.

Chairman TOM DAVIS. Madam Secretary, thank you. I will start the questions. And I know you are pleased to be here, and we are happy to have you here, but we appreciate your proactivity in this area and your leadership. I have a few questions.

How many cattle have been tested as of today under USDA's expanded BSE surveillance system?

Secretary VENEMAN. Since June 1, just over 17,000.

Chairman TOM DAVIS. Now, does this put us on track with the number you hope to test by the end of the 12 to 18 months?

Secretary VENEMAN. Keith Collins, our Chief Economist, has done some tracking, and at the current rate we would anticipate we could collect the 268,500 samples in the 18-month period. However, if you look at the numbers, we have continued to increase the number of samples collected each week. Therefore, the ramping up of the program is continuing. We are still in the early weeks of the program. So we would anticipate that clearly we can stay at least on the 18-month schedule, and perhaps conclude even earlier than that.

Chairman TOM DAVIS. There have been some concerns, given the voluntary nature of the surveillance plan, that you might not be able to meet the goal. But you are seeing basically an upward trend at this point and strong voluntary compliance?

Secretary VENEMAN. I would say that our early data is extremely encouraging. When you think about the fact that we have collected over 17,000 samples since June 1, and in the last 2 years we have taken 20,000 samples in the entire year, I think this shows that we have been able to implement a program very quickly, efficiently, because we are seeing that the samples are coming in from the whole range of sampled selection sites that I identified in my testimony: from farms, from rendering plants, from diagnostic laboratories; the whole range we are getting samples in. So I must say we are very pleased with the preliminary numbers we have seen in terms of the samples that are coming in. We will continue to review those numbers and to evaluate to make sure that we are staying on track.

Chairman TOM DAVIS. Do you think the food supply and the food chain are far safer today, as a result of what we have implemented here, than say a year ago?

Secretary VENEMAN. I think that is a fair statement, absolutely, because, as I mentioned in my testimony, when you remove the specified risk materials from the food supply, as the chairman of the International Committee said to me, that is the most important thing that you do to protect public health. So I do believe that the food supply is safer today.

Chairman TOM DAVIS. Now, the Inspector General has recommended in their draft audit report a number of things; they have a number of recommendations. You have noted that they

merit attention. Are you planning on implementing any of these, or have you made a decision yet as to which ones you may or may not? Can you share any of those with the committee?

Secretary VENEMAN. As I indicated, I think that the Inspector General has made a very good set of recommendations with regard to where we need to place attention. There are things that we have already implemented that they recognized as issues. For example, in the discussion about whether or not we have tested CNS animals, we put into place a policy that says we will test all CNS animals and all ante-mortem condemned animals, taking some of the subjectivity out of the system that the IG recognized as a problem and that we recognized as a problem, and thereby putting clear guidelines for those veterinarians who are out in the field as to what will be tested and what won't be tested.

We have also, I think, made tremendous strides in another area of weakness, and that is that our Animal and Plant Health Inspection folks were not working closely enough with our Food Safety inspection people. We are now doing joint trainings, joint conference calls, joint memoranda from the two administrators. It is very critical that our two agencies work closely together in this BSE surveillance program, and I think we are on track to do that.

As I indicated, we think that many of the OIG's recommendations also relate to the importance of measuring performance. We believe that is very important. As I indicated in my remarks, the Agricultural Marketing Service is assisting the Animal and Plant Health Inspection Service in reviewing the plan, the implementation, the review of the various aspects, and we are working alongside the OIG as we do that in the hope that we can be partners in that review of how we measure the performance and the effectiveness of this plan.

Chairman TOM DAVIS. Thank you very much. My time is up.

Mr. Waxman.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

Secretary Veneman, I am pleased that you are here. Assuring the public about the safety of the food supply is a complicated matter; it involves a lot of details. But let me raise the big picture to you, and that is the question of credibility. It is important that the job that is being done by this Government is credible to people, both here in the United States and abroad. Now, there have been some warning signs that have recently come up about the administration's efforts on mad cow disease. Six months after promising to take important steps to protect the cattle feed, FDA retreated. USDA also had to admit in court that we let in millions of pounds of meat from Canada that it shouldn't have.

But today we are hearing, and we are going to hear later from the Inspector General about a draft report on your new surveillance program. The Inspector General found many serious flaws across a range of issues: from the plan's design, to its implementation, from what the plan assumes, to how the plan is portrayed to the American public. And I want to explore some of those matters with you.

One of the specific issues discussed by the Inspector General speaks directly to the Department's priorities and credibility. When USDA announced its new surveillance plan, the Department told

the American public it would be able to detect one cow with mad cow disease among 10 million cattle. This means that if there are just five affected cows in the entire country, your testing program will catch at least one of them. That is an impressive and reassuring claim, and one we want to make sure is going to be accurate.

One of the assumptions behind all of this is that mad cow disease is contemplated to be confirmed in high-risk target groups, and not present in all the healthy-appearing cattle. But this assumption has been called into question by many scientists. Today the Inspector General, as well as Professor George Gray of the Harvard Center for Risk Analysis, Dr. Peter Lurie, of Public Citizen's Health Research Group, have submitted testimony indicating that in fact BSE can be found in cattle that appear to be healthy.

So what I want to ask you is your response to this challenge of the assumption that we only need to look at downer cows and high-risk cows, and not the otherwise healthy appearing cows, in order to detect every case of mad cow disease.

Secretary VENEMAN. Thank you, Mr. Waxman, for your question. First let me say that as we have dealt with this issue over the past 6 months, we have done everything that we can to give as much information as possible to the public. I think we tried to do that from December 23 on, and to maintain our credibility. Certainly, as you go forward, you have instances where you look at things in greater detail, but we have tried to give the best available information that we have at the time.

Now, with regard to your questions, let me just say a bit about how we have designed this program, and then I may ask the gentlemen on either side of me to comment as well.

Mr. WAXMAN. Secretary Veneman, I want to go into a lot of the details of the surveillance program, but in the 5 minutes I have, the first question I would like you to answer is whether you are still working on the assumption that the target group of high-risk cows are the only ones that need to be tested, not those cows that appear to be healthy.

Secretary VENEMAN. I was about to answer that question. We have targeted high-risk animals because we know from virtually all of the science that is available that high-risk animals are the ones in which we are most likely to find the disease. But we also said in the plan that we released in March that we would test a group, we said 20,000, of normal appearing animals over 30 months, in other words, normal older animals, so that you would get a sampling or a group of tests that would be targeted at the normally appearing populations, as you say.

But I think it is very important to recognize that it is most likely that we will have the disease in the high-risk populations, and that is exactly what we have tried to target. It is what we call a biased sample, biased to the highest risk animals.

Mr. WAXMAN. Just in conclusion, do you still think you can catch 1 cow in 10 million that might have mad cow disease? Can you achieve that goal in the system that you have put in place?

Secretary VENEMAN. I am not a statistical expert. I might have Dr. Collins just comment briefly on that statistical—

Mr. COLLINS. I would be happy to, Madam Secretary.

Mr. Waxman, that assumption that you are referring to is one of a number of assumptions the statisticians made in designing the sampling plan. First of all, most importantly, that we wanted to get a random representative sample; and questions have been raised about that the Secretary just responded to, such as the voluntary nature of the program. Second, we made an assumption about the prevalence of BSE in the high-risk or target population, and an assumption about the prevalence in the rest of the population. Where do those assumptions come from? If you look at the history of the United States, with the program that began in 1989, with a testing program that began in 1990, with risk assessments in the mid-1990's, with the Harvard risk assessment in 2001 and in 2003, all of that analysis indicated that the possibility of infectivity in the United States was very, very low. That is in the target population. But in the rest of the population it is extremely low.

So what APHIS did in designing this program was develop a sample where they could detect as few as five positive animals in the target population. If there are five positive animals in the target population, there is a very low number in the rest of the normal population; they assumed zero. It is an assumption. It is a working assumption to get the data collection started; it is not our estimate of the prevalence of BSE in the United States. That is the purpose of the testing program. We are going to establish the prevalence as the testing program completes and is done.

Now, the point you raised, some people have said, OK, your analytical assumption may not be the best possible. There are questions raised about the appropriateness, I would say, of the analytical assumption. You mentioned Dr. Gray, and others have raised it as well. We respect that. The IG has raised that issue and we have agreed with the IG that we are going to look at this issue. Analytically, scientifically, it is an unsettled issue because you are talking about assumptions. So how do you determine the relationship between infectivity in the high-risk population and in the normal population? How do you do that?

Mr. WAXMAN. If your assumptions are wrong, however—

Chairman TOM DAVIS. Mr. Waxman, your time has expired.

Mr. WAXMAN [continuing]. The program is not going to be as effective as it needs to be to give people the assurance that they need.

Chairman TOM DAVIS. Henry, I let you have a couple extra minutes. We have to move on; we have a lot of Members who have questions.

Mr. Goodlatte.

Chairman GOODLATTE. Madam Secretary, welcome. I am delighted to have you, as well as Dr. DeHaven and Dr. Collins, with us today to answer questions about this important issue.

As I said in my opening statement, and as you said in your statement, this is a very important issue, but also one in terms of assuring the public of the safety of the beef supply in the country, one where the testing issue is one of indicating where there might be problems to address. And the Department has been very proactive, both before and after the finding of the one cow in Washington State, which I would hasten to note was born in Canada and born before the very significant changes in our feed rules were made

several years ago; nonetheless, very proactive in making sure that additional changes and careful review of the policy has been made to make those changes.

I wonder if you might respond to some of the criticism that the announcement of the BSE-positive cow in December was not entirely transparent. I remember the conversations that we had, and I remember seeing you all over America's television networks talking about this issue and making sure that the public was aware of the fact that this had been discovered, and what steps the Department was taking to address it. But I wonder if you might address the criticism that the disclosures of the recent inconclusive results needlessly roiled the commodity markets. I don't find that to have been the case, and I wonder if you could outline the Department's thinking on how it discloses the information that it discloses.

Secretary VENEMAN. Thank you very much, Mr. Goodlatte, for the questions. First, as I indicated earlier in response to Mr. Waxman's question, we tried very hard to get the information out as quickly as possible, with as much information as we knew and as it became available in the early days of the discovery of BSE. On December 23 we had a press announcement the very afternoon that we found out about the BSE-positive find. We tried to give as much information as we knew to the public without unnecessarily scaring people, but also to let people know that we did indeed have a case of BSE in this country. We followed that up every day with a technical briefing by Dr. DeHaven, a representative of the FDA and a representative of the Food Safety Inspection Service, so that people would have the needed technical expertise available to them and get updates on what was happening.

As we implemented the program for the new testing, we are using what are called rapid tests.

Chairman GOODLATTE. Let me ask you an additional question as part of the rapid tests. It is my understanding that the rapid test kit manufacturer recommends running tests in duplicate to avoid misreporting of false positives, of which we have now had two that I am aware of. Likewise, we are informed that BSE testing protocols in Europe include similar safeguards. And I wonder if that option has been evaluated by APHIS as a part of your analysis of how to proceed.

Secretary VENEMAN. Let me just respond to that question first. It was determined by the scientists at APHIS that as we initially began using this test, we ought to determine that an inconclusive was one that was obtained after one test. As you indicate, the recommended means by which this test should be used is you repeat the test before you determine it to be an inconclusive. But because this was a new program, APHIS made the determination that they should deem an inconclusive to be an inconclusive after one test. That being said, the sample is then immediately sent to the laboratory in Ames, IA for further testing using what is called the "gold standard."

Now, with regard to announcing these inconclusives we had several discussions about how and whether or not we should release information about inconclusive. The determining factor in our discussion was the potential market impact of an inconclusive result pending and being—

Chairman GOODLATTE. Madam Secretary, my time is about to expire. Let me ask one more question, then you can respond to that and finish that one as well. I am going to try to stay within the rules here.

In ruling against APHIS's October 2003 and April 2004 revisions to the list of eligible low-risk Canadian meat products, the judge challenged the agency's risk assessment. Regardless of the process errors that you have already acknowledged, would importation of products listed in the October or April revisions significantly increase risk to human or animal health?

Secretary VENEMAN. No. The products were all products from approved products and all had valid permits.

But if I might just say, about the inconclusive, we did decide to announce those inconclusives based upon the potential market impact, if it were to leak out during that 4- to 7-day period that it takes to retest with the gold standard test, that would have a significant market impact, and it was determined, particularly after consultations with the CFTC, that the policy we implemented was the appropriate one.

Chairman GOODLATTE. But you will continue to evaluate whether or not two tests would eliminate many of the false positives and possibly review that in the future?

Secretary VENEMAN. Yes. I think that will be something we continue to evaluate, but in the initial stages the determination was made that we should, after one test, determine whether or not there was an inconclusive. But we will continue to re-evaluate that.

Chairman GOODLATTE. Thank you, Madam Secretary.

It is now my pleasure to recognize the ranking member of the Agriculture Committee, the gentleman from Texas, Mr. Stenholm.

Mr. STENHOLM. Thank you, Mr. Chairman. I want to pursue the last questioning just a little further, because many have raised concerns about the number of false positives that may result from the current rapid testing.

Would you or one of your staff please explain how the decision has been made to employ this particular test and share, in your opinion, why you believe this test has been selected over any other test, particularly over any other test that might have a lower potential rate of false positives?

Secretary VENEMAN. I am going to ask Dr. DeHaven to answer this question, but I will say that it has been our scientists in the Animal and Plant Health Inspection Service that have made the determinations about the tests.

Dr. DEHAVEN. Thank you, Madam Secretary.

I would start by pointing out that, in fact, we have run, as the Secretary indicated, just over 17,000 samples so far and have had two inconclusives thus far. That would suggest, even with laboratories that are somewhat inexperienced in running those samples, that we have a very low false positive rate, recognizing, again, that we are taking every action that we possibly can to mitigate the disruption to the markets.

At the time that we were ramping up for this surveillance program in May, at the time we had one test that was not only licensed, but also was or was very close to completing the field validation process. It is one thing to license or permit a test; it is an

other to field validate it, where we are testing samples as we would be testing field samples in an actual program. So it was the Biorad test that we had the most experience with that had been or was very close to being field validated.

We have, in the meantime, licensed or permitted four other tests. We are, on an expedited basis, going through the field validation process for those other tests so that at the end of the day we would one, feel comfortable with any of those tests that might be used and two, that there would be an opportunity for a fair competition among those competitions for the testing market.

Mr. STENHOLM. Have any of these tests been field tested in Europe or other areas where they have had a greater incidence of BSE?

Dr. DEHAVEN. Indeed, some of those tests have been used and used extensively in Europe, to include the Biorad test that we are currently using. We do have, not just for BSE tests, but for all of the tests that would be used in animal disease eradication and control programs, a process where we license and then validate those programs. So while some of these tests may in fact have been used in Europe and elsewhere, we still go through the validation process, that quality assurance process within our own country and our own programs.

Mr. STENHOLM. Madam Secretary, as we heard in your testimony and we will hear in other testimonies later today, the single most important aspect of protecting the human food supply from BSE contamination is the removal of specified risk materials [SRMs]. Furthermore, Dr. Peter Lurie will later testify that the removal of non-ambulatory cattle from the human food chain will not greatly reduce the risk to humans. Having said that, is USDA reconsidering its across-the-board ban on non-ambulatory cattle? And in answering this question, with the ban on downer cattle from entering the food chain in place, it became inherently obvious that on-farm testing and surveillance would have to drastically improve in order to reach these animals in the high-risk population. How many on-farm tests have you conducted thus far? And are you finding adequate cooperation to conduct on-farm surveillance?

Secretary VENEMAN. Thank you, Mr. Stenholm, for that. First of all on the ban on downers or non-ambulatory disabled cattle that we announced on December 30 and it was put into place with our interim final regulation on January 12, that regulation is still in interim final form, which means we have received comments on that rule, and we are still reviewing those comments. I can tell you that my agencies have told me that there were many comments received on the rule and many of those comments received were on the issue of banning downer cattle.

With regard to the populations that we are testing, we are finding, just in our very preliminary results, which we have analyzed in a preliminary way from the month of June, we have found that we have obtained a significant number of samples from on-farm. But one of the most significant things we have found is that about nearly 69.7 percent or something like that of the samples obtained have been from already dead animals. In other words, that would indicate that these are on-farm animals going to rendering plants, going to what we call 3D/4D plants, and already dead animals

would be the ones coming from the farms. So we believe, with this 70 percent of the samples obtained number, that we are in fact doing very well with regard to dead animals from farms.

Chairman TOM DAVIS. Thank you very much.

Mr. Putnam.

Mr. PUTNAM. Thank you, Mr. Chairman. I just want to say, as a cattleman as much as a Congressman in the cow calf business in central Florida, that this disease had the potential to decimate an entire industry, and it didn't. In fact, the demand for beef is still extraordinarily strong in this country; people stand in line for 2 hours to eat a steak. They won't wait in a drive-thru for 5 minutes to eat a chicken. The Atkins Diet obviously has had a positive influence on that, but at the end of the day this was an outbreak that could have totally undermined not just an industry in agriculture, but undermined all public confidence in Government and Government's ability to deal with crises; and it did not.

And I think that is a credit to this Secretary and her Department in the way that they actually responded to the outbreak; in the way that they communicated their response to the public, to the consumers, and to the press; and, frankly, it reflects very well on generations of sound management in the Department and in Government that builds up that public confidence over time. Americans' public confidence in their food safety system is tremendously greater than it is in Europe, and it is a reflection of the professional science-based approach and open communications that this Department has heralded.

And I think that all of us can Monday morning quarterback and look for ways to improve on the next outbreak, and that is an important exercise to go through, but at the end of the day it is also important to give credit where credit is due, and the due credit is borne out in the fact that there is still a high level of confidence. Beef prices are still at an above average, not necessarily an all-time high, but certainly higher than average rate, and good return for the growers and good value for the consumer.

I just want to give the Secretary an opportunity to comment on the decision about the Creekstone slaughterhouse and give us some explanation of the basis for the decision not to test, and give you an opportunity to respond to that. So I will begin with that.

Secretary VENEMAN. Thank you, Mr. Putnam, and I appreciate your words of support for the actions of our people at the Department of Agriculture.

The Creekstone situation was one in which the slaughter company came to USDA and wanted to test all animals with BSE tests to basically use as an assurance on food safety. And I think the first thing that is important to recognize is that these tests will detect a BSE-infected animal only about 6 months or less from the time that animal would show clinical signs. So from a food safety perspective in testing younger animals, it would not give any real food safety assurance.

Second, and I think very importantly, as I indicated in my testimony, the International Review Committee report clearly indicated that there is no scientific justification for testing every animal. We have discussed that additionally with the OIE, who agrees with that, as well as other outside scientific bodies, all of whom say

there is not a justification. The only place in the world that this is being done is in Japan, and it was done in response to an outbreak that was first discovered on September 10, 2001. Subsequently, I think they have had a total of 11 animals. But as a result of their outbreak, they had a strong distrust in their food safety systems and consumer confidence went way down, and Japan, as a result, implemented a system that would test every animal.

Now, there is nobody that will say that has a scientific justification. They did that as a reassurance to the people of Japan. And we have been in discussions with Japan to try to reopen the market, and we are hopeful that we will find a way to allow us to continue to ship beef into the Japanese market without testing every animal, as they require currently under their domestic protocols.

I am not sure if Dr. DeHaven would like to add to that.

Dr. DEHAVEN. Thank you, Madam Secretary. I think you have done an excellent job of summarizing the situation. I would just add a couple of comments.

One, the focus on surveillance testing is just that, surveillance, to determine whether or not we have the disease in this country and, if so, at what prevalence. Food safety is taken care of, as we have done through the Secretary's announcement on December 30, by removal of specified risk materials. So the purpose of testing is for surveillance purposes. Because, in fact, it is a disease with an incubation period of typically 5 years or more, and because the current tests that we have available, as the Secretary indicated, will not detect an animal that is infected until just a matter of a few months or weeks before they develop clinical signs and then progress to death, that in fact there is no food safety value. We would, for the most part, be testing animals under 24 months of age, when this is a disease of animals typically 5 years of age or more, and then again the tests would only test positive, even for those infected animals, during a very narrow window. So there is no food safety value, but the act of testing would certainly suggest or at least imply a food safety value.

The OIE, the world animal health organization, recognizes for testing that we should focus our efforts, first of all, on animals over 30 months of age for that testing program, and then target that population, specifically those that are exhibiting CNS signs or other clinical evidence of disease, such as non-ambulatory animals, and that is precisely that we are doing. We would gain no surveillance value. In the international arena there would be no value placed on the animals that we would be testing under the Creekstone scenario in terms of determining what the prevalence of the disease is in this country.

Mr. PUTNAM. Thank you, Mr. Chairman.

Chairman TOM DAVIS. Thank you very much.

Mr. Tierney.

Mr. TIERNEY. Thank you, Mr. Chairman.

Madam Secretary, you stated in response to Mr. Waxman's question that you recognize the assumption that all cows with mad cow disease will be in the high-risk population may be false. If the experts are right and it is false, doesn't that mean that the program may not reach the claimed effectiveness of catching 1 positive cow in 10 million?

Secretary VENEMAN. I am going to ask Dr. Collins, as he discussed this previously, to discuss the statistical issue.

Mr. COLLINS. The short answer is yes, if the assumption is false.

Mr. TIERNEY. Thank you.

Mr. COLLINS. I would say, in response to that, and it is a question that Mr. Waxman asked as well, that we realize that there is a scientific debate about that assumption, that there is no one single right answer, but that we would like to work with Harvard, we would like to work with other experts in the field, and over the coming months provide alternative assumptions, alternative calculations and recharacterize or amplify what we have said at this point.

Mr. TIERNEY. Thank you.

Mr. COLLINS. And that is also, by the way, one of the recommendations of the draft IG report.

Mr. TIERNEY. Now, coming at this as a New Englander, where we may not know as much as others may know on this subject, I know that in January Health and Human Services Secretary Tommy Thompson and the FDA Commissioner Mark McClellan announced new policies to reduce the chance that cattle are fed to cattle, the primary method of mad cow disease. Now, I know that direct cattle-to-cattle feed has been outlawed already, but from my information from reading the IG report, the cow parts or the protein pellets are sometimes fed to chickens and some fall to the floor and they are mixed in with other protein sources or the fecal matter or the feathers, and then circulated somehow back to cows. So that use of poultry litter has been banned from cattle feed, and you testified, I think, on January 27, in response to a question that the ban of poultry litter for cattle feed, you said, I certainly agree with the ban. It has been one that has certainly got a lot of attention and a lot of questions have been raised about it. We have been working closely with FDA on the actions that they have decided to take and are supportive of those actions. So I assume you support those policies because keeping cattle from being fed to cattle is critical to controlling mad cow disease. Is that fair to say, Madam Secretary?

Secretary VENEMAN. What we do know about mad cow disease is that it is clearly spread from ruminant-to-ruminant feeding, that means cattle-to-cattle feeding. And that has been banned in this country since 1997.

Mr. TIERNEY. But I am talking here about—and I know it has been banned, and I think that is obviously an excellent idea. But we are talking now about poultry litter or other sources of protein, where it might not come directly, but sort of the back or side door.

Secretary VENEMAN. I was getting to that.

Mr. TIERNEY. I keep saying that because we only have 5 minutes and I would like to get to the crux of it.

Secretary VENEMAN. What FDA said was that they were going to take additional actions to strengthen the feed ban. On Friday they released an Advanced Notice of Proposed Rulemaking to get comments on exactly how that policy could be implemented.

Mr. TIERNEY. Let us be frank. Essentially they pulled back from banning it, which is what they were originally going to do, and now they have just said basically we are going to think about it some

more and we are going to take comments on it. How do we get to that point, from a point where first we were going to ban it, and I think everybody, including you, thought that was a good idea, to all of a sudden pulling back and now we are just going to think about it some more and take some more comments? I mean, from the consumers' standpoint, that is not a very comforting prospect.

Secretary VENEMAN. As I understand it, there was some re-evaluation of what exactly the FDA would request based upon the recommendations of the International Review Committee report that came out subsequent to their initial announcement. They then began to look at that report along with what they had previously announced, and it was finally decided—again, FDA is not under the jurisdiction of the U.S. Department of Agriculture—

Mr. TIERNEY. But you thought it was a good idea at one point in time. You stood up there and said: "I certainly agree with the ban." So have you changed your mind, you no longer think the ban is important?

Secretary VENEMAN. No, I have not changed my mind.

Mr. TIERNEY. OK. So how are consumers supposed to have any confidence when we go from supportive of a ban to just pulling it back? It leaves us with a concern are we more interested in protecting the industry or are we more interested in protecting the public here? Why not implement the ban while you are thinking about other things that you may want to do? Why not have an interim protective rule that is reasonable, and you believe it is reasonable and I think most of us believe it is reasonable, and then take your comments for further action, instead of just pulling back and leaving it out there?

Secretary VENEMAN. Congressman, it is really not possible for me to answer on behalf of the Food and Drug Administration, and I think that question would be more appropriately directed at them.

Mr. TIERNEY. My question to you is do you think it is reasonable to not put in the ban?

Chairman TOM DAVIS. The time of the gentleman has expired.

The Chair now is pleased to recognize the gentleman from Oklahoma, Mr. Lucas, one of our subcommittee chairmen.

Mr. LUCAS. Thank you, Mr. Chairman. And I am sure we are all waiting with great anticipation for FDA to formulate their rule to address the litter question.

But for just a moment let us just step back, Madam Secretary, to the question about the statistics and how we arrived at the decision about how many animals to test, and, for that matter, whoever probably on the panel is best prepared to answer that. But could you give us a little discussion about how we came up with this number of animals and what the percentage of likelihood of finding was, and why we arrived and what we hope to accomplish by our statistical sample?

Mr. COLLINS. Mr. Lucas, yes, I will try. Leading up to the development of the current surveillance plan, APHIS had been using as a test standard that they were trying to detect, with 99 percent confidence, to detect as few as 5 infected animals in the target population. That was the old plan. Under the new plan they wanted to dramatically increase the detection level, so they went to about one-tenth of the 45 and they said that our goal would be, with 99

percent confidence, to detect as few as five infected animals in the target population. The target population has roughly been estimated at about 446,000 animals.

Now, the total adult cattle population in the United States, that is, animals over 30 months, has been roughly estimated at 45 million animals. So if you assume all of the infectivity is concentrated in the target animals, and not in the rest of the adult herd, which you have just heard from Mr. DeHaven is largely undetectable, then you would get this detection level that you could find 1 in 10 million.

So the debate here has been about whether that is a valid relationship, to say you would have 5 infected animals in the target population and none in the rest of the adult animals coming to slaughter. And the 45 million is not that germane an issue because they are not presenting a threat to the feed supply or presenting a threat to the food supply, it is the 6.2 million adult cattle that come to slaughter every year. So the question is what is the relationship between the assumption of 5 infected in the target population and what might be in the 6.2 million coming to slaughter?

Now, APHIS assumed zero for lots of reasons. It is an analytical assumption to determine a sampling level. Other folks, Harvard Center for Risk Analysis, have said, there are alternative ways to try and come up with a more realistic assumption. One way might be to look at the European Union experience and look at the relationship between positives in the target population and positives in the normal adult population. So what do you look at, which country do you look at? Do you look at all countries? Do you try and find an analog country that has an experience like ours? It is not clear, but there is certainly some information there.

Second, Harvard University has a wonderful simulation model where they can introduce infected feed at one point in the cattle population and then track out how that might spread into BSE in the animal population over a long period of time, then take a snapshot and figure out where BSE might be in the distribution of animals. That is another approach. That is a mathematical simulation model.

These different approaches have arisen over the last several months as the university community and others have started to look at the APHIS assumption. So all we have said is we have assumed zero out of the 6.2 million adult cattle coming to market. If you use the overall average European experience for the year 2002 and just assume that relationship between the infected animals in the target population and the infected animals in the normal adult population, you would conclude there might be as many as 2 infected animals in the 6.2 million coming to slaughter. That is just one possible alternative scenario.

Because of the debate that this assumption has engendered, we have agreed that we want to look at alternative assumptions, we want to look at what the analytical experts have to say and see if we can characterize what the alternative assumptions might mean.

But let me finish with this critical point. All of this discussion is not germane to our sampling program. Our sampling program does what the OIE says it should do, what the International Review Team says it should do, what the Harvard Center for Risk

Analysis says it should do: it focuses on the high-risk animals. And regardless of the assumption we make about the infectivity level in the normal adult populations, it does not change our sampling plan one iota. It is useful information for one main purpose, and that is, when all is said and done and we have gone through a whole year of testing, if we find zero positive BSE animals, then we want to be able to characterize the prevalence in the national herd, and that is where that assumption would come into play. If we start finding positive animals, then it is going to be the actual data that we collect that we are going to use to establish that distribution.

So it is a very interesting analytical and academic debate, and it will help inform us as we move forward, but it is not germane to our sampling program, our attempt to detect BSE in the herd today.

Chairman TOM DAVIS. The time of the gentleman has expired.

The gentleman from Minnesota, Mr. Peterson.

Mr. PETERSON. I thank the gentleman.

Madam Secretary, welcome, and I want to commend yourself and your staff for your response to this situation, especially in December. You and I were on the phone, as I know you were with other Members, and I think you guys really were on the ball and did a good job. So I commend you for that.

And on the surveillance system, I am not a statistician or an actuary, so I have to assume, Mr. Collins, that what you said is correct, that you are following all the right procedures and hopefully this will work. I think you have put a lot of time into this, and I commend you on the effort to try to better get a handle on what the situation is out there in the countryside.

But I want to use this time to follow up a little bit on the subject Mr. Stenholm brought up. At a time when we have a wider audience, and maybe we are on C-Span, I don't know, the American public understands. I think you did too good a job, Madam Secretary, you went a little further than you should have on this downer animal situation. And I want folks to understand what this has done to producers, and I think maybe bring up a potential problem. But the system we should have, and I thought we had prior to this happening, was that we should test these animals, and if they are not positive, that they could go into the meat supply. That makes sense, and that is the way it ought to be done and that is the way it should have been done. By banning these animals, a lot of whom are just injured loading them or whatever, you have put producers in a real problem, and I have gotten more calls about this than any other thing that has happened out of this whole situation.

We now have a situation, and I don't think it has been corrected yet, where the butcher shops in Minnesota that butcher these animals for farmers and others for their personal consumption are not butchering the animals because of this situation. So what you have done is you have made these animals that are perfectly fine worthless. In fact, you have made it a situation where they actually have to pay money to get rid of them. And what I think is probably happening in some cases is they are just burying these out in the back 40 or putting them in a dump or something. So I think you caused a problem there.

So I think people need to understand that this whole downer animal thing, it sounds good, but I don't think it is really getting us any place, and it is putting a tremendous burden on producers. And folks need to end that, and I will end that editorial with that. And I hope that we can do something about this rule, and I know you are considering that, and I hope we can.

The last thing, the question I want to ask is if we do find another BSE situation in this surveillance program, or, God forbid, that we get foot and mouth disease in this country, I am concerned about our ability to trace back and get on top of this. How long did it take for us to trace back the situation with this cow in Washington State, before we finally determined where it came from?

Secretary VENEMAN. I think it took about 4 or 5 days. About 3 days.

Mr. PETERSON. Three days.

Secretary VENEMAN. Now, keep in mind—and I appreciate, Congressman Peterson, your personal interest in animal identification, and we appreciate the fact that we have been able to work with you as we look to try to implement a reasonable animal identification system in this country. We share the view that this needs to be done.

What was important about the cow in Washington State is that because it was a dairy cow, it did have an animal identification that was pretty easily traceable. I think most of the large dairies in this country have animal ID systems, which makes that easier to do.

Now, as you know, we are trying to implement an animal identification system in this country. We are working through APHIS. Dr. Collins has been involved, our general counsel has been involved, our CIO has been involved, because the technology, the legal requirements, and how we are going to implement it are all critical issues. So we have this team that is working with APHIS to get this implemented. But you are absolutely correct, animal identification is a priority. It is a priority for us in the Department, I think it is a priority for certainly you and many other Members of Congress, and—

Mr. PETERSON. Before my time expires, I just want to say that I appreciate what you are doing, but I still think we are moving too slow on this. And if we ever got foot and mouth disease in this country, in Joplin, MO, for example, where I am told these animals can be, within 24 hours, on both the west coast and the east coast, I don't think we are in a position right now to be able to trace that stuff back quick enough.

Secretary VENEMAN. If I just might add, you are absolutely right that the animal ID is most critical for a very contagious, fast-spreading disease like foot and mouth.

Chairman TOM DAVIS. Thank you. The gentleman's time has expired.

Mr. Murphy.

Mr. MURPHY. Thank you, Mr. Chairman, and I thank the panel for being here.

Let me make sure I understand. In selecting animals for testing, you randomly select, you do not do the entire population of cattle. Do you inspect all down cattle; are all of them tested?

Dr. DEHAVEN. Congressman Murphy, first of all, let me explain that our testing program is not designed to be a random sampling, but, rather, our intent is to test as many animals as we possibly can in that high-risk population. So it is not a matter of—

Mr. MURPHY. I am trying to get to a certain point here in 5 minutes. I understand the point you are making, and you have scientific reasons for how you do the selection, but all cattle that are downer cattle, are they all tested?

Dr. DEHAVEN. The downer animals would be in that high-risk population. We will test as many as we possibly can. Being realistic about it, however, some of the animals are going to go down, they would become non-ambulatory on the farm. We may never know about some of those animals and may never have an opportunity to test them.

Mr. MURPHY. What I understand from some of the farmers in my district is if you have a downer cattle, and as long as they are not going to the food supply, no one has to alert anybody to test them. Is that true?

Dr. DEHAVEN. There is no requirement to report a non-ambulatory animal.

Mr. MURPHY. OK. So a non-ambulatory cattle may have BSE, but we wouldn't know if there is no requirement for any testing to be done, correct?

Dr. DEHAVEN. And that goes to the statistical issues and the statistical basis for our sampling. Knowing what that overall total population of high-risk animals is, that would include non-ambulatory, whether we catch every one of them or not, if we can test enough of them, then we have statistical validity about what we can say about the prevalence of the disease.

Mr. MURPHY. Do you try and do the testing before they get to the slaughterhouse?

Dr. DEHAVEN. There is a number of collection sites that would include animals if they become non-ambulatory at slaughter, on the farm; some are euthanized and go to renderers.

Mr. MURPHY. Do you do some testing in a collective way of materials, for example, central nervous system materials of cattle, en masse at a slaughterhouse? For example, if there has been 1,000 cattle there with a sample from each collected and then mix them together and perform one test, would that be a valid test doing that sort of assessment?

Dr. DEHAVEN. None of our testing would involve mixing of samples; they are all samples that are collected on the individual animal, identified to that individual animal and tested individually.

Mr. MURPHY. I am just asking in terms of—how much does it cost per test to do this?

Dr. DEHAVEN. The cost of the test depends on a number of factors. One would be the cost of the actual testing itself, the test kit, which runs in the neighborhood of \$15 to \$25. More substantial is the cost of actually collecting that sample, getting it to the laboratory, and then reporting it.

Mr. MURPHY. I'm looking for the total cost. What is the total cost?

Dr. DEHAVEN. It will vary depending on where that sample is collected. It would be substantially less—

Mr. MURPHY. Give me a ball park.

Dr. DEHAVEN. I think ball park maximum would be \$100.

Mr. MURPHY. OK, \$100. What I am just wondering here, because I know we all share a concern for making sure that as many are tested. I just know it is done in some areas where you have a collection of specimens that may be mixed together, and, indeed, one might have that if you are separating out materials in a slaughterhouse, there might be central nervous system materials. I don't know enough about the actual testing, if once you have a number of things mixed, you can go through that and then say, OK, somewhere in this last 1,000 cattle that have been mixed together we found a positive, and we have to now back-track for that. I am just trying to think of other mechanisms that might work here in multiple levels in the food chain.

Madam Secretary, you had a comment on that?

Secretary VENEMAN. I think it is important to point out that the only known means by which we can test for BSE right now is through this testing from the brain. That is what the tests are sensitive to. So it is not as if you can take a lot of random material from a slaughter plant and test that.

Mr. MURPHY. Oh, I understand that, but my assumption is that categories of certain areas of the cow are not all heaped together. Some categories may appear together. That is what I was just wondering, because I know in other areas of medical testing some of these things are done as a group, for example, blood testing.

Dr. DEHAVEN. Congressman, we are focusing on animals at slaughter, and the animals that we would test at slaughter are going to be identified ante-mortem either because they are exhibiting central nervous system disorder, because they are non-ambulatory, or perhaps they arrived dead.

Mr. MURPHY. Yes, but they could also be asymptomatic and still have BSE, right?

Dr. DEHAVEN. But those animals that are asymptomatic wouldn't be targeted for our testing program. But again, a good point to emphasize: public health, food safety is assured not by testing, but by removing specified risk materials from the food chain any tissues that might be infected. So, again, the purpose of the testing is for surveillance purposes to determine whether or not we have the disease and, if so, at what prevalence in the national herd. Food safety is assured by removal of SRMs.

Mr. MURPHY. I was just asking—

Chairman TOM DAVIS. The gentleman's time has expired.

Ms. McCollum.

Ms. MCCOLLUM. Thank you, Mr. Chairman.

My questions are somewhat along the same line. And to your point, Doctor, about the testing is to see if the food that the animals are being given is safe goes back to Representative Tierney's question, then why are we delaying the ban?

It is my understanding that the tests are voluntary except for the Federal tests that are conducted where the Federal inspectors are at the slaughterhouses. Is that correct?

Dr. DEHAVEN. Yes, ma'am, that is correct, it is a voluntary testing program.

Ms. MCCOLLUM. And in Minnesota, when we received the information about going forward with doing the voluntary testing, our Animal Board of Health found that no money came along with it, so at their own expense they sent out postcards with a 1-800 number to contact you, and along with that comes the disposal needs and other higher costs for people who are going to be sample providers. And along the questions that the gentleman just had, have you attempted to project these costs and determine how establishments will adequately and timely be compensated, when necessary? Do you have any time when we can expect information like that for our farmers?

Dr. DEHAVEN. There are several issues. One goes to the voluntary issue of the program, and APHIS has a long history of successful animal disease—

Ms. MCCOLLUM. Sir, I really don't mean to be rude, but I have one other question, so I am going to ask it now, because I am afraid with your answer going into all the history, I might not. Consumers who buy organically labeled meat products, it is my understanding that if I purchase an organically labeled meat product today, that the cow might have ingested the brain and won't have been BSE tested, in other words; that there is a point—I am not saying this very smoothly. There is a point at which an organic label would certify to a consumer that a cow in fact would not have received any of the products that they eat that would have had the BSE. What is that cutoff deadline for organically labeled meat?

Dr. DEHAVEN. I would just clarify that what you are suggesting with regard to what cattle can eat would be true for all cattle. We have had, since August 1997, a feed ban that prohibits—

Ms. MCCOLLUM. Sir, there is an assumption when people buy things that are organically labeled, that they have a different meaning. An organically labeled beef is something that I have heard consumers say, I can eat that and I don't have to worry about anything because it is organically fed. And that is a false assumption at this point in time, is it not?

Dr. DEHAVEN. What is important is that the current ban prohibits the feeding of ruminant proteins to ruminants, regardless of whether it is an organic feed or not. I am not familiar enough with the organic standards to know if it addresses specifically what animals could eat. Some animals receive feed supplements that are typically protein supplements, but what we are saying is—and perhaps are suggesting by feeding organic feed it doesn't include those supplements at all. We are saying, through the feed ban, whether animals are fed protein supplements or not, that protein cannot have originated from other ruminants, and that is how the disease transmission is blocked.

Ms. MCCOLLUM. So my question would be more appropriate to the Food and Drug Administration. Who is in charge of labeling organic?

Secretary VENEMAN. We do, in our Department, oversee the organic program; it is not under Dr. DeHaven's agency. I think it is really important to point out that ruminant-to-ruminant feeding of animals cannot occur in any of the livestock production in this country, regardless of whether or not it is organic. The organic rules prohibit any mammalian protein to be fed to animals that are

marketed as organic since the organic rules have been implemented, which has been in the last couple of years.

Chairman TOM DAVIS. At this time——

Ms. MCCOLLUM. Mr. Chairman, I know my time has expired, but if they could provide to the committee the other question that he didn't have time to answer.

Chairman TOM DAVIS. All right, see if you can get back to us on her follow-up question. Thank you very much.

At the conclusion we will hold the record open to give all witnesses an opportunity to respond to questions posed in writing.

At this time it is my pleasure to recognize the gentleman from Michigan, Mr. Smith.

Mr. SMITH. Thank you, Mr. Chairman. I have been interested in following the BSE since it was first identified in 1986 in Europe. Oversight is appropriate, Mr. Chairman; however, there is some danger to sending some confused signals out to consumers in the United States. The first one is that if it is a joint committee hearing, there must be some real danger out there.

A lot of words have been said this morning about whether we can guarantee 100 percent or do a better job of surveillance. I would like to try to make a couple of comments, maybe getting some of the hay out of the mow and down on the barn floor, where we can sort out some of the chaff.

Madam Secretary, in conclusion of my four points, I would like to see if you agree with my four points.

One, there has never been an animal raised in the United States that has ever been identified as having BSE. What happened with the identified animal in Washington a little over 6 months ago was an animal that was imported from Canada that was subject to eating the kind of bone scraps and slaughter scraps that, as a footnote, have been identified as a way that BSE is transmitted from one bovine to another. This animal came from Canada. Again, it was raised at a time before the ban went on in 1997 of using those particular feed scraps.

Actually, the fact that every time, Madam Secretary, that USDA decides to announce a suspect is being sent in for further tests, consumption, because it is sort of a scare point, goes down. So if there is one question or maybe one suggestion, if you decide it is the wise thing to do to announce that you are sending in a suspect animal for a so-called gold test, that you make very clear in that announcement that this animal has not been identified as BSE. And I know you would do it with one sentence. I think it needs to be more aggressive. We are disrupting an industry in the United States because of the potential of fear.

So, No. 1, an animal has never been raised in the United States that has ever been identified as having BSE. The one animal that was identified in Washington actually was imported from Canada and subject to eating the kind of scraps that have been identified as the only way that we know of to transmit this disease.

So my suggestion is with all of the words and comments said this morning, that somehow we need to boil it down to try to tell the American consumer what the real risk is. And there is a lot of media coverage. The tendency of that media is to take maybe the most bold, scary statements.

So, your reaction.

Secretary VENEMAN. Thank you, Mr. Smith. I appreciate your comments. And you are correct that the animal that was found in Washington State was traced back to originate in Canada. It was of an age, it was determined, that predated the feed ban. There was also an animal discovered to have BSE in Canada in May of last year. That animal was also found to have predated the feed ban, which hopefully explains how these animals would have potentially gotten the disease. And that feed ban has been in effect since 1997; it is the means by which current science shows us that the disease is transmitted from animal to animal. So obviously the ruminant-to-ruminant feed ban is a key component of our program here to prevent the spread of BSE in this country; it is probably the single most important thing in terms of preventing the spread.

Mr. SMITH. But there is one further—excuse me, go ahead.

Secretary VENEMAN. Go ahead.

Mr. SMITH. I was just going to say one further suggestion. I think we need to refine the downer animal. The tendency is for most farmers, to maybe limit the inspection of the kind of animals that might be potential suspects, unless we refine some of the rules on downer animals.

Secretary VENEMAN. As I indicated before, the downer issue is in the rulemaking process. It was announced as an interim final rule, and those comments are now being evaluated.

If I might just say also that in terms of the announcing of the inconclusives, we have no evidence that has impacted consumption in the United States. We have seen very strong consumption numbers here in the United States; we have seen some minor market reaction on the days when those were announced, but there was a quick bounce back as the facts became known and that they were deemed to be negative.

Chairman TOM DAVIS. The time of the gentleman has expired.

It is now my pleasure to recognize the gentlewoman from South Dakota, Ms. Hersetth.

Ms. HERSETH. Thank you, Mr. Chairman.

Just to follow up a little bit on the testing and the samples here. You have talked about how you are targeting the high-risk population, and you just finished describing how the case from Washington was traced back to Canada. Have there been any efforts by the USDA to take any actions to specifically identify Canadian born cattle in the United States for this testing program if, as you have stated, the testing is more for surveillance actually than for food safety?

Dr. DEHAVEN. In fact, associated with the two investigations, one involving the Canadian cow found on May 20 in Canada, as well as the cow found in the State of Washington on December 23, there have been extensive epidemiological investigations ongoing on both sides of the border. As part of that investigation, a large number of animals were sacrificed, all of them tested and all of them tested negative. So there certainly has been a lot of testing of Canadian cattle as it relates to those two investigations.

We do indeed import a large number of cattle from Canada. Most of them or many of them are going to feed lots and then to slaughter; many were, prior to May 20, when we imposed the restrictions,

going directly to slaughter. We also know, of course, that there is a large number of breeding cattle and dairy cattle that have come into the United States from Canada, and through our surveillance program, as they have been integrated into the national herd, they are subject to the same safeguards, firewalls, if you will, as our national herd in terms of subject to the same feed ban, subject to the same removal of specified risk materials at slaughter, subject to the same surveillance program.

Ms. HERSETH. OK. Over the past few days I have had a chance to talk with a number of my constituents in South Dakota who are producers about the handling of the reporting of the inconclusive results, and there hasn't necessarily been a consensus. Some feel that it has been handled appropriately; others feel that there was more than a minor effect on the market and they feel that perhaps, if there is any consensus, it is if these inconclusive findings are going to be reported, then report all the information. Where were these two cases that resulted in false positives? Were they samples taken at rendering facilities that had no chance of entering the food chain? If we have 4 to 7 days from the initial screening test, from the rapid test to the more comprehensive scientific-based test, doesn't that give us time then to trace that animal back, particularly if it is from a dairy herd, to determine the nation of origin of that sample?

So I guess there is almost the sense among producers and others in the cattle industry in South Dakota that either don't report the tests until you have the conclusive findings, or if you are going to report the initial findings that are inconclusive, report more information as it relates to the origin of the animal, as it relates to the age of the animal, and as it relates to where the sample was collected.

Do you have any thoughts? The Secretary, as you mentioned in determining the timetable of releasing this information, that one of the primary rationale was the potential impact on the market based on the delay before the conclusive test and the potential leaks that would be involved.

Mr. COLLINS. Perhaps I could start with a comment on the market and then ask Dr. DeHaven if he would amplify on the availability of further information.

This question about dealing with inconclusives, I was sitting here as I was listening to you, the answer to that is sort of like the answer to the question of when have you stopped beating your spouse. If we don't put any information out and it gets leaked into the marketplace, then we, I think, will be quite criticized for not providing information to the market, creating uncertainty on the part of the Government for not providing information. On the other hand, I think if we provide too much information, we might be getting ahead of ourselves, such as identifying the location of the sample, as you mentioned.

Ms. HERSETH. But wait a minute if I could stop you there for just a second, because it gets at some of the other questions that were being asked as it relates to—I think it was Congressman Smith's questions about the consumers' reaction to this, and perhaps there isn't any evidence as yet that there has been a reduction in consumer consumption. But if the public doesn't know in the reporting

that the sample was collected at a facility in which the particular animal being tested had no chance of entering the food supply, wouldn't that be somewhat helpful as it relates to minimizing the market impact?

Mr. COLLINS. Let me just make one comment about the market impact, and then I will turn it over to Dr. DeHaven to address the rest of the question.

With regard to the market impact, you mentioned the Secretary's characterization of the impact being minor. What happened when we first released the inconclusive on June 25, the next trading day was Monday, the 28th, the market went down roughly 3 percent. The day after that the market went up roughly 1.5 percent. And then on Wednesday, on June 30, was the next trading day after we announced the second inconclusive on the night of the 29th. The market went down again roughly 1.5 to 2.5 percent that day, and the market was mixed for quite a bit after that.

One of the notable things, I think, about that is the market we are talking about is the futures market. During that period of time when the market dropped, if you look at any of the trade commentary on what was happening in cash markets, producers were not selling their animals; they were sitting, waiting to see if the inconclusive issue would be resolved. So the question of how much money was lost by producers, the answer to that is not really clear, the market impact, because we know that trading was very light on the days after the inconclusive were reported.

Now, with respect to how much information we should be reporting, I will give that easy question to Dr. DeHaven.

Ms. HERSETH. OK. And if I could just make one other comment on the flip side.

Chairman TOM DAVIS. The gentlelady's time has expired. We will let them answer your question, then we need to move on.

Dr. DEHAVEN. Thank you.

Chairman TOM DAVIS. Briefly.

Dr. DEHAVEN. I think it is important, first and foremost, to point out the fact that by definition these animals are not going into the human food supply. Whether they are animals with CNS signs, non-ambulatory, or obviously dead animals, they are not going into the human food supply. The only potential would be when we ramp up our testing or normal slaughter animals, and even then we will have a policy of holding those carcasses pending a negative test.

When we announce these inconclusives, we make it a point to say that these animals have not entered the human food chain. So there is no public health issue with regard to those particular animals.

I would also point out that so far, out of 17,000 plus or minus animals that have been tested, we have only had two inconclusives. I don't want to minimize the impact on the markets of reporting those, but in fact that is not a large number given the number of animals that we have tested. And Keith does a more thorough job than I do of explaining that the impact on the market is certainly minimized by us reporting it as opposed to us trying to minimize the impact of leaked information.

If we were to report the location of these inconclusive samples, we think that there are a couple of bad precedents that we would

set. First of all, an inconclusive that confirms negative is simply a negative test, it is no different than any other sample that we test that turns out to be negative. So we don't think it is appropriate to handle those animals any differently, assuming that we get negative confirmatory test results. Second, if we were to report the location of those samples, then we can suggest or guess that producer or that renderer or that slaughter plant, and even the laboratory where the sample was tested, would be subject to a lot of scrutiny by the media and could in fact damage what has been up to this point excellent cooperation from all of the industries that we are working with. From the laboratories to the renderers to the slaughter plants to the producers and several other industries that I am probably failing to mention, we have had excellent cooperation. We don't want to do anything by prematurely reporting information that could damage that excellent cooperative relationship that we currently enjoy with the industries that we are working with and, in fact, must have if this is going to be a successful program.

Chairman TOM DAVIS. Thank you very much.

Mr. Ose.

Mr. OSE. Thank you, Mr. Chairman. I want to examine a couple of things, but before I do I want to get in the record some empirical data. Mr. Chairman, on your leadership, one of the agencies over which we have oversight is USDA, and one of the issues we have followed most closely quietly is this issue of BSE in cattle herds. One of the things we have dug out, which, by the way, for everybody's edification, one of the most informative Web sites you can go to is the one that APHIS puts up under the USDA Web site, where it actually tracks historically the number of tests that have been done over the past 10 or 12 years. And if you look at that Web site, you will find that under the BSE surveillance programs that have been in place since May 1990, the only true focus that has been put on this issue has been under Secretary Veneman's leadership. And I would cite for you the numbers of tests that have actually been done, and I am going to go by year. In 1990 there were 40 tests done. I am talking in the entire herd, 40 tests for BSE done. 1991, 175; 1992, 251; 1993, 736; 1994, 692; 1995, 744; 1996, 1,143; in 1997, concurrent with the FDA ban on the feedstock, 2,713; then in 1998 it fell to 1,080; in 1999, 1,302; in the year 2000, 2,681.

Now, when Secretary Veneman came into office, 5,272 were done in 2001; in 2002, 19,990 were done; in 2003, 20,543; in 2004 it tailed off a little bit, 15,513.

The point of reciting these numbers is to show that for the first time since the early 1990's we have in fact got somebody on the job who is paying attention to this, trying to protect the consumer from buying beef that is otherwise tainted with BSE.

In addition to that, one of the things that the USDA has done is instead of relying on a single lab located in Ames, IA, they have authorized testing to be done by now 12 newly approved labs, 7 of which have been approved—is it 5 or 7 of which just quite recently? The USDA has also gone and imposed under an interim rule the removal of specified risk material, a test and hold policy for any

suspect carcasses, they are working on an animal ID system that will actually be efficient.

I put this in the record for the purpose of showing that contrary to the efforts of some that the USDA is not on the job, the facts of the matter say that for the first time since 1992 the USDA is on the job.

Now, my questions have to do not so much directed toward Secretary Veneman as to ask why the FDA isn't here testifying today.

Chairman TOM DAVIS. We didn't ask them to. We just didn't request that they be here today. We have a full hearing, as you can see, with three panels, and we couldn't get everybody here.

Mr. OSE. The reason I ask the question is the only way by which science has established that this disease is communicable from cow to cow is by virtue of the feedstocks. Now, it is clear from the evidence, which I would have been happy to share with anybody, it is a public record, it is on the APHIS Web site, it seems to me that our challenge is really over at FDA, not at USDA. USDA is actually doing something for the first time in a decade. I mean, this administration actually got out of their chairs and have done something. So we ought to have a hearing about FDA, not about USDA's efforts.

Chairman TOM DAVIS. Let me just say to the gentleman we can do this at a subcommittee level, but it was a joint decision between the Agriculture Committee and this committee that we focus the attention on the expanded surveillance system, not on the FDA regs.

Mr. OSE. I appreciate that, Mr. Chairman. Before I yield back my time, I just want to make sure that the facts get in the record that the USDA has, at least on a comparative basis, done upwards of 10 times what the previous administration ever did.

I yield back.

Chairman TOM DAVIS. Thank you.

Mr. Van Hollen.

Mr. VAN HOLLEN. Thank you, Mr. Chairman.

Thank you, Madam Secretary and gentlemen for your testimony. And I think we all agree that our overall objective is to make sure that the consumer has justified confidence in our food safety. I am just trying to get a better idea of exactly how all this works, and since I only have 5 minutes, if you could give me as brief a response as possible.

My understanding from your testimony is that there is no requirement that anybody report a downer animal. Is that right? There is no requirement that be reported.

Dr. DEHAVEN. That is correct.

Mr. VAN HOLLEN. OK. And there is no requirement that animal be tested, is that right?

Dr. DEHAVEN. That is correct.

Mr. VAN HOLLEN. So the testing is a voluntary program entirely.

Dr. DEHAVEN. I would just add one minor correction to what I said before. There is a requirement to test ante-mortem condemned animals at slaughter.

Mr. VAN HOLLEN. At slaughter. But there is no requirement to test, obviously, every downer animal.

Dr. DEHAVEN. There is at slaughter, but not elsewhere.

Mr. VAN HOLLEN. OK. Elsewhere, not at slaughter, but elsewhere, that is a voluntary requirement.

Dr. DEHAVEN. It is indeed. And our initial numbers would suggest that we are getting very good voluntary cooperation in support of that program.

Mr. VAN HOLLEN. But, I mean, to the extent that it is voluntary, it is still not a random sample, isn't that right?

Dr. DEHAVEN. We arrive at a randomness by ensuring that we are getting collection of samples from all of the collection sites, whether they be animals at slaughter, renderers, salvage plants, on the farm, diagnostic laboratories, and we ensure that we have some randomness injected by ensuring that we are getting animals in appropriate numbers from all the different categories of animals that we want to test: those animals that are exhibiting central nervous system disorders, those animals that are non-ambulatory, those animals that are dead. And as Secretary Veneman has testified, we are encouraged by the first month's results and with the preliminary information. It would suggest that we are getting that randomness inserted through good collection at all of the different sites and of good representation of the different categories of animals that we want to test.

Mr. VAN HOLLEN. All right, let me ask you this. Is there a requirement that a downer animal be tested before it enters the non-cattle animal food supply?

Dr. DEHAVEN. No, there is not. And, again, the purpose of surveillance testing is not to ensure that an infected animal doesn't go into the feed supply; that is why we have a feed ban in place. The purpose of the testing is to determine prevalence of a disease.

Mr. VAN HOLLEN. Right. But getting back to Mr. Tierney's point, which as of now the FDA has not put into place a ban on the poultry litter issue, I want to just explore the question about whether or not you could have the disease spread from a downer cattle into the non-cattle food supply. So my understanding of your testimony is that there is absolutely no requirement before that animal be rendered and go into the non-cattle food supply that it be tested, is that right?

Dr. DEHAVEN. Our goal is to test all non-ambulatory animals. So to the extent that animals going into the feed supply go to renderers and salvage plants and other locations, in fact they would be subject to testing. And, as I mentioned, we are getting good voluntary cooperation from the renderers and the salvage plants, those locations that are producing meat and bone meal for the feed supply. So in fact I would suggest that we are testing those animals.

Mr. VAN HOLLEN. Those that are tested, there is no requirement, as I understand it, that you hold the animal, the results, before it is distributed to the non-cattle food supply before you get the results of the test, is that correct?

Dr. DEHAVEN. It makes good business sense for a renderer not to put a carcass into the feed supply until there is test results.

Mr. VAN HOLLEN. But there is no requirement that you wait for the results of the test, is that right?

Dr. DEHAVEN. No requirement, but in fact almost all of the renderers are in fact holding them. Should any of those samples come

back positive and the carcass not held, there is a mechanism through FDA to recall that feed.

Mr. VAN HOLLEN. But wouldn't it make sense that rather than having to trace it after the fact, wherever it may have been disseminated, that we wait and hold it until we have the results of the test? Do you believe that would make sense as a policy?

Dr. DEHAVEN. And, in fact, that is what is happening in the majority of situations.

Chairman TOM DAVIS. The time of the gentleman has expired.

Mr. VAN HOLLEN. But why not make it a requirement?

Chairman GOODLATTE. Thank you. The time of the gentleman has expired.

The gentleman from Kansas, Mr. Moran, another of our subcommittee chairs, is recognized for 5 minutes.

Mr. MORAN. Mr. Chairman, thank you. I thank Mr. Davis and the ranking members as well.

Madam Secretary, if beef consumption, which I assume measures consumer confidence, and a strong cattle market are any indications of your efforts, the Department's efforts in regard to addressing this issue, by those standards I would like to comment that I think the USDA has done an exceptional job in your response. We have weathered this storm much better than I think many anticipated, and I think the USDA's reaction, involvement, full engagement has a lot to do with that. So I thank you for those efforts.

Release of information about inconclusive tests is a significant issue, and I would again comment upon Dr. Collins' comments, which I think USDA would be in a no-win position on this issue. If you don't release information, we will be complaining that there is inside information and the market is being manipulated; and if you do release the information, we are going to complain that there are false positives. I do think that the gentlewoman from South Dakota raises an interesting point about the amount of information that could be helpful, and I think that is an issue that the USDA ought to review.

False positives are important because they do affect the market, and I think the USDA recognizes that. I remember when you announced your decision in regard to 100 percent testing. One of the reasons that you were reluctant to support 100 percent testing was the concern about false positives. So I think that is the issue or an issue that I would be delighted if USDA continues to monitor, tries to find ways to improve. And in that regard I would ask you if there is any significant differences in the tests that are available to test for BSE, any significant difference in the results as far as false positives. Is there another test that is likely to have fewer false positives but provide the same level of confidence in the results?

Secretary VENEMAN. Let me ask Dr. DeHaven to review that, because it is the APHIS scientists, as I indicated before, who are reviewing the various rapid tests, as we call them.

Dr. DEHAVEN. Thank you, Madam Secretary.

Indeed, one of the things that we look at as part of our licensing and permitting processes for these tests, as well as the field validation, is the potential for false positive results. Again, I would point to the statistics thus far with somewhere in the neighborhood of

17,000 animals that have been sampled and most of them tested at this point, and so far two inconclusives. If my math is right, that comes up with a false positive rate so far of 0.012 percent, a very small percentage.

I don't have at my disposal presently what the published data may be with regard to false positives on some of the other tests. I would just assure you that we would not license or permit a test, approve it to field validation unless we felt that we were getting acceptable results. So we do have a very rigorous quality control process in place that ensures that we are not allowing tests to be used that don't have appropriate accuracy and sensitivity.

Mr. MORAN. I assume, Doctor, that you would confirm that you have and will continue to take every effort possible to reduce the number of false positives, even if that means a different test, different procedure.

Dr. DEHAVEN. Absolutely.

Mr. MORAN. One of the questions raised about additional information is related to Canadian cattle, and I am interested in knowing if there is any reason to believe that cattle in the United States that originate from Canada are any more likely to test positive for BSE than a non-Canadian cow. My question really is are the same rules and regulations, the same criteria in place in Canada, in the same timeframe, the same implementation, so that supply from Canada versus a U.S. born-bred raised cow, that there is no difference?

Secretary VENEMAN. You are exactly right. I think it is important to point out that Canada did implement the feed ban the same year, basically the same time the United States did, that we worked over the years very closely with Canada in terms of all of the control measures for BSE. We have had very consistent programs. We have continued to work with them very closely as they had their find on May 20, 2003 and we had our find on December 23, 2003. We continue to have constant dialog at our technical levels to ensure that the regulations are as close as possible in terms of the actions that are being taken and that we share the science that we have.

When we made the determination in December to appoint an international review panel, that was essentially the same panel that had looked at the Canadian situation. We thought that was important because they had looked at the North American situation post the May 20 find. So we believe there is a very close correlation in terms of the kinds of actions that have been taken to protect the North American beef supply between the United States and Canada.

Chairman TOM DAVIS. The time of the gentleman has expired.

The gentleman from North Dakota, Mr. Pomeroy.

Mr. POMEROY. Madam Secretary, the last time we had a chance to visit was regarding that May 20 Washington Post story regarding imports allowed in from Canada, at a level contrary to the position that you had earlier announced in what would be allowed. Specifically, it took litigation against a proposed rule by R-Calf to bring to the forefront the fact that certain imports and import certificates were allowed by the U.S. Department of Agriculture, contrary to your own stated position. This was acknowledged by you

in our meeting and we have a standing request for such information as you might bring us in terms of what are you doing about it. I thought this really might be a situation where heads would roll, because literally all of the testing, all of the things we have been talking about regarding U.S. supply are undercut if you are allowing imports in from Canada that are contrary to what you said should be allowed in. What is the status of your follow-up on the import issue?

Secretary VENEMAN. Congressman, we have, as you know, based upon the lawsuit that you referenced, entered into an agreement that goes back to the import permits that were permitted as of the August announcement. I can let Dr. DeHaven explain this more completely, but APHIS had made the decision to permit additional products that were within the range of those products that were announced in August. Then in April there was a decision made in APHIS to allow, based upon some discussions with Canada, to allow bone-in beef. That decision should not have been made. And so as a result of the court action, all of that was pulled back.

I will tell you that no product entered the United States that did not have a valid permit. No product entered the United States that was not consistent with the kinds of product that was permitted into the United States under the permits. I think there were a number—

Mr. POMEROY. On that one, Madam Secretary—I am sorry to interrupt, but time is so short. I believe that permits were issued specifically on items like ground beef or processed beef products, and this was perhaps coming from plants where otherwise boxed beef products might have been permitted, but the issue is that inspection was completely impossible. Basically without U.S. inspectors at these Canadian plants, we were just left to their good word, which is why you didn't allow that within the range of imports you initially allowed. And so I am not sure that it is a correct statement that product didn't come in under permits that were inconsistent with what you had announced would be allowed in.

What I am wondering is because you have within APHIS people allowing decisions contrary to your decision, what have you done about making sure that doesn't happen again?

Secretary VENEMAN. I think that is a fair question. We have indicated with both Under Secretary Hawks, as well as Dr. DeHaven and all his folks, that these decisions should not have been made, particularly the bone-in decision, and Dr. DeHaven has ensured me that he has taken actions to ensure that this type of action would not happen again.

Mr. POMEROY. What is the status of the pending rule on live cattle imports from Canada?

Secretary VENEMAN. As you know, that rule was initially proposed last fall; it was proposed before we had the find of BSE in our country. We initially closed the comment rule as scheduled, then reopened it. Because of the wide range of comments that we received in response to that rule, it is taking longer than we had originally anticipated to finalize that rule. It is still in the review process within USDA, reviewing the comments that came in during both comment periods, and I can't, at this point, give you an exact

time as to when we might be issuing a rule with regard to the Canadian product.

Mr. POMEROY. It is my own observation that for all of the discussion this morning about the efforts, many of them laudable, by USDA to improve testing and surveillance of the U.S. product, allowing Canadian imports in would seem to me to undercut consumer confidence in the beef products without a conclusive determination that equivalent steps are made in Canada. In addition, as we have discussed earlier, I believe that allowing imports in before we have gained these vital export markets back for our ranchers does not make good sense. It is up to the United States to gain its export markets back based on what we have done and it is up to Canada to gain its export markets back based on what they have done. If we allow imports before gaining our markets back, it seems to me that you and the trade representative will have to carry the burden of not just our case, but making Canada's case as we try to win the markets back.

Thank you. I yield back.

Chairman TOM DAVIS. Thank you very much.

Mr. Duncan.

Mr. DUNCAN. Thank you, Mr. Chairman. I apologize, I have been at other meetings.

Ms. Veneman, maybe you have already discussed this, but I was a little surprised a while ago when I heard you testifying, you said there had been—I don't know as much about this as a lot of people, as most people here, and I was surprised when you said there had been 180,000 cases discovered since 1986. That seemed like an awfully big number to me; I didn't know that there was that much of it. And what I am wondering about, you mentioned in your testimony all of these things that are being done. All these things we are doing, is that leading to the discovery of more cases or are we seeing some progress, are the numbers of cases going down? Were they much higher in the late 1980's and early mid-1990's, and now they are going down? You may have already discussed that, but I have had to be in and out.

Secretary VENEMAN. That is exactly the case. Let me just make a few comments, then I can have Dr. DeHaven, who is the expert, give you the actual numbers. It is important to recognize that is 180,000 cases worldwide. This includes all of the cases in the U.K. The U.K., by far, I think has more than 90 percent of the cases worldwide. So this was a concentrated disease for the most part. And once it was discovered that ruminant-to-ruminant feeding was the big issue, you then saw cases peak and begin to come back down. And so I think that while we can recognize the number of cases worldwide, the peak certainly was, as you say, during, I think, the early 1990's when we saw the most number of cases.

Dr. DEHAVEN. The Secretary is absolutely right. There have been somewhere in the neighborhood of 187,000 cases worldwide. The vast majority have been in Europe and, most notably, most of them have been in the U.K. And that goes to the fact that while the disease may have originated there, they had unknowingly, because we didn't know much about the disease at that point, had a widespread problem before it was discovered how widespread and how the disease was spread. So while they have instituted very effective

measures since then, they didn't know to institute those measures early on. Many of the measures that they took, of course, that are now showing reward—and, in fact, the numbers of cases that they are finding now is dramatically less than what they were finding back in the mid-1990's—would suggest that those measures have been effective; and, of course, we are applying many of those same measures here in the United States and elsewhere in North America.

So I think the danger is in terms of equating the European experience with the North American experience, and, in fact, they are very much different; our level of exposure has been much less. We instituted protective measures simply because we had some of the benefit of the European experience, but we instituted some of those safeguards much earlier on in the process, so the level of exposure in the United States has never been what it was in many of the European countries. So, obviously, we should have an overall BSE program tailored to our experience and our situation, as opposed to the European situation.

Mr. DUNCAN. What percentage of our beef do we import from other countries, roughly?

Mr. COLLINS. We produce about 25 billion pounds; we import about 3.5 billion pounds this year. So roughly, what is that, about 10 percent or so?

Mr. DUNCAN. OK. All right, thank you very much, and I certainly am pleased that you are making such good progress. Thank you.

Chairman TOM DAVIS. Thank you very much.

Mr. Ruppertsberger.

Mr. RUPPERSBERGER. Thank you, Mr. Chairman.

Secretary Veneman, one of the major challenges in the surveillance program is reaching cattle at the highest risk of having mad cow disease and those cattle with signs of central nervous system damage. Now, some of these animals are condemned at slaughter; others are killed at the plant and sent to State labs for rabies testing. In both cases, past and current USDA policy is for all such animals to be tested for BSE. Now, the Inspector General found that because of several operational weaknesses, cattle condemned for slaughter for CNS symptoms were not always tested, and brain samples from cattle testing negative or rabies were not always submitted to BSE for testing.

Those weaknesses, by the way, include insufficient monitoring of slaughter data, the lack of effective coordination, and lack of formalized agreements with non-Federal laboratories engaged in rabies testing. The Inspector General reports that the problems testing high-risk cattle still exist under the expanded program in effect after June 1 of this year.

Now, this spring, when a single suspect cow was not tested for mad cow disease in Texas, there were national headlines. But the Inspector General found that in fiscal year 2004, 17 adult cattle with central nervous system signs were not tested. Nearly 200 such cattle have been missed over the last 3 years, and five State laboratories visited by the Inspector General sent only 16 percent of rabies negative samples for mad cow testing, and one State lab official told the Inspector General that he or she didn't know it was possible to send samples for mad cow testing.

Now, I have two questions. First, how can you explain USDA's failure to date to coordinate the testing of this group of cattle that is so important for surveillance? And, second, would you be willing to report a quarterly basis progress in testing these high-risk cattle, including the total number of condemned cattle and the number of those tested for mad cow disease, and the total number of rabies negative samples and the number of these tested for mad cow disease?

Secretary VENEMAN. Thank you, Congressman. Let me just say that with the new surveillance program we are targeting the highest risk cattle, and I think that our initial results that we have seen for the first month indicate that we are getting a very good cross-sampling from the various sites, whether it is on-farm, slaughter plants, renderers, public health labs, veterinary diagnostic labs, salvage plants, or stockyards.

Understanding the issue you talk about with CNS, I think there are two issues. One is there are a number of cattle that weren't tested because they were under the age and simply APHIS did not test them as the underage CNS cattle. After the incident in Texas that you talked about, when this was brought to light, the USDA changed its policy. Both FSIS and APHIS put out a directive saying that all CNS cattle, cattle with CNS signs, would be tested regardless of age. We have taken any discretion out of the system, any subjectivity. In addition, we announced that all ante-mortem condemned cattle at slaughter plants, except for veal calves that don't show CNS, would also be tested. So we have attempted to take some of the issues that were raised, both with the Texas situation as well as in the IG report, and address that directly with these new directives.

I think the other issues that you bring up from the IG report, we are working very closely on the data issues; we have gotten our CIO involved. We know that there are still data collection issues that we need to improve upon, but we are working closely with both the IG and with the—

Mr. RUPPERSBERGER. How about the issue of the quarterly testing? We all need accountability; we need a system. It is a system that is in place.

Secretary VENEMAN. I couldn't agree with you more that we need accountability. I am not ready to commit today on a quarterly system, but we will report as much as we can on a periodic basis. We are reporting on our Web site how many cattle are tested every week, and that is updated on a weekly basis. I am not sure you were here when I indicated that—as of today, since June 1, we have tested over 17,000 animals.

Mr. RUPPERSBERGER. What is your concern about the quarterly testing; it is just too voluminous?

Secretary VENEMAN. No. I mean, it may very well work, I just simply—

Mr. RUPPERSBERGER. I see my red light is on. The chairman is going to get me out.

Chairman TOM DAVIS. You can follow up with any questions; we are going to keep the record open.

Mr. RUPPERSBERGER. That is fine.

Chairman GOODLATTE. I am pleased to recognize at this time the gentleman from Georgia, Mr. Burns.

Mr. BURNS. Thank you, Mr. Chairman. I want to thank both chairmen for holding the joint hearing; I appreciate the USDA's response in this.

I want to first join my colleagues in saying thank you to USDA. I think you have handled this challenge quite well. As a cattle producer, and recognizing the potential threats, we could hardly have done better, given the challenges in December.

Certainly I want to also say I have some concerns about false positives. We have discussed that, I think, at length. It certainly generates market concerns and some volatility. Certainly the solution, I think, is the elimination of false positives. And I am glad to hear your comments on that will work toward that goal.

I want to focus my question really on one issue, and that is testing versus animal ID and maybe the effectiveness and the efficiency and the efficacy of our testing program as a method of ensuring a healthy and safe beef supply vis-a-vis an animal ID system. Whether we look at testing at slaughter or whether we look at testing on the farm, targeted population testing, give me your input on which of these approaches is preferable. Right now there is certainly a dual track. We are looking at both of these things, but where are we getting the bang for our buck?

Secretary VENEMAN. Well, I think, Congressman, that these are two elements of our overall BSE response plan that are critical. Now, with regard to surveillance, we have had a lot of discussion of that today. We have substantially increased our surveillance program to test at least 268,500 animals in the high-risk population, and we are well on track to achieving that goal.

I also announced on December 30 that we would accelerate the implementation of a national animal identification system. I think it is important to recognize that an animal identification system is important for a much broader purpose than just BSE. We really began looking at the animal identification system, a national system, because of the scare that we had with foot and mouth disease back in the early days of this administration. Fortunately for the United States and for our cattle producers, that didn't come to this country, but we certainly saw the devastation that was done in Europe as a result of that disease.

One of the key elements in a disease that spreads quickly like foot and mouth disease is the ability to quickly trace back. Because that disease spreads so quickly, you have to know where the cattle have been. It is also important to be able to trace back when you have a BSE-positive cow, but it is not because the disease is going to spread if you don't trace it back immediately. So there are two different kinds of tracks that you would be using animal ID for.

And so as we encountered the BSE situation, we said we have been working on this system and it is important, to the overall ability to monitor and to respond to animal diseases, to have a strong animal identification system. So we have a program in place. We are beginning to implement that program. We are working with all aspects of the industry to identify where animals are already identified, particularly to put together a system where we

have a uniform system of premise identification, because you have to have a way of identifying those premises.

So I would not see these as mutually exclusive programs. We think they are both necessary components of, in the case of BSE, our overall response, but in the case of the animal ID, it is an important program with regard to our overall animal disease and surveillance programs generally.

Mr. BURNS. From a resource allocation perspective, can you share with us percentage of resources allocated to both of these important projects?

Secretary VENEMAN. We have obtained additional money for both of these projects. We anticipate that for the surveillance program, that this is a year to 18-month program that depending upon what we find will determine the resources we need for the future. If we find no additional cases, I would anticipate that we would scale back to testing probably fewer animals. If we find additional cases, we may change our assumptions and have more testing.

On the animal identification, there are some initial costs that we have included in our budget. In terms of ramping up this program, I think there will be some ongoing costs, but hopefully it will not be long-term extensive costs to the U.S. Government.

Mr. BURNS. Thank you, Mr. Chairman. I yield back.

Chairman GOODLATTE. The gentleman from Arkansas, Mr. Ross.

Mr. ROSS. Thank you, Mr. Chairman.

And, Madam Secretary, thank you for joining us here today. As ranking member of the Livestock and Horticulture Subcommittee of the full Agriculture Committee, as you know, I have been very involved in all of this business and policy dealing with BSE in hearings not only up here, but the hearing we had in Houston as well.

A few questions. Let me begin by mentioning this to you. In the July 10 New York Times, there was an article entitled "U.S. Moving to New Ban for Mad Cow, Officials Say." A Federal official was quoted as saying that in an effort to eradicate mad cow disease, they were moving toward a policy to ban the feeding of any farm animal to other farm animals.

Madam Secretary, is this based on sound science? And to follow up on that question, is there any hard evidence that prions are transmittable from beef to other species such as chicken?

Secretary VENEMAN. As far as I know, there is no scientific evidence that I am aware of that would indicate that the disease is transmissible from ruminant to poultry. I think that the article you are referring to was referencing the recent announcement of the Advance Notice of Proposed Rulemaking that was recently issued by HHS and USDA, specifically requesting comment on a whole series of issues, including additional actions that may be taken with regard to feed. And as you know, those actions would be proposed by the Food and Drug Administration under the Department of Health and Human Services. So I am not familiar with the exact article you are talking about, but I believe that it would be in reference to the ANPR that was announced on Friday.

Mr. ROSS. I would simply hope that whatever policies are put in place are based on sound science.

Secretary VENEMAN. We absolutely believe that science has to control what we do with regard to animal disease and prevention in this country. We try to follow sound scientific principles in the decisions that we make.

Mr. ROSS. On another issue, export markets are believed to be the only expandable market in the cattle industry, and, as we know, they have not reopened for the most part. Currently, the Animal Plant and Health Inspection Service lists 58 countries, 58 whose borders have been closed to the import of U.S. beef. Many place blame on the United States's lack of an animal ID program. What is your position on the animal ID program? Does USDA still want to move with a voluntary program or has USDA finally realized to get these markets opened back up it is going to have to be a mandatory animal ID program?

Secretary VENEMAN. First let me say that I have not heard that countries are keeping their borders closed because of lack of an animal ID system, but it is—

Mr. ROSS. There are 58 countries, Madam Secretary, so why are they?

Secretary VENEMAN. It has been the practice of the United States also when a country gets a case of BSE in its country, that we close our borders to those countries. Other countries have responded to us the same way. We have worked very hard to open up our export markets. We have succeeded in opening up the Mexican market to about 90 percent of the product they were previously importing. We have had a series of meetings with the Japanese about reopening the market; that is our No. 1 export market. We have had discussions with the Koreans.

I might go back just for a moment. With regard to the Japanese, we are very encouraged by those discussions. We have had technical level discussions for the last 2 months. We will have another technical discussion later this month, with a policy discussion to follow in August, and we are hopeful that after that we can come to some agreement under the terms by which the Japanese market may be opened.

Likewise, we have had discussions with countries like Korea; I have had discussions with China; the Philippines has maintained that market open; some of the Central American countries are opening their markets back up. So the trade issue with regard to BSE has been a very important issue for us, and we have worked very hard.

It was within 4 days after the announcement of the BSE cow in December that we announced that we were sending a team to Japan and Korea, which we did between Christmas and New Years. That is how important we looked at our export markets. And so we tried to ensure that has been a part of our overall BSE program as we have moved forward, is to work with our trading partners to explain to them what we are doing, why we are doing it, the science behind it, and we are hopeful that we will see additional progress in opening up some of those markets soon.

Mr. GOODLATTE. The time of the gentleman has expired.

The gentleman from Minnesota, Mr. Gutknecht, another of our subcommittee chairs.

Mr. GUTKNECHT. Thank you, Mr. Chairman.

And I want to thank the distinguished panel, clearly distinguished and very important public servants, Dr. Collins and Dr. DeHaven. I might just say for the benefit of the Members who are still here, Dr. DeHaven, about a week after the discovery of the incident in the State of Washington, was kind enough to go on a radio show with me and talk to 12 radio stations at the same time in southern Minnesota, and did a wonderful job of explaining the disease; where it comes from, how it is spread, and what the USDA was doing. And I think largely, and I attach myself to the remarks by my colleague from Florida earlier; I think the very prompt response by your Department, Madam Secretary, and basically the unstopping flow of information from people like Dr. DeHaven I think really prevented what could have been a catastrophe in the beef market. So my congratulations to you.

I am going to use my few minutes here in more of a comment than a question to sort of compare how the USDA deals with these kinds of things relative to our friends over at the FDA. And I will be somewhat critical of the FDA because I think Members, both those who are left here, need to understand the difference in the safety risk.

And I don't want to downplay the seriousness of this malady, because it is fatal; it is something we need to take very seriously, but I think you do have to compare the differences. We know, for example, that in any given year, on average, about 6,000 Americans will die of getting the wrong prescription drug while being kept in a hospital here in the United States; 6,000. When you compare that to the probability—and, in fact, I think there was a Washington man who a couple of weeks ago said—and I am neither a statistician or particularly good in math, but I am told that there was a man here in Washington who said recently that the likelihood of an American getting BSE or mad cow disease is about the same as being struck by a bolt of lightning while you are holding the winning Powerball ticket. And I think this hearing is important and I think all of the work that you are doing at USDA is important, but I think it is also important for us to put this in context. Because of the efforts not only of the USDA, but of the producers themselves, I think we all believe, and I certainly am a very strong believer, that the food supply here in the United States is very safe, and the beef supply is the safest in the world. So I think we need to put that into perspective, that while this hearing is important, what the USDA is doing is important, when you compare it to the safety of virtually everything else that we put into our mouths, it may well be that beef today is the absolute safest thing.

And I will just end parenthetically with one last comment, and that is, frankly, you are much safer taking drugs imported from Canada than you are just about anything else as well. So I will continue to badger the good people over at the FDA.

With that I yield back the balance of my time.

Chairman GOODLATTE. I thank the gentleman.

The gentleman from North Carolina, Mr. Hayes, also a subcommittee chairman, is recognized.

Mr. HAYES. Thank you, Mr. Chairman. I would like to submit my opening statement for the record, if I might, and move on.

Chairman GOODLATTE. Without objection.

Mr. HAYES. Thank you.

[The prepared statement of Hon. Robin Hayes follows:]

THE HONORABLE ROBIN HAYES
JOINT HEARING OF THE COMMITTEE ON AGRICULTURE AND THE
COMMITTEE ON GOVERNMENT REFORM

REVIEW OF THE U.S. DEPARTMENT OF AGRICULTURE'S EXPANDED BSE
CATTLE SURVEILLANCE PROGRAM

JULY 14, 2004

I would like to thank both the Chairman and Ranking Member of the Agriculture and Government Reform Committees for holding this hearing to review USDA's expanded BSE surveillance program. While USDA has only been implementing the new program a little over a month now, it is important to discuss the significant progress that has been made as well as some of the challenges to the program.

Our regulatory agencies have been pro-active in taking the proper risk mitigation steps to prevent BSE from entering the United States since BSE was first discovered in England. Over time, our regulations have been adjusted as we learn more about this disease. With the discovery of one BSE case back in December, additional measures have been taken to prevent the spread of the disease and our surveillance program has been stepped up. I am pleased that the program has been developed based on science and standards outlined by the World Organization for Animal Health in addition to input from a panel of internationally recognized experts in this field and those at the Harvard University Center for Risk Analysis.

I hope the response USDA and FDA have shown will also prove to our trading partners that we are serious about preventing the disease and the situation is under control since no other positives have been found to date. I appreciate USDA's diligent work with our major export markets, particularly Japan, to resume trade. It appears that progress is being made through the technical meetings, and I am hopeful these ongoing negotiations will result in a re-opening of these markets as soon as possible, but not at potentially unreasonable demands that are not based on science.

Again, I appreciate the opportunity to discuss USDA's expanded BSE surveillance plan, and I know the House Agriculture Committee as well as the Livestock and Horticulture Subcommittee will continue to closely monitor this program.

Mr. HAYES. Madam Secretary, thank you very much for being here today, and your folks being with you. I think it is very obvious that you all are aggressively working to deal with the issue of BSE, and I think the fact that the IG is here is very appropriate. Questions which is her purview have been raised and you all have clearly answered them, and we appreciate that. I also appreciate the way that you have been working with our trading partners, Japan and others, to make sure, of course, food safety is first, but, above that, to make sure that the markets are properly dealt with as it relates to this, and we appreciate that as well.

I would like to identify myself with Mr. Putnam's remarks, trying to eat at a steakhouse, and I am not going to tell you where it is because you can't get in anymore. It used to be you would call for a reservation; now you call and tell them you want to come, and they will call you back if and when you can come. So that is a very clear indication that you all are doing a good job on the market issue. And Mr. Ose's raising the points of how you have aggressively pushed that forward is very important.

Thursday, July 22, at 10 a.m., we will be holding an animal ID hearing to pick up on the issues that have been raised here today. That is another important part of the puzzle, and we want to move forward making sure that the industry controls that and we take care of confidentiality, so on and so forth.

My question for you—you have answered most everything today—is on the issue of animals on the farm, the new program collecting on-farm samples, can you talk a little bit about it and explain what the USDA is doing to encourage producers to contact you when they have animals that need to be tested? And the samples taken since June 1, when your program began, what percentage of these samples have come from the farm?

Secretary VENEMAN. Thank you for that question. I think it has been a question that has been raised several times. As I indicated earlier, we do have preliminary data, and I think the data is encouraging. First of all, what we are doing to collect from farms, we are conducting an outreach program to reach as many producers as we possibly can to tell them of the importance of giving the samples to us so that we can determine the prevalence of this disease. One of the heartening things is that the gentleman whose dairy the BSE cow was discovered on in Washington has agreed to do a public service announcement for us, telling other producers how important it is. And I think that is a very important thing that has happened in terms of our outreach; it will help tell other producers from a personal point of view. So we are working to get as much outreach with producers, with large animal veterinarians, with State veterinarians, State diagnostic laboratories that deal with producers, and to get the message out in every way that we can.

I would say that from the initial numbers that we have, that we are getting a good representation from on-farm. The number that has been tested on-farm, the percentage that has been tested on-farm—again, these are preliminary numbers from June—is about 7.4 percent. But that does not really indicate the number of samples we are getting from farms because many of the samples that we are getting from rendering plants, which is about 30 percent,

those that we are getting from salvage plants, which is about 40 percent of all samples, also come from on-farm.

My understanding from my experts is that one of the most telling things about the samples that we are getting from on-farm is the fact that about 70 percent of the samples we have gotten in the first month are animals that are being presented for sampling that are already dead. That would be an indication that most of those are coming from on-farm. So we believe, and the experts in my Department believe that we have had a very good indication in the first month that the kinds of samples that we are getting are exactly the kind that we are targeting, those high-risk samples, and particularly those that are coming from farms.

Mr. HAYES. Thank you, ma'am. In addition to the hearing on the 22nd, we will be having a trade show here showing different types of ways to track animal ID, again to encourage our producers and ranchers to use the best and most efficient way possible.

Mr. Chairman, thank you. I yield back.

Chairman GOODLATTE. I thank the gentleman.

It is now my pleasure to recognize the gentleman from Texas, Mr. Neugebauer.

Mr. NEUGEBAUER. Thank you, Mr. Chairman.

First of all, Madam Secretary, I want to thank you for the fact that all through this process you have let science lead us through this, and not politics, and I think that is very refreshing, quite honestly, in Government. I think many times when we have issues come up in this country, we let the politics drive it, not the science. So I commend you for letting the science drive this issue.

I have a question first for Dr. DeHaven. Are you sampling behind the rapid test to ensure that the rapid tests are producing the appropriate results? In other words, for a kind of reliability check.

Dr. DEHAVEN. We are certainly doing that in a number of ways. Let me clarify. First of all, we want to make sure that the 12 laboratories that we have approved to do this testing are doing a good job, so we have a proficiency testing system where they would be provided known samples, samples with known results, and then having those 12 laboratories run those samples and comparing the results. So we have a quality control system that will be in place for those laboratories. A certain number of the samples that are being tested at those laboratories have repeat tests at NVSL, our national reference laboratory. So we think that we have a good quality control system in place.

Mr. NEUGEBAUER. Thank you.

Madam Secretary, when it comes to SRM, I visited a packing plant not too long ago, in fact, it was my second visit there, and we were talking to some of the folks that work in those plants, and obviously initially the policy was to go out and really identify anything that might be at-risk material. But what I think some of them are saying is there some science that would indicate that some of the material that is currently banned could be used in the future. Kind of give me a feel, again talking about that concept of letting the science lead the train here, where you are as far as reviewing SRM policy and where we see that going forward.

Secretary VENEMAN. Congressman, when we implemented the SRM ban, which was part of the December 30 announcement and

the January 12 Federal Register notice interim final rule, we looked at international standards, we looked at what other countries were doing, we looked at the best available science in determining what we should include as a specified risk material. All indications are, I think by the International Review Team that looked at the actions we had taken, is that we made the appropriate decisions with regard to SRM. All of these decisions we are constantly looking at, primarily because in the scheme of things, BSE is still a relatively new disease and there is a lot of science that we don't know. So we have to continually review the science as we know it to make sure the actions that we are taking are appropriate with what is currently known about the science.

Mr. NEUGEBAUER. I know that we have talked about the downer issue, but I do want to encourage you to, as you move forward, to give producers as many options as they can for animals that would fall under the downer category, but truly in fact have marketability in the marketplace, and not just salvage. I think that is important to our producers, and particularly to our smaller producers. To a large producer, maybe that is not as big an economic blow, but to some of our smaller producers losing an animal here or losing an animal there that, for whatever reason, fall in that category causes some economic problems for them.

You touched briefly on Japan, and I know that the Japanese were in Colorado, I believe, with you last week or have been there a couple of weeks. You said you were encouraged. We are kind of going through a two or three step process. Could you just elaborate briefly on that and what kind of timeline you think we might be on with the Japanese?

Secretary VENEMAN. As I indicated, we first started meeting with the Japanese within the first week after BSE was discovered in this country, because it is our most important beef export market. This has been a difficult discussion with the Japanese primarily because they had an outbreak just 2 years ago of BSE in their own country, and they have had to deal with a huge drop in consumer confidence in their country, something we didn't experience, as you know, in our own country.

We had several sets of meetings, we had the Japanese here, and it was clear that we weren't making progress, and so we worked with an interagency process within the Japanese Government and set up a series of technical meetings where a number of issues would be discussed, and the first one of those was held in Japan in May, was followed by this meeting you reference in Colorado in June, followed by another one scheduled for Japan in July. That will be followed then by a policy level meeting we believe in August, after which time we are hopeful that the policy meeting will then come out with some parameters by which we can see some opening of the Japanese market. Again, I can't predict exactly what is going to happen, but I can tell you we have been very engaged in this process, very engaged with discussions with the Japanese, working closely with them throughout this process, and we are hopeful that we will see an opening of the Japanese market in the near future.

Mr. NEUGEBAUER. Thank you.

Chairman GOODLATTE. The time of the gentleman has expired.

The gentleman from Nebraska, Mr. Osborne, is recognized for 5 minutes.

Mr OSBORNE. Thank you.

We are winding down here. Appreciate your patience and your endurance; it has been remarkable. Just an observation and maybe a question at the same time. I have heard a lot from producers in my State that are concerned about the possible you-you effect on the markets if continued suspected positive cases being reported, and maybe I am observing this, I hope I am, that as time goes on, maybe the media will kind of back off on reporting, and unless we actually get a positive case, maybe this will settle down. Do you hope that this is what is going to happen or do you have any comment on that?

Secretary VENEMAN. I think that, Congressman, you are correct that this is something that is not a familiar situation for our country, and so as we have introduced this new system of these rapid tests and announced that because of market impacts we would announce the inconclusives, that would create a fair amount of media interest. I think that if we in fact get additional inconclusives and this becomes more routine, that you get an inconclusive and then you send it to NVSL for testing, that people will understand that this is the normal part of our surveillance process and it won't generate quite so much attention. But it is hard to project because we don't know how many inconclusives we may get; we don't know if we may get additional actual positive animals. That is what this testing program is really all about, is to measure the prevalence of BSE that may or may not be in our cattle herd.

And I might say that we are constantly also working with the CFTC in terms of these kinds of announcements because the market impacts are really what we are watching very closely, and the CFTC has a very strong interest in that, and so we consult with them regularly on these issues.

Mr. OSBORNE. Thank you. And I understand why you are reporting, and I think it is probably the right way to go, but we do hear a lot about it.

One other question that somewhat dovetails with what Mr. Neugebauer was asking about, and that is Japan. It is my understanding that we are going to maybe ask an independent international agency to examine our testing policy, and if they were in agreement that we are doing a good job, that maybe this would result in a case before WTO if the borders aren't open. Is this a rumor that I have heard that is not correct or what?

Secretary VENEMAN. I am not exactly sure what you are referring to, but I would say that we have had our surveillance plan, we consulted with the OIE, the world health organization. We had it reviewed before we released it by our International Review Team. We thought that was a prudent thing to do because they had suggested this enhanced surveillance plan. And we had it reviewed by our Harvard Risk Assessment team that has been working with us on the overall risk assessment for BSE. We continue to work with international experts from all of these arenas, and I believe we will continue to do so. I think it is very important to have that kind of international top-notch oversight into the decisions we are making because all of these programs that we are implementing are

brand new. We are trying to do the best possible job that we can, and so we try to get the best expertise from a scientific perspective that we possibly can.

So we did have some discussions with regard to Japan about having the OIE look at our respective systems and give some advice, and that was one of the offers that we had on the table.

Mr. OSBORNE. One last thing very quickly. Another thing I hear about a lot is opening the borders with Canada. Maybe that has been asked previously, and I know this is related to BSE, but do you have any comment you can make as to what process is going to be involved here?

Secretary VENEMAN. Again, this is in the rulemaking process as we speak. We had a proposed rule that the comment period closed initially on January 5. We reopened the comment period on that because of the find of BSE in this country. That comment period closed in April. And because of the number of comments that we have received, we are still in the process of evaluating all of those comments. We received a lot of comments on that rule, and as you know, you have to review all of the types of comments that you get when you receive a rule. We are reviewing the risk assessment and cost benefit analysis and all of those things that come along with a rulemaking process, so at this point it is impossible for me to project when we might see that rule completed.

Mr. OSBORNE. Thank you.

And thank you, Mr. Chairman.

Chairman GOODLATTE. I thank the gentleman for his questions.

Madam Secretary, we thank you very much for giving us 3 hours of your time, and Dr. DeHaven and Dr. Collins too. We know that in addition to their time here, there is a lot of time to prepare for something like this, to handle so many diverse questions so much, and we thank you very much. And I will tell you that, for myself, I continue to feel that the Department is doing a good job assuring the country that its efforts continue to make the U.S. food supply the safest in the world.

Chairman TOM DAVIS. Thank you.

Madam Secretary, let me just say our committee, as you know, had concerns with the old BSE surveillance system and the lack of written protocol in place for the discovery of BSE-infected cow, but APHIS has recently provided the committee with written protocols for the expanded BSE surveillance program. I am encouraged that this written guidance is a step in the right direction for the program over the next 18 months. We look forward to continue to work with you, and you have recorded yourself well. Thank you very much for your time.

Mr. WAXMAN. Mr. Chairman, if I might also join in thanking the Secretary for being here today. You have been here to answer a lot of diverse, different questions over a many-hour period. I did write you a letter yesterday, and while the letter asked you to be prepared to discuss some of the issues that we raised in it, we really didn't have a full opportunity to do that, so I would like a written response. My major concern, which is yours as well, is that we have a system that works, but I want it to be credible. And what I don't want is a presentation of the issue in a way that cannot be sustained on a scientific basis given the way the whole thing is struc-

tured and the assumptions upon which it is based. So we hope to continue working with you on this effort.

Chairman TOM DAVIS. Thank you.

The committee will take a 2-minute recess while we bring our next panel forward.

[Recess.]

Chairman TOM DAVIS. We now move to our next panel. Joining us on the second panel is the Honorable Phyllis Fong, the Inspector General for the U.S. Department of Agriculture. Ms. Fong's testimony will address the Office of Inspector General's audits of USDA's previous surveillance program and its subsequent expanded surveillance plan. Marlane Evans, the Deputy Assistant Inspector General for Audit, and Mark Woods, the Assistant Inspector General for Investigations, accompany Ms. Fong to answer questions posed by Members.

As you know, it is our policy to swear in witnesses. If you would rise with me and raise your right hands.

[Witnesses sworn.]

Chairman TOM DAVIS. Thank you very much.

Your entire statement is in the record and, as you know, it and much else has been released and read by Members, so if you could keep it to within 5 minutes, we will try to move as quickly as we can. Thank you very much for being with us.

STATEMENT OF PHYLLIS K. FONG, INSPECTOR GENERAL, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY MARLANE EVANS, DEPUTY ASSISTANT INSPECTOR GENERAL, AUDIT; AND MARK WOODS, ASSISTANT INSPECTOR GENERAL, INVESTIGATIONS

Ms. FONG. Thank you very much, Chairman Davis and Chairman Goodlatte, and Ranking Members Waxman and Stenholm, for the opportunity to testify this morning. As you mentioned, accompanying me today are Mark Woods, who is in charge of our investigations program, and Marlane Evans, who has led the audit review for our office.

The possible presence of BSE in the American herd is a matter of great concern and interest to all of us because of its potential impact on animal and human health, food safety, the economy, and international trade. We recognize that the USDA has significant responsibilities in this area and a long history of involvement in animal health and food safety initiatives.

With the discovery of the Canadian BSE-positive cow last year and the Washington State cow this year, the USDA has faced an enormous challenge to implement an effective surveillance program to determine whether and to what degree BSE may be present in the U.S. herd. This effort has been complicated by the size and the geographical dispersion of the herd, the short timeframes involved, and the complexity of the effort involving Federal, State, local, and private entities.

Our objectives in initiating investigative and audit work have been very simply to take an impartial look at the program as designed, as well as specific situations that have arisen, to determine the facts and to make constructive recommendations early in the process to assist the USDA as it moves forward in implementing

its program. Our work, by definition, presents a snapshot of the program at specific points in time. It is not intended to detract from the Department's ongoing efforts to continually refine and improve the program. On the contrary, we are encouraged by the commitment of the Secretary and the Department to address many of the issues that we have raised.

Much has been accomplished by the USDA since last December. We have received excellent cooperation from numerous USDA officials and APHIS and FSIS staff. We also appreciate the oversight and leadership that your committees are bringing to this issue, and we look forward to working with you as we collaborate and move forward.

I want to briefly highlight some of our key findings, particularly on the Washington State investigation, which is of great interest to a number of people. Our first investigation concerned the identification and status of the cow slaughtered last December in Washington State which eventually tested positive for BSE. We looked at allegations that the cow was in fact a healthy ambulatory cow, rather than a downer, as described publicly by USDA officials, and we looked at allegations that the U.S. vet who examined the cow subsequently falsified inspection records under duress.

Our investigation found no instances where the USDA personnel knowingly conveyed false or misleading information or engaged in intentional misconduct. We discovered no evidence that the USDA personnel on site at the facility falsified any records pertaining to the condition of the cow at the time of its inspection.

The VMO on site who examined the cow found that it was non-ambulatory at the time it was presented for ante-mortem inspection. The plant owner also acknowledged the cow was non-ambulatory. Sworn statements provided by others who saw the cow that day did not contradict this evidence and contained no claims that the cow was ever ambulatory at that facility. And, finally, traceback evidence established by Canada and USDA does not support the allegation that the cow had a white hide, as was originally alleged by the former employee of that meat processing plant.

We also did an investigation of the Texas situation, which is summarized in my written statement, so I won't summarize that today.

The reason we highlight these conclusions is because they illustrate some of the difficulties USDA faces in implementing an effective program. We have also done an audit, as you are well aware, that has been discussed in quite a lot of detail this morning, and I just want to emphasize that our report, as you know, is in draft. The Department has 30 days in which to respond. Our normal process is to take the Department's responses and to address them and to incorporate them as appropriate within our own report, which we will then issue in final. We pointed out a number of areas where the Department could tighten up its surveillance plan in a number of areas. Again, those were fully discussed this morning. And we are encouraged by the fact that the Department is moving forward to deal with many of the issues we have raised, and we are looking forward to getting their final response so that we can go ahead and implement this program at the Department.

So, in conclusion, I want to thank you again for inviting us to testify, and we look forward to addressing your questions.
[The prepared statement of Ms. Fong follows:]

A Review of the USDA's Expanded BSE Cattle Surveillance Program

Testimony of The Honorable Phyllis K. Fong

Inspector General

U.S. Department of Agriculture

Before a Joint Hearing of the

House Committee on Government Reform

and House Committee on Agriculture

United States House of Representatives

July 14, 2004

Thank you, Chairman Davis and Chairman Goodlatte, and Ranking Members Waxman and Stenholm, for inviting me to testify on the U.S. Department of Agriculture's (USDA) Bovine Spongiform Encephalopathy (BSE) Expanded Surveillance Plan. It is an honor to be invited to this morning's joint oversight hearing.

The Office of Inspector General (OIG) at USDA fully recognizes that any occurrence of BSE in America's cattle population is a matter of widespread public concern, and can cause deep injury not only to our beef industry, but also to the sense of confidence that both American and foreign consumers have in our beef products. For me personally and for my colleagues and staff at OIG, BSE-related work is a top priority and one of the most difficult challenges we face. I appreciate the oversight and leadership that your Committees bring to this issue, and pledge OIG's assistance in this effort.

I want to thank USDA officials, and APHIS and FSIS employees, for their cooperation with OIG auditors and investigators. I want to especially thank Secretary Veneman for her interest in and support for OIG's efforts to review the Department's plans for its expanded BSE surveillance plan. Our goal is to assist the Department in its development and implementation of an effective BSE surveillance plan.

The Department faces a major undertaking in developing and implementing programs to keep BSE out of the U.S. cattle herd. Preventing BSE from raising concerns about the health of our cattle industry and public perceptions of food safety in the U.S. will require coordinated and cooperative efforts not only within the Department, but among all cattle industry stakeholders.

My testimony today will cover two distinct areas in which we have invested extensive resources over the past 5 months. First, I will summarize the results of the 2 investigations we conducted into allegations of misconduct with respect to the identification of a BSE-infected cow in Washington State in December 2003 and our investigation into the actions of USDA personnel involved in the failure to test a suspect cow in San Angelo, Texas in late April 2004. The second part of my testimony will

cover the findings and recommendations resulting from our audit of the Department's BSE surveillance program.

I. OIG BSE Investigations

A. Investigation of Statements Pertaining to the BSE-Positive Cow in Washington State.

Overview

A cow slaughtered on December 9, 2003 by Vern's Moses Lake Meats (Vern's), a beef processing company in Moses Lake, Washington State, tested positive for BSE on December 23, 2003. Allegations arose in news reports that a person or persons employed by USDA may have provided false or misleading information concerning the ambulatory status of the BSE-positive cow.

On February 3, 2004, an article in *The New York Times* reported that a former employee at Vern's "claimed that the BSE cow was ambulatory (a walker) and not a non-ambulatory (or downer) as recorded on the inspector's report." The former employee "believed the government changed the report on Dec. 23, during the panic at Vern's when a positive test was found."

On March 4, 2004, a UPI article reported further allegations from the same former employee. He alleged that due to duress from USDA management, the Veterinary Medical Officer (VMO) changed his inspection sheet to indicate it was a downer cow after it tested positive for BSE. This improper alteration allegedly was done to provide false support for the USDA position that its surveillance program for BSE, focused primarily on downer animals, was effective.

OIG initiated investigations to determine whether any USDA personnel or private parties provided false information or engaged in any intentional misconduct. We also examined whether USDA personnel and employees of the beef processing facility followed proper

procedures during the inspection of the BSE-positive cow, and during their collection, handling, and delivery of tissue samples from the infected cow.

Summary of OIG Findings

Our investigation found no instances where USDA personnel knowingly conveyed false or misleading information, or engaged in intentional misconduct. While some procedural errors led to concerns about whether USDA officials had accurately identified and traced the BSE-positive cow, APHIS and the Canadian Food Inspection Agency (CFIA) concluded that they accurately identified the BSE-positive cow.

OIG discovered no evidence that USDA personnel on site at Vern's on December 9, 2003, falsified any records pertaining to the condition of the BSE cow at the time of its inspection. On December 23, when the FSIS District Manager asked the FSIS VMO at Vern's to provide his inspection records from December 9, the VMO at Vern's did update and annotate the forms filled out during his inspections at the facility the day the BSE-positive cow arrived.

Our investigation did reveal procedural errors and inconsistent descriptions that gave rise to some of the public concerns that the identification of the BSE-positive cow may have been mishandled. For example, the VMO who inspected the BSE-positive cow did not comply with a regulatory requirement to affix an identifying ear tag to the suspect cow.

Our investigation also found that the former employee of Vern's, who alleged that the BSE-positive cow was ambulatory and healthy when it arrived at the facility, described a different animal from the one that arrived in the same trailer and later tested BSE-positive. The former employee's statements pertained to a white Holstein cow that arrived at Vern's on December 9, 2003, while the cow that tested BSE-positive was a black and white cow.

Description of Key Events

To address the allegations concerning the BSE-positive cow's condition upon arrival at Vern's, and allegations that USDA personnel engaged in misconduct or falsified reporting documents, OIG investigators performed the following activities: reviewed all pertinent USDA and processing facility records and forms containing information on the BSE-positive cow's handling and identification; reviewed pertinent USDA statutes and regulations, and policy directives; interviewed USDA officials and personnel involved in the case; interviewed managers and former employees of Vern's; interviewed officials at the company which sold the BSE-positive cow to Vern's; and interviewed the independent hauler who actually transported the cow to the facility.

i. Status of the BSE Cow

Several non-USDA employees involved in this matter provided OIG with comments on the condition of the BSE-positive cow on the morning it was delivered to Vern's. The independent hauler who transported the BSE-positive cow to the Vern's facility said in a sworn statement that the cow was ambulatory *at the time of loading*. The hauler did not remember the cow's condition when it arrived at the Vern's facility. The co-owners and foreman of the company that provided the cow to the hauler said the cow walked into the delivery trailer, but it had been seriously injured prior to its shipment to Vern's. One of the owners, who is also a veterinarian, told OIG investigators that while the BSE positive cow did walk into the trailer for delivery, it was very weak and it was possible that it became non-ambulatory by the time it got to the slaughtering site.

OIG investigators interviewed the former employee of Vern's who alleged that the BSE-positive cow arrived at Vern's in a healthy, ambulatory condition, and that the FSIS VMO at the facility later falsified his inspection sheet. He declined to provide a sworn statement. He described the BSE-positive cow as white, ambulatory, and in good condition. The former employee said he had no direct evidence that USDA officials changed their initial reports after the positive BSE test was reported. He said he believed

evidence of alteration would be provided by the fact that only one cow *did not* have its temperature taken, as shown by a handwritten notation of “unable to get temp” on the relevant form. He said that notation proved that the BSE-positive animal was a “walker,” not a downer, because, had it been a downer, the VMO would have taken its temperature.

OIG investigators interviewed the Co-Owner of Vern’s. He said the cow was lying down at the time the FSIS VMO inspected it, but he did not refer to the BSE-positive cow as a “downer” because he had a policy of not permitting non-ambulatory animals into his facility. The Co-Owner also said the (livestock) haulers understood this policy and that they signed an agreement that they would not mechanically load any animals for transport to Vern’s. This was due to his concerns about animal welfare activists having previously protested the forced movement of downer animals in his area. In a written statement provided to a non-governmental organization, the Co-Manager said the cow was lying down in the delivery trailer when it was inspected by FSIS, but “the cow was *capable* of walking off the trailer and therefore was an ambulatory, non-downer cow.”

The FSIS VMO who performed the first inspection of the BSE-positive cow at the delivery site (Vern’s) provided a sworn statement to OIG investigators. He said the animal arrived at Vern’s in a non-ambulatory (downer) condition -- it was lying down in the cattle trailer, along with 10 other animals. Ultimately, 2 of the 11 were able to get up and were deemed ambulatory. Two others were condemned and not allowed to enter the plant, one being dead on arrival. Thus, seven cows remained suspect downers. The cow that ultimately tested positive for BSE was in this group.

The VMO told OIG investigators that there was a white cow standing in the trailer, which he remembered because it was unusual for a Holstein to be almost entirely white. The VMO said this white Holstein was ambulatory during his inspection, and he did not determine it to be a suspect cow for disease. The VMO stated that the ambulatory white Holstein delivered to Vern’s that morning was a *different* animal than the non-ambulatory cow, which he subjected to further inspection and which later tested BSE-positive. The

FSIS VMO said he never saw the BSE-positive cow get up and walk that day, and said no one on-site ever advised him that the cow became ambulatory prior to being killed.

The VMO told OIG investigators that he did not affix an ear tag to the BSE-suspect cow nor take its temperature. The VMO explained his actions by saying he did not affix ear tags in that instance in order to prevent the animals from experiencing further stress. He said he did not take the temperature of the cow that eventually tested BSE-positive because its position in the delivery trailer prevented him from doing so, and his professional judgment (based upon visual diagnosis) was that it was unwarranted.

On December 23, 2003, two weeks after his inspection of the suspect cow, the VMO said the District Manager for the FSIS Boulder, Colorado Field Office called him to request information about certain cows slaughtered at Vern's on December 9, without explaining why he wanted the information. (No internal or public announcement had yet been made that a cow from the facility had tested BSE-positive.) The VMO provided verbal information and later faxed copies of various FSIS and plant records to the District Manager, along with an unofficial form he had created and used to record inspection information at Vern's.

Just before faxing the records to the District Manager, the VMO stated he made additional notations on his original, unofficial form, such as "unable to get temp" for one cow under the column for temperature readings for suspect cows, and putting an asterisk and the name of the company that provided the cow. The VMO said he had no idea at that time that the cow for which those annotations were made had tested BSE-positive, and that he added the annotations to clarify the information on the form for the District Manager.

The VMO stated he did not falsify any document before or after the announcement that the cow tested positive for BSE, and that no USDA officials ever urged him to do so. He recorded the condition of the cow as he observed it at the time of inspection on December 9, 2003 -- using the term "sternal" to identify it as a downer animal, lying on its sternum.

An FSIS Consumer Safety Inspector was present when the VMO received the telephone request for information on a particular cow at the Vern's facility on December 23, 2003. The Consumer Safety Inspector said he overheard the District Manager request pertinent records from the VMO, and that he assisted the VMO in retrieving them. The Consumer Safety Inspector witnessed the VMO making the notations described above, and said the VMO described them as clarifications for the District Manager. The Consumer Safety Inspector also told us that the VMO commented to him at that time that the cow in question had likely been positioned against a wall, thereby preventing the VMO from taking its temperature on December 9th.

The FSIS District Manager in the Boulder Field Office who requested the FSIS and plant records from the VMO at the facility provided a sworn statement to OIG. The District Manager said that on December 23, 2003, he called the VMO and requested information on the disposition of all ante-mortem and post-mortem findings, as well as the tag number and trace-back information about one specific cow. He said the VMO had classified the BSE-positive cow as a downer upon inspection at the plant, and declared it a "U.S. Suspect" animal before it entered the plant (triggering requirements, generally, that such livestock be further examined/tested, the inspection be documented, suspect ear tags be affixed, etc.) The FSIS District Manager said that to his knowledge, the VMO was not asked to change or annotate any of the records or documents in question.

OIG took a sworn statement from a retired FSIS District Manager in Oregon who had been asked by Vern's Co-Owner to serve as a consultant to the facility after the public announcement that a BSE-positive cow was identified at his plant. (The retired FSIS official had no prior involvement in the case.) The retired FSIS District Manager said that on approximately December 24, 2003, the Co-Owner told him that the BSE-positive cow was a downer at the time of slaughter, but that if the cow had been prodded with a lot of effort it could "probably" have gotten up. Additionally, a FSIS Consumer Safety Inspector stated to OIG investigators that she observed that the BSE sampling process at the facility was not as well organized as at other plants she had worked at.

ii. The Identity of the BSE Cow.

The trace-back investigation conducted by APHIS and the Canadian Food Inspection Agency in January 2004 successfully identified the original Canadian owner of the BSE-positive cow, which enabled the agencies to locate the cow's hide, and DNA testing was then used to conclusively determine the cow's identity and origin. The cow's identity and origin were substantiated by the concurrence of the cow's Canadian ear tag registration number, photographs of the animal, a written description on its Canadian Health Certificate, inspection of its hide, and DNA testing. The trace-back evidence established by APHIS and Canadian officials shows that the BSE-positive cow had a black and white hide. OIG agents obtained photographs of the hide and verified its color and pattern. The trace-back evidence does not support the allegation that the BSE-positive cow had a white hide, as alleged by a former employee of Vern's.

The OIG investigation found no evidence of falsification of records or other intentional misconduct by USDA personnel. Our investigation found that the FSIS VMO who performed the inspection and oversaw the processing of the suspect cattle at the delivery site, including the BSE-positive cow, did not comply with a requirement to affix a "U.S. Suspect" ear tag to all downer animals. We determined that the VMO's failure to affix an ear tag and decision not to take the BSE-suspect cow's temperature did not have a material effect on the handling, testing, or identification of the cow by USDA.

Our investigation further determined that one brain tissue sample from a suspect cow was mistakenly left at the USDA office in the facility by a Washington State veterinary official on December 10, 2003, when he picked up samples for mailing to the USDA's National Veterinary Services Laboratory (NVSL) in Ames, Iowa. The State veterinary official subsequently gave an erroneous sample number to the sample. However, this improperly handled tissue sample was not from the BSE-positive cow, and did not affect the identification of the infected cow.

B. Investigation of Handling of CNS-Suspect Cow in San Angelo, Texas

Overview

On May 4, 2004, the FSIS Acting Regional Director in Dallas, Texas reported that a cow identified as having Central Nervous System (CNS) symptoms by an FSIS veterinarian at Lone Star Beef Processors (Lone Star Beef), a beef processing facility in San Angelo, Texas was not tested for BSE after it had been slaughtered. The initial decision by the FSIS Veterinary Medical Officer (VMO) on-site at Lone Star Beef to have the cow tested for BSE was overturned by a senior APHIS official and the cow's carcass was sent to a rendering plant. FSIS regulations at the time of the incident required VMOs to contact the APHIS Assistant Area Veterinarian in Charge (AAVIC) to allow APHIS to collect a BSE surveillance sample from suspect cattle.

OIG initiated an investigation to determine if the AAVIC in Austin, Texas, provided a false statement to USDA FSIS investigators during their inquiry of his decision not to test the animal at Lone Star Beef. To conduct our investigation, OIG reviewed previously obtained statements, various documents and USDA regulations, and interviewed APHIS, FSIS, beef processing facility, and rendering company personnel.

Summary of OIG Findings

The OIG investigation found no substantive evidence that the USDA official(s) responsible for the decision not to take brain tissue samples from the cow for BSE testing, or any other USDA personnel, provided false information or engaged in intentional misconduct. We determined that a misjudgment was made by at least one USDA veterinary official in the handling of the suspect cow. Sworn statements provided by the two responsible USDA veterinary officials involved differ as to whether both concurred in this decision.

The suspect cow's carcass was sent to a rendering plant in San Angelo on April 27, 2004 for processing as inedible by-product. APHIS then utilized its "Indemnity Plan"

procedures to purchase the by-products as a preventative safety measure, and disposed of it at a local landfill in accordance with applicable environmental standards.

Evidence shows that at the time of this incident, communication problems occurred between the APHIS and FSIS employees involved. Taken together, the statements of both APHIS and FSIS personnel and other evidence indicate inconsistencies in their understanding of procedures for BSE tissue sampling of CNS suspect cattle in certain circumstances, and the handling of the carcass pending test results. It is apparent from the sworn statements provided to OIG that APHIS and FSIS personnel and Lone Star Beef officials could not resolve how best to proceed, and that confusion existed about how to properly handle the CNS-suspect carcass.

On May 5, 2004, FSIS and APHIS Veterinary Services announced a new joint policy regarding BSE sampling of condemned cattle at slaughter plants. The policy establishes protocols for the agencies' responsibilities to obtain samples from condemned cattle exhibiting signs of CNS disorders, regardless of age. The policy provides that FSIS will henceforth do all sampling at Federally-inspected slaughter facilities. For any condemned cattle that APHIS samples for BSE at other facilities, the protocols request (though not require) that the carcass not go to inedible rendering until the sample comes back negative.

Description of Key Events

At approximately 8 a.m. on April 27, 2004, the cow that later became the subject of controversy was delivered to Lone Star Beef in San Angelo, Texas. The cow's owner informed OIG investigators that it had injured itself some months earlier and, subsequently, experienced difficulty in walking. Upon its arrival at Lone Star Beef, an FSIS VMO and a Lone Star Beef employee saw the cow stagger, fall, and then get up. The VMO condemned the cow for exhibiting CNS disorder symptoms. The cow was then immediately killed and injected with dye by Lone Star Beef workers, to mark the carcass as unusable for human consumption. These actions by Lone Star Beef

employees were premature because, at that time, APHIS's regional BSE protocol called for CNS-suspect cattle to be transported live to Texas A&M University for observation, tissue sampling, and disposal.

The FSIS VMO notified an APHIS Animal Health Technician that he had condemned a cow at Lone Star Beef for CNS symptoms, and the Technician arrived at the facility to take a brain tissue sample for BSE testing. Before a tissue sample was taken, the FSIS VMO and APHIS Technician spoke to Lone Star Beef officials about what to do with the cow's carcass during the period in which the BSE testing of the tissue would be performed. The USDA personnel and Lone Star Beef officials could not reach agreement on proper retention of the carcass; company officials did not want to keep a decomposing carcass on site, since they believed that a local landfill would refuse to take the carcass.

Seeking a resolution to the dispute, Lone Star Beef's vice president placed a phone call to the AAVIC at the regional office in Austin, Texas. In the sworn statement he provided to OIG investigators, Lone Star Beef's vice president said he informed the AAVIC that, based upon an employee's description of the cow's condition before it was killed, the vice president believed the cow was possibly experiencing wheat poisoning, not CNS disorders. The vice president informed the AAVIC that he rejected the recommendations of the USDA personnel on-site to preserve the carcass at the facility, or transport it to a landfill, for the reasons stated above. The vice president said the AAVIC then told him APHIS would not require a brain tissue sample for BSE testing from the carcass, and that it could be sent to a rendering facility.

The most senior facility official on site, the president of Lone Star Beef, said he was present at the meeting where this phone call to APHIS took place, and that his vice president informed him that the AAVIC said APHIS was not going to take a tissue sample.

The APHIS Technician who had arrived on site intending to perform the tissue sample extraction from the carcass provided a sworn statement to OIG. She stated that in a

phone call subsequent to that between the Lone Star Beef vice president and the AAVIC (described above), she was directed by the AAVIC not to take a brain tissue sample. The FSIS VMO who had condemned the cow told OIG investigators that upon being handed a cell phone by the Technician, he spoke with an unidentified person at APHIS who said, “*We have decided not to take a sample.*”¹ The VMO assumed this to mean that APHIS had determined no sample for BSE testing was necessary. However, the VMO told OIG investigators that he never changed his original diagnosis of CNS. This phone conversation between the APHIS AAVIC and the FSIS VMO was the determining action that prevented BSE testing of the CNS suspect carcass.

The AAVIC’s sworn statement differs with the FSIS VMO’s description of what substantively transpired during the phone call. The AAVIC said that when he received the earlier call from the Lone Star Beef vice president about the problem of handling the carcass, the vice president said the following: the “FSIS” at the facility (namely, the VMO who condemned the cow) had improperly handled the cow; he believed the cow likely had wheat poisoning, not a CNS disorder; and that his facility did not have a place to hold the carcass during any BSE test analysis period. The AAVIC said he then followed up this conversation with a call to the FSIS VMO on site.

The AAVIC states that he and the VMO then discussed the suspect cow’s condition before it had been slaughtered. He said the VMO advised that the only problem observed with the cow was that it had fallen and could not get up. The AAVIC said the VMO never said the suspect cow had ever staggered. The AAVIC said that during this conversation, he and the VMO agreed on the following points: many things could have caused the animal to fall and not be able to arise, therefore it need not be sampled for BSE or classified as a CNS condemnation; and due to the lack of CNS symptoms, the carcass could be sent to a rendering facility. At approximately 2:45 p.m., the carcass was picked up by San Angelo Services, and taken to its rendering facility.

¹ The individual was the AAVIC. The AAVIC states in his sworn statement to OIG that he spoke on the phone with the VMO.

At the conclusion of this phone call with the FSIS VMO, the AAVIC said he called Lone Star Beef's vice president to inform him that he (AAVIC) and the VMO agreed the carcass could be sent to the rendering facility. The AAVIC then directed the APHIS Technician on-site not to take any tissue samples from the carcass. When questioned about this decision by OIG investigators, the AAVIC said the decision made on this particular animal was not out of the ordinary, and that as an AAVIC, he made such decisions on a regular basis.

This concludes the summary of OIG's investigations into the conduct of USDA personnel involved in BSE-related incidents in Washington State and San Angelo, Texas. We found no criminal conduct or intentional misconduct by USDA personnel. However, the cases are significant for illustrating some of the difficulties USDA faces in establishing and implementing an effective BSE surveillance plan. Our investigative findings demonstrate the need for the Department to issue clear regulations and policies for BSE inspection and testing, and to provide APHIS and FSIS field personnel with the training and guidance to effectively implement them.

II. OIG's BSE Audit Work

I will now provide an overview of our audit work pertaining to the Department's BSE surveillance efforts.

On July 1, 2004, we provided the Department with a draft audit report containing the results of the first phase of our assessment of USDA's BSE surveillance plan. The focus of our audit was to review the statistical validity of the expanded BSE sampling and testing program, to determine if the plan would enable USDA to achieve its stated statistical objectives. Because the plan's development and implementation were still evolving, we also conducted fieldwork prior to June 1 to provide observations on any issues and inherent challenges USDA will need to address to ensure a successful expanded program as it is implemented.

Customarily, the Department has 30 days to respond to official draft OIG audit reports. I therefore want to emphasize that our report is not final, since the Department has not had sufficient time to fully evaluate and officially respond to our findings and recommendations. Once we receive their response, we will evaluate their comments and make any necessary modifications to the report, including incorporating their response where appropriate.

This audit is the first in a series of reports we are planning to issue on our evaluation of USDA's BSE surveillance activities. We initiated this audit while the Department was in the process of developing its expanded surveillance program, which began on June 1, 2004. Our goal has been to provide impartial observations and recommendations early in the process to assist the Department in meeting its stated objectives. We did field visits (to the NVSL testing lab, slaughter facilities, rendering and 3D/4D plants², Federal and State participating agencies) to observe processes in place prior to the June 1, 2004 implementation date, to determine whether there were any issues that the Department needed to consider in designing and implementing effective program and management controls. As a result of our audit work, we identified a number of areas where additional efforts by USDA will improve the success of the expanded BSE surveillance program. I hope my overview this morning of its major elements will be informative.

USDA's Initial BSE Surveillance Program (1990-2003)

Since 1990, APHIS has led an interagency effort to monitor the potential existence of BSE in the U.S. cattle industry. Central to this effort was the testing of cattle in a high-risk category – those that exhibited a disorder in their central nervous systems (CNS), such as difficulty standing, walking, etc., and cattle that died on the farm from unclear causes. With the discovery of a BSE-infected animal in December 2003, APHIS determined to expand its surveillance program to test a larger number of high-risk animals. The goal of the program before 2004 had been to test 12,500 animals per year;

² Designation refers to dead, dying, disabled, or diseased animals.

under the expanded program, the goal extends to over 200,000 animals to be tested in a 12 to 18 month period.

USDA's Expanded BSE Surveillance Program, 2004

After the discovery of a BSE-infected cow in Washington State in December 2003, the Department took multiple administrative steps, including tracing the cow back to its herd of origin, depopulating animals of interest from identified herds, recalling meat products derived from the cow, and issuing a number of regulatory changes related to beef products. In January 2004, FSIS banned "specified risk materials" (*brain, skull, eyes, spinal cord, vertebral column, tonsils, etc.*)³ from the human food supply in the U.S. Additionally, the USDA redesigned its surveillance program to expand testing for BSE.

On March 15, 2004, USDA announced the details of its expanded surveillance effort for BSE in the U.S. APHIS's fundamental objective is to determine if BSE is actually present in the U.S. cattle population, and if so, to determine at what level. The primary focus of the enhanced surveillance effort would continue to be testing of high-risk cattle. However, USDA plans to greatly increase the number of target animals tested. The new plan would include a random sample of apparently normal, adult cattle. The precise elements of the plan will continue to evolve.

In its expanded BSE surveillance plan, APHIS re-estimated the number of high-risk cattle in the United States as closer to 446,000, or more than double its original estimate.⁴ APHIS officials concluded they would need to test about 268,500 high-risk animals to be 99 percent confident that it would detect at least 1 of these 268,500 cattle with BSE. This conclusion was reached upon APHIS's assumption that 5 of the estimated 446,000 in the high-risk population had the disease. By assuming BSE was limited to these high-risk cattle, APHIS concluded it would be 99 percent confident that it could detect BSE if its

³ See 9 CFR 310.22(a).

⁴ The 446,000 figure comes from three sources: FSIS 2002 data for animals partly or wholly condemned at slaughter by FSIS, APHIS 2002 data for animal disease investigations conducted by APHIS, and data collected by APHIS through the National Animal Health Monitoring System on the number and causes of deaths on farms (1996 data for beef breeding; 2001 data for dairy).

prevalence rate was 1 in 10 million. The sampling of an additional 20,000 apparently normal animals would come from 40 federally inspected plants that handle about 86 percent of the 6.2 million⁵ adult cattle slaughtered at federally inspected facilities each year. The carcasses from these animals would be held and not allowed to enter the human food chain until test results showed the samples were negative for BSE.

The goal of the program before 2004 had been to test 12,500 animals per year. The expanded program's goal extends to over 200,000⁶ animals to be tested in a 12 to 18 month period. USDA planned to test 40,000 animals by September 30, 2004. (These numbers are subject to adjustment by the Department.) In support of its expanded sampling plan, USDA advises that it has the support of the Harvard Center for Risk Analysis.

OIG's Audit of the USDA's BSE Surveillance Plan

The Department's BSE surveillance program has been of continuing interest to OIG. We planned to initiate an audit for FY 2004 to review the Department's BSE surveillance program, and were beginning to define its objectives when the Department announced the discovery of the BSE-positive cow. In light of that development, we focused this audit on the following objectives:

- 1) Determine whether the surveillance program in place at the time of the December 2003 discovery of BSE had been adequately implemented; and

- 2) Determine whether the expanded program will accomplish its stated goal of determining if "...BSE is actually present in the population and if so, at what level."

⁵ In the BSE Surveillance Plan, dated March 15, 2004, APHIS approximates this 6.2 million based on NASS data (pages 10-11). It is consistent with the 6,256,000 slaughtered under Federal inspection in 2002 per Table 7-13 of NASS publication Agricultural Statistics 2003 (equals 2,607,000 dairy cows plus 3,051,000 other cows plus 598,000 bulls and steers).

⁶ Total will depend on the confidence level desired. A 95% confidence level would require 201,000 cattle to be tested. A 99% confidence level would require 268,500.

With respect to the first objective, we found that we could not fully evaluate the Department's surveillance program as implemented prior to the discovery of the BSE-positive cow, due to the lack of adequate documentation for the basis of the plan. We did, however, perform field tests to determine how the program was operating prior to June 1, 2004, the date that the new plan would be fully implemented. Our purpose was to provide input to the Department on issues they may need to address as implementation of the expanded program moves forward. Our evaluation of the second objective -- assessing if the plan can determine the level of potential BSE infection in the U.S. -- is unavoidably limited, to some degree, because the design and implementation of the Department's BSE surveillance program is still evolving.

I want to emphasize that my testimony and our audit are based on our review of the Department's plan as it was published on March 15, 2004, as well as our review of all other documents provided to us and interviews with Department personnel. (We have received new data and information from the Department as recently as this week.) To provide a basis for our findings and recommendations, we reviewed the Department's plan utilizing the following extensive audit procedures, among others:

- Interviews of responsible program officials from APHIS and FSIS, including agency veterinarians, and interviews of plant personnel concerning the surveillance program and other BSE-related food safety initiatives;
- Review of slaughter plant records and observations of operations related to the inspection and condemnation of cattle, and written policies, procedures, and regulatory functions relating to the BSE surveillance program;
- Analysis of available documentation pertaining to the Department's development of the BSE expanded surveillance program, as well as the records, regulations, and management controls developed for cattle slaughter operations resulting from the discovery of the BSE-infected cow;

- Evaluation of the role of the NVSL in Ames, Iowa, and its responsibilities for the BSE surveillance program. Additionally, we are validating the NVSL's CNS testing data by tracing it back to FSIS and individual slaughter facility records that are their source;
- Creation of an expanded database for FY 2002, 2003, and 2004 (through February 2004), using information contained in the NVSL BSE database and utilizing sample submission forms. We evaluated this data to determine NVSL sample and testing data accuracy, trends, and anomalies; and
- Review of rendering plant records related to brain samples for BSE testing and observation of sample collection at rendering and slaughter establishments.

The Results of OIG's Audit

USDA's expanded surveillance program is based largely on a broadened plan of sampling, based upon the Department effort to more accurately determine the population of high-risk cattle (via use of NASS studies and FSIS condemnation records, etc.) This sampling plan has been announced as scientifically based and representative of the population of U.S. cattle as a whole. However, we believe that several limitations inherent in the expanded sampling plan need to be clarified so that industry, the public, and U.S. trading partners understand what the results of the testing actually imply.

The sampling is not truly random because participation in the program is voluntary. The BSE sampling plan, as designed, assumes each animal in the target population has the same chance of being selected for BSE testing, which will not be true if testing is voluntary. APHIS has the authority to collect samples, but it has chosen not to exercise this authority, except at federally - inspected slaughter facilities. Our audit, currently in draft form and recently provided to USDA for official review, provides the following observations regarding the BSE surveillance plan:

- The expanded plan emphasizes the confidence level of detecting at least one case of BSE in the adult U.S. cattle population, if it exists. Because of the plan's design, discovery of any BSE cases should cause the confidence level of its estimate of the maximum prevalence of BSE to drop dramatically. Therefore, any statistical projection of the maximum prevalence of BSE may give the appearance of being more reliable than it is; in other words, the conclusions reached as to the prevalence of BSE may be less reliable than as projected by APHIS.
- As the plan is currently designed, APHIS cannot obtain a statistically appropriate geographical representation of the U.S. cattle population. Because the program is voluntary and the universe of high-risk cattle is difficult to identify, obtain, and test, the surveillance plan needs to be clarified and its conclusions relating to the prevalence of BSE may need to be qualified.
- APHIS' sampling plan assumes BSE is confined to the high-risk cattle population; other studies show that healthy-looking animals may also have BSE.
- APHIS' plan to test 20,000 clinically normal cattle may give the incorrect impression that these few tests will suggest a level of assurance higher than warranted about the 45 million adult cattle in the United States.⁷
- APHIS cannot easily identify, obtain, or test cattle in its high-risk population; therefore, the chances of detecting BSE, if it exists, may be reduced and the projected maximum BSE prevalence rate may be unreliable.

Identifying the universe of high-risk cattle and developing detailed operational procedures for all BSE surveillance requirements are critical to the success of the expanded program. Because of inherent problems with identifying this universe, the

⁷ National Agricultural Statistics Service, Agricultural Statistics 2003, per Table 7-2 for 2002, 44,474,000 (equals 33,118,000 beef cows plus 9,112,000 milk cows plus 2,244,000 bulls).

Department faces significant challenges in estimating a maximum BSE prevalence rate for high-risk cattle. Our fieldwork, completed prior to June 1, 2004, identified some of the challenges in identifying, obtaining, and testing cattle in the high-risk population. Examples of these challenges are:

Cattle condemned at slaughter plants for CNS symptoms were not always tested for BSE. This occurred because of confusion in testing requirements and lack of coordination between APHIS and the agency that condemns cattle at slaughtering plants, the Food Safety and Inspection Service (FSIS). Of the 680 cattle FSIS condemned for CNS symptoms between FYs 2002 and 2004, we could validate that only 162 were tested for BSE. This was graphically illustrated in our investigation in San Angelo, Texas in late April 2004. On May 20, 2004, the Department issued a directive to its field staffs to clarify the requirements for testing all animals condemned for CNS, regardless of the age of the animal. FSIS and APHIS now need to develop sufficient management controls to ensure this policy is followed.

Additional testing is warranted for rabies-negative brain samples. Rabies cases exhibit clinical signs not inconsistent with BSE, and a negative rabies test means the cause of the cow's disorder has not been diagnosed. Nevertheless, this high priority population has not been adequately pursued for BSE testing. Public health and State veterinary diagnostic laboratories did not always submit rabies-negative samples for BSE testing because there was no formal mechanism in place to ensure the submissions. We suggested that APHIS develop formal processes, in coordination with public health and State veterinary diagnostic laboratories, for testing rabies negative samples for BSE.

A process for obtaining samples from animals that "died on the farm" has not been developed. These samples are important because the high-risk animals that die on the farm comprise the largest component of the targeted high-risk population and the most difficult to identify, obtain, and test. Identifying truly

high-risk cattle that die on the farm may be complicated by the reluctance of producers to submit them for testing or the motivation to mischaracterize low risk carcasses as “high risk” since only the latter may qualify for reimbursement. The Department has initiated outreach efforts to inform producers of the need for testing these animals.

Confusion may arise regarding non-standardized age requirements for BSE testing. Current testing guidance contains inconsistent age criteria for testing cattle for BSE. Some documents emphasize testing of livestock at 20 months of age, some at 24 months of age, and at least one—the APHIS Surveillance Plan of March 2004—over 30 months of age. This confusion has created and will continue to create a potential that some cattle may not be subject to BSE testing.

The second primary focus of our audit was to review the Department’s existing program management and administration capabilities with respect to implementation of the BSE surveillance program. The program can only be effectively implemented if USDA establishes a strong management control structure, one that will provide assurance to American consumers, industry, and U.S. trading partners. Our audit reviewed the Department’s surveillance processes that were in place up until June 1, 2004. Our goal was to identify concerns about agency management processes that could be improved if the Department’s surveillance program is to meet its objectives. Some of our audit’s primary findings regarding management and administrative procedures pertaining to the BSE surveillance programs are described below:

APHIS’ sampling and data collection processes could be improved to protect the integrity of surveillance data. Current APHIS processes do not ensure that all samples submitted are properly identified as to the animal’s origin; that all animals whose tests are recorded are within the target or non-target population; and that all samplers retain backup samples of brain tissue for purposes of verifying any positive tests.

APHIS needs to establish consistent terms and conditions in its agreements with non-Federal entities participating in the surveillance program. Prior to June 1, 2004, APHIS did not have standard written agreements in place to ensure consistent performance from non-Federal laboratories and reasonable arrangements/charges from meat plants and contractors who provide sampling services. Generally, arrangements with such entities contain no written agreement and have no national guidance. *(Ex: In one sample region, APHIS offices had written agreements with only 4 of the 31 slaughter/rendering facilities participating in the surveillance program. Also, our survey of arrangements with meat plants and sampling contractors showed that some were informal, and resulted in costs ranging from \$0 to \$100 per sample taken.)*

Most importantly, the Department needs to have a supportable methodology for assessing the effectiveness of its overall surveillance program. A supportable methodology is essential to provide credibility for any USDA assertion regarding the prevalence of BSE in the United States. Also, performance measures and continuous risk analysis are needed to better target limited resources and assess whether all program participants are fulfilling their respective roles and responsibilities.

When finalized, our audit will contain a series of recommendations for USDA to improve its BSE surveillance plan, and to strengthen USDA's administrative actions to prevent and mitigate BSE exposure in the U.S. cattle industry. We will also recommend that the Department fully disclose any assumptions that it made in designing its sampling plan, and clarify any limitations that exist in the assumptions made, and that exist in the data it will collect.

Mr. Chairmen and Ranking Members, Members of the Committees, I again thank you for inviting me to testify before your Committees and hope this information is helpful to you in your oversight efforts. We will provide our final audit directly to you upon completion. We offer our findings and recommendations to the Secretary and the Congress in the spirit of improving and refining our nation's BSE prevention and

detection activities so they are as effective as possible. We look forward to working with you in this important effort.

Chairman TOM DAVIS. Thank you very much.

Let me start. How do you plan to continue oversight of the expanded BSE surveillance program over the next 12 to 18 months?

Ms. FONG. We have a number of initiatives underway. As was referenced this morning, we have initiated a review of the situation where beef was brought in over the Canadian border. We have that review. We started about a week ago on that and we anticipate it will take a little bit of time to nail that down. In addition, we have some audit work planned to review the results of the implementation of the surveillance plan as it moves forward, and also to look at how the Department handles SRM materials in that particular program area.

Chairman TOM DAVIS. Your audit states that APHIS' current IT system is inadequate to support the expanded surveillance system. Can you speak specifically to APHIS' IT challenges and your recommendations?

Ms. FONG. Yes, thank you. Our audit looked at the current IT system and concluded that it was not adequate to support the expanded surveillance program and the expanded volume of samples that the Department expects to gather. We found that APHIS needs to implement an integrated system that tracks samples from collection through testing through reporting of results, and a network that integrates the network of diagnostic testing labs. Currently, APHIS uses two databases. There is some issues about whether those two databases are compatible, whether the data is consistent, and so we made recommendations to USDA to improve that system.

We understand that the Office of the Chief Information Officer has been working very closely with APHIS and FSIS on this. We understand that they have a system in the design and implementation stage and testing, and we are actually quite encouraged by the progress that the Department is making on that.

Chairman TOM DAVIS. Your audit states that APHIS can't easily identify, obtain, or test cattle in its high-risk population. Can you elaborate on this statement and your recommendations in terms of APHIS being able to remedy that situation?

Ms. FONG. Yes. That is a significant portion of our audit; it does address the issue of whether the targeted population can be adequately accessed through the testing program. And we had comments in a number of areas relating to high-risk cattle condemned for CNS symptoms, cattle who tested negative for rabies who should then be referred over for BSE testing, confusion regarding the whole definition of downers and the age on that. And we made a number of recommendations to the Department that it consider issuing more precise guidelines to deal with those issues and that it train FSIS and APHIS staff so that they could adequately implement those new guidelines.

Chairman TOM DAVIS. And also could you elaborate on your concerns regarding the testing of rabies negative brain samples?

Ms. FONG. Basically, our concern dealt with the lack of formalized process for ensuring that tests that are sent to labs for rabies purposes—because cattle with rabies can exhibit similar symptoms to central nervous system disorder, it is important that a cow whose rabies test is negative then be referred over for BSE testing

so that can be looked at, and we were concerned because there did not appear to be formal procedures that would ensure that those kinds of samples were referred from the State labs to the appropriate labs for diagnostics.

Chairman TOM DAVIS. So basically they ought to be testing for both; if it is negative on one, it just makes sense, given the symptoms on them.

Ms. FONG. Yes.

Chairman TOM DAVIS. Thank you.

Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman.

Thank you very much for being here and for your report. I think you are playing a very important role with the Department in critiquing their proposal, and hopefully your comments will be taken to heart by the Department and improve their surveillance program.

But their surveillance program seems to be based on an assumption that the downer cows are the highest risk, and perhaps the only ones that we need to be worried about. A lot of that goes back to the first and only cow that we found with the mad cow disease, that was the cow in Washington; and there has been a controversy as to whether that cow was a downer cow or not.

You testified that you didn't find any knowing or intentional misrepresentation, but you do admit that there is some controversy over whether that cow was a downer cow or not, don't you?

Ms. FONG. That was the allegation that was presented to us back in January/February, that the employer of the meat processing plant thought that the cow that was BSE positive was not a downer. So that has been one of the major issues that we have focused on. We have, through interviews of everyone that had contact with that cow during that time period, and interviews of that employee and interviews of USDA employees, we have not found any evidence that would indicate that at the time the cow was presented for inspection, that it was ambulatory. At the time that it was presented for inspection, the USDA vet who was charged with the responsibility of making the professional call, in his professional judgment, determined that it was in fact a downer. And all the other statements that we have obtained have not been inconsistent with that.

Mr. WAXMAN. That highlights one particular moment in time.

Ms. FONG. Right.

Mr. WAXMAN. But there are other witnesses who said at other times that the cow was ambulatory, that it didn't appear to be a downer cow. Now, if that is the reality, not perhaps at that moment when the inspector came in, then one would have to question whether it is correct to say that the only cows that can get BSE are downer cows, if this wasn't in fact a downer cow.

It is important because this assumption is driving everything else. I didn't really get a chance to pursue this with the Secretary, and regret it, because I was mainly questioning her about some of your criticisms of her inspection plan itself, but do you think that we ought to be basing all of our activities on this assumption that the only cows that can be infected with mad cow disease are downer cows?

Ms. FONG. I think our audit report states that is one of the concerns that we had with the surveillance plan as drafted. We understand the need to focus as a priority matter first on cows that are in the high-risk group. We do not have a quarrel with that assumption. But we also wanted the Department to consider the fact that the normal appearing adult population of cattle should also be looked at, because the extrapolation from the high-risk to the normal adult cattle population is a very difficult extrapolation to make, and so we have been involved in discussions on that issue.

Mr. WAXMAN. I am glad that you are, because it seemed like the Department made an assumption. It might have found the cow out of luck rather than their system working the way it was supposed to work, but then made an assumption that this was what they ought to base their whole policy on, and it is an assumption that they then use to assure everyone that their system was working. And I am not sure that it is working, and it sounds like you are not sure if the plan is only to look at downer cows and assume that is all we need for giving the American people and others the reassurance about the food supply, that is sufficient.

So I want to point that out, because this administration has had problems in the past of taking an assumption, even if there is evidence to the contrary, and staying with it sometimes beyond any point where it makes sense.

I thought your criticisms in detail were very important. One of the points that the Secretary made to me was, well, those criticisms were not of her new plan, but the old plan. And I wanted to just go through some of these points with you, because a lot of what you have listed did seem to apply to her present plan, not the old plan, isn't that correct?

Ms. FONG. We believe that some of the lessons that we have learned from implementation of the plan over time, old and new, applies to the implementation of the plan as we move forward, and so they raise legitimate issues to be discussed.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

Thank you for your testimony.

Chairman TOM DAVIS. Thank you.

Chairman Goodlatte.

Chairman GOODLATTE. Ms. Fong, thank you very much for participating today and for your extensive work in this area, we very much appreciate that, and your associates being here with you as well.

Is it true that draft audits can be modified significantly after full consultation with the agency involved, in this case with APHIS, as you exchange information and find that some of your assumptions may not be quite the same way when they have an opportunity to respond and give you some evidence of what they are indeed doing?

Ms. FONG. The audit process does provide for that exchange of views and viewpoints. And as I pointed out in my testimony, when we receive the Department's response, we will evaluate it. It is conceivable that it will or could result in some change in our audit. Now, I just want to clarify that. In terms of our audit work and the factual basis for the audits, the data that we actually looked at when we went to the field establishments, it is unlikely that

data will change unless there is data that we just weren't aware of during the course of the audit.

Chairman GOODLATTE. Sure. But that is an opportunity for them to provide that before a final audit is delivered.

Ms. FONG. Exactly.

Chairman GOODLATTE. And when was your draft delivered to the Secretary?

Ms. FONG. July 1.

Chairman GOODLATTE. And is it appropriate for a draft audit to be considered publicly as the final conclusion of the Inspector General on an issue that is under discussion?

Ms. FONG. In our view, our final audit is our final position.

Chairman GOODLATTE. And when you made the draft available to members of the Government Reform Committee and to members of the Agriculture Committee, did you expect that it would be made public?

Ms. FONG. When we transmitted it, we transmitted it to the committees with the understanding that it was essential to you in your oversight capacities, and that you would use it in that light and with the appropriate safeguards.

Chairman GOODLATTE. Thank you. I just wanted to make that very clear, that while we want to be very transparent in what we are doing, we also want to make sure that what is made public is something that has been carefully audited and has the full availability of the evidence that might be provided by the Department in their discussions with you.

Now, to the substance of the issue, is a cow a downer for a month, a week, a day, or is the downer distinction drawn at the point that the USDA veterinarian inspects the cow and makes a professional judgment?

Ms. FONG. That is a very difficult question, and I am not a vet or an APHIS employee, so I hesitate to substitute my judgment as to animal health. I would say that it is important that the Department have a clear definition of what it means by downer or non-ambulatory and ambulatory. Once that definition is established and implemented appropriately, then it is up to the individual vet who is charged with the responsibility of exercising his or her judgment to apply that definition in an appropriate way.

Chairman GOODLATTE. Absolutely. But if a cow has some difficulties, it may well be able to walk some of the time and may be down some of the time as well. And if the cow is presented to the veterinarian in a downed position, that is certainly a reasonable conclusion for the veterinarian to draw when they conclude that it was indeed a downed animal that they were examining.

Ms. FONG. That is in fact the situation that happened with the Washington State cow. There was testimony that we had from witnesses that we interviewed that indicated the cow walked onto the trailer that morning, but by the time the cow arrived at the slaughter facility, the cow was sternal.

Chairman GOODLATTE. Right.

Ms. FONG. Was lying down. And so the vet, at that time, called it a downer. That is not an inconsistent statement.

Chairman GOODLATTE. Sure. Absolutely. And it is also very true that the scientific evidence would point to animals manifesting

symptoms of illness, either downed or ambulatory, would be the animals for which they would pay their greatest attention to in their testing, is that not correct? The likelihood is far greater that is where you might find BSE. And so far in the thousands of cows that have been tested since the change in the rules, none have been found to have that disease, thankfully. But it is also true that there could be some cattle in the larger population that might have this disease that are not showing symptoms of being down, whether they are ambulatory part of the time or then downed or not, there could be some cows out there like that. But in terms of using the resources to find the illness that is involved here, it is true, I would assume, and I would like your opinion on this, that the principal focus should be on those animals that are most likely to manifest the disease, with some testing, and it is indeed the case with the new regime that some testing is taking place, for what is called the healthy animal population.

Ms. FONG. That is the Department's approach, and we do not have a quarrel with that in terms of priorities. The only comment that we would have is that the Department be very clear in what its priorities are and its goals, and that its plan clearly communicate to the public what it is trying to accomplish.

Chairman GOODLATTE. We understand that, and they will certainly have an opportunity to respond to your draft audit in that regard, and we certainly hope and expect that they will respond to your points, which are well taken.

At this time, Mr. Davis, we will recognize the gentleman from Texas, Mr. Stenholm, the ranking member of the Agriculture Committee.

Mr. STENHOLM. Thank you, Mr. Chairman.

I want to follow up on the last line. The primary purpose of all of our food safety and inspection service, all of our activities, is to make sure that the consumer has a wholesome, safe supply of food. That is the purpose of this hearing. And I find it rather interesting that in the headlines of the Washington Post in the story today, the title says "USDA Mad Cow Detection Challenge: Report Says Animal Wasn't A Downer." That is not what your report said. Your report found no evidence of intentional falsification or failure to test the one downer cow. That is what you said. Someone else read this; what they wanted to see in it was that there was possibility that it was or it wasn't. You have testified, in answering the questions, very specifically that based on your investigation, as came from USDA was accurate, but there are differences of opinion, correct?

Ms. FONG. I think that is correct.

Mr. STENHOLM. And you investigated the differences of opinion and found no evidence to corroborate those who had a different opinion than the inspector.

Ms. FONG. Our investigation indicated that the inspector made the call at the time, and there is no evidence that contradicted that. I will say that investigation reports are not always easy to understand; they can be very technical, and it is easy to be misled by some of the terminology.

Mr. STENHOLM. And I can fully appreciate that, having dealt with this question myself for a few years. There are those, and I don't question their intentions or their integrity, or anything about

those who have differences of opinion regarding our food safety and inspection service. But I think it is not helpful when we leak a report, whoever did, and then come to a conclusion that is not substantiated by what the report said.

Now, in your testimony you state that APHIS cannot easily identify, obtain, or test cattle in its the high-risk population. Mr. Waxman, and I think not totally incorrectly, is suggesting that we perhaps need to look at other animals other than the high-risk in order to be as absolutely certain as we need to be, and it is my understanding, based on the current procedure, that is exactly what we are doing now, we are looking at a pretty broad-based number of samples so that the concerns raised by Mr. Waxman are now being met by the procedures. Is that your finding?

Ms. FONG. The expanded surveillance plan as drafted by APHIS provides that APHIS will sample 20,000 cows from the normal appearing adult population. And we had some concern about how that sample was going to be handled and the statistical analysis underlying it. I think that through our conversations recently with APHIS and the Department, that this is an issue that both sides need to continue to talk about, because it is not an easy issue to address. But my sense of this is that the Department understands that we do need to do some sampling in the normal population, and so we need to work together to figure out the best way to do that.

Mr. STENHOLM. But as someone who warned about the problem that might be associated with banning downer animals, I am tempted to want to agree with your assessment of the problems that have been associated with that policy. However, given the rate of testing among higher risk cattle that USDA seems to have achieved, what evidence do you now have to support that original assertion?

Ms. EVANS. Can you repeat the question, please?

Mr. STENHOLM. In your testimony you state that APHIS cannot easily identify, obtain, or test cattle in its high-risk population. One of the concerns that many of us had was the downer animal, I wanted them to continue to come into the slaughter plant, have a veterinarian determine whether or not that was a sick animal. If it was, it is out; if it is a broken leg process, that it would continue in. That has now been changed. You came to the same conclusion: that because of that it was creating a problem identifying the high-risk population.

Ms. EVANS. Right.

Mr. STENHOLM. I said where I was attempting to agree with you. That is not the point today, that is being looked at and in the interim rule being determined. The question is: given the rate of testing among the higher risk cattle that we are now achieving, or seem to have achieved, what evidence do you have to support your original assertion that we had a problem in that area?

Ms. EVANS. We have not done any analysis as to the testing that has been done since June 1. That is part of what we plan to do in the future, in looking at the effectiveness of what the Department has done and in responding to our recommendations.

Mr. STENHOLM. Thank you.

Chairman GOODLATTE. It is my pleasure to recognize the gentleman from Kansas, Mr. Moran.

Mr. MORAN. Mr. Chairman, thank you. Just perhaps a couple of followup questions to questions that the IG has answered.

Let me make sure I understand the period of time which your audit covers. And a significant part of that, I think, is that none of that audit was conducted post the new surveillance being implemented, is that true?

Ms. FONG. We completed our field work during the spring of 2004. We initiated the audit, I believe, in February and we completed our field work through June.

Mr. MORAN. And the new surveillance was announced in March but implemented on June 1, so the conclusions that are drawn in your report are really based upon events and, therefore, methodology, policies that predate the new surveillance of June 1?

Ms. FONG. Our audit is based on our analysis of data that was available prior to the June 1 implementation.

Mr. MORAN. And then in response to Mr. Stenholm's inquiry about the downer, part of what you are indicating is that we need a clear definition of what a downer animal is, and perhaps a time-frame in which an animal becomes or remains a downer, is that true?

Ms. FONG. Yes.

Mr. MORAN. But you are also indicating that if we exclude downer cattle from the food supply system, we are limiting the ability to test the cattle that may be at most risk for BSE, is that true?

Ms. FONG. That is an issue that we have put on the table with the Department. The question is if those animals are no longer going to the slaughterhouses, how will we, the Department, be able to access them for sampling; and that is something that we believe needs to be looked at.

Mr. MORAN. Do you have any preliminary answer to that question? Is the Department doing anything to have surveillance test those animals?

Ms. FONG. I am not aware of anything in particular. Now, that is not to say that is not going on, it is just that we may not be aware of it at this time.

Mr. MORAN. And I guess that is my final point, is that much may change as you have conversations with USDA, APHIS, and you reach your final conclusions. We ought to again look at this report to see what your final conclusions are, is that accurate?

Ms. FONG. Right.

Mr. MORAN. That is good advice, I assume?

Ms. FONG. Yes, it is. And we do plan to, when we issue the report, to provide it to the committee for the record.

Mr. MORAN. Thank you very much, Ms. Fong. I always find you a very impressive witness, and I thank you for your testimony.

Ms. FONG. Thank you.

Chairman TOM DAVIS. Thank you. Both committees, you will supply it to both committees for the record?

Ms. FONG. Absolutely.

Chairman TOM DAVIS. Ms. Fong, I just want to thank you for your testimony today and for the audit work that you have done on the old system, and we look forward to continue to work with you and the Department as this new system takes hold to make

sure that we continue to have a safe food supply in this country. Thank you.

Ms. FONG. Thank you.

Mr. WAXMAN. Mr. Chairman.

Chairman TOM DAVIS. Mr. Waxman.

Mr. WAXMAN. If I might, I would like to take another round to clarify some issues here.

Chairman TOM DAVIS. Our problem is we are expecting votes in a couple minutes, and I want to get the next panel on.

Mr. WAXMAN. I appreciate that, Mr. Chairman, but we don't have a lot of Members here.

Chairman TOM DAVIS. I know.

Chairman GOODLATTE. I think we could take questions in writing and make sure that they are answered.

Mr. WAXMAN. Mr. Chairman, I would like to pursue less than 5 minutes of questions, if I might.

Chairman TOM DAVIS. Mr. Waxman, we have tried to indulge everybody today, and this hearing started at 10. What I would like to do at this point is have you submit the questions in writing.

And, Ms. Fong, will you try to respond to them and get back to him on that? I think that is appropriate.

I would like to move to the last panel and get them in before the vote if we can; otherwise, they can be stuck here for a much longer period of time.

Mr. WAXMAN. Mr. Chairman, I regret that I can't have the opportunity to ask more questions, but I will submit them in writing.

Chairman TOM DAVIS. That would be fine. If we had Members here, we could have had them yield, but I just want to move this along.

Mr. WAXMAN. I didn't think I would have to call some Member to give me the courtesy of asking a few more questions, but next time we will do that, Mr. Chairman.

Chairman TOM DAVIS. All right, thank you.

Now you are dismissed.

In fact, this looks like a time, with the vote coming on, maybe we ought to recess.

Mr. WAXMAN. Mr. Chairman, since we are not going to have a chance to put on the next panel, may I have a few minutes to ask some questions of Ms. Fong?

[Recess.]

Chairman TOM DAVIS. We now move to our next panel.

I want to thank our witnesses for appearing today. Joining us in our third panel will be Dr. George Gray, the executive director of the Harvard Center for Risk Analysis; Dr. Peter Lurie, the deputy director of the Public Citizen's Health Research Group; Mr. Jim Hodges, president of the American Meat Institute; and Dr. Gary Weber, who is the executive director of the National Cattlemen's Beef Association.

Again, gentlemen, it is our policy that we swear everybody in, so if you would rise with me and raise your right hands.

[Witnesses sworn.]

Chairman TOM DAVIS. Thank you all for being with us and for your patience. It has been a long day for those of you sitting out there.

Dr. Gray, why don't we start with you and we will move straight on down. If you can keep it to 5 minutes, your entire testimony is in the record, and then we will go ahead to questions.

**STATEMENT OF GEORGE M. GRAY, EXECUTIVE DIRECTOR,
HARVARD CENTER FOR RISK ANALYSIS**

Mr. GRAY. Thank you, Mr. Davis, Mr. Goodlatte, and Mr. Waxman. As I have just been introduced, I am George Gray from the Harvard Center for Risk Analysis. You can learn more about our group by looking at our Web site, our mission, our research, and our funding.

My comments today are based on my research and experience as a scientist, a risk analyst, and a public health professional. They shouldn't be attributed to anybody else, including the Center for Risk Analysis or the Harvard Center of Public Health.

I do want to recognize publicly the contribution of my colleague, Dr. Joshua T. Cohen, to work the work upon which this testimony is based. Part of this testimony is based on a review of USDA's enhanced surveillance plan that we did for the Department at the request of the Department in March 2004, and that is attached to my testimony.

I really want to make three main points today, and I will try and do them very quickly. The first one is surveillance that provides us information that helps us to manage risk. It helps us to do this by understanding whether BSE is present in the U.S. cattle herd and how extensively it might have spread. We have to remember that it is not a public health measure. The U.S. Government has already taken many steps to help reduce the risk of BSE to animals, primarily there through the feed controls that the FDA put in place in 1997, and to humans; and some of the most important things have already been discussed today, the removal of high-risk materials from human food. So surveillance helps us determine if those measures have been successful, and they will help us decide whether additional or even fewer measures are needed going forward.

My second point is that USDA's focus on testing high-risk animals is the best way to monitor the population. Of course, the most accurate estimate of the number of animals with BSE in the United States could be developed if we tested every single animal, but much of the energy there would not be productively spent. And I do want to touch on some knowledge that we know from what has happened in the rest of the world about how high-risk this high-risk group is that we are talking about.

Data from Europe—and here I am going to talk about combining information across all of the European Union and the data from their testing in 2002 and 2003. But there it tells us that the prevalence of BSE in the high-risk animals, virtually the same definition that the USDA is using, the rate in those animals is about 25 times higher than the prevalence in apparently healthy animals over 30 months of age. So there is the potential for BSE in apparently healthy animals, and that is an important thing we have to recognize. However, in testing, this tells us that in Europe they have to test, on average, about 1,300 high-risk animals to find 1 BSE case. They have to test over 33,000 apparently healthy ani-

mals. So if we want to find the cases, we should look where we know they are, and that is in the high-risk group.

Now, Dr. Cohen and I have some concerns about the assumptions underlying the estimates of the sensitivity of the USDA plan, and we discuss those in some detail in our memo that you can read. So I think that it is important to say that we are going to have to go back and reevaluate exactly what we learn from this system, but this surveillance plan is the best way to get a handle on what is happening in the United States with BSE.

So to summarize, I think that the USDA expanded surveillance plan will provide us useful knowledge for BSE risk management, it will help us to make better decisions. However, it is important to remember that protecting human and animal health depends on other measures, which have already been taken or, in some cases, they have been proposed by Government agencies. The expanded surveillance plan as designed, it is targeted and it is efficient, and it will provide us useful information. There will be challenges in interpreting and in communicating the results, but I am confident that these challenges can be met.

Thanks for the opportunity to address you, and I would be happy to answer any questions.

[The prepared statement of Mr. Gray follows:]

Testimony of George M. Gray
Harvard Center for Risk Analysis
Harvard School of Public Health

U.S. House of Representatives
Committee on Government Reform
Committee on Agriculture
July 14, 2004

Chairman Davis, Chairman Goodlatte, members of the Committee, thank you for the opportunity to appear before you today. I am George M. Gray, Ph.D., Executive Director of the Harvard Center for Risk Analysis. You can learn more about our Center, its mission, research, and funding at our website (<http://www.hcra.harvard.edu/>). My comments today are based on my research and experience as a scientist, risk analyst, and public health professional. These comments are my own and should not be attributed to the Harvard Center for Risk Analysis or to the Harvard School of Public Health. I do want to recognize the contribution of my colleague, Dr. Joshua T. Cohen, to the work on which this testimony is based. Part of this testimony is based on our March, 2004 review of the USDA Enhanced BSE Surveillance Plan, a copy of which is attached to my testimony.

I want to make 3 main points today:

First, surveillance provides useful information for deciding the appropriateness and extent of risk management efforts, but it is not a public health or animals protection measure;
Second, USDA's plan to focus on high risk animals is the most efficient and effective way to conduct surveillance; and
Finally, there will be challenges to using the information generated by the surveillance program to estimate the possible extent of BSE in the United States, but these issues can be addressed.

I turn now to my first point – that the surveillance information helps us to manage risk. Surveillance does so by helping us to understand whether BSE is present in the U.S. cattle herd and how extensively it may have spread. The U.S. government has already taken many steps to reduce the risk of BSE to animals and humans. Surveillance helps us to determine if those measures have been successful, and whether additional – or fewer – measures are needed going forward.

It must be recognized that surveillance itself does not protect animal health or human health. Bovine Spongiform Encephalopathy (BSE) has a long incubation period, meaning that there can be a long period of time between the point when an animal becomes infected and the point when it exhibits clinical signs of disease. Because there are no known tests that can detect disease until just before the appearance of clinical signs, tests can miss animals that have BSE. Tests therefore offer limited protection against contamination of human food and animal feed. Instead, these risks have been addressed by USDA to remove high risk animals and tissues from human food and by FDA acting to reduce the risk of BSE spread among cattle. Surveillance only helps us to identify and quantify the problem.

My second point is that USDA's focus on testing high risk animals is the best way to monitor the population. Of course, the most accurate estimate of the number of animals with BSE could be developed if we tested every animal in the U.S. But much of the energy that would go into testing apparently healthy animals would not be productively spent.

For example, data from Europe¹ tell us that over the last two years the prevalence of BSE in high-risk animals has been about 25 times higher than the prevalence in apparently healthy animals over 30 months of age. That means that in Europe, where almost all experts agree BSE is a much more serious problem than it is in the U.S., testing 1,300 high risk animals is sufficient to find a single case of BSE with high probability. To find a single case of BSE among apparently healthy animals over 30 months of age with the same probability, more than 33,000 animals must be tested. Clearly, with limited resources, including testing facilities, USDA's focus on high-risk animals is the most effective and efficient way to test for the presence of BSE in the United States.

My final point has to do with the challenges involved in interpreting the results of a surveillance program that focuses on high risk animals. In particular, how do we extrapolate the findings from the high risk population, which USDA's Expanded Surveillance Plan appropriately focuses on, to apparently healthy animals? In the February, 2004 version of that plan, USDA estimated that if no additional animals with BSE were discovered after testing some 268,000 high risk animals and 20,000 apparently healthy animals, we could be 99% sure that the prevalence of BSE among slaughtered animals and animals that die would be no more than one in 10 million.

Dr. Cohen and I expressed some concerns about the assumptions underlying this estimate and offered a strategy for modifying the calculations to address these concerns. In particular, we explained that the prevalence rate in the apparently healthy population can be estimated by scaling down the measured prevalence in the high risk population. Weighting the two prevalence rates to reflect the sizes of these two populations yields a prevalence for the entire U.S. cattle herd. While the revised calculations will yield somewhat higher estimates for the total number of BSE cases in the U.S., we believe they will continue to show that the Expanded Surveillance Plan can detect BSE even if the prevalence is very low.

Our memo also points out that there are two ways to define the prevalence of BSE. One way would be to include only animals that have had BSE for a long enough period of time so that it can be detected by testing. Using that definition would have the advantage of making our prevalence estimates comparable to those reported by other countries, which also effectively exclude animals that have had BSE for too short a period of time for it to be detectable. Focusing on the detectable animals also makes sense because they have a much greater amount of infectivity than non-detectable animals and therefore pose a much greater risk to animals and humans. Alternatively, we could include in our estimate of prevalence all animals with BSE, including those that have not had the disease long enough for it to be detectable by testing. We described in our memo how the number of such animals could be estimated mathematically. The number of animals with undetectable BSE can be important because the incubation period for BSE can last many years and the disease is detectable by testing only near the end of this period.

I close with two concerns about our testing program. The first is the difficulty that the U.S. and the rest of the world have in dealing with countries when BSE is detected. The draconian act of completely shutting down trade makes the discovery of a BSE case such a major event that it creates possible disincentives to test thoroughly. The international community must come to agreement about ways to distinguish in trading decisions between countries with 10, 100, 1000, or 100,000 BSE cases. With appropriate risk management measures we should still be able to trade while protecting

¹ The following discussion is based on EUROPEAN COMMISSION - HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL (2004) REPORT ON THE MONITORING AND TESTING OF RUMINANTS FOR THE PRESENCE OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE) IN THE EU IN 2003, INCLUDING THE RESULTS OF THE SURVEY OF PRION PROTEIN GENOTYPES IN SHEEP BREEDS. 04-D-420525

human and animal health. This approach will also reduce incentives to hide possible cases and increase our ability to characterize BSE levels around the world.

My second concern is the way in which the results of the Expanded Surveillance Plan and the risks of BSE are communicated to the public, especially if another case is detected. A very important result from the analysis that we conducted² is that measures taken by the government, primarily the feed controls enacted by FDA in 1997, would reduce the prevalence of BSE in this country if it were introduced. However, we would need ongoing surveillance to demonstrate a decreasing prevalence over time. At this time no follow-up surveillance is planned. In addition, this follow-up would be very difficult and expensive and plagued by uncertainty given the low level of BSE likely to be found in the U.S. These factors will complicate the risk communication that must accompany discussions of the surveillance effort.

In summary, the USDA Expanded Surveillance Plan will provide useful knowledge for BSE risk management. However, it is important to remember that protecting human and animal health depends on other measures, many of which have been adopted or proposed by the relevant government agencies. These steps by USDA and FDA have already reduced BSE risks to humans and cattle. The Expanded Surveillance Plan as designed is targeted, efficient and will provide useful information. There will be challenges in interpreting and communicating the results, but I am confident that these challenges can be met.

Thank you for the opportunity to address you today. I will be happy to answer any questions.

² Cohen, J. T., Duggar, K., Gray, G. M. and Kreindel, S. (2003). *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States: Report to the U.S. Department of Agriculture (revised October, 2003)*. Boston, MA, Harvard Center for Risk Analysis. Available at: <http://www.hera.harvard.edu/pdf/madcow.pdf>.

Harvard Center for Risk Analysis

To: Ron DeHaven, Deputy Administrator, Veterinary Services, APHIS
From: Joshua Cohen and George Gray, Harvard Center for Risk Analysis
Date: March 12, 2004
Re: Comments on USDA bovine spongiform encephalopathy (BSE) surveillance plan

At the request of USDA, the Harvard Center for Risk Analysis has reviewed the Department's draft surveillance plan (USDA, 2004) designed to better estimate the prevalence of BSE in the U.S. cattle population. The draft plan addresses a number of issues, including the number of animals to test for BSE, which types of animals to test, sample collection logistics, costs, and communications. Our comments provide advice on how to best use the information gathered by surveillance for the purpose of estimating the overall prevalence of BSE in the U.S. cattle population. While we do not have the technical expertise to address other issues relevant to the plan, USDA's treatment of these issues seems appropriate to us.

In summary, we agree with USDA's focus on testing high risk cattle. If there are additional BSE-infected animals in the U.S., the likely high false negative rate for laboratory detection of BSE in normal adults and juveniles (animals that do not yet show signs of disease) would make a focus on these populations inefficient. The main interpretation challenge for USDA is the extrapolation of test results from the high risk cattle population to normal adult and juvenile cattle. Doing so requires the development of explicit assumptions about how the BSE prevalence rates in these sub-populations are related. We propose an approach and develop some initial estimates for these assumptions.

Before proceeding, we note that estimating the prevalence of BSE requires further consideration of USDA's goals. On the one hand, USDA could choose to estimate the prevalence of detectable BSE in the U.S. cattle population. Here, we refer to the fact that current tests can only detect BSE near the end of the disease incubation period. Such an approach would not account for animals that are infected but have disease that is not detectable. These estimates have the advantage of being comparable to estimates reported by other countries, which also report the prevalence of detectable BSE. The detectable animals also pose a much greater risk than non-detectable animals because they have a much greater amount of infectivity. We describe how both prevalence rates can be estimated.

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As we understand it, USDA's plan proposes the laboratory testing of as many high risk cattle as is practical (amounting to 268,444, based on statistical and other considerations), and 10,000 adult cattle that are clinically normal. The high risk population represents 445,886 cattle, including 251,532 adult cattle that die on the farm, 194,225 satisfying FSIS condemnation criteria (non-ambulatory cattle, cattle with CNS signs and/or rabies negative, cattle with other signs potentially associated with BSE, and dead cattle), and 129 foreign disease investigation animals.

USDA explains that its sampling of the high risk population is sufficient to detect a prevalence rate of one case in 10 million, which when applied to the entire population of adult cattle (45 million), corresponds to a total prevalence of approximately five animals. USDA does not explicitly quantify the prevalence rate that could be detected by its sampling of 10,000 normal adult cattle, but using their calculations (which are based on formulas described by Cannon and Roe (1982)), we calculate that they can detect a prevalence rate of 3×10^{-4} with 95% certainty.

We note that USDA's derivation of a sensitivity level for their surveillance plan (one in 10 million animals with 99% certainty) assumes that all the infected animals in the U.S. belong to the high risk population group. In particular, USDA correctly calculated that the proposed plan would detect the presence of BSE with 99% certainty if as many as five high risk cattle had BSE. Dividing five into the adult cattle population size of 45 million yields approximately one in 10 million. However, because there may be BSE-infected animals in the normal adult and normal juvenile populations, a more rigorous set of assumptions must be developed to estimate a prevalence for the entire population.

For the purpose of quantifying the relationship between prevalence among high risk cattle and prevalence in the normal adult and normal juvenile sub-populations, we first define the population of interest to be those cattle that die or are slaughtered each year. For the purpose of quantifying the prevalence rate for the entire cattle population (including those that are alive), this definition leads to an upper bound because cattle that are slaughtered or that die are at higher risk for BSE than cattle that continue to live because the former have lived longer and have had more opportunities to be exposed to the BSE agent. On the other hand, for the purpose of quantifying the total prevalence (number of BSE positive cattle) for the entire cattle population, our definition leads to a lower bound. However, because only animals that die or are slaughtered can cause the spread of the disease to other cattle or exposure of humans to BSE-contaminated tissues, it is the

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BSE prevalence among cattle that die or are slaughtered that is most relevant from a risk management perspective.

The remainder of this memo reviews alternative approaches for estimating BSE prevalence. The first approach depends on direct measurement of BSE in the component cattle sub-populations. We explain that high false positive rates in the normal sub-populations render this approach inefficient. The second approach focuses surveillance efforts on the high risk population and uses the estimated prevalence in this group to estimate the prevalence in the other groups.

1 Direct measurement of BSE prevalence in cattle sub-populations

This approach estimates BSE prevalence for the entire cattle population by adding the prevalence values for each group. The total number of BSE cases (n_{Total}) is $n_{HR} + n_A + n_J$, where the *HR* subscript refers to the population of “high risk” animals, the *A* subscript refers to normal adult animals, and the *J* subscript refers to normal juvenile animals. Table 1 defines these sub-populations based on the animal’s age and whether it displays clinical signs of disease.

**Table 1
Cattle Sub-Population Definitions**

| | Age < 24 months | Age 24 to 29 months ^(a) | Age ≥ 30 months |
|-------------------|-----------------|------------------------------------|-----------------|
| No clinical signs | Normal Juvenile | Normal Juvenile | Normal Adult |
| Clinical Signs | Normal Juvenile | High Risk | High Risk |

Notes:

- (a) We consider adults to include cattle at least 30 months of age. However, consistent with the definition of its targeted cattle population (USDA, 2004, p. 2), we assume animals with clinical signs that are at least 24 months of age are in the high risk sub-population.

Estimates for each of these components (X_i) can be calculated as the product of the sample prevalence rate (\hat{r}_i), the number of animals in each population (N_i), and an adjustment for the false negative test detection rate ($\frac{1}{1 - FN_i}$). Hence, the total number of BSE cases can be estimated as

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$$\hat{n}_{Total} = \sum_i \hat{r}_i \times N_i \times \frac{1}{1 - FN_i} \quad \text{Eq 1}$$

If we optimistically assume the false negative rate is zero, this approach and USDA’s proposed surveillance plan would be capable of detecting with 95% certainty a prevalence rate of 2.8×10^{-4} among the 6.2 million normal adult and high risk cattle that die each year (*i.e.*, 1,740 BSE cases). However, this interpretation of the data provides no insight regarding the prevalence rate among normal juveniles (see Table 2).

Table 2
95% Upper Confidence Limit on BSE Prevalence if no Animals Test Positive:
Estimates Based on Testing Only

| Population | Number of Positive Detects | 95% Upper Confidence Limit on r ^(a) | Number of Animals Slaughtered per Year | Assumed BSE False Negative Rate | 95% Upper Confidence Limit on n |
|--------------|----------------------------|--|--|---------------------------------|---------------------------------|
| HR | 0 of 268,444 | 7.3×10^{-6} | 446,000 | 0 | 3 |
| A | 0 of 10,000 | 3.0×10^{-4} | 5,800,000 | 0 | 1,736 |
| J | 0 of 0 | - | 30,000,000 | - | n_j |
| Total | | | | | 1,739 + n_j |

Notes:
 (a) Estimated using Cannon and Roe (1982).

The sensitivity of this approach could in theory be substantially increased by testing the same proportion of animals in each sub-population. For example, testing approximately 4.4% of the high risk animals and 4.4% of the normal adults, *i.e.*, 20,000 high risk animals and 258,000 normal adults, would be capable of detecting a BSE prevalence of around 2×10^{-5} (132 positive animals among the 6.2 million normal adult and high risk cattle) with 95% certainty. However, this result depends on the assumption that the false negative rate is zero. It also continues to ignore the normal juvenile sub-population.

While the assumption of a zero false negative rate may be reasonable for full blown cases that would presumably belong to the high risk sub-population, this assumption is likely to be very optimistic for other cattle. After an animal is infected with BSE, definitive post mortem tests for the presence of the agent yield false negative results until not long before clinical signs develop. Although it is not known precisely when these tests become effective, a reasonable estimate is

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three months prior to the development of clinical signs (personal communication, Lisa Ferguson, USDA APHIS, Veterinary Services, March 1, 2004).

We have estimated the false negative rates for normal adult and normal juvenile animals using a modified version of Harvard's BSE simulation model. This modified version of the model reports the characteristics of each BSE-positive animal that dies during the simulation. Characteristics reported include the animal's type (dairy, beef, beef reproductive), gender, age (months), months since the animal was infected with BSE, fraction of the incubation period elapsed at time of death, and death location (farm or slaughter facility). We assume that animals with BSE test negative if less than 90% of their incubation period has elapsed. We simulated the spread of BSE for 20 years following the introduction of contaminated feed (250 ID₅₀s) into the U.S.³ Our results indicate a false negative rate of 92% for normal adult cattle. For normal juvenile cattle, the false negative rate is 99.99%. Accounting for these false negative rates and the potential for BSE among normal juvenile animals suggests that the evaluating the surveillance data as described here is a relatively insensitive approach for detecting the presence of BSE in the U.S. cattle population.

Taking into account the false negative rates estimated in the previous paragraph (and continuing to ignore the normal juveniles for the moment) decreases the sensitivity of the "optimal" surveillance plan described earlier (20,000 high risk animals and 258,000 normal adults) so that only a BSE prevalence rate of 1.4×10^{-4} or greater can be detected.

2 Extrapolation of the BSE prevalence rate from the high risk sub-population to the normal sub-populations

The modeling approach described in this section uses empirical data or the Harvard BSE simulation to better characterize the relationship between BSE prevalence rates in different groups. In particular, we propose 1) estimating the number of BSE-positive animals in the high risk category using surveillance, and then 2) estimating the number of BSE-positive normal adults by scaling \hat{n}_{HR} by an estimate of the ratio of n_A to n_{HR} (designated $Q_{A:HR}$). Similarly, \hat{n}_J is estimated as $\hat{n}_{HR} \times Q_{J:HR}$. Hence, the total number of BSE-positive animals is estimated as

³ We simulated the introduction of contaminated feed, rather than the introduction of infected animals, because we did not want our results to be influenced by the characteristics of the animals introduced.

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$$\hat{n}_{Total} = \hat{r}_{HR} \times N_{HR} \times \frac{1}{1 - FN_{HR}} (1 + Q_{A:HR} + Q_{J:HR}). \quad \text{Eq 2}$$

We present two ways to estimate the values of $Q_{A:HR}$ and $Q_{J:HR}$. First, we can estimate these ratios using similar empirical values measured in other countries. In Switzerland, the BSE prevalence rate among fallen stock (FS) and emergency slaughter (ES) animals aggregated over the years 1999 and 2000 was approximately eight times greater than the BSE prevalence rate among routine slaughter animals. Recall that USDA's proposal to test approximately 268,000 high risk animals would be sufficiently powerful to establish that the prevalence rate is no more than 7.3×10^{-6} with 95% certainty. Assuming a zero false negative rate and applying the prevalence rate ratio of eight from the Swiss data, this result would imply a BSE prevalence rate of 9.1×10^{-7} among normal adult cattle ($7.3 \times 10^{-6} \div 8$). This rate corresponds to a total prevalence among normal adult cattle of approximately 5 BSE cases (5.8 million $\times 9.1 \times 10^{-7}$). The Swiss data do not provide any information on the BSE prevalence rate among juvenile cattle. Nor do they take into account the potential for a higher false negative rate among normal adult cattle than among high risk cattle. Finally, as noted earlier, differences in agricultural practices across countries make extrapolation of results from Switzerland to the U.S. uncertain.

An alternative approach for estimating $Q_{A:HR}$ and $Q_{J:HR}$ uses the modified version of Harvard's BSE simulation model described earlier in this memo. We again consider the characteristics of cattle infected with BSE at the time of their death following the introduction of 250 ID₅₀s into cattle feed. Table 3 summarizes the distribution of values for $Q_{A:HR}$ and $Q_{J:HR}$ based on 1,000 simulation runs. We provide two sets of distributions. The first set of distributions pertains to the total BSE prevalence rate – *i.e.*, including all animals infected with BSE even if laboratory testing would be incapable of detecting the presence of the disease. The second set of distributions pertains to the prevalence of detectable BSE only. It is the second set of distributions that is relevant for the purpose of comparing U.S. prevalence to other countries because other countries estimate only the rate of detectable BSE in their cattle populations.

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Table 3
Summary Statistics for the BSE Prevalence Ratios

| Fractile | Total BSE Prevalence | | Prevalence Among Normal Adults and Juveniles of Detectable BSE Only | |
|------------------|----------------------|------------|---|----------------------|
| | $Q_{A:HR}$ | $Q_{J:HR}$ | $Q_{A:HR}^{(a)}$ | $Q_{J:HR}^{(b)}$ |
| 5 th | 0.42 | 1.55 | 0.034 | 1.5×10^{-4} |
| 10 th | 0.50 | 1.82 | 0.040 | 1.8×10^{-4} |
| 25 th | 0.73 | 2.29 | 0.058 | 2.3×10^{-4} |
| 50 th | 1.00 | 3.00 | 0.080 | 3.0×10^{-4} |
| 75 th | 1.50 | 4.20 | 0.12 | 4.2×10^{-4} |
| 90 th | 2.25 | 6.25 | 0.18 | 6.3×10^{-4} |
| 95 th | 3.00 | 8.33 | 0.24 | 8.3×10^{-4} |

Notes:

- (a) Assumes a false negative rate of 92%.
 (b) Assumes a false negative rate of 99.99%.

Estimating the total BSE prevalence

Using the median values from columns 2 and 3 of Table 3 in Equation 2, along with the assumption that the false negative rate is zero for BSE-positive cases in the high risk group, testing 268,000 animals from the high risk group would be capable of detecting a BSE prevalence (\times) of around 16 with 95% certainty ($3.25 \times (1 + 1.0 + 3.0)$). Using the upper 95th percentile values for these ratios yields an upper bound for (\times) of around 40 ($3.25 \times (1 + 3.0 + 8.3)$). Because the total number of animals slaughtered in the U.S. each year is approximately 35 million, 40 animals corresponds to a prevalence rate one per one million cattle that die or are slaughtered. More refined bounds could be calculating by developing estimates for $Q_{A:HR}$ and $Q_{J:HR}$ using more realistic scenarios for the introduction of BSE into the U.S. and by establishing a more relevant time horizon for the simulation.

Estimating the prevalence of detectable BSE

Using the median ratios in columns 4 and 5 of Table 3 in Equation 2, testing 268,000 animals from the high risk group can detect a prevalence of approximately 3 with 95% certainty, a level that corresponds to a prevalence rate of approximately 1 per 10 million cattle that die or

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are slaughtered. Even the upper bound estimates from columns 4 and 5 yield virtually the same result.

While the ratios in columns 4 and 5 of Table 3 are most appropriate for comparing the prevalence of BSE in the U.S. to the BSE prevalence in other countries, it is reasonable to ask what level of risk (to humans or other cattle) the non-detectable cases might pose. Using the simulation described earlier, we estimate that the average infectivity loads in normal juveniles and normal adults that have non-detectable BSE are approximately 120 and 130 cattle oral ID₅₀s, respectively. Because they are slaughtered at a young age, there are virtually no juveniles that reach the detectable stage of the disease. However, among normal adults that reach the detectable stage, the infectivity load is more than 20 times greater (average of 2,800 cattle oral ID₅₀s). Of course, the average infectivity load in animals that reach full clinical status is higher still, at 10,000 cattle oral ID₅₀s.

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Mr. GOODLATTE. Thank you, Dr. Gray.
Dr. Lurie, welcome.

**STATEMENT OF PETER G. LURIE, DEPUTY DIRECTOR, PUBLIC
CITIZEN'S HEALTH RESEARCH GROUP**

Dr. LURIE. Thank you. Like Dr. Gray, I too am going to make three points.

The first is that the previous and, indeed, the now proposed surveillance system has never been able to detect BSE at the level claimed; it was never able to detect BSE at the level of one in a million adult cattle. And the now proposed one will not be able to do so at the level of 1 in 10 million cattle, as claimed.

The second is that although important to remove downer cattle and other high-risk cattle from human consumption, the contribution in terms of reducing the overall risk of BSE exposure to human beings is quite limited and not as high, I think, as has been implied by USDA.

And, finally, as the IG has very well documented, the system has been characterized by inconsistent sampling of downer cattle and still more risky CNS cattle, as well, as we now learn, the rabies negative cattle, and we don't think there has been adequate geographical distribution, either.

On the first point, the USDA has claimed on its surveillance Web site in the past that it could detect the disease at a level of 1 or more cases per million in the adult population, and they now reiterate that with respect to 1 in 10 million at the 95 percent confidence interval for the new expanded program. Both claims, it has been very clear today, rest on the false assumption that there are literally no cows likely to turn up positive in the normal appearing animal population. Dr. Gray has just said that is not the case, the IG has said that is not the case, and, indeed, from what I can understand, Secretary Veneman herself is now backing off from the claim of 1 in 10 million, and it is none too soon.

It is certainly true that the risk for BSE is higher in the downer than in the non-downer cattle; there is no question about that. The question, though is if literally all of the risk is located among the downer or other high-risk animals. In fact, 287 normal appearing cattle tested positive for BSE in Europe in 2002. So although Dr. Collins, I believe his name was, says there is debate about the extent of the risk among the lower risk animals, one thing that there is no debate about is that the USDA's assumption is absolutely false, i.e., that it is zero risk. Nobody endorses that position, yet that is precisely the assumption upon which the 1 in 10 million and 1 in 1 million, previously, estimates have been based.

Let me draw your attention quickly to a graph that I have attached to my testimony and try to walk you through it. The way this works is along what I would call the X axis, the bottom part, you learn that if the risk of downer and high-risk animals is 500 times higher than that among normal appearing animals, most of the risk for BSE does in fact appear in the high-risk category, about 83 percent of all risk. However, as you move to the left, lower and lower fractions of the total BSE risk are among the downer and high-risk animals. We based our estimates on the data from Europe, where there is a 31-fold increased risk among the high-risk

animals compared to the lower risk ones, something similar to what Dr. Gray has done. In fact, if anything, we have been conservative in so doing. And what that arrow shows, using the European data, which, after all, are the only data we can use because there are no comparable American data, is that only 24 percent of the total risk is among the higher risk animals.

There are two implications to this. The first I have already stated repeatedly, which is that the 1 in 10 million assurance is false. The second is that by removing downer cattle from consumption, again, a good move, you have only had a limited impact upon the overall risk of U.S. humans for contracting BSE.

I almost don't need to say much about the problems that have been portrayed by the IG with respect to the implementation of this program because I think that she has done a very good job of them, but we ourselves have done a study back in 2001 in which we showed a 600-fold difference in the rates of testing among dairy cattle for BSE, from the highest state compared to the lowest state in terms of rates, so a truly massive variation in terms of the rates of testing by state, when they should be approximately equal.

Much has been said about the case in Texas, I don't think I need to reiterate that. The case in Washington, all of these indicate that there are questions about the implementation of the program, in addition to the way risk communication has occurred.

In sum, then, there is much about the design of USDA's expanded surveillance program that is praiseworthy. The focus on high-risk animals, not the exclusive focus, but the general focus on high-risk animals is a good thing, as is the greatly increased number of tests, the expansion of testing to include 20,000 normal appearing animals, and the approval of more rapid testing technologies. But the program has also been riddled with deficiencies in the risk communication and implementation fields. After all, this is a program, we have heard, that is not random, has incorrectly estimated a 1 in 10 million risk, by removing the downer cattle has only removed about 24 percent of the risk in the targeted population, has missed 55 percent of cattle with CNS symptoms, has missed 84 percent of those that are negative for rabies, and appears not to be geographically distributed. If the public and potential importers of U.S. cattle and cow products are to be reassured, it can only be on the basis of accurate scientific information, rather than the false or misleading information that has represented a significant portion of the USDA response to date.

Thank you.

[The prepared statement of Dr. Lurie follows:]

Testimony of Peter Lurie, MD, MPH
Deputy Director
Public Citizen's Health Research Group
on Mad Cow Disease Surveillance
before a Joint Meeting of the
United States House of Representatives
Committee on Government Reform and Committee on Agriculture
July 14, 2004

Any consideration of the prevention of bovine spongiform encephalopathy (BSE) in the United States must begin by acknowledging that the two most important firewalls against the disease are a) the ban on the importation of ruminants from countries with cases of BSE; and b) the ban on the feeding of certain animal parts to ruminants (the feed ban). Unfortunately neither firewall has been adequately in place. It has become clear that, even while the U.S. Department of Agriculture (USDA) claimed to be considering whether or not to allow processed beef into the United States from Canada, where two cattle appear to have acquired BSE, the agency was routinely permitting the importation of such beef.¹ And while the Food and Drug Administration (FDA) claimed in January that it would be eliminating such unjustified exemptions to the ruminant feed ban as chicken litter (spilled feed, bedding, feathers and fecal matter from poultry) and plate waste (uneaten meat and other meat scraps rendered into animal feed) in the form of a soon-to-be-issued Interim Final Rule,² consideration of these exemptions has now been relegated to the status of an Advance Notice of Proposed Rulemaking³ and thus is unlikely to be finalized for months, if not years.

The USDA's Expanded Surveillance Program⁴ must be seen in this context. The purpose of this plan and its predecessor is to quantify the extent of any BSE outbreak, not to prevent disease *per se* (as witnessed by the now-abandoned practice of allowing most cattle with pending BSE tests to enter the food supply). Of course, quantifying any outbreak provides the basic raw data for later efforts to prevent further disease. Critical elements of any surveillance program include a) proper communication of its limits to the public; and b) consistent implementation of the program as designed. In both respects, USDA's efforts to date have been lacking. In particular,

1. The previous surveillance system was never able to detect BSE if it was present in only one in a million adult cattle, as the USDA has claimed; the Expanded Surveillance Program will be similarly unable to detect BSE if it is present in one in 10 million adult cattle, as the USDA now claims.
2. The removal of non-ambulatory ("downer") cattle from the human food supply will not greatly reduce the risk to humans.
3. The previous surveillance system was characterized by inconsistent sampling of downer cattle or the still-more-risky cattle with central nervous system (CNS) disease, and appears not to have obtained adequate geographical representation.

The USDA has claimed on its surveillance website⁵ that the agency's previous surveillance system "should allow detection of a case if BSE truly exists at a level of one or more cases per million in the adult cattle population," a claim reiterated repeatedly by USDA officials in the aftermath of the Washington BSE case. Now, with expanded surveillance, the agency claims that "Assuming all the BSE positive cattle are part of the high risk population," this new "level of sampling would allow us to detect BSE at a rate of 1 positive in 10 million adult cattle at a 95 percent confidence level."⁴ Both claims rest on a false assumption which has been rebutted by testing data from Europe, some of which actually appear on the USDA website.

It is certainly true that the risk of BSE is higher in downer than in non-downer cattle; this has been the justification for the USDA BSE surveillance program's particular focus to date on downer cattle. But the USDA has gone further and assumed that *all* BSE infections that might exist in the United States would occur in the downer/high-risk population. In fact, data from the European Commission demonstrate that 287 normal-appearing cattle tested positive for BSE in Europe in 2002.⁶ While the fraction of normal-appearing cattle that tested positive for BSE in Europe was predictably lower than that fraction in the downer population (the same should be true domestically), there are approximately 100 times more normal-appearing adult animals than there are downer/high-risk animals in the United States (446,000 downer/high-risk animals among 45 million adult cattle).⁴ Thus, unless the risk of BSE among downer/high-risk animals is *much* higher than that among normal-appearing animals, there can actually be substantially more BSE risk among normal-appearing animals than among downer/high-risk animals. By analogy, a higher fraction of drivers of red sports cars may be at risk of incurring or causing injury than drivers of other cars, but most injuries do not involve red sports car drivers.

The attached figure illustrates this point. Based on the USDA's data on the number of animals in the downer/high-risk population, we have constructed a curve that demonstrates how the fraction of total BSE risk that exists among downer/high-risk cattle varies according to how many times more risky such cattle are than normal-appearing cattle. If, for example, downer/high-risk cattle are 500 times more at risk for BSE than normal-appearing cattle, 83% of all BSE cases would be expected among downer/high-risk cattle and a policy of excluding all downer/high-risk cattle would have a significant impact in reducing BSE risk to humans. On the other hand, if downers and other high-risk animals were only five times more risky, only 5% of the risk would be among those animals. Actual testing data from Europe,⁶ not adjusted for animal age, suggest that we are closer to the latter than the former: cattle populations analogous to what are termed downer cattle in the United States have a BSE prevalence 31 times higher than non-downer cattle.* If this ratio is applied (rather than the USDA's assumption that there is no risk whatsoever among normal-appearing animals and that the ratio is therefore infinite), we can see from the figure (indicated by the arrow) that only an estimated 24% of the total U.S. risk occurs among downer/high-risk animals, with the remaining 76% occurring among the normal-appearing cattle that, until recently, were not being tested in the United States.

* Due to lack of specific-enough data, this testimony assumes that the prevalence of BSE in downer animals is about equal to that in other high-risk animals.

This observation has two main implications. First, the USDA claim that testing to date could detect BSE at a level of one in a million adult cattle was false as is the analogous claim that the Expanded Surveillance Plan could detect BSE at a level of one in 10 million adult cattle, because both claims rest on the same false assumption. In order to truly be able to detect the one in 10 million risk, some mix of downer/high-risk and significantly more testing of normal-appearing animals would be necessary.

The numbers are daunting. If the USDA-proposed 20,000 tests over approximately one year on normal-appearing cattle are all negative, one can still only assume (at the 95% confidence level standard in such calculations) that BSE does not exist at a prevalence exceeding 150 per million. If we apply that proportion to the 12% of the 35.7 million cattle slaughtered annually in the United States⁷ that are over the age of 20 months⁵ (the age above which all BSE cases worldwide have been detected), that would still mean as many as 643 infected cattle of that age could proceed to market that year without a single case being detected.

To completely eliminate BSE risk would require the testing of all cattle (or at least those over 20-30 months). Testing as many downer/high-risk animals as possible, combined with testing a large number of older normal-appearing cattle, as the USDA is currently proposing, will generate a more informative estimate of the extent of the disease. This approach is consistent with that recommended by the USDA's international subcommittee,⁸ the U.S. Food and Drug Administration's (FDA's) Transmissible Spongiform Encephalopathy Advisory Committee⁹ and an editorial in the *New England Journal of Medicine*.¹⁰

The second implication is that although removing downer/high-risk cattle from human consumption was appropriate because these animals are more risky, the overall risk to the public was only slightly reduced by this measure because only 24% of the risk resides in the downer/high-risk population. The benefit of removing downer/high-risk cattle from human consumption has, in our view, been oversold as a public health protection measure. Strong enforcement of the FDA's feed ban, the import ban and the removal of risky material from human consumption remain our primary protections against this disease.

We acknowledge that our calculations are based on data collected in Europe, which might, in theory, differ from data collected in the United States. But there is simply no alternative to using the European data to generate estimates as analogous U.S. data do not exist. One cannot calculate the ratio of the fraction of infected downer/high-risk animals to the fraction of infected normal-appearing animals when no indigenous cases in the United States have ever been found. It is better to use available European data, where BSE experience is greatest, to make an estimate than to insist, as the USDA does, that this ratio is equal to infinity, even while acknowledging on its website that this is not true. It is noteworthy that this limitation of the surveillance programs has been raised by the Harvard Center on Risk Analysis.¹¹ In its review of the Expanded Surveillance Plan, the Center observed discretely "However, because there may be BSE-infected animals in the normal adult and normal juvenile populations, a more rigorous set of assumptions must be developed to estimate a prevalence for the entire population." In Harvard's statistical

estimates, their base case scenario used a value of eight for the ratio of the downer/high-risk animal infection rate to the rate among normal-appearing animals, based on Swiss data;¹² our analysis is based on data from all of Europe and actually leads to a more conservative analysis.*

In addition to these risk communication problems, USDA's surveillance program has been plagued by poor administration. In 2001, we conducted a study comparing the rates of BSE testing across states.¹³ Instead of finding approximately equal testing rates, we found a 600-fold difference between the states with the highest and lowest testing rates for dairy cattle (an older population and thus of particular interest), suggesting a program in disarray. (While some of this difference might be accounted for by the movement of cattle to other states for the purposes of slaughter, this is unlikely to explain the massive variations we observed, particularly when, as the USDA itself has assumed in its Expanded Surveillance Plan "most of these animals will not be moved significant distances (that is, most rendering or salvage facilities collect animals from a limited geographical area)."¹⁴

Furthermore, there appears to be no accepted procedure for deciding which animals to test, a point echoed in the dispute over whether the Washington BSE case was a downer animal.^{14,15} Press reports indicate that no BSE testing was conducted in the entire state of Washington in the first seven months of 2003.¹⁶ The case in Texas, where, apparently due to a decision by a USDA official not at the plant, even an animal with CNS symptoms was not tested,¹⁷ only highlights these concerns because CNS animals are the most high-risk of all cattle. Finally, some USDA inspectors have testified that the industry itself selects the cattle brains for testing.¹⁸

The Washington case has also highlighted the major deficiencies in our ability to track livestock. Only 29 of the 81 cattle in the same herd as the index BSE case could be located by the USDA investigation.¹⁹ A comprehensive, mandatory life-long tracking system must be implemented as soon as possible. However, now that downer cattle have been removed from human consumption, farmers have an incentive to bury suspect animals on the farm, without notifying the USDA. Therefore, farmers should be compensated for providing their downer animals for testing and heavy penalties should be provided for any attempts to elude testing once an on-farm surveillance system is in place.

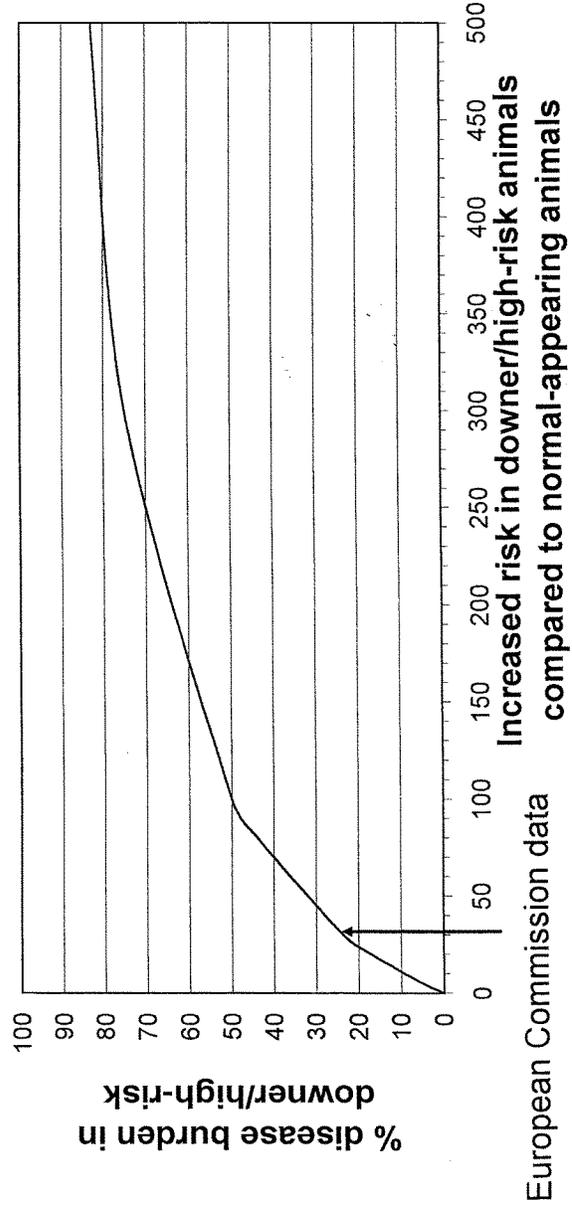
There is much about the design of the USDA's Expanded Surveillance Program that is praiseworthy: the focus on high-risk animals, the greatly increased numbers of tests, the expansion of testing to include 20,000 normal-appearing animals and the approval of more rapid testing technologies. But, the program to date has been riddled with deficiencies in the risk communication and implementation spheres. In contrast to

* An additional problem for any BSE surveillance program is that there are certain (primarily younger) cattle that may be infected but cannot be detected by any currently available test. Fortunately, these animals are considerably less infectious. Such animals might develop symptoms of BSE or become downer animals should they live long enough. But our calculations do not address this additional problem of undetectable BSE infection, because they are based on actual tests that have been conducted in the field (detectable BSE).

what the USDA has repeatedly claimed or implied, the infected animal in Washington was probably not a downer (if it was, the claims for the effectiveness of the surveillance system would seem more credible), the previous surveillance system could not detect the one in a million risk and the Expanded Surveillance System will not detect a one in 10 million risk, the removal of downer animals from human food will have only a small protective effect on the safety of the food supply and the program has been implemented in an inconsistent fashion. If the public and potential importers of U.S. cattle and cattle products are to be reassured, it can only be on the basis of accurate scientific information, rather than the false or misleading information that has represented a significant portion of the USDA response to date.

- ¹ Kaufman M. USDA allowed Canadian beef in despite ban. Washington Post, May 20, 2004, p. A1.
- ² Expanded "mad cow" safeguards announced to strengthen existing firewalls against BSE transmission. U.S. Department of Health and Human Services Press Release, January 26, 2004. Available at: <http://www.hhs.gov/news/press/2004pres/20040126.html>.
- ³ Federal measures to mitigate BSE risks: considerations for further action (Advance Notice of Proposed Rulemaking), July 9, 2004. Available at: <http://www.fda.gov/OHRMS/DOCKETS/98fr/04n-0264-nap0001.pdf>.
- ⁴ Bovine Spongiform Encephalopathy (BSE) Surveillance Plan. US Department of Agriculture. March 15, 2004. Available at: http://www.aphis.usda.gov/lpa/issues/bse/BSE_Surveil_Plan03-15-04.pdf.
- ⁵ Bovine spongiform encephalopathy: surveillance. US Department of Agriculture. Available at: <http://cofcs66.aphis.usda.gov/lpa/issues/bse/bse-surveillance.html>.
- ⁶ Health and Consumer Protection Directorate-General. Report on the Monitoring and Testing of Ruminants for the Presence of Transmissible Spongiform Encephalopathy (TSE) in 2002. European Commission, June 2003. Available at: http://www.europa.eu.int/comm/food/fs/bse/testing/annual_report_2002_en.pdf.
- ⁷ National Agricultural Statistics Service. http://www.usda.gov/nass/pubs/agr03/03_ch7.pdf.
- ⁸ Kihm U, Hueston W, Matthews D, MacDiarmid SC, Heim D. Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States. Available at: http://www.aphis.usda.gov/lpa/issues/bse/US_BSE_Report.pdf.
- ⁹ Ault A. Federal panel recommends more testing for mad cow. New York Times, February 14, 2004.
- ¹⁰ Donnelly CA. Bovine spongiform encephalopathy in the United States – an epidemiologist's view. New England Journal of Medicine 2004;365:539-42.
- ¹¹ Food Chemical News, March 22, 2004 (BSE News).
- ¹² Cohen J, Gray G. Comments on USDA bovine spongiform encephalopathy (BSE) surveillance plan. Harvard Center for Risk Analysis, March 12, 2004. Available at: http://www.aphis.usda.gov/lpa/issues/bse/BSE_Harvard03-12-04.pdf.
- ¹³ Public Citizen and Government Accountability Project. USDA'S Mad Cow Disease Surveillance Program: A Comparison of State Cattle-Testing Rates. Available at: <http://www.citizen.org/publications/release.cfm?ID=6783>.
- ¹⁴ McNeil DG. Man who killed mad cow has questions of his own. New York Times, February 3, 2004.
- ¹⁵ Davis T, Waxman HA. Letter to USDA Secretary Ann Veneman. Committee on Government Reform, U.S. House of Representatives, February 17, 2004.
- ¹⁶ Mitchell S. UPI exclusive: no mad cow tests in Wash. United Press International, January 15, 2004.
- ¹⁷ Kilman S. U.S. confirms a failure to use mad-cow test. Wall Street Journal, May 4, 2004, p. A6.
- ¹⁸ Carney P. Affidavit. January 14, 2004. Available at: <http://www.citizen.org/documents/paulcarneyaffidavit.pdf>.
- ¹⁹ Final BSE update. US Department of Agriculture, February 9, 2004. Available at: <http://www.usda.gov/Newsroom/0074.04.html>.

Downer/High-Risk Disease Burden According to their Relative Risk for BSE



Chairman GOODLATTE. Thank you, Dr. Lurie.
Mr. Hodges, welcome.

**STATEMENT OF JIM HODGES, PRESIDENT, AMERICAN MEAT
INSTITUTE FOUNDATION**

Mr. HODGES. Thank you, Mr. Chairman.

A review of some basic facts is necessary in order to understand the purpose and adequacy of any BSE surveillance program. Erroneous comparisons have been drawn between the United States and Europe with respect to the risk of BSE and its animal health consequences. The facts show that the U.S. risk is many orders of magnitude lower than Europe's. More than 180,000 cases of BSE have been diagnosed in cattle since the disease was first discovered in the U.K. in 1986. At the height of the epidemic, in 1992, more than 1,000 cases per week were being diagnosed, and that is only the diagnosed cases. Experts have estimated that between 3 and 4 million cases of BSE actually occurred, and that is compared to 2 cases of BSE in North America, both of which were determined to be of Canadian origin.

Potential human exposure to the BSE infective agent in the United States is exceedingly small. The United States is not Europe. We will not experience the animal disease epidemic or the number of human illnesses that occurred in the U.K. because we took preventative steps to protect both human and animal health.

Considerable debate has ensued regarding how best to protect the public. The first objective is to prevent the introduction and spread of the disease in the cattle population. To that end, firewalls have been constructed, as you have heard earlier today, to protect the U.S. cattle herd. Import restrictions on countries that have BSE were first put in place in 1989. In 1990, the United States was the first country in the world to implement an animal disease surveillance program when the disease was not known to exist in this country. A precautionary ruminant-to-ruminant feed ban was implemented in 1997 to prevent the amplification and spread of the disease in our cattle herds.

Those firewalls have been significantly strengthened in recent months. All slaughter facilities must now remove potentially infectious material, or the so-called specified risk material. Experts from around the world agree that removing SRM from the food supply is the most effective means to protect public health.

An effective surveillance program is a necessary component of an effective animal disease prevention program, but it is not a food safety program. Testing cannot guarantee that BSE is not present in the animal, nor can testing protect public health. All of the laboratory methods currently used can only detect the disease a maximum of 6 months prior to the clinical onset of the disease where visible signs of the disease can be observed. Testing young animals under 30 months of age is scientifically indefensible. In fact, one leading BSE expert said that testing young animals constitutes veterinary malpractice.

Given the average age of clinical onset of the disease is 4 to 7 years, and the limits of testing methods, the U.S. surveillance program is appropriately focused on the cattle population that is most likely to exhibit the disease. To illustrate, as Dr. Gray did earlier,

data from Europe show that approximately 1 in 4 animals that show clinical signs of a central nervous system disorder test positive; in the emergency slaughter and fallen stock, or what we would term dead or downers, it is approximately 1,000; and for the older, normal appearing animals, approximately 1 in 30,000 test positive. Let me make clear, however, that the industry supports a robust animal disease surveillance program. If the disease is present in the United States, we want to know it. It is a very important way that we can effectively determine if our BSE prevention measures are working properly.

The appropriate level of animal disease surveillance is a matter of how much confidence you need or want in the data, or stated differently, how much sampling error are you willing to tolerate. At the projected sampling rate of approximately 270,000 animals in the high-risk population, we would be able to detect the disease if it exists in more than 1 in 10 million animals in the target population with a 99 percent confidence level. That is a high degree of statistical confidence that greatly exceeds world animal health standards.

Critics of the USDA's surveillance program have focused on a lack of random sampling, poor geographical distribution, and an inability to determine an accurate prevalence rate. These criticisms might be justified if the USDA were collecting data for a peer-reviewed scientific journal article, but this is not an academic exercise; it is an ongoing animal disease surveillance program. The objective is to sample as many animals as possible in the cattle population that is most likely to exhibit the disease. The dead and downer category is estimated at approximately 440,000. USDA plans to sample in excess of 200,000 head, or about one-half of this high-risk population. If BSE exists in our domestic herd, we will find it.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Hodges follows:]

TESTIMONY OF JAMES HODGES

Thank you for inviting me to testify at this joint hearing on the U.S. Department of Agriculture's Bovine Spongiform Encephalopathy (BSE) Surveillance Program. I am honored to be a part of this distinguished panel.

BSE has garnered considerable attention since the first indigenous cases of BSE in North America were diagnosed in Alberta, Canada on May 20, 2003 and Washington State on December 23, 2003. A review of some basic facts is necessary in order to understand the purpose and adequacy of any BSE surveillance program.

Comparisons have been drawn between the U.S. and Europe with respect to the risk of BSE and its animal and human health consequences. The U.S. remains a very low risk country in comparison to many countries around the world. Despite speculation to the contrary, the facts show that our risk level is many orders of magnitude lower than Europe's.

More than 180,000 cases of BSE have been diagnosed in cattle since the disease was first discovered in the United Kingdom in 1986. And more than 95 percent of the cases worldwide have occurred in the U.K. At the height of the epidemic in 1992 more than a 1,000 cases per week were being diagnosed. In 1992 alone, more than 36,000 cases were diagnosed. And that's only the diagnosed cases. Experts have estimated that between 3 and 4 million cases of BSE actually occurred. That's compared to two cases of BSE in North America, both of which were determined to be of Canadian origin.

Fortunately, the number of BSE cases in the U.K. has declined every year since 1992. The epidemic appears to be drawing to a close with approximately 1,200 BSE cases being diagnosed worldwide last year.

Unfortunately, British citizens were exposed to massive doses of the infective agent during the early years of the epidemic. Even given this massive exposure, slightly more than 150 human illnesses in the world have been attributed to the BSE agent. The number of variant Creutzfeldt-Jakob disease (vCJD) illnesses has declined for four consecutive years and only one case of vCJD was reported last year.

Bottom line: Potential human exposure to the BSE infective agent in the U.S. is exceedingly small compared to the massive human exposure that occurred in the U.K. The U.S. is not Europe. We will not experience the animal disease epidemic or the number of human illnesses that occurred in the U.K. because we took preventive steps to protect both human and animal health. For more than 15 years, we have learned and adopted interventions based on the U.K.'s experience.

Even though the public health risk from BSE in the U.S. is exceedingly small, considerable debate has ensued regarding how best to protect the public. The first objective is to prevent the introduction and spread of the disease in the cattle population. If the disease does not enter and reside in the cattle population, then a significant level of human health protection is achieved.

To that end, firewalls have been constructed to protect the U.S. cattle herds. Import restrictions on countries that have BSE were first put in place in 1989. In 1990, the U.S. was the first country in the world to implement an animal disease surveillance program when the disease was not known to exist in this country. And a precautionary ruminant-to-ruminant feed ban was implemented in 1997 to prevent the amplification and spread of the disease in our cattle herds. Those firewalls have been significantly strengthened since December 23, 2003 when a case of BSE was diagnosed in Washington State.

Most importantly, for consumer health protection, all slaughter facilities in the U.S. must now remove potentially infectious material, the so-called specified risk materials or SRMs, from the food supply. Experts from around the world agree that removing SRM from the food supply is the most effective means to protect public health.

Only SRMs have been shown to be vectors of the infective agent, beef muscle has not. In the event additional BSE cases are diagnosed in North America, effective SRM removal prevents human exposure to the infective agent. Without exposure there is no human illness.

As an added precaution, animals most likely to harbor the disease—clinical suspects and non-ambulatory or downer animals—are prevented from entering the food supply.

I provide this background to highlight the point that an effective surveillance program is a necessary component of an effective animal disease prevention program, but it is not a food safety program. Testing cannot guarantee that BSE is not present in the animal, nor can testing protect public health. Removal of SRM protects public health.

Existing BSE testing methods have limitations. All of the laboratory methods currently used can only detect the disease a maximum of six months prior to clinical onset of the disease where visible signs of the disease can be observed.

BSE has an extremely long incubation period before clinical signs can be observed. The youngest case diagnosed last year in Europe occurred in an animal that was 50 months of age. The disease could not have been detected with existing testing methods until the animal was almost four years old. Testing young animals is scientifically indefensible. In fact, one leading BSE expert said that testing young animals constitutes veterinary malpractice.

Given the average age of clinical onset is 4 to 7 years and the limits of testing methods, you can readily see why the USDA surveillance program is appropriately focused on the cattle population that is most likely to exhibit the disease. To illustrate, 2002 data from the European Union shows that approximately 1 in 4 animals that show clinical signs of a central nervous system disorder, test positive. In the emergency slaughter and fallen stock category, or what we would term dead and downer, approximately 1 in 1,000 tested positive. For older, normal appearing animals, approximately 1 in 30,000 tested positive.

It should be noted that a higher level of infectivity is present in the European cattle population when compared to the U.S. herds. We would expect cattle in Europe to be diagnosed at a younger average age than in the U.S. since the age of clinical onset is inversely proportional to the infective dose. So you can see that testing young animals under 30 months of age—which make up more than 80 percent of our domestic slaughter—provides no reliable information for determining the prevalence of BSE in the cattle population or for enhancing our animal disease surveillance program.

Let me make clear, however, that the industry supports a robust animal disease surveillance program. If the disease is present in the U.S. we want to know it and we want to know its prevalence. That's a very important way we can effectively determine if our BSE prevention measures are working properly.

You might ask, "Why don't we test all older animals over 30 months of age as is done in most of Europe?" The answer is very simple. Europe's decision was not made based solely on the scientific evidence. Europe, and even more so Japan, over reacted to a severe loss of consumer confidence in its government institutions to protect them from harm. Large scale testing was implemented to regain consumer's confidence and to provide cover for the politicians. In contrast, U.S. consumers have maintained a high level of confidence in U.S. beef safety.

From a scientific perspective, the appropriate level of animal disease surveillance is a matter of how much confidence you need or want in the data. Or stated differently, how much sampling error are you willing to tolerate. At the projected sampling rate of approximately 270,000 animals in the high-risk cattle populations, we would be able to detect the disease if it exists in more than 1 in 10 million animals in the target population with a 99 percent confidence level. That's a high degree of statistical confidence that greatly exceeds recommended world animal health standards.

In closing, I would like to emphasize three points. First, the risk of BSE in U.S. cattle is very low and the risk to human health from BSE is even lower. This fact has been confirmed by numerous risk assessments. Second, sound scientific principles and reliable data must underpin all of our preventive control measures. To do otherwise endangers the credibility of all our institutions. Finally, a robust animal disease surveillance program is an integral part of our BSE preventative control measures but it is not a food safety program.

Thank you for inviting me to present the meat industry's views on BSE testing and surveillance.

Chairman GOODLATTE. Thank you, Mr. Hodges.

Dr. Weber, welcome.

STATEMENT OF GARY M. WEBER, EXECUTIVE DIRECTOR, REGULATORY AFFAIRS, NATIONAL CATTLEMEN'S BEEF ASSOCIATION

Mr. WEBER. Thank you. It is a pleasure to be here, and we appreciate this opportunity to share our perspectives with this organization, this committee, this process, as we have engaged in it many times in the past.

And I think just to reiterate, rather than go through a redundancy, all of the things the United States has done since 1989, it is important, though, to reference that these steps were taken before we have ever had the disease, and we are the first country in the world to take that kind of an aggressive approach.

I have enclosed a timeline in my testimony which clearly illustrates how different the United States has been, how proactive we have been in preventing BSE. And so from that perspective we enter this discussion about surveillance from a position of being proactive.

This program, as I said, began in 1989, and it has been supported and expanded and analyzed by both democratic and republican administrations, and so we are in this mode now of analyzing a surveillance program that is built upon a long history of being aggressive and proactive. This expanded BSE surveillance program represents one recommended by an International Review Team, supported by the international animal health scientific community, supported by risk analysis experts, and we support it being developed and implemented fully.

Obviously, we had a case of BSE, it was of Canadian origin, and the International Review Team, in recognizing this, still suggested

that we expand the surveillance program to confirm our assumptions that have been made in previous risk assessments that the disease prevalence in the United States is very low. And, indeed, as experts have determined, if it is present, we believe that the current feed restrictions, as they are being fully enforced, are in the process of eradicating the disease if it were present. So as others have said, we support this expanded testing program.

There has been a lot of discussion about whether it is absolutely capable of determining this level of 1 in 10 million, but in the animal health arena it is important to recognize that we are estimating the prevalence of a disease. That estimate will work its way into other risk assessments and analysis of whether additional measures need to be taken. It is just an estimate, it is not meant to be an absolute, and we support a process that can reach a desired level of surveillance that we can feel confident in, and we believe this program will do that.

Under the current surveillance program, the USDA has established an outstanding network of approved laboratories that will contribute to the national BSE surveillance effort. It is important to review that it is our understanding that these laboratories are using a rapid test that is used in many countries. It is an automated system, the ones that are currently in place in the seven laboratories, and that it does have very high sensitivity that can produce a fairly high level of inconclusive test results that have to be proven by the gold standard, whether or not they are actually BSE or not, and that is the immunohistochemistry method. And we, again, support this process of looking at inconclusives. All of these samples are sent to our National Veterinary Services Laboratory in Ames, IA, and, again, we support the transparent process that is underway here.

The only issue we have with USDA and the laboratories is that we want to make sure that the laboratories are using the best quality assurance program possible to ensure the quality of test results. We don't want to miss any true inconclusives, but we also do not want to have a high number of such results that are reported simply on the fact that normal variations of operation in the lab systems, because this does have an effect on our markets and on consumers. To date, consumers remain completely confident in our system, as evidenced by beef demand, and we want to continue that, and we believe we are building on a foundation that USDA has helped establish of that confidence; we want to continue doing that.

The NCBA has offered our support in ensuring that USDA has access to as many animals in the targeted risk population as possible. Data from this expanded surveillance program will be important for many reasons. These estimates will provide data to our longstanding programs, the analysis of those, and I think it will show that staying on the course that we have established since 1989 will continue to protect animal health. And it is important to note that public health is protected by the SRM removal practices. The removal of animals from the downer/dead/disease population from the human food supply is an appropriate additional safeguard. The NCBA will continue to analyze the situation as the sur-

veillance program works forward and determine what, if any, additional science risk-based measures are necessary.

Thank you again for this opportunity to share our views with you, and I look forward to your questions.

[The prepared statement of Mr. Weber follows:]



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Comments Presented to the House Committee on Government Reform
and the Committee on Agriculture

Hearing on

The U.S. Department of Agriculture's Bovine Spongiform Encephalopathy

Expanded Surveillance Program Plan

On Behalf of

The National Cattlemen's Beef Association

Wednesday, July 14, 2004

Washington, D.C.

By

Gary M. Weber, Ph.D. Executive Director, Regulatory Affairs

National Cattlemen's Beef Association

AMERICA'S CATTLE INDUSTRY

Denver Washington D.C. Chicago

Mr. Chairman and members of the Committee, I am Gary Weber, Ph.D., Executive Director Regulatory Affairs for the National Cattlemen's Beef Association. The National Cattlemen's Beef Association (NCBA) is the largest organization representing America's cattle industry. Initiated in 1898, the NCBA is the industry leader in providing education and in influencing the development and implementation of science and risk analysis-based public policy to protect the health of the U.S. cattle population, provide safe and wholesome food and improve producer profitability. In this regard, the NCBA also strives to preserve the industry's heritage and ensure our future.

We appreciate this opportunity to share with you our perspectives on the U.S. Department of Agriculture's (USDA) Bovine Spongiform Encephalopathy (BSE) Expanded Surveillance Program Plan.

In order to effectively put into perspective the expanded surveillance program plan, it is important to use as a reference point the actions taken in the United States since the disease was first identified in the United Kingdom in 1985. I have enclosed a time line in my written testimony that illustrates the actions taken by the USDA since 1989 to prevent the introduction of BSE into the U.S. and to monitor the U.S. cattle population for the disorder.

The time line also lists the comparable actions taken by other countries around the world to deal with BSE. One important point clearly differentiates the United States from other countries in the world with cases of BSE. The U.S. has a history of being first when it comes to preventing BSE. We were the first country in the world without the disease to

ban the importation of cattle, beef and beef products from countries with BSE. We were the first country in the world without the disease to begin a BSE surveillance program. This program began in 1989 and has continued to be supported by and expanded as deemed appropriate by both Republican and Democratic administrations. We were also the first country in the world without the disease to ban the use of feed ingredients for cattle that had been identified as being capable of transmitting the BSE agent. Last but not least, we were also the first country in the world without the disease to carry out an independent, comprehensive analysis of the risk of BSE and the prevention measures that have been put in place. By contrast, the European Union and some Asian countries did not initiate BSE safeguards until well into the advanced stages of disease spread. This fact makes scientific comparisons between the situation in North America and other countries invalid.

All of this history, a history of being aggressive and proactive in preventing BSE for over 14 years, leads us to today and this hearing on the expanded BSE surveillance program plan.

The expanded BSE surveillance program represents an action recommended by an international review team, assembled by the USDA, that were asked to analyze our BSE status and prevention measures. This group was organized in response to the identification of BSE in a cow of Canadian birth origin in the United States identified as a result of our existing BSE surveillance program. The international review team suggested we establish an expanded surveillance program to confirm the assumptions

made in the previous risk assessment that the disease prevalence in the U.S. was very low, and if present, the disease was being eradicated as a result of the current feed restrictions. The NCBA supports conducting this one-time, large scale testing program to estimate potential disease prevalence.

The expanded testing program will provide data that will be capable of determining if the disease is present at a frequency of 1/10 million animals in the higher risk population of animals with a confidence level of at least 99 percent. The U.S. cattle population in the higher risk age range is estimated at around 40 million head. The expanded surveillance program thus is designed to detect the disease if as few as 4 animals from this population have the disease.

Under the current surveillance program, the USDA has established a network of approved laboratories to contribute to the national BSE surveillance effort. It is our understanding that the laboratories are using one of the rapid test systems. It is also our understanding that the automated testing systems in place are being operated in a very sensitive mode that may produce a fairly high level of inconclusive test results that prove to be negative when verified by the gold standard test, the immunohistochemistry (IHC) method. The labs are sending all inconclusive samples to the National Veterinary Services Laboratory (NVSL) in Ames, Iowa. In an effort to provide for transparency, all laboratory results are posted on the APHIS website at the end of each work day. The NCBA supports the efforts of the USDA to be open and transparent with the data from this testing program. The only issue we have is that USDA and the laboratories must use

the best quality assurance programs possible to ensure the quality of the test results. We do not want them to miss any true inconclusives but we also do not want a high number of inconclusives reported that are simply an artifact of the normal variations in the operation of the testing systems.

The NCBA has offered our support in ensuring the USDA has access to as many animals in the targeted risk population of cattle as possible for this expanded surveillance program. Data from this expanded surveillance program will be important for many reasons. If the data indicates our long-standing BSE prevention programs have been effective, then staying on that course will be sufficient to continue to protect animal health in the United States. If the data indicates our status is other than expected, the NCBA will work to analyze the situation and determine what, if any additional science and risk based measures may need to be taken to protect animal health.

Thank you again for this opportunity to share our views with you. I look forward to your questions.

| | United States | Canada | UK | EU | Germany | Japan |
|------|--|---|--|---|---|--|
| 1986 | | | 1986: UK finds first BSE cases. | | | |
| | 1988: USDA establishes BSE working group. | | 1988: UK bans ruminant MBM ¹ in cattle feed & starts passive BSE testing. | | | |
| | 1989: U.S. bans imports of cattle & cattle products like MBM ¹ from countries w/BSE. | | | 1989: Republic of Ireland reports first BSE case outside the UK. | | |
| | 1990: U.S. begins formal BSE testing program. | 1990: Canada bans imports of cattle from UK. ² | | | | |
| | | 1992: Canada starts BSE testing program. | | | 1992: Germany's first imported BSE case. | |
| | 1993: U.S. testing program expanded to include "downers" | 1993: Canada finds first case of BSE in imported cow. | 1993: UK BSE epidemic peaks at 1,000 cases per week. | | | |
| | | 1994: Canada's import ban expanded to any countries with domestic cases. | 1994: UK bans all mammalian protein in ruminant feed due to cross contamination. | 1994: Ban on feeding ruminant MBM ¹ to cattle instituted for all EU countries. | 1994: Germany bans feeding ruminant MBM ¹ to cattle. | |
| | 1996: U.S. beef industry calls for voluntary MBM ¹ cattle feeding ban. | | 1996: UK starts feed sampling program to test feed-ban compliance. | 1996: EU commission bans cattle & feed imports from UK to EU member countries. | 1996: Germany supports EU-wide ban on cattle & feed imports from UK. | 1996: Japan starts testing 200-400 BSE samples per year through 2001. |
| | 1997: U.S. govt. bans ruminant MBM ¹ in cattle feed. Import ban expanded to all of EU. | 1997: Canada bans feeding ruminant MBM ¹ to cattle. | | | 1997: Germany diagnoses five more BSE cases in imported animals through 1997. | 1997: Japan bans live cattle and MBM ¹ imports from UK. |
| | 2000: U.S. bans import of all rendered animal protein from Europe, regardless of species. | 2000: Canada bans imports of all rendered animal protein from countries with BSE. | | 2000: FVO ³ study reports EU member states not adequately enforcing feed ban. | 2000: FVO ³ study finds Germany not enforcing feed ban. Germany finds first domestic BSE case. | |
| | 2001: Harvard Center for Risk Analysis says U.S. is robust against the spread of BSE if introduced. | | 2001: UK starts active BSE surveillance program. | 2001: EU states required to start BSE testing & to ban feeding any animal protein to livestock. | 2001: Germany begins active BSE testing program and finds 125 BSE cases. | 2001: Japan finds first BSE case, starts 100% testing, bans MBM ^{1/2} live-cattle imports from BSE- countries and expands feed ban. |
| | 2002: FDA responds to GAO ⁴ report with increased feed ban enforcement. Now > 99% compliance. | | | | | |
| 2003 | 2003: U.S. finds first BSE case in imported Canadian cow. | 2003: First domestic BSE case in Canada. | | | | |

Timeline of BSE Prevention Measures

¹ Meat and bone meal (MBM) from BSE-infected cattle used as a protein supplement in cattle feed is believed to cause the spread of BSE
² MBM imports from the UK were banned by Canada in 1978 for reasons other than BSE prevention.
³ The European Commission's Food and Veterinary Office (FVO).
⁴ General Accounting Office 2002 report, which identified potential steps for strengthening the U.S. feed ban firewall.

Chairman GOODLATTE. Thank you, Dr. Weber.

Thank you all.

We will now start with questions, and I am pleased to recognize the gentleman from California, Mr Waxman.

Mr. WAXMAN. There has been some confusion about whether the cow in Washington State was a downer cow, and I tried to clarify this issue with the Inspector General from the Department of Agriculture, but I was not given the time to do so. And I wondered, Dr. Lurie, maybe you could help set the record straight. The Inspector General testified the USDA inspector noted that the cow was lying down when it arrived at the slaughter facility. This isn't a surprise to me; I have noticed this fact in every letter I have noted on the subject. But isn't the veterinarian's assessment of whether the cow was lying down the very definition of a downer? It is that one moment in time when the cow was lying down that makes it a downer cow or not?

Dr. LURIE. It seems clear that there is at least the potential for misunderstanding based on differing definitions that seem to be floating around, but I think probably the way to consider this is through a directive from the FSIS, 6900.1, revision No. 1 from November 1998. And in that the definition of a downer cow, and let me read this into the record, is:

Livestock that cannot rise from a recumbent position (downer) or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

So the definition, then, is an animal that cannot rise.

Mr. WAXMAN. Now, Chairman Davis and I received a sworn statement from the owner of the slaughter facility that the cow did get up after its examination by the veterinarian. Moreover, the veterinarian told congressional staff that he believed the cow's standing up after his exam was a distinct possibility. Is your view that this cow was unquestionably a downer?

Dr. LURIE. The definition, based on what I have just read to the record, does not appear to be based on a momentary assessment. If it is an animal that cannot rise I read at any moment in time. In fact, you appear to have, from what I am reading from your letter from yesterday, there are now a total of five people who have said that there was a moment at which it rose, maybe even most of its moments, and by that definition it seems reasonable to conclude that it wasn't a downer.

Mr. WAXMAN. Now, this is a matter I would have liked to pursue with the Inspector General. I am going to send written questions to her, and I appreciate your view on it. Let me ask you one other question. Senior USDA officials have said that the discovery of mad cow disease is proof that our surveillance system worked as intended, but the Inspector General found that several USDA employees knew that the slaughter facility had a special contract to test non-downers and in fact did test cows that were ambulatory by everybody's definition. Without this contract, which violated USDA policy, the owner says there would have been no cows tested at the slaughter facility at all.

Do you think the system worked or did we just get lucky in finding this cow with mad cow disease?

Dr. LURIE. Clearly the practice at the plant appears to have been inconsistent with USDA directives, so it is hard to say that the system worked as intended. Moreover, any claim of the effectiveness of the surveillance system as being demonstrated by the detection of a cow is inconsistent with the way that USDA has, at least at times, presented the purpose of its surveillance system and, indeed, the way I think everybody on this panel has put forth. The purpose of the surveillance system is in fact not to protect the supply, the purpose is to be able to estimate the prevalence.

Mr. WAXMAN. Now, if we are estimating the prevalence, do you think that we can say, as the Secretary has, that there is a 1 in a million or 1 in 10 million—that we are going to be able to detect cows in that kind of scenario?

Dr. LURIE. Absolutely not, and for exactly the reasons that I have said, that Dr. Gray has said, and now that the USDA appears to be acknowledging, that there is a non-zero risk among the lower risk animals. In fact, the IG report makes the estimate, based on assumptions different than ours, but in general of the same order, that 15 per 10 million, not 1 per 10 million, but 15 per 10 million is the limit on the detection at 268,000 animals.

Mr. WAXMAN. I appreciate that. I see the yellow light is on, and I know I am going to be gaveled as soon as it is red, but had there been a more honest assessment of the status of the cow, perhaps USDA would have avoided a mistaken assumption, which Secretary Veneman backed away from today, that all cows with mad cow disease would be downers or other high-risk cattle. This would have prevented misleading statements to the public about what the testing program can accomplish. Do you agree with that?

Dr. LURIE. I do.

Mr. WAXMAN. Thank you.

Chairman TOM DAVIS. Dr. Lurie, let me start with you. Do you feel that with the new BSE surveillance program, that at least the meat supply is safer today than it was a year ago?

Dr. LURIE. I don't particularly think that because I don't think that the surveillance program is really about that. The surveillance program is about estimating the extent of the disease. So in that sense I don't think it makes much difference in that sense. As has been repeatedly pointed out, what protects us against BSE in this country is the import ban, the feed ban, and the SRM ban. The surveillance system is about measurement, not really about protection.

Chairman TOM DAVIS. Dr. Gray, I will ask you to comment on that, but also you were tasked by the Government to assess all aspects of USDA's BSE surveillance program. In Dr. Lurie's testimony, which I heard in the back, he challenges many aspects of this program. Having reviewed this program as part of your work, do you have any comments?

Mr. GRAY. Sure. First of all, we were asked if we would review this, and it was something that we sort of did nights and weekends, and a little extra time to help out. When we looked at this, I think that if you look at our testimony, we fundamentally agree with the approach of looking at high-risk animals. Again, if we are going to look for BSE, let us look where we know the disease is, and all the data from countries that have much worse problems than we do suggests that the rate is much, much higher in the ani-

imals that—Europe somehow has a definition of downers that they use too, their down stock, their fallen stock, their high-risk animals. That is the place to look.

The question of estimating prevalence—the difficult thing here is going to be what if we don't see any cases. What do we tell the American people about what we could have found if it was really there? That is what this 1 in 10 million fight is about. One in 10 million, that prevalence can be estimated in a variety of different ways, and we suggest in our memo a couple of different ways of doing it. I think the important point here is not exactly what that number is; and I think there will be quibbles. I think that the Department has learned, we have learned, others have learned, as time has gone by, how to do a better job of estimating that. But at the end of the day we will be able to tell people that the rate in this country is probably very low. We can calculate it. We have time to work on the data when it comes in. I think we will do a good job of that.

And then the third point is that we know what to do without surveillance. And this goes back to the point that surveillance is not our public health measure. We know what to do, and those steps have already been taken. Surveillance is going to be something that is going to help us figure out how well things are going.

Chairman TOM DAVIS. Let me ask over here for Dr. Weber and Mr. Hodges, what effect does the disclosure of inconclusive rapid test results have on the cattle markets, in your opinions?

Mr. WEBER. I think the prevailing opinion is that early on in this process it will create significant volatility. The way these tests have been designed and operated, according to the manufacturer and other countries in Europe, in those settings, if they come up with an inconclusive, the odds are fairly high that it will be determined to be positive by the immunohistochemistry test. The way the test is being operated now is any one of these positive reactors is sent to Ames and declared an inconclusive. I think that the industry, the markets I don't think will ever be desensitized by the number of these; they can't afford to. And so, consequently, we want to try to minimize the extent to which we have inconclusives, but not jeopardize the sensitivity of the testing system; that is not our objective. But we do want to make sure that good laboratory practice is in place, good procedures are in place, that we do not have an inordinate number of these, because it will affect the market I think throughout the process.

Mr. HODGES. Mr. Chairman, it is AMI's belief that no results should be released until the results are confirmed, using the most sensitive assays. Releasing test results before they are confirmed may falsely suggest to consumers that there is a public health urgency. The BSE agency is not contained in beef and therefore carcasses will be held or destroyed pending test results. Therefore we see no compelling need to communicate such preliminary and, as the name would suggest, inconclusive information.

Chairman TOM DAVIS. Finally, my last question to all of you, and I will start with you, Dr. Gray, is as of December 30 non-ambulatory are prohibited from entering the human food supply regardless if they are exhibiting signs of CNS diseases or not. Do you agree

with the ban on downer cattle, and how effective do you think the ban is?

Mr. GRAY. I am not dodging this, but we have studied BSE extensively; we have done analysis. We haven't looked at this whole problem. Everything that happens when we make a decision is going to have consequences. If we ban downers, they are going to go somewhere, and that could potentially create problems. I don't know if we have thought through this question all the way. I personally haven't, so this is not something I have a strong feeling on.

Dr. LURIE. I am not going to dodge the question. I think that the decision to remove downer animals from the human consumption is the correct decision, and in terms of effectiveness, I think it will remove 24 percent, by my estimate, of the overall risk to American consumers. I think that the policy is in place; I think it deserves a chance to work. I am encouraged by the data from the Secretary that they are doing a good job of getting animals that are dead on the farm, and that suggests to me that there is at least a good chance that this downer animal ban will not result in the hiding of animals that someone would prefer not to see tested.

Chairman TOM DAVIS. My time is up, but I would just opine so then the food supply is safer than a year ago because of that downer, if for no other reason.

Dr. LURIE. No, I thought the question had to do with surveillance, and I said with respect to the surveillance program. That is not about surveillance. The downer animals are safer because they can't be eaten, not because they are tested.

Chairman TOM DAVIS. If you have answers, you don't have to answer my question in terms of the ban on downer cattle.

Mr. HODGES. Mr. Chairman, AMI supports the condemnation of cattle that exhibit clinical signs consistent with CNS disorders. We are also supportive of an inspection system that identifies and condemns cattle that fit certain scientifically based measures indicative of clinical BSE. However, AMI does not support wholesale condemnation of cattle based upon a broad definition of non-ambulatory disabled status. Cattle may become non-ambulatory for a variety of reasons, both chronic and acute, and we believe that the Department should carefully consider whether some of these animals would be acceptable for slaughter.

Mr. WEBER. I guess to add to that, it is similar to the policy that Jim Hodges has espoused. We have had concerns about denying access to the market for these animals because we wanted to make sure we had them available for the surveillance program. I think that the success this first month of surveillance, with over 17,000 samples, indicates that USDA is effectively gathering many of those, and that is going to continue. We do feel that many animals go to market in a humane manner, which could be processed, especially by individuals, who, if it is their own animals, for their own consumption. And I think in contrast to some of the information that has been shared here today, it is my understanding, if you look at BSE and the risk in this dead/down/diseased/disabled population, and, in fact, if you look at it from a disease perspective and what is called the LD-50's, the doses of infectivity, in Europe that is over 96 percent of the potential risk of the BSE agent is in that population. So indeed we dramatically are reducing risk when we

remove animals over 30 months that may be non-ambulatory from the human food supply.

Chairman GOODLATTE. Dr. Lurie, in his written testimony, states that the removal of non-ambulatory or downer cattle from the human food supply will not greatly reduce the risk to humans, and that is because, as he and many others have correctly noted, the testing system for BSE is a surveillance system, it is a system designed to determine whether the problem exists. And if cattle don't get to the places where they are tested, then you are not getting full access to that information. So we point that out for the record.

However, Dr. Lurie has also testified that the way you do present BSE from occurring are all things that the Department is doing, and I think have increased those things that they are doing in terms of determining what parts of cattle are allowed into the beef supply and how cattle can be fed.

Dr. Weber, Mr. Hodges, I wonder if you want to respond, as Dr. Gray had the opportunity to respond to Dr. Lurie's main contention, which seems to me to be that the old system—most of his quarrel seems to be with the old system in terms of statistics. I think he has some disagreement with the current system as well, but I would like you to give us your view of whether we are doing the necessary things to determine whether BSE exists in our food supply and to what prevalence.

Mr. WEBER. Clearly, as you have said and others have reiterated, the beef supply is safe because of the actions that have been taken. That is not a question. It seems as if we are debating what the absolute prevalence number will be through the surveillance program. But it is, I think, quite honestly the case we will have an estimate from this, and that number will help us evaluate future BSE prevention measures in the United States.

Chairman GOODLATTE. Mr. Hodges.

Mr. HODGES. The industry is concerned about whether BSE exists in this country to give us an indication of whether our preventative measures should be reviewed and adjusted. It is less important to have the absolute prevalence rate, because we can calculate that rate. It is simply a matter of the confidence intervals that we have around that rate. But we believe that the Department of Agriculture's aggressive sampling program, is extraordinary. If you compare it to other major exporting countries around the world, where they test in hundreds or a few thousand, compared to the hundreds of thousands that USDA now is projected to test. So we believe that this is a very good program. Obviously it will require some refinements over the course of time, but fundamentally it is in the industry's best interest as afforded.

Chairman GOODLATTE. Both of your organizations and the hundreds of thousands, if not millions, of people that you represent in the cattle business and in the meat processing business have a great deal at stake here in terms of making sure that the confidence of the American consumer is high. I would take it that you believe the best way to do that is to have a transparent system that assures the public that full testing is being done.

Mr. HODGES. Absolutely.

Chairman GOODLATTE. Now let me address this issue briefly about the cattle in Washington State. That was detected under the

old system, not the new one, but there seems to be still some suggestion that this was not a down cattle. The testimony is very direct. The Office of Inspector General has conducted two investigations of this question, and their reports clearly establish that the BSE-positive cow sampled was a downer. Quoting from one of the investigations: "Ultimately, the owner of Vern's acknowledged that the animal identified as the BSE index cow was lying down in the trailer when it was presented to the USDA veterinarian for ante-mortem inspection." In fact, Tom Ellestad, the co-owner of Vern's, made numerous public statements refuting whether or not the cow was a downer; however, when interviewed by the Office of the Inspector General Ellestad advised,

At the time animal tag No. 6810 was presented to the Veterinarian Medical Officer Thompson, it was lying down.

Further, Ellestad explained that the cow was a downer at the time of slaughter and said,

If she had been prodded with a lot of effort, she probably could have gotten up.

Ellestad said, however, that they were careful not to prod the downer animal due to humane handling purposes and, instead, stunned her while down.

We will make that statement and several others of other witnesses a part of the record.

Mr. WAXMAN. Will the gentleman yield?

Chairman GOODLATTE. I would be happy to yield.

Mr. WAXMAN. I just want to point out that I think you are not quoting Mr. Ellestad, but quoting somebody else who seems to be citing Mr. Ellestad. Perhaps we could leave the record open and have further information on what Mr. Ellestad did or did not say.

Chairman GOODLATTE. We would certainly welcome the record to remain open for clarification.

Mr. WAXMAN. Thank you.

Chairman GOODLATTE. The gentleman from Kansas, Mr. Moran, is recognized.

Mr. MORAN. Mr. Chairman, having just arrived, I don't have any questions. Thank you very much.

Chairman GOODLATTE. Thank you. You are bringing us to a rapid conclusion.

Gentlemen, we thank you all for your participation in this hearing today, and I have some remarks I would like to share to bring this to a close.

I would like to close by saying that prior to today's hearing a great many things have been said, either out of ignorance or malice, about the previous BSE surveillance program and the current expanded surveillance program that do great harm to our ability to shape a sound public policy. Anyone of clear mind who has reviewed the totality of the testimony presented today could only come to two obvious conclusions: first, that the cow tested in December was from the appropriate sampling population and, second, that while the BSE surveillance program in the past has had certain administrative failings, USDA is currently in the process of implementing a much improved, much expanded program and remains committed to ongoing improvements.

As I observed in my opening statement, the Department of Agriculture's expanded BSE surveillance program is intended to take a snapshot of what is going on in this herd, this herd of 100 million head of cattle. The surveillance is not intended or designed to prevent BSE. While not a direct protection measure itself, it will continue to contribute to the policy process determining our BSE defenses. The result of these tests will help shape how we maintain or modify the protective firewalls already in place, which include important bans on live cattle and certain ruminant products, feed bans prohibiting the feeding of most mammalian protein to ruminants, and exclusion of high-risk materials and high-risk animals in our food supply.

As a result, I remain confident that our food supply in this country, and most particularly our beef supply in this country, is of the highest quality, and I commend those in the Department and those in the industry who have taken this matter very seriously. It is a serious matter, but it is also very important that we look at fact and, in doing so, allow the American public to look at the facts that assure them that their food supply is very safe.

The gentleman from California.

Mr. WAXMAN. Thank you, Mr. Chairman. I wouldn't have objected for your additional time, even though you had taken up your 5 minutes in questions.

I just want to say that we all support the idea that we do the most effective job of protecting the consumers in this country from any unhealthy or unsafe food product. I think that as we look at the situation of that so-called downer cow, I think the question is a lot more open than my colleague from Virginia would indicate. From what we have seen from many instances of evidence of testimony from people that were involved, I think we got lucky, rather than did the right thing, and that our system was well tailored to meet the situation.

What strikes me as the most important matter is that we be credible. We do what is necessary, and if we can't get a zero risk or a 1 in 10 million, or even a 1 in 1 million kind of reduction of risk, then we be honest about it. And I don't think that representations are to be made citing Harvard or citing anyone else when the evidence does not support those representations.

I hope that the result of this hearing will be very constructive. I want the Secretary to succeed in the efforts of the Department. I think she should take to mind all the points raised by the Inspector General. I think the Inspector General found, as if she were looking for whether there was a criminal violation, she found there was no intentional misrepresentation, no wrongdoing, no one wanted to misrepresent the situation, but I think that was a very carefully phrased response to what was a broader issue of whether that cow was a downer cow or not. The issue is one under the USDA definition, and if that cow had the potential to get up and walk, it was not officially a downer cow, might not otherwise have been tested, and we might not have known what is going on in this issue.

I think we shouldn't make wrong assumptions and then follow through with policies that are based on wrong assumptions, and I think we ought to be honest with the American people about what

we can and cannot do. We need to do the best we can do, but not mislead people into thinking that we have solutions and then close their minds to additional evidence that shows that our assumptions may have been incorrect to start with.

Chairman GOODLATTE. I thank the gentleman for his comments.

This debate will continue, and, in fact, I will ask unanimous consent that the record remain open for 10 additional days for the submission of answers to any questions raised by members of the committee and for other documentary information. And we will make a notation that we want to see that final audit from the Office of the Inspector General, and that will probably take longer than that, so for that one item we will hold the opportunity to submit that later.

Mr. WAXMAN. Mr. Chairman, I know you have asked consent of this, and I won't disagree, but I do want to point out that to get those final audits from inspectors general can be a year or more. We are waiting for some of the reports that they were supposed to have done on listeria and other matters. That is why it is important not to wait until the final audit, but to make use of interim reports so that we can learn from and let the public know about those interim reports. But if the final report comes in, I think it ought to be part of the record.

Chairman GOODLATTE. We are advised that it will be much shorter than that, but we will make sure that is made a part of the record. And, again, I would point out that taking an audit that is incomplete is inappropriate when the party being audited has not had an opportunity to respond. It would be like a bank examiner taking an audit and publishing it before the party that is being examined has an opportunity to produce whether they have a receipt to demonstrate this or that or the other activity took place.

Mr. WAXMAN. I am going to disagree with you, Mr. Chairman, but it don't know if we want to prolong the debate.

Chairman GOODLATTE. I am not going to prolong the debate. You have had two cracks at it, and I think we will call it there. We will wait for that final audit and we will also continue to work with you and everybody who has been involved with this to make sure that we do have a safe food supply in this country.

With that, the hearing will be adjourned.

[Whereupon, the committees were adjourned, to reconvene at the call of their respective Chairs.]

[The prepared statements of Hon. Dennis J. Kucinich, Hon. Rosa DeLauro, and Hon. Lincoln Davis and additional information submitted for the hearing record follow:]



Statement for Gov't Reform/Ag Joint Hearing on BSE

Rep. Dennis J. Kucinich

July 14, 2004

For years, the cattle industry cried foul whenever anyone suggested the United States required better protection against Mad Cow disease. The industry claimed, over and over again, that because no cases had been found in the United States, there was no need for better protections. As we all know now, all of that came to an end last December. The discovery of a positive BSE case led to over 50 countries around the world boycotting American beef.

In response, the USDA has implemented some additional protections but those protections do not provide the same level of assurance found in many other nation's BSE prevention programs. The bottom line is that the USDA should greatly expand its testing program to ensure the safety of the beef supply.

There are several protections that the USDA should implement as soon as possible. These initiatives will close the gap of safety standards, provide Americans a much safer beef supply, and ensure that beef exports will not be harmed.

I call upon the USDA to test all cattle 20 months or older for mad cow disease. While USDA officials have said they would increase testing of cattle from 20,000 to approximately 268,000 per year, this is less than 1% of all the cattle slaughtered each year in this country and does not include all older animals. This gap is problematic because cattle as young as 20 months of age have been identified with mad cow disease in other countries.

The USDA should allow beef producers to test their cattle for mad cow disease. The USDA has adamantly opposed requests by private cattle producers for permission to test their cattle voluntarily. Private testing would supplement government testing without costing taxpayers. It could increase the safety of the food supply by potentially finding and removing more diseased animals. It would also allow producers to recover lost export markets or serve niche markets in the U.S. where customers want more testing than currently planned by the U.S. government.

The USDA must give high priority to implementing a national animal identification and tracking system. A national identification and tracking system is needed to speed recalls of tainted beef and to swiftly identify and locate herd mates of cattle found to have mad cow disease to prevent its spread. A tracking system would also enable the USDA to trace back pathogens, like deadly forms of E. coli, to identify and change practices on farms with conditions that foster these problems.

Finally, the USDA should establish USDA mandatory recall authority for contaminated meat. USDA should have clear recall authority necessary to remove meat contaminated with mad cow disease or other pathogens from the food supply. USDA should also reverse its policy that bars the release of store names that have received suspect meat, denying consumers important information.

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STATEMENT FOR THE RECORD BY CONGRESSWOMAN ROSA DELAURO, CT-3

To the Committee on Government Reform and the Committee on Agriculture

Hearing: "A Review of USDA's Expanded BSE Cattle Surveillance Program"
Wednesday, July 14, 2004
Room 2154 Rayburn House Office Building

Mr. Chairman:

I want to commend you for holding this important hearing on BSE Cattle Surveillance.

As co-chair of the bi-partisan Congressional Food Safety Caucus I have been actively tracking developments on the surveillance system being put in place by USDA, as well as examining and presenting information on prion research and its coordination within the federal government. We all must work together to prevent the United States from falling into the trap of ignoring a critical disease until an outbreak presents us with tremendous public health and economic consequences.

Unfortunately, in December 2003, one cow of Canadian origin was diagnosed with Bovine Spongiform Encephalopathy (BSE). We all know that, of course, but I wonder if the drastic result of that one case was really understood by U.S. Department of Agriculture (USDA) when it took six months to implement an increased surveillance program. There did not seem to be a sense of urgency at USDA as they were presented with these animal disease challenges, and I, frankly, see none today. Yet every minute that we delay sows more doubt with consumers and causes economic hardship for our cattlemen.

USDA's own Economic Research Service (ERS) has recently reported that both beef and poultry exports have been drastically reduced this year. Prior to the discovery of BSE, beef exports were at record levels in 2003 - about 2.5 billion pounds. Now ERS predicts that in 2004 beef exports may be as low as 451 million pounds - meaning that we only expect to export about 18% of the amount we exported just last year. To be blunt, that is a serious problem for the industry and for our economy alike.

I have been working with the USDA on this problem. Their refusal to address the issue of comprehensive voluntary testing and failure to permit small, niche market beef processors to perform BSE voluntary testing, at their own cost, in order to satisfy their private customers

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overseas is contrary to economic and business practices throughout our country. It is beyond me how USDA feels comfortable interfering in the normal customer/supplier relationship, when specifications for quality and safety between commercial parties are so common in other parts of business life.

At one point, USDA informed me that BSE testing was an issue of animal health, not human health. They indicated that public health was being protected by mechanical steps at slaughter. I realize that the BSE testing is being done by APHIS (not the agency normally charged with responsibility for human public health), but in this day of zoonotic disease prevention, surely BSE testing, and testing for other animal diseases that can be passed to humans, should be considered as a strategy for human public health protection.

Recent developments at the Food and Drug Administration (FDA) related to their authority to regulate the feed supply for animals are equally troubling. Instead of following their initial judgment and issuing emergency regulations to close certain loopholes to ensure feed not be contaminated with ruminant by-products, they have instead issued an Advanced Notice of Proposed Rulemaking -- extending an important rulemaking process over years - not more months.

Mr. Chairman, the management of one incident of BSE by the administration has been both disappointing and frustrating. APHIS and the Harvard Study have quite correctly predicted that a comprehensive surveillance program may identify several cases of BSE within the United States' borders, reminding us that surveillance is critical, but we must also be vigilant with regard to other management and organizational issues as well.

This BSE incident illustrates all too well how divided government leads to inconsistent regulation, confusion and delay with potentially dire consequences. I believe all these issues would be better managed were we to create an independent Food Safety Administration. Right now, there are no fewer than 12 federal agencies charged with some aspect of food safety. That is a recipe for bureaucratic inefficiency and deadlock. Consolidating them into a single entity would lend efficiency to the process and strengthen our efforts against potential bio-terrorism threats. A single food agency would eliminate these management conflicts, and coordinate the actions of both Health and Human Services' FDA and USDA to make a priority of protecting the public health of the American people.

Opening Statement of Congressman Lincoln Davis

Joint hearing to review USDA's Expanded BSE Cattle
Surveillance Program

7-14-04

I'd like to first thank Chairman Davis, Chairman Goodlatte, as well as Ranking Members Waxman and Stenholm for holding today's hearing to review the USDA's Expanded BSE Cattle Surveillance Program. I don't think we can overstate the importance of this issue to the American cattle producer and the American consumer. Since December, 2003, this issue has been on the minds of all those who raise cattle, those who are involved with the cattle industry, and those who simply enjoy beef products. It is particularly important for me and my constituents since cattle is the number one agricultural product for Tennessee, and my district is home to three of the top four cattle producing counties in the state.

I feel that, over all, the USDA has done a good job of handling the BSE issue since the announcement in December, but I do have concerns about the two June announcements stating additional cows had tested positive for mad cow disease in preliminary tests. Of course, we all know that later conclusive tests determined neither cow had BSE. I know that I don't have to point out to anyone here the negative impacts these announcements have on the markets. We must have consistency from the USDA, especially when it comes to making announcements regarding agricultural diseases and blights that will have direct market and consumer effects. I would argue that public announcements shouldn't be made unless they are conclusive. It doesn't do anyone any good to get the market and the consumer riled up about something, only to recant initial findings at a later date. Additionally, I am concerned that differing reports and eyewitness accounts as to whether or not the December BSE cow was in fact a downer. With today's hearing I would like to make sure that the USDA has the tools and resources necessary to ensure the American beef supply stays BSE free and the cattle markets remain stable. I look forward to the testimonies we will hear today from all of our distinguished witnesses.

**Ranchers-Cattlemen Action Legal Fund –
United Stockgrowers of America
(R-CALF USA)
Bill Bullard, C.E.O.
Billings, MT**

**Before the
House Committee on Government Reform
and House Committee on Agriculture**

On USDA's BSE Surveillance Program

July 14, 2004

My name is Bill Bullard and I am the C.E.O. of the Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (R-CALF USA). R-CALF USA is a non-profit trade association representing more than 52,000 independent cattle producers, 10,000 of which are individual members of R-CALF USA in 46 states, and over 42,000 are members of R-CALF USA's 60 affiliated organizations. R-CALF USA is dedicated to ensuring the continued profitability and viability of the U.S. cattle industry.

I want to thank Chairman Goodlatte, Chairman Davis, Ranking Member Stenholm, Ranking Member Waxman and all of the members of the committees for having this hearing. I very much appreciate the opportunity to share our views on the United States Department of Agriculture's (USDA's) current bovine spongiform encephalopathy (BSE) surveillance policy because this issue is so critical to the long-term health of our industry.

I have four major points to make today on USDA's BSE surveillance policy. First, USDA should make identification and testing of Canadian cattle that are already in the United States a priority. Second, USDA should change its destructive policy on announcing inconclusive BSE test results by *either* not announcing those results until confirmed *or* by releasing enough other information with those results to make them meaningful. Third, USDA should grant the requests by cutting edge packers, like Creekstone Farms Premium Beef and Gateway Beef, to be permitted to voluntarily test 100 percent of the animals they process. Finally, we need a public conversation regarding whether BSE testing should be used solely to determine the prevalence of the disease, as USDA contends, or whether testing should be used as a safety measure, as experts such as Nobel Laureate Dr. Stanley Prusiner contend. The Congress as well as USDA and outside experts ought to be engaged in this important policy discussion.

1. USDA Should Identify and Test Canadian Cattle that are in the United States

USDA has said that its surveillance program targets cattle from populations that are considered at the highest risk for BSE. USDA considers adult cattle over 30 months of age that either show clinical signs consistent with BSE, or that are dead or non-ambulatory as its targeted cattle population. In addition, USDA plans to sample approximately 20,000 clinically normal slaughter cattle over 30 months of age.

Unfortunately, USDA is missing perhaps the most important indicator of risk for BSE and that is the country of origin of the animal. The World Organization for Animal Health (OIE) classifies a country's disease status based on the risk that they have BSE in their native herd. The place of birth of the animal is scientifically recognized as the key factor for determining where the disease originated and whether the disease poses a risk to other animals. The OIE's health code only recommends a change in disease status for countries with BSE in their native herds. For countries where BSE is reported, but reported in imported animals only, the OIE does not recommend a change in disease status, nor does it recommend any additional food safety mitigation measures. What the OIE does recommend, however, is that countries should include, as a part of their surveillance, the targeting of imported cattle that originated in countries where BSE is known to exist. Specifically, the OIE suggests that countries consider targeting cattle that are identifiable as imported from countries not free from BSE.

Canada has had two cases of BSE in its native cattle herd. The United States has not had a single one. Canada, therefore, no longer meets the requirements of the BSE disease free categories established by the OIE, while the United States does. Because Canada has not had its feed ban in place for the requisite 8 years, combined with the confirmation of two cases of BSE in native animals, Canada has fallen at least two OIE disease categories below the United States, and it can now only meet the criteria set forth for a country with a moderate risk of BSE. The United States continues to meet at least the standards of the provisionally BSE free category, and likely the standards of the BSE free category as well.

Following the scientific guidance provided by the OIE risk classifications, and the OIE's explicit recommendation that countries consider targeting cattle that are known to originate from a country where BSE exists is the most straightforward way for USDA to target for testing those animals that are at the highest risk of carrying the disease. The OIE risk classifications are used by more than 164 World Trade Organization member countries to evaluate BSE risks. Consistent with the OIE principles, we need to immediately begin identifying and testing the Canadian animals that are in our country.

This point should have been driven home by the discovery of a cow with BSE in Washington State in December 2003. USDA has established that this cow came into this country from Alberta, Canada. Making the identification and testing of Canadian cattle in the United States, cattle that were imported from a country where BSE is known to exist, a centerpiece of USDA's surveillance program will help ensure that we are protected should one of those animals turn out to have BSE.

Dr. Louis Anthony Cox, Jr., a nationally recognized expert on risk analysis, has just completed a study demonstrating that there are enormous economic benefits that would flow from identifying and permanently marking the Canadian cattle currently in the US so that the country of origin of tested cattle is known at the time of testing.

Identifying Canadian cattle in the United States would not be difficult or expensive. Dr. Cox estimates that benefits would flow to the cattle industry even if the cost of identifying Canadian cattle were less than \$35 per head. However, North Dakota, for example, recently conducted a trace-back of the Canadian herd cohorts (as defined by USDA) of the first Canadian cow discovered with BSE in May 2003. By reviewing the International Health Certificates

maintained in the office of the State Veterinarian, North Dakota was able to determine the premises that received these imported cattle within a matter of weeks. Each head of cattle enters this country with an international health certificate. Copies of these certificates go to the state veterinary office and presumably to USDA's Animal and Plant Health Inspection Service (APHIS). The numbers on these certificates can be matched to the metal ear tags affixed by Canada when the cattle were exported without too much difficulty. In addition, these numbers may be readily associated with subsequent U.S. brucellosis ear tags affixed by U.S. veterinarians upon interstate shipment of these imported animals. Finally, a coordinated effort by APHIS, state veterinary offices, and U.S. cattle producers using an industry survey could be used to identify a large percentage of these Canadian imports.

The relatively modest cost of targeting these animals is more than offset by the benefits of this approach. Locating and testing these animals can help open some of our lost export markets for beef and can help curb the potential losses to the industry if an animal with BSE is detected in the future. Dr. Cox found that failing to track these animals will cost us about \$90 million per year, while it would only cost about \$10 million to track them. He further found that if aggressive tracking and testing of Canadian cattle can win back lost U.S. exports, then the value of information of a tracking program for Canadian cattle could increase to over half a billion dollars to our industry. It is in our clear economic interest, then, to identify and test these potentially higher risk animals within our country.

2. *USDA should not shock the US cattle markets with unsupported "inconclusive" results*

USDA should change how it currently releases an "inconclusive" BSE test result. USDA should *either* not release any "inconclusive" test results *or* if it does release such results, it should release the necessary information relating to that animal such as its country of origin.

With two inconclusive results so far, we have seen the devastating effects of USDA's current policy. The cattle markets have experienced large losses and volatility as a result of USDA's incomplete announcements. Rumors have run wild with major newspapers and trade press reporting rumors about the cattle tested. USDA did nothing to stop or correct these rumors.

Interestingly, USDA claims it is releasing inconclusive results in order to head off the possibility of rumors about such tests. USDA's actions, however, have instigated these rumors as has its refusal to release other information. It has become a game for the media and traders to try to find out the facts. For the traders, doing so can amount to having inside information and, potentially, help them turn a quick profit at others' expense.

If we were to look at the widespread rumors reported by major media following the first, June 25, 2004 "inconclusive" test result announcement, we can readily see how USDA's failure to release pertinent information beyond a mere disclosure of an "inconclusive" test was detrimental to the market. The media reports indicated the first "inconclusive" was a California dairy cow between the ages of 16-18 months. Market participants couldn't confirm this information due to USDA's silence and we saw the future market respond to a worst-case scenario: falling the limit down. However, if USDA had confirmed this additional and pertinent information, market participants would have recognized that the probability of detecting BSE in a 16-18 month old animal is all but impossible using the USDA's rapid test (Immunoassay test).

It would, in fact, have been the youngest animal ever tested positive for BSE, the previous record was an animal 21 months of age. This example reveals how USDA's practice of withholding important, market-sensitive information is unnecessarily harming U.S. cattle producers.

There is no need for USDA to damage the cattle markets in this way. Senator Conrad Burns made these points well in his July 6, 2004 letter to Secretary Veneman. Senator Burns, a former livestock auctioneer, knows this business well strongly urged Secretary Veneman to "stop disclosing unconfirmed information that sends shockwaves through our markets." Senator Burns made clear that USDA's release of unsubstantiated test results caused producers and consumers unnecessary worry and caused the cattle markets to plummet. If USDA continues to release "inconclusive" results, then it must also release the country of origin of the animal tested. This additional information will prevent unnecessary concern about the U.S. beef supply and prevent some of the problems we have seen to date.

3. USDA Should Allow Packers to Voluntarily Test 100 Percent of the Animals that They Process

R-CALF USA encourages the United States Department of Agriculture (USDA) to reconsider its denial of the request by Creekstone Farms Premium Beef (Creekstone) to voluntarily test 100 percent of the cattle it processes for BSE. We are extremely disappointed in USDA's outright refusal to allow Creekstone to meet the demands of its customers for 100 percent BSE-testing of its beef products. Rather than opposing Creekstone's efforts, the USDA should be working with Creekstone and other like-minded beef processors to help them establish standards for voluntary BSE-testing that respond to the demands of both its international and domestic customers. This will also result in an added benefit – it will enhance USDA's efforts to protect consumers from exposure to BSE by increasing the numbers of animals tested.

USDA is preventing Creekstone from creating a higher-value beef product through the voluntary imposition of an additional, market-driven standard for its products. Creekstone's 100 percent BSE-testing proposal is directly analogous to the USDA Organic standards, which were established by USDA working closely with producers and processors to reflect specific production and/or processing standards that enable consumers to assign value to the resulting products.

The consequences of USDA denying Creekstone's request is to shield the less innovative, less nimble, and less responsive beef processors from the competitive capacity of cutting-edge beef processors like Creekstone. USDA should not use its regulatory authority to hamstring market competition, particularly in this instance where Creekstone intends to use identical BSE-testing procedures currently used by USDA.

Instead of thwarting innovation, USDA should be applauding and facilitating Creekstone's entrepreneurial spirit. Creekstone is leading the beef processing industry into a new era – one that is predicated on meeting the needs and wants of its customers. In so doing, Creekstone has discovered a reasonable, efficient, and timely means for resuming export trade with Japan. Other like-minded meat processors are sure to follow if Creekstone's efforts attract financial rewards.

We support Creekstone's effort to meet its customer's demands by testing all cattle slaughtered at its plant for BSE. We encourage Congress and USDA to take necessary steps to immediately begin assisting Creekstone in its efforts.

4. We Need a Public Dialogue on BSE Testing in the United States

We need a full examination and discussion of the objectives of USDA's BSE surveillance program. On March 15, 2004, USDA announced its plan for an intensive national BSE surveillance plan. USDA explained that its goal is to test cattle in its targeted high-risk population during a 12-18 month period. USDA stated that this "one-time effort" should provide a snapshot of the cattle population in the U.S. and help determine whether BSE is actually present in the population, and if so, at what level. Through this surveillance program, USDA claims that it will be able to provide consumers, trading partners and industry increased assurances about the BSE status of the U.S. cattle population.

Above and beyond our concerns about which cattle USDA is choosing to test and how it is handling results, we are concerned that USDA is taking a particular view about the use of BSE testing without fully exploring the possibilities and the latest science. There are nations that use BSE testing as a safety measure in conjunction with other safety measures such as an appropriate feed ban and removal of specified risk material during processing.

USDA has insisted that its testing is merely to determine the prevalence of the disease and they have been vehement in their refusal to publicly examine this choice and receive feedback from scientific experts on other approaches. There are too many uncertainties about BSE and study in this field is developing too rapidly for us to refuse to discuss the latest developments. We think the Congress should push USDA to have this public conversation and that USDA should solicit feedback from experts and interested parties on the uses and goals of a BSE testing program.

A recent article in the Scientific American written by Dr. Stanley Prusiner explores some of the latest developments in this field. Dr. Prusiner won the Nobel Prize in 1997 for his work

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uncovering the misformed proteins, called prions, which are the BSE agent. For many years he was derided for his work in this field, but mainstream science has now embraced his prion research and he is arguably the world's foremost expert on BSE. In his article, Dr. Prusiner examines the latest testing advances and what we know about BSE. He concludes that the most straightforward way to protect the public from BSE is to simply "test the animals being slaughtered for food and then stop the infected ones from entering the food supply..." Dr. Prusiner reports that accurate test results can be derived in a matter of hours with the types of tests used in Europe and Japan. Based on the development of these rapid, sensitive tests, Dr. Prusiner concludes that "universal screening can become the norm." He also claims that USDA's tests are slow and cumbersome. The new tests, specifically the Conformation-Dependent Immunoassay (CDI), can more accurately detect lower levels of infectivity and, Prusiner concludes that there is "no other option for adequately protecting the food supply" than using testing as a safety measure.

Is Dr. Prusiner's conclusion right? We don't know. But it concerns us that USDA does not know either because it has not undertaken a sufficient inquiry. We should not forego what is potentially good policy because of an unwillingness to take an unflinching look at the latest scientific evidence.

* * *

We have an opportunity to do things right here in the United States. We have the benefit of looking back at mistakes made in Great Britain and other nations with BSE and learning from them. The discovery of BSE in Canadian cattle should be a wake up call. We should strive to have the best food safety measures in the world in the future as we have in the past. Doing so means resisting temptations to lower our standards, properly targeting and conducting our BSE testing program, and fully examining all evidence and viewpoints on BSE and BSE testing without fear about what policy outcomes the evidence might suggest. If we do that we can continue to have the strongest and safest beef industry in the world – and that is a goal we all should support.

I sincerely appreciate this opportunity to share R-CALF USA's views with you on this important issue.



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Dear Chairman:

On Thursday, July 22, the Center for Progressive Regulation will be publishing a comprehensive report on the Federal Government's responses to the December, 2003 discovery of a mad cow in Washington State. Because of the relevance of this report to your important joint hearing on the constantly changing BSE surveillance program of United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), CPR is writing to share with the committees a summary of the analysis and conclusions of this forthcoming report relevant to that issue. The full report, which will address a wide variety of topics in addition to the BSE surveillance program, will be released at the 9:30AM on July 22 at the National Press Club in Washington, D.C.

The Center for Progressive Regulation (CPR) is a nonprofit research and educational organization of university-affiliated academics with expertise in the legal, economic, and scientific issues related to regulation of health, safety, and the environment. CPR supports regulatory action to support public health, safety and the environment, and rejects the conservative view that government's only function is to increase the economic efficiency of private markets. Through research and commentary, CPR seeks to inform policy debates, critique anti-regulatory research, enhance public understanding of the issues, and open the regulatory process to public scrutiny.

The BSE surveillance program is one of the so-called “firewalls” that the Federal Government has erected to protect the public health from the risk of mad cow disease. The accuracy with which USDA and the general public can know the true incidence of BSE in the U.S. cattle population and, consequently, the capacity of this “firewall” to protect public health and the agricultural economy depends upon the range and intensity of the surveillance efforts that USDA undertakes. CPR has concluded that neither the range nor the intensity of the efforts that USDA has undertaken so far are sufficient to detect the true incidence of BSE in the U.S. cattle population. Of even greater concern, there are strong indications throughout the history of USDA’s surveillance efforts that the Department has adopted a “see no evil” policy toward BSE. As a result, we do not yet know the true incidence of BSE in the U.S. cattle population.

History of USDA’s BSE Testing Program

USDA’s BSE surveillance efforts prior to January, 2004 focused primarily on slaughterhouses where FSIS inspectors or company employees could easily take samples of brain tissue from animals selected for testing. Inspectors employed by the Food Safety and Inspection Service (FSIS) have since the early-1990s been on the lookout for cattle exhibiting signs of central nervous system (CNS) disorders. At the same time, APHIS, an entirely separate agency within USDA, bears the primary responsibility for implementing the USDA BSE Surveillance Sampling Program. FSIS inspectors condemn non-ambulatory (downer) cattle and other animals exhibiting signs of CNS disorders and send samples from their brains to APHIS laboratories for BSE analysis. Private veterinarians have also been encouraged to refer cases of possible CNS disorders to APHIS for BSE analysis.

Beginning in 1990, APHIS began an active BSE surveillance program aimed at sampling the brains of several hundred downer cattle per year for signs of BSE. Virtually all of this testing was voluntary. USDA would pay slaughterhouses for brain material from downer cattle selected by company employees and sent to APHIS for analysis. By the end of 2002 APHIS had tested a total of about 30,000 downer cattle from among the 300,000,000 animals slaughtered during the previous nine years. In FY 2003, APHIS expanded the testing program, and it later reported testing more than 20,000 cattle for BSE in that year alone. This represented only a tiny fraction of the 35 million cattle slaughtered annually in the U.S.

After the discovery of the Mabton, Washington mad cow, the beef industry announced that it would no longer oppose testing a broader range of cattle for BSE with greater intensity, and USDA yielded to public pressure for greater testing by gently expanding its testing program from 20,000 tests per year to 40,000. APHIS continued to limit the program to downer cattle or adult cattle displaying signs of CNS disorders, and the program continued to be wholly voluntary.

A subsequent report from an International Advisory Panel, a recommendation from an FDA advisory committee, and continued public pressure from consumer groups forced APHIS to initiate a one-time only enhanced testing program. On March 15, 2004, Secretary Veneman announced that USDA would reprogram \$70 million of USDA funds to pay for testing as many animals as possible in the high-risk population of downer cattle and cattle showing signs of CNS disorders over a 1.5 year period beginning on June 1, 2004. In addition, the program would for

the first time include approximately 20,000 healthy looking animals of more than 30 months in age. Early predictions were that this would increase the total number of animals tested to between 200,000 and 268,000 animals over the 1.5 year life of the expanded testing program.

The Department's announcement did not say whether the expanded program would continue to depend upon voluntary submissions of animals for testing by slaughterhouses, but a spokesperson later confirmed that the program remained entirely voluntary. It would not be random, but would instead concentrate on the 40 slaughterhouses that have historically slaughtered 86 percent of all slaughtered cattle at federally inspected plants. APHIS would make some attempt to assure geographical diversity. The additional sampling program for 20,000 "normal" animals would also not be random and would be limited to cattle older than 30 months of age.

At the same time that USDA was dramatically expanding its own testing program, it refused to allow individual producers and slaughterhouses to test their cattle voluntarily for mad cow disease. In late February, 2004, Creekstone Farms, a small company specializing in gourmet meats for export, announced that it had received assurances from its Asian customers that their governments would accept its beef products if the company voluntarily tested all of the animals that it slaughtered for BSE. Creekstone petitioned USDA to allow it to use one of the rapid BSE testing kits that USDA had recently approved to conduct universal testing on its animals. Creekstone even invested \$500,000 in a state-of-the-art mad cow testing laboratory.

USDA rejected Creekstone's petition in early April 2004, and it reportedly threatened to file a criminal action against Creekstone if it conducted any testing at all. The head of APHIS explained its refusal to allow Creekstone to use recently approved kits for the purpose of testing 100 percent of its cattle on the ground that USDA was determined to "stick to the science" in testing for mad cow disease. As discussed below, science could have had very little to do with this decision, which was in fact dominated by economic and policy considerations.

The Flimsy Surveillance Firewall

USDA has since the discovery of mad cow disease in England been in a perpetual state of denial about the potential for an outbreak of BSE in the United States. In both Democratic and Republican administrations, USDA has consistently belittled the risk to the U.S. herd of BSE infection, in later years justifying its confident assurances on a mathematical modeling exercise undertaken at USDA's behest by the Harvard Center for Risk Analysis, an industry-supported center associated with the Harvard School of Public Health. Until December, 2003, USDA stressed at every opportunity the "fact" that "[n]o cases of BSE have been confirmed in the U.S.A. with 13 years of active surveillance." Indeed, the USDA website still conveys that comforting, if wholly inaccurate message. The "13 years of active surveillance" have in fact been 13 years of careful efforts to avoid finding mad cow disease while appearing to be looking for it.

Overemphasis on Downer Cattle.

APHIS has in the past designed the BSE surveillance program to focus exclusively upon testing downer cattle and cattle displaying signs of CNS disorders. The recent revisions did not change the agency's overall approach to testing cattle for mad cow disease, despite the well-known fact that not all cattle suffering from BSE are old or exhibit clinical signs of BSE infection. The expanded testing program announced on March 15, 2004 will test an additional 20,000 apparently healthy cattle in the category of older cattle, but that remains an exceedingly small sample. A doctor for a prominent public interest group has concluded that the expanded program "seems to be designed to give the public and would-be importers of American cattle false assurance."

Incomplete Universe of Cattle.

As USDA implements its recent ban on the use of downer cattle in human food, downer cattle will no longer be presented for slaughter at commercial slaughterhouses. The APHIS surveillance program will therefore have to focus on rendering establishments, local veterinarians, and the producers themselves to locate downer cattle and those suffering from CNS disorders. Because the program remains entirely voluntary, however, APHIS will not have access to cattle from producers who decline to participate. USDA lacks authority to test animals until they are physically unloaded from trucks at slaughterhouses or rendering establishments. Thus, if a producer decides to dispose of downer cattle other than by rendering, such cattle are highly unlikely to be tested for mad cow disease under the APHIS surveillance program. A producer can even avoid testing of ambulatory cattle that show signs of neurological disease at the slaughterhouse by keeping them on the truck. Indeed, anecdotal evidence exists of producers loading wobbly cattle back on to trucks before USDA inspectors could spot them. Although the Department plans to use some of the \$70 million re-allocated to the BSE surveillance program to provide financial incentives to owners of downer animals to present those animals for testing, there will still be a strong incentive on their part to avoid testing.

Unscientific Selection Criteria.

The surveillance program has never been a scientifically designed random sampling program. Instead, it has historically been an almost completely voluntary hit or miss operation aimed at only a very small sample of a small class of especially suspect cattle. For example, a search of USDA records undertaken after the discovery of the Mabton mad cow revealed that APHIS had not tested any cattle at commercial slaughterhouses in Washington state during the first seven months of 2003 and that it had not undertaken a single BSE test in any of the six federally registered facilities in that state for the previous two years. The same search disclosed that during the previous two years, BSE tests had been conducted at fewer than 100 of the 700 known slaughterhouses, that no tests had been conducted at some of the nation's largest slaughterhouses, and that cattle from states accounting for 70 percent of all slaughtered cattle were providing animals for only 11 percent of the tests. This study dramatically demonstrates that APHIS's extremely limited BSE surveillance program has historically been conducted in an entirely unsystematic way that was by no means random.

In an 18-page affidavit prepared for a House committee investigation, Thomas A. Ellestad, one of the principle operators of Vern's Moses Lake Meat, Inc. explained how the APHIS BSE Surveillance Sampling Program has worked in the real world. After one of Vern's largest customers was publicly attacked by animal rights groups, the customer adopted a no-downer policy and demanded that its suppliers do so as well. Consequently, in February 2003, Vern's implemented a "humane" policy in which it no longer accepted downer cattle for slaughter. In June 2003, APHIS offered to pay Vern's \$10.00 apiece for samples from the brains of up to 1000 downer cattle. Because Vern's no longer accepted downer cattle, it declined the proffered contract. USDA officials, however, pressed Ellestad to accept the contract because USDA was having difficulty in that region obtaining the number of samples required for the surveillance program. After much negotiation, Vern's signed an amended contract that did not require the samples to be from downer animals. Since the contract did not specify any sampling protocol, Vern's employees selected the brains to be sampled for the APHIS program from among the ambulatory cattle processed at the plant.

Under the expanded BSE surveillance program that USDA announced on March 15, 2004, USDA will attempt to test as many downer cattle as it can locate during the twelve to eighteen months that the program is in existence. The Department said that it would attempt to make the tests geographically representative, but it did not say that it would attempt to obtain a statistically valid sample. Since the program still remains voluntary, it is hard to see how it could be conducted randomly.

The expanded program will test 20,000 apparently healthy cattle of greater than 30 months of age, but these animals will be selected from the 40 slaughterhouses that process most of the older dairy cattle. The Department would not reveal the names of the companies because it feared that it would make the companies less cooperative. Although USDA's chief veterinarian assured the press that the animals would be randomly selected, he did not say whether APHIS would test cattle over the objections of a slaughterhouse in order to ensure the statistical validity of the tests. And even a random selection from a limited universe of only 40 out of 700 slaughterhouses will not necessarily represent a random selection of the U.S. aged cattle population. It is also not at all clear why USDA has limited the expanded testing program for 20,000 non-suspect cattle to older cattle. BSE has been detected in cattle much younger than 30 months of age, and the exclusive focus on older cattle will rule out such younger cattle. Even if they were chosen randomly, testing only 20,000 of the 35 million animals slaughtered per year is probably not sufficient to yield statistically significant results.

Disturbing Indications of a "See No Evil" Policy.

Within a week after confirming that a mad cow had been slaughtered at the Vern's Moses Lake facility, according to Mr. Ellestad's affidavit, APHIS ordered the facility to discontinue all sampling of brains for BSE testing. This reaction to the first positive BSE sample in the history of the program could hardly be characterized as "science-based." If one or more of the dairy farms and producers that were sending cattle to Vern's for slaughter were harboring BSE-positive herds, the "scientific" response would surely have been to expand testing to include as

large a sample of the cattle being slaughtered at that facility as possible to determine the extent of the mad cow outbreak in that geographical area. Instead, APHIS ensured that any outbreak would go undetected by discontinuing the testing program at the Vern's facility.

In the wake of the discovery of the Mabton mad cow, several FSIS inspectors expressed considerable frustration over the performance of the APHIS laboratory at Ames, Iowa, claiming that it was quite secretive and had a history of producing ambiguous and conflicting results. The tension between the two agencies had grown so high that one FSIS veterinarian reported that APHIS employees seldom bothered to pick up brains from suspect cattle that were under 30 months of age. Another FSIS veterinarian reported that many of his colleagues did not seriously attempt to sample brains from suspect animals any more because they believed there was little chance that the APHIS laboratory would report a positive result if it found one. Steve Mitchell, USDA Vets Question Agency's Mad Cow Lab, United Press International, February 9, 2004.

A recently reported APHIS response to a BSE testing request from a Texas FSIS inspector provides even stronger evidence that APHIS is pursuing a "see no evil" policy with respect to the incidence of mad cow disease in this country. When a cow at the San Angelo facility staggered and collapsed, the FSIS veterinarian at the plant determined that it should be tested for BSE and contacted the Regional Office of APHIS in Austin. The APHIS regional director, for no stated reason, determined that testing would not be required and ordered the animal not to be held for testing. The cow was then rendered into feed for pigs without ever being tested for BSE. This constituted a clear, but unexplained breach of USDA protocol for testing animals with signs of CNS disorder. The 12-year-old animal had consumed cattle feed manufactured prior the FDA's 1997 feed restrictions, and it might very well have contracted mad cow disease during its earlier years. Since the animal's brain was not preserved for testing, the question whether the cow was in fact BSE-positive will never be answered.

USDA attempted to quell the public relations storm that resulted from these revelations by immediately (and very publicly) issuing a brief memorandum to all APHIS regional directors reiterating that it was official APHIS policy "to sample all cattle condemned by FSIS on ante mortem inspection for exhibiting signs compatible with central nervous system diseases, regardless of age." On the very next day, however, USDA's Dallas district office issued a gag order forbidding all Texas employees to discuss the San Angelo cow with the press and instructing them to refer all inquiries to the USDA Congressional Public Affairs office. Steve Mitchell, USDA Orders Silence On Mad Cow in Texas, United Press International, May 11, 2004.

USDA's Adamant Opposition to Universal Testing.

Despite its reluctant and gradual movement toward more comprehensive BSE testing, USDA remains adamantly opposed to universal testing, even of the subcategory of animals more than 30 months old. In response to Japan's insistence that USDA follow Japan's practice of testing all cattle, Secretary Veneman testified to the House Agriculture Committee that "testing of all animals is not based on sound science." Secretary Veneman's invocation of "sound science" in this context, however, is puzzling. Dr. Stanley Prusiner, who won the Nobel Prize for his work

in identifying the mad cow prion, remains convinced that eventually every cow should be tested. At a cost of a few pennies per pound of beef, Prusiner concludes that the added security that universal testing would provide is easily worth the cost.

USDA trade advisor David Hegwood probably came closer to disclosing the real reason for the Department's refusal to order universal testing when he maintained that it was "scientifically not necessary, not justified and we don't want to go down that road because it diverts resources from where we really need to be putting them in doing surveillance and taking other risk mitigation measures for this disease." Charles Abbott, Test All Cattle To Be Safe From Mad Cow-Nobelist, Reuters, January 28, 2004.

The question whether an additional test is "scientifically *necessary*" is not the same as whether it is *desirable* from a scientific perspective. Science is generally hungry for data because every additional valid data point can enhance understanding. The question of diversion of resources is not strictly a scientific question at all. To the extent that the resources that go into BSE testing are not available for other scientific enterprises, universal testing may detract from the pursuit of science in a very limited way. But no one has suggested that the monies expended on additional BSE testing would otherwise be devoted to scientific research. It is much more likely that such dollars would otherwise go to increasing the wealth of beef industry shareholders or perhaps toward keeping U.S. beef prices low. It is, frankly, silly to suggest that the pursuit of science will be significantly hampered by universal BSE testing.

The USDA's chief veterinarian explained that universal testing would be "like a doctor testing every patient who comes through the door for prostate cancer." Donald G. McNeil Jr., Mad Cow Case May Bring More Meat Testing, New York Times, December 26, 2003 (quoting Dr. Ron DeHaven). This is not a "scientific" objection to universal testing, but it is a reasonable economic efficiency-based objection. The analogy, however, seems inappropriate. While prostate cancer is, like mad cow disease, a devastating disease, a single case of prostate cancer in a human being cannot be spread to hundreds or even thousands of other human beings. A single case of mad cow disease can result in the spread of infectious prions to hundreds or thousands of consumers of meat derived from that cow.

In any event, it would appear that devoting additional scientific resources to studying the incidence of mad cow disease, which can be debilitating to the beef industry and to human beings who contract vCJD, would not be wholly out of order. Given the huge uncertainties that attend the scientific understanding of how BSEs are transmitted, any additional data point in the otherwise woefully incomplete data set on the incidence of BSE in the U.S. is undeniably desirable from a scientific perspective. Dropping one more object from the leaning tower of Pisa to test the theory of gravitation may be scientifically senseless. Dramatically increasing testing for mad cow disease in a huge population of cattle that has not historically been carefully monitored is clearly supported by "sound" scientific considerations.

The trend in other countries that have experienced mad cow outbreaks has been to increase BSE testing dramatically to the point of universal testing of all slaughtered cattle or universal testing of cattle beyond a prescribed age. Japan requires testing of all cattle upon slaughter and prior to

release for human consumption. The European Union in 2000 mandated testing of all cattle over 30 months of age for BSE. The EU also requires testing of all downer cattle of greater than 24 months in age. Germany, Italy and France all test for BSE in all cattle older than 24 months prior to slaughter. This amounts to about one in every four animals slaughtered. Thus, France tests more cows in one week than the U.S. has tested in a decade. Sandra Blakeslee, *Jumble of Tests May Slow Mad Cow Solution*, New York Times, January 4, 2004.

Not surprisingly, universal testing has resulted in the detection of more mad cows. For example, of the more than 1.6 million animals that have been tested in Italy, 103 have tested positive for BSE. Although this may be disturbing to the cattle industry, it has yielded important scientific information that could be useful in preventing the further spread of mad cow disease. Because Italy tests all animals over 30 months of age for BSE prior to slaughter, Italian scientists detected two cases of mad cow disease in healthy looking cows and further discovered that the strain of BSE that infected the cows was very similar to the TSE that causes sporadic CJD in humans. This represents a real, if highly disturbing, contribution to the scientific understanding of TSEs.

USDA's Inexplicable Prohibition on Privately Conducted Testing

USDA flatly rejected a petition by Creekstone Farms to conduct universal testing of its cattle at a \$500,000 on-site testing laboratory and reportedly threatened the company with criminal prosecution if it went ahead with its universal testing program. Despite the fact that it has recently licensed five new "rapid test" kits for testing tissue for BSE, USDA justifies its adamant refusal to allow companies voluntarily to engage in universal testing of their cattle on the ground that universal testing is not "sound science."

The Department's obstinate opposition to an effort to gather more information about a little understood phenomenon is, however, incomprehensible from a scientific perspective. As Professor David Westaway, a molecular biologist and prion specialist at the Centre for Research in Neurodegenerative Diseases at the University of Toronto, explains, "tests are better than no testing" because testing is necessary to "to get the prevalence." Andrew Nikiforuk, *North Americans Haven't Tested Rigorously Enough For Mad-Cow Disease*, Boston Globe, January 8, 2004, at A21.

USDA may in its wisdom have decided that universal testing would be a grossly inefficient use of its limited resources. It is, however, paternalistic in the extreme for USDA to be so confident in its assessment that it is unwilling to abide the possibility that Japanese consumers (or American consumers for that matter) might rationally decide that they would prefer to pay a little extra for the additional assurance that testing brings to their dinner tables.

One USDA official has argued that if a private slaughterhouse conducting individual testing came up with a "false positive" reading and if the word got out to U.S. trading partners, the current import restrictions could be extended and new restrictions imposed. The companies advocating universal testing, however, are apparently willing to allow USDA or some other agency to confirm the tests to ensure against false positives. Stephanie Simon, U.S., *Some*

Ranchers Clash Over Mad Cow Tests, Los Angeles Times, May 24, 2004 (quoting John Tarpoff of Gateway Beef). This should put to rest any fears about false positive results.

Another fear expressed by USDA spokespersons is that a company engaged in universal testing would quietly destroy cattle that tested positive for BSE without reporting the positive test to USDA. This objection seems especially preposterous for several reasons. First, until USDA's universal animal identification program becomes effective sometime in the future, a cattle producer can already destroy suspicious cattle, whether or not they test positive. Second, USDA could easily promulgate regulations or guidelines holding slaughterhouses engaged in universal testing accountable for all tested animals. Finally, and most importantly, it would seem vastly preferable to destroy BSE-positive cows, quietly or otherwise, rather than have them enter the human food supply because they had not been tested at all.

In the final analysis, it seems clear that the real reason that USDA is willing to threaten companies that voluntarily test for mad cow disease with criminal prosecution has much more to do with the economic well-being of the five huge companies that control 84 percent of the meatpacking market than with the efficiency with which USDA or consumers allocate their resources. The larger companies, which primarily serve domestic markets, did not see any drop in demand for their products and could therefore keep prices steady while at the same time paying less to producers for cattle in markets depressed by reduced exports. Alwyn Scott, For Some in Beef Industry, Mad-Cow Disease "Almost a Windfall," Seattle Times, February 29, 2004. They no doubt understood that as soon as smaller competitors were able to reestablish export markets, the windfall profits they were deriving from depressed cattle prices would dry up.

The large companies and the trade association that they dominate also expressed fear that universal testing by any company would give rise to U.S. consumer expectations that domestic meat has been tested, and this would create consumer pressure on larger companies to engage in universal testing. The CEO of the National Cattlemen's Beef Association complained that "If you let one company step out and do that, other companies would have to follow." Donald G. McNeil Jr., Niche Meatpacker Is Cut Off From Its Best Markets, New York Times, April 18, 2004.

The dominant companies in any industry are, of course, always concerned about innovative competitors, and the big five meat processors had every reason to be concerned about Creekstone Farms, which was founded by a former head of the American Meat Institute. One way to prevent "upstart" companies like Creekstone Farms from intruding into a comfortable market is to pressure USDA to prevent them from exercising their acumen and competitive instincts by testing every animal for BSE.

Ultimately, USDA's obstinacy may harm all U.S. cattle interests other than the big five slaughterhouses. If USDA allows universal testing, the specialty beef producers who are willing to test for BSE will stay in business, and increased export markets will increase prices for domestic cattle. As Creekstone farms lays off employees and careens toward bankruptcy as a result of USDA's inexplicable determination to protect the big five meat producers, Australian

beef producers are rapidly establishing themselves, perhaps inextricably, in Japanese meat markets.

Additional Actions Congress Should Take

Require testing of All Downer Cattle.

Since downer cattle are the most at risk for mad cow disease, it is critical that at the very least all downer cattle are tested for mad cow disease. The International Panel that Secretary Veneman Appointed in January, 2004 recommended that all downer cattle be tested for BSE, and USDA has decided to test as many downer cattle as possible during the next year-and-a-half. Because downer cattle may no longer be slaughtered for human consumption, however, the sampling for the testing will have to take place at rendering facilities or at the ranches and other production facilities where the animals first attain downer status.

USDA's authority to require ranchers to sample the brains of downer cattle before burying them or sending them to a landfill is not at all clear. Congress should amend the FMIA to require any owner of an animal that becomes non-ambulatory to notify USDA of that fact within 24 hours and to hold that animal for sampling for up to an additional 48 hours before sending the animal to a rendering establishment or otherwise disposing of the animal. Renderers that are presented with downer cattle should have an equivalent obligation to notify and hold downer cattle if such notification has not already been provided.

The universal animal identification program that USDA hopes to establish within the next few years should help ensure that ranchers do not simply destroy downer cattle in violation of the requirement that they first be tested, because all cattle will ultimately have to be accounted for. The USDA International Panel on BSE believed that it was "imperative that the USDA take additional steps to assure that facilitated pathways exist for dead and non-ambulatory cattle to allow for collection of samples and proper disposal of carcasses." The panel recognized that this "most likely would involve expending resources to assist with costs associated with sampling, transport and disposal." Congress should provide such "facilitated pathways" for testing downer cattle by providing appropriate economic incentives for farmers to present downer cattle for inspection and testing before destroying them.

Require Additional BSE Testing.

Now that mad cow has afflicted the United States, some consumer groups have demanded USDA to follow Japan's lead and implement a universal BSE testing requirement for cattle brought to slaughter or rendering. Although USDA has increased its testing program, it is still very far behind the surveillance efforts of other countries. If USDA persists in restricting its BSE testing program to downer cattle and a few nonrandomly selected health cattle, Congress should require the Department to follow the example of the EU and test all cattle of greater than 30 months in age for BSE prior to slaughter for human consumption. To eliminate any doubt, Congress should clearly grant USDA explicit authority to make such testing mandatory.

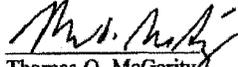
Allow Voluntary BSE Testing.

If USDA does not discontinue its incomprehensible efforts to protect the five dominant meat producing companies from competition by preventing companies like Creekstone farms from testing some or all of their cattle for mad cow disease, Congress should intervene. Congress should amend the aging Virus, Serum and Toxin Act to provide that any company may use USDA-approved tests to test some or all of its meat for food-borne diseases. If deemed necessary, Congress could further provide legal authority to USDA or (preferably) the Federal Trade Commission to prevent a company from relying upon such tests to provide a misleading characterization of the safety of its meat and meat products.

The fundamental underlying problem with USDA's approach to BSE surveillance is the fact that it views its primary mission as one of protecting animal health and not human health. In defending the APHIS BSE surveillance program, an APHIS spokesperson was explicit about this: "APHIS is not a human-health agency. APHIS is an animal-and-plant agency." Diedra Henderson, *USDA's Selective Screens Aren't Enough, Say Some Firms, Scientists*, Denver Post, May 31, 2004. The APHIS testing program may be reasonably effective as a surveillance program to determine the incidence of mad cow disease in the U.S. cattle population, but it is not driven by concerns for protecting human health from vCJD. Unless some fundamental problems with the program are fixed, however, merely expanding the number of animals tested for a brief interval will not yield an adequate testing program.

I will be happy to answer any questions that you or committee members may have after the release of the full CPR report next Thursday.

Sincerely


Thomas O. McGarity

President
Center for Progressive Regulation

APHIS Services

May 20, 2004



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Bovine Spongiform Encephalopathy (BSE)

Surveillance

The U.S. Department of Agriculture (USDA) constantly evaluates its means and methods for safeguarding American agriculture from foreign animal diseases, such as bovine spongiform encephalopathy (BSE). As science moves forward and new information and technologies become available, USDA continually works to ensure that the latest advances are incorporated in its efforts to prevent the introduction of foreign diseases and pests.

The U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and industry groups actively work to maintain this status. The measures USDA's Animal and Plant Health Inspection Service (APHIS) has taken in this regard include:

- prohibitions and/or restrictions on certain animal and product imports,
- ongoing surveillance for the disease in the United States,
- preparation of an emergency response plan in the event an introduction were to occur,
- ongoing educational efforts.

APHIS actively shares information and coordinates closely with other Federal agencies, as well as the States, livestock and affiliated industries, veterinary and research communities, and consumer groups, in order to ensure that the U.S. has a uniform approach to transmissible spongiform encephalopathies (TSE's) that is based on sound scientific information.

APHIS has a surveillance program in place in the United States to ensure detection and swift response. This surveillance program incorporates both the location of imports from countries known to have BSE and targeted active and passive surveillance for either BSE or other form of TSE in cattle.

APHIS has conducted a traceback effort to locate each of the 496 UK and Irish cattle that were imported into this country between January 1, 1981, and July 1989. None of these animals remain alive in the United States. In July 1989, the U.S. prohibited the importation of ruminants from countries affected with BSE. Five head of cattle imported from other countries in Europe in 1996-97 remain under quarantine ([figure 1](#)). In December 1997, the prohibition was expanded to include the entirety of Europe due to risk factors associated with BSE. In addition, APHIS, in cooperation with the States and industry, continues to purchase these animals for diagnostic purposes. No evidence of BSE has been found in any of these imported animals.

Targeted Active Surveillance

The United States has had an active surveillance program for BSE in place since May 1990. BSE is a notifiable disease, and there are more than 250 Federal and State regulatory veterinarians specially trained to diagnose foreign animal diseases, including BSE. There are several agencies involved in the surveillance program, including the Food Safety Inspection Service (FSIS).

APHIS leads this interagency effort. The surveillance samples include field cases of cattle exhibiting signs of neurologic disease, cattle condemned at slaughter for neurologic reasons, rabies-negative cattle submitted to public health laboratories, neurologic cases submitted to veterinary diagnostic

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laboratories and teaching hospitals, and sampling of cattle that are nonambulatory ("downer cattle"/fallen stock) has been practiced since April 30, 1993 (or in FY 94). We have also begun to sample adult cattle dying on farms. As of April 30, 2004, over 72,500 brains have been examined for BSE or another form of a TSE in cattle (figure 2).

Risk analyses were performed in 1991, 2000, and 2001 to assess the risk factors associated with BSE. The risk assessments have continued to demonstrate that the overall risk of BSE in the U.S. is low and is decreasing. These risk analyses have also been used to identify the portion of the cattle industry that would be at the highest risk of contracting BSE, and this population is where the majority of the active surveillance (brain submission and examination) has occurred. Specifically, this surveillance has been targeted at adult animals that demonstrated neurologic abnormalities, animals that were nonambulatory, or adult cattle dying on farms from unknown causes (figure 3).

APHIS' Surveillance Strategy

USDA takes a national approach to BSE surveillance (figure 4). The goal is to have surveillance be representative of the distribution of the adult cattle population in the United States. Based on movements of adult cattle going to slaughter, we have constructed regions, each with its own regional surveillance goals based on international standards as if each region were an individual country. The goal of testing 12,500 samples was established to detect one BSE-infected animal per million cattle (figure 5). This is an effective, scientific approach designed to take into account regional differences while striving for uniform surveillance throughout the country. It is also an approach widely accepted around the world.

The prevalence of classical CJD in human populations appears to be approximately one in a million worldwide. It has been hypothesized that other spongiform encephalopathies also might occur in the host populations at the same rate. (Brown et al., 2001) This is what has led the USDA to set a prevalence level of one in million as the target for our BSE surveillance.

The international animal health organization (OIE) has established guidelines for the number of samples that should be tested each year (see http://www.oie.int/eng/normes/mcode/A_00154.htm). For the United States, OIE recommends a surveillance level of 433 samples per year. However, USDA wanted the extra measure of security that a higher sampling level would provide, and therefore we have maintained surveillance far above the OIE-recommended level since 1994 (figure 6). USDA set out to design a surveillance program that is based on being able to detect if we had one BSE-infected animal in a population of a million. Given that the United States has an adult cattle population of approximately 45 million, if we did have BSE in this country at the one in a million level, we could assume that we would have 45 infected animals. To achieve a 95 percent confidence level in the accuracy of a random sample of adult cattle, we would have to sample and test some 3 million animals.

However, to conduct a more efficient, targeted, and effective survey, USDA's program instead focused on the higher risk population of cattle: adult cattle with central nervous system clinical signs and nonambulatory cattle. APHIS believes that it is incorrect to focus on the slaughter cattle population in regards to BSE surveillance. Cattle less than 20 months of age make up approximately 88 percent of the slaughter population, and no where in the world has a case of BSE been diagnosed in cattle less than 20 months of age. The cattle population APHIS considers as the target for BSE surveillance would be those most at risk to be exposed to the disease, not the slaughter population. The surveillance in the United States is designed to sample those cattle where BSE would most likely occur (most susceptible) and where the disease would most likely be detected.

Defining nonambulatory cattle as a high-risk population is based on the BSE surveillance experience of European countries that have BSE, since their experience and testing schemes have proven nonambulatory cattle to be an appropriate population for active targeted surveillance. For example, in Switzerland, testing of fallen stock and emergency slaughter cattle (these two

populations combined are essentially equivalent to the U.S. nonambulatory cattle population) has revealed BSE prevalence of 0.2 percent in 1999 and 0.12 percent in 2000.

In comparison, Switzerland's BSE prevalence in routine healthy slaughter populations was 0.004 percent in 1999 and 0 percent in 2000. BSE surveillance in France during the year 2001 identified 91 cases (19.4 percent) from the 49 cattle exhibiting central nervous system clinical signs, and 100 BSE cases (0.07 percent) from the 133,889 nonambulatory cattle tested. French testing of healthy slaughter cattle found 83 BSE cases (0.003 percent) from the 2,382,225 tested. These data also support the decision to conduct a targeted surveillance scheme rather than a simple random sampling scheme.

The next step is to determine the number of nonambulatory cattle there are in the United States. No one knows the exact number; however, an estimate of 195,000 per year was obtained from a survey conducted of American Association of Bovine Practitioners (Hansen et al., 1999) members. An assumption is made that the 45 potential cases of BSE would all be found in the high-risk cattle population. Dividing the potential cases into the high-risk population (45/195,000) gives a prevalence of 0.023 percent. This is the level of disease that needs to be detected in the high-risk population. Using Cannon and Roe's formula to determine the sample size needed to be tested to detect disease at a prevalence of 0.023 percent, it is determined that, nationally, a sample size of 12,500 is needed.

Sampling at this level will not prove that BSE does not occur at a lower prevalence level, but it should allow detection of a case if BSE truly exists at a level of one or more cases per million in the adult cattle population.

Conclusion

The combination of all of these factors, including both active and passive surveillance, has shown no evidence that BSE or another cattle TSE exists in the United States. The rate of surveillance in the United States for each of the last 5 years has been at least double the amount recommended by the OIE. In 2001, the rate of surveillance was ten times that recommended by OIE. In 2000, the number of brains examined was more than five times that which is recommended by international BSE surveillance standards. Surveillance will continue in the United States and, as in the past, it will be adjusted as science or risk factors dictate.

Figures

Figure 1: Status of Cattle Imported into the U.S. from other European countries in 1996-97 (as of October 18, 2002)

Figure 2: BSE Surveillance—Yearly Totals May 1990–FY 2004 (through 4-30-04)

Figure 3: Surveillance: NVSI, Bovine Brain Submissions FY 93–04 (through 4-30-04)

Figure 4: U.S. Regions for BSE Surveillance

Figure 5: U.S. Regional Goals for BSE Surveillance—FY 2003

Figure 6: U.S. Regional Goals for BSE (9/30/03)

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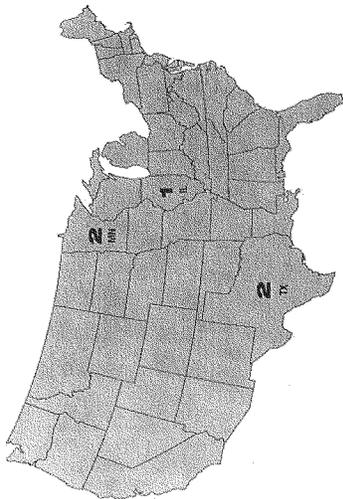
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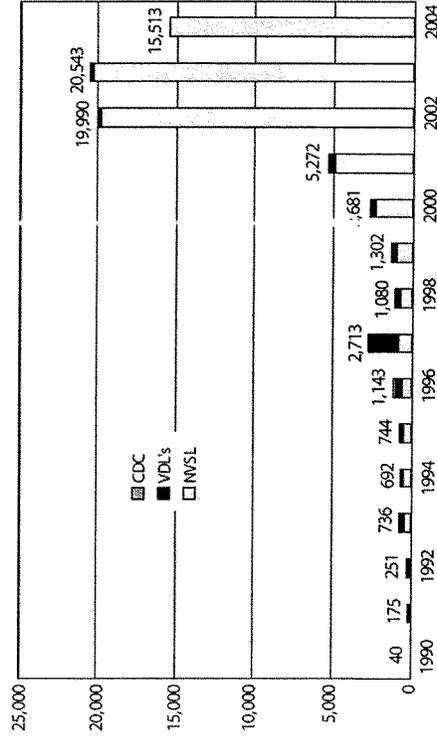
Figure 1

Status of Cattle Imported Into the US. From Other European Countries in 1996-97 (as of October 18, 2002)



[2]

BSE Surveillance – May 1990 – FY2004 (through 4/30/2004)



(b)

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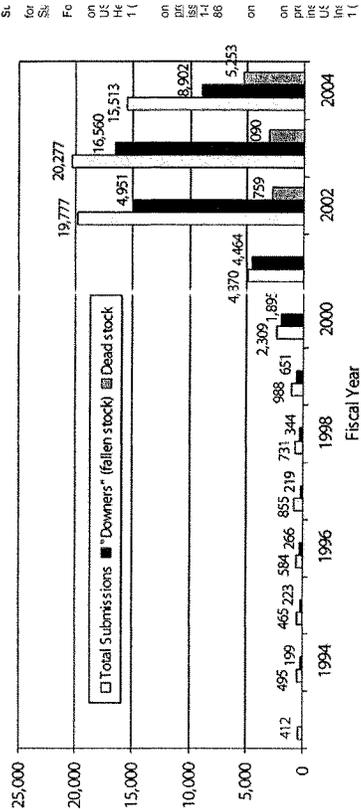
Figure 3

Surveillance: NVSL Bovine Brain Submissions FY 93-04 (through 4/30/04)

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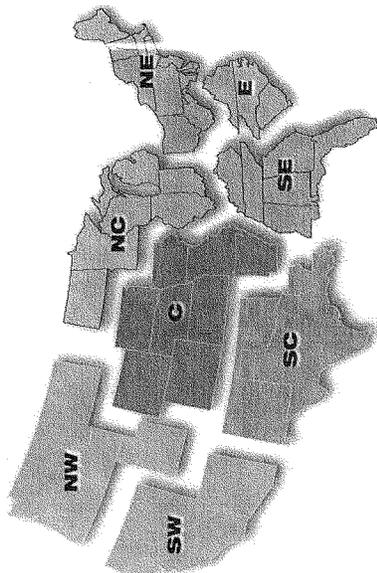
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Figure 4

U.S. Regions for BSE Surveillance



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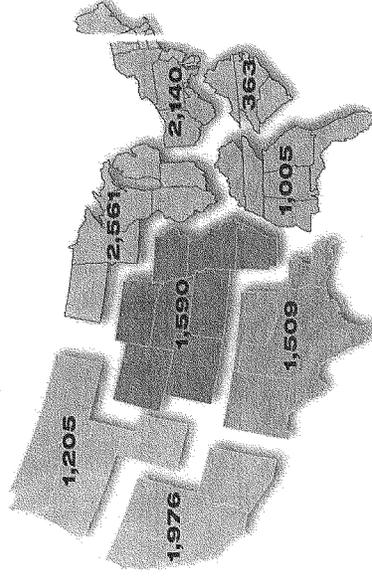
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Figure 5

U.S. Regional Goals for BSE Surveillance—FY 2003

A Total of 12,500 Samples



[D]

Figure 6

**U.S. Regional Goals
BSE Surveillance (9/30/03)**

| | FY 01 Goal | FY 01 | FY 02 Goal | FY 02 | FY 03 Goal | FY 03 |
|----|---------------|-------|---------------|-------|---------------|-------|
| NW | 564 | 695 | 1,205 | 2,224 | 1,205 | 781 |
| SW | 466 | 564 | 1,976 | 2,753 | 1,976 | 3,645 |
| C | 766 | 332 | 1,590 | 2,356 | 1,590 | 2,628 |
| SC | 734 | 872 | 1,509 | 1,810 | 1,509 | 1,890 |
| NC | 606 | 620 | 2,561 | 3,780 | 2,561 | 5,620 |
| NE | 462 | 805 | 2,140 | 2,190 | 2,140 | 2,595 |
| E | 312 | 401 | 363 | 1,381 | 363 | 514 |
| SE | 644 | 953 | 1,005 | 3,156 | 1,005 | 2,800 |



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July 16, 2004

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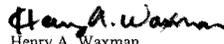
Dear Mr. Ellestad:

In order to clarify issues raised at the July 14 joint hearing of the House Government Reform and Agriculture Committees, please provide a brief written response to the following questions regarding the BSE-infected cow slaughtered on December 9, 2003:

1. Did you see the cow walk or stand on the day of slaughter?
2. What did you tell the Inspector General's office about the cow's status upon arrival, during its examination by Dr. Thompson, and after the examination?

Thank you very much for your assistance. I request that a written response for the record be faxed to (202) 226-3348 as soon as is possible. Please call Naomi Seiler on my staff at (202) 226-3623 if you have any questions regarding this request.

Sincerely,


Henry A. Waxman
Ranking Minority Member

VERN'S MOSES LAKE MEATS, INC.

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MOSES LAKE, WASHINGTON 98837



July 19, 2004

Henry A. Waxman
Ranking Minority Member
Committee On Government Reform

Dear Mr. Waxman:

This is in reply to your request that I answer several questions to help clarify issues raised at the July 14 hearing. In your letter to me dated July 16, 2004 you asked two questions. Following are those questions and my response. My answers do refer to what USDA has referred to as the index cow that tested positive for BSE.

1. Did I see the cow walk or stand on the day of slaughter?

My answer is Yes I did.

2. What did I tell the Inspector General's office about the cow's status upon arrival, during its examination by Dr. Thompson, and after the examination.

My answer: When this particular load of cows arrived the hauler told me that the first four cows that we would take off the trailer could be unloaded in the pens and would be able to walk up the ramp to the kill floor. These four cows were lying down in the trailer when I looked at them so I gave Dr. Thompson the option of having us get them up and unloading them in the pens if he was in a hurry to leave on that day. His response was that "I am here for the duration today so just bring them in order". What I told OIG about killing the cow was "Subsequently, they did, all four of them, stand and two of them for sure walked off the trailer, but I did see all four of them standing. And as my recollection is, the 6810 was one of them that walked off the trailer." Dr Thompson did note in his records that he did see one of the four cows standing when he just happened to look out the back door. When he was there for all day it was not our policy to inform him if a cow had gotten up after he had looked at it.

I hope this clarifies the issue for you. We have appreciated the sincerity and dedication to the task of each member and staff from the COMMITTEE ON GOVERNMENT REFORM. If we may be of further assistance please let us know.

Sincerely, Tom Ellestad



July 26, 2004

The Honorable Tom Davis
Chairman
Committee on Government Reform
2157 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

I appreciate the opportunity to comment on the progress of surveillance efforts by the U.S. Department of Agriculture (USDA) regarding *bovine spongiform encephalopathy* (BSE). In particular, I would like to encourage USDA's careful consideration of rapid testing methods that eliminate "false positive" readings of BSE.

Since the December, 2003 outbreak of BSE, USDA has worked tirelessly to reassure both American and international consumers of the wholesomeness of U.S. meats. I applaud the efforts made by the department to carefully and methodically gather and analyze the data necessary to quell public concerns. USDA reacted quickly to stem the loss of consumer confidence through the ban of "downer" cattle in the human food chain, a "test and hold" policy for suspicious animals, as well as stricter requirements and removal of specified risk materials from the food supply, among other practices. I applaud the efforts of the Secretary and Dr. DeHaven for their tremendous commitment during a time of national crisis.

I hope USDA will continue these strenuous methods in its ongoing surveillance program for BSE by doing everything possible to eliminate uncertainty. This must include the highest level of verification technologically possible in rapid testing. As has already been seen in two cases, the reported "false positives" disrupts the market unnecessarily and only adds to consumer concerns about the safety of U.S. meats.

Fortunately, the technology exists to eliminate the uncertainty caused by "false positives" in rapid testing. Currently, this proven method, known as the Western Blot test, is used successfully throughout Europe as well as Canada, Mexico, Australia and New Zealand. In fact, the Western Blot test has been used more than 20 million times and has never returned a "false positive" reading. Independent panels around the world have examined and approved this failsafe test.

On behalf of cattlemen, pork producers and consumers in southeastern Indiana, I request USDA's speedy incorporation of this demonstrated test into its surveillance program. At this critical time for international trade and domestic economic stability, every available resource must be used to preserve our worldwide reputation as reliable and safe food producers.

Thank you again for your commitment to the safety and stability of American agriculture by holding this important joint hearing. I appreciate the chance to share my thoughts on this critical issue.

Sincerely,

Baron P. Hill
Member of Congress

BPH/lis

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INDEPENDENT

July 16, 2004

The Honorable Phyllis K. Fong
Inspector General
United States Department of Agriculture
1400 Independence Avenue SW
Washington, DC 20250

Dear Ms. Fong:

Thank you very much for testifying at the joint hearing of the House Government Reform and Agriculture Committees on July 14, 2004. As agreed to at the hearing, below are several questions for the record regarding the results of your investigations of the detection of BSE in Washington State:

1. In December, Secretary Veneman stated publicly that the infected cow in Washington State had been a downer since giving birth.
 - a. Was this statement consistent with the eyewitness accounts of the three people you interviewed at the dairy farm where the cow came from?
 - b. Was this claim consistent with the account of the hauler you interviewed who picked up the cow that morning?
2. The owner of the slaughter facility swore in an affidavit that he remembered the cow standing up after its antemortem examination. The USDA veterinarian who performed the exam told Committee staff that there was nothing on postmortem examination that indicated the cow could not have stood. He also said that the cow's having stood after his examination was a "distinct possibility."
 - a. Did you find any evidence demonstrating that the cow could not or did not stand after its examination?
 - b. What did the slaughter facility owner tell your investigators about whether the cow stood after the antemortem inspection?

The Honorable Phyllis K. Fong
July 16, 2004
Page 2

3. Secretary Veneman and other senior USDA officials have characterized the detection of the cow in Washington State as evidence that the surveillance program worked as intended. The program in place at the time was designed to exclusively test downers and other high-risk cattle.
 - a. Did USDA's agreement with the facility permit testing of nondowner cattle?
 - b. Did you find evidence that nondowner cattle were in fact tested through this agreement?

Thank you for your cooperation. I request a response in writing by Wednesday, July 21.

Sincerely,



Henry A. Waxman
Ranking Minority Member



UNITED STATES DEPARTMENT OF AGRICULTURE
OFFICE OF INSPECTOR GENERAL
Washington D.C. 20250



AUG - 2 2004

The Honorable Thomas M. Davis III
Chairman
Committee on Government Reform
U.S. House of Representatives
2157 Rayburn House Office Building
Washington DC 20515 6143

Dear Chairman Davis:

The Office of the Inspector General (OIG) at the Department of Agriculture (USDA) received a July 16, 2004, letter from Ranking Member Waxman, which provided several Questions for the Record (QFRs) regarding the joint hearing of the House Government Reform and Agriculture Committees on the USDA's BSE surveillance plan.

Enclosed is our response to the QFRs. We hope it provides additional helpful information about our investigative results pertaining to the BSE-positive cow identified in Washington State in December 2003.

We sent a similar letter containing our QFR response to Ranking Member Waxman and will also do so for Chairman Goodlatte and Ranking Member Stenholm of the Committee on Agriculture. As I mentioned in my testimony, we will provide our final audit report on the USDA's BSE surveillance plan directly to the Chairmen and Ranking Members of the House Government Reform and Agriculture Committees upon its completion.

We appreciate the opportunity to provide information from our BSE-related work to you. Should you have additional questions about this information, please contact me at (202) 720-8001, or have a member of your staff contact Mr. Paul Feeney of our Legal Staff at (202) 720-9110. We look forward to working with you and your colleagues on matters of interest to the Committee on Government Reform.

Sincerely,

A handwritten signature in black ink that reads "Phyllis K. Fong".

Phyllis K. Fong
Inspector General

Enclosure

Office of the Inspector General
U.S. Department of Agriculture
Response to Representative Waxman's July 16, 2004 Questions for the Record
July 14, 2004 Hearing on the USDA's Expanded BSE Cattle Surveillance Plan

Question 1.

1. In December, Secretary Veneman stated publicly that the infected cow in Washington State had been a downer since giving birth.
 - a. Was this statement consistent with the eyewitness accounts of the three people you interviewed at the dairy farm where the cow came from?
 - b. Was this claim consistent with the account of the hauler you interviewed who picked up the cow that morning?

OIG Answer to Question 1.

1a. The three people we interviewed at the dairy farm where the BSE-positive cow came from provided the following information that is responsive to your question.

One co-owner of the dairy farm, who was also a practicing veterinarian, made several relevant comments to OIG in his sworn statement:

- Due to prior injuries, the BSE-positive cow preferred to remain recumbent but would "rise if enough pain was induced to overcome her discomfort due to the injury." The cow was able to rise if stimulated aggressively but was reluctant to do so.
- The BSE-positive cow could fit a reasonable definition of ambulatory or non-ambulatory. He said there were three cows from the dairy farm that were loaded on the trailer for delivery to the facility on the same day, and any of the three cows could be classed as non-ambulatory downers.¹
- This cow walked onto the trailer for delivery to the facility, but it was very weak and it was possible it was non-ambulatory by the time it arrived.² He stated he was not, however, present during the actual loading of the cow.

¹ This second sentence comes from OIG agents' Memorandum Of Interview of a second interview with this co-owner. A sworn statement was not taken during OIG agents' second interview with the co-owner of the dairy farm.

² This sentence is from OIG agents' Memorandum Of Interview.

- “It is my opinion based on the understanding of how the BSE surveillance was designed to work and based on the condition of this cow, as I understand it, the selection process by USDA worked exactly as it should have in this case.”

The second co-owner of the dairy farm told OIG in his sworn statement:

- The cow injured herself after calving. She was able to stand up on her own and to walk, though she was never stable after the injury. The cow was ambulatory, but he also was not present at the actual loading of the cow.

The foreman who worked for the owners of the dairy farm and who was present during the loading of the cow made the following pertinent comments to OIG in his sworn statement:

- She injured herself after calving; she was able to stand up on her own and to walk. After a second injury, she was never stable on her legs, and preferred to lie on the ground. The cow was ambulatory.
- On December 9, 2003, the cow arose on her own, but struggled to her feet due to her injuries. The cow walked onto the trailer without assistance and remained standing until the trailer left.
- He noted that a cow’s physical condition can change during transport and her classification could go from an ambulatory cow (“walker”) to non-ambulatory (“downer”) cow, or vice versa.

1b. In his sworn statement to OIG agents, the hauler stated that the cow infected with BSE was a healthy walking cow and it walked onto the trailer. The hauler picked up two additional cows, besides the BSE-positive cow, at the dairy farm that morning. He wrote in his hauling documentation that one of the two had a broken leg, but his recollection was that they were also healthy walking animals and walked onto the trailer. He further stated: “If any of the animals were lying down at the farm when I got there and unable to walk up onto the trailer by itself I would not have loaded it, and instead would have left it at the farm.” He could not recall the ambulatory status of the BSE-positive cow when at the slaughter facility.

The comments of the foreman of the dairy farm that supplied the cow contrast with those of the hauler. Regarding one of the additional two cows (not the BSE-positive cow) picked up that day, the foreman said in his sworn statement that he, “rolled her into a bucket and mechanically lifted her into the trailer.” The foreman said that it was either unable or unwilling to walk or stand. Both co-owners of the dairy farm said in their sworn statements to OIG that this additional cow (not the BSE-positive cow) could not walk or stand.

Question 2.

2. The owner of the slaughter facility swore in an affidavit that he remembered the cow standing up after its antemortem examination. The USDA veterinarian who performed the exam told Committee staff that there was nothing on postmortem examination that indicated the cow could not have stood. He also said that the cow's having stood after his examination was a "distinct possibility."

- a. Did you find any evidence demonstrating that the cow could not or did not stand after its examination?
- b. What did the slaughter facility owner tell your investigators about whether the cow stood after the antemortem inspection?

OIG Answer to Question 2.

See also information provided in answer to questions 1a. and 1b., above.

2a. The USDA Veterinary Medical Officer (VMO) on-site, who was the USDA official with the responsibility to make determinations whether cattle entering the facility should be condemned, told OIG in a sworn statement that the cow was down during antemortem inspection. The VMO stated that at no time on December 9, 2003, did he see the BSE-positive cow stand or walk. The VMO further said no individuals at the facility informed him that day that they ever saw the BSE-positive cow in an ambulatory condition; nor did anyone subsequently ask him to reassess the animal after his examination. He also stated that the BSE-infected cow did not exhibit any signs of central nervous system disorder during ante-mortem inspection.

An FSIS inspector on-site that day told OIG in a sworn statement that some of the cattle were non-ambulatory and others were ambulatory. She did not see any cow that was a downer subsequently rise and walk. She said she could not recall that the individual who stunned the animals told her that any cow that had been down later stood.

2b. The facility owner told OIG in a deposition that the cow was down during antemortem inspection, but it stood later on. He further stated:

And as my recollection is, the [BSE-positive cow] was one of them that walked off the trailer. She was for sure one that stood up. You know, on the trailer and could have even all walked off.

Additionally, the facility owner said, "[t]his particular day, because he [the FSIS VMO] said he was there all day, we did not have any reason to come and get him when these cows got up."

Question 3.

Secretary Veneman and other senior USDA officials have characterized the detection of the cow in Washington State as evidence that the surveillance program worked as intended. The program in place at the time was designed exclusively to test downers and other high-risk cattle.

- a. Did USDA's agreement with the facility permit testing of nondowner cattle?
- b. Did you find evidence that nondowner cattle were in fact tested through this agreement?

OIG Answer to Question 3.

3a. USDA's agreement with the facility, in the form of a purchase order, was non-specific as to the type of "animals" to sample. It was for the period 10/1/03 - 9/30/04, and stipulated a payment of \$10 each for cattle carcass disposal fees for animals from which BSE samples are collected, not to exceed 1,000 animals.

3b. This issue was not a focus of our investigation, but we did gather information relevant to it. We found that non-downer cattle were among the cattle tested at this facility on December 9, 2003. Below is a summary of pertinent comments made by different witnesses about the testing of downer and non-downer cattle at the facility.

The APHIS Assistant Area Veterinarian in Charge

- She told OIG the target type of animals APHIS wanted tested were cows 30 months old or older and U.S. Suspected as "downer," non-ambulatory animals by FSIS. APHIS did not want any ambulatory animals unless "they were referred by FSIS, and "suspected" with CNS symptoms on ante-mortem inspection."
- She trained the co-owner's son, who was the kill floor foreman, in the BSE sampling procedure. On at least two occasions during the training she explained the target type of animals that APHIS wanted tested.

The APHIS Veterinary Medical Officer

- He repeated the above information to OIG, but added that the slaughter facility had what was known as the "backdoor" policy. Any animal too weak to walk up the ramp to the animal stunning area was hoisted through the backdoor after being stunned. BSE samples were taken from animals that came through the "backdoor." He learned of the "backdoor" policy after the BSE finding.

The Washington State veterinarian

- The state veterinarian who worked with the facility told OIG that the APHIS program required testing of only U.S. Suspected cattle that were over 30 months old and U.S. Suspected cattle that were “downer” cattle.
- According to the state veterinarian, the facility owner had an agreement with his truck drivers that they would only pick up cattle that walked onto the trailers when loaded. Sometimes, because the animals were weak, but not sick, they would go down in the trailer. Instead of forcing them to stand up, the animals were presented to the backdoor for ante-mortem inspection, then stunned and hoisted into the facility. Personnel at the facility referred to these animals as “backdoor” animals.
- If APHIS wanted the “backdoor” animals for their surveillance program and not animals referred to as downers, then the plant owner was willing to participate in the BSE testing program.

The FSIS Veterinary Medical Officer (VMO)

- The FSIS VMO told OIG that the owner of the slaughter facility told him that he had an agreement with APHIS to take BSE samples from all “backdoor” animals, except for dead cattle and those condemned during ante-mortem inspection. These were the animals delivered to the backdoor of the facility, some of which were ambulatory. Of the 11 animals delivered to the backdoor of the facility on December 9, 2003, one arrived dead and another down cow was condemned during ante-mortem inspection. All of the other animals were down initially, but one stood up during inspection and a second stood up later. These two walking cows were determined not to be suspect animals.
- BSE samples were taken from all of the cattle, including the two non-suspect cattle, because they came in through the backdoor.

The Owner of the Slaughter Facility

- The facility owner told OIG that his plant did not process “downer” animals because he required that the animals walk into the trailers when picked up. The animals could be down in the trailers when delivered, but would not be forced to get up for humane reasons. The facility processed such animals through the backdoor.
- When establishing the type of animals to be selected for BSE testing, the facility owner said the facility suggested to APHIS that backdoor animals be tested, as they were the “least ambulatory.” However, ambulatory animals were also taken in through the backdoor and BSE-tested.

- On December 9, 2003, he said the BSE-infected cow and three others were down at the time of ante-mortem inspection, but later stood up. Of these, two walked off the trailer. BSE samples were taken from all of them.



**Bio-Rad
Laboratories**

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**Testimony of Bio-Rad Laboratories
Submitted on July 14, 2004
Joint Hearing of the House Committee on Agriculture and the House Committee on
Government Reform**

Thank you for this opportunity to submit testimony to the House Committee on Agriculture and the House Committee on Government Reform.

Bio-Rad Laboratories, Inc. is a multinational manufacturer and distributor of life science research products and clinical diagnostics. The company is based in California and serves more than 70,000 customers worldwide through a network of 30 wholly owned subsidiary offices.

Bio-Rad is the market leader in testing for Bovine Spongiform Encephalopathy, or BSE, more commonly known as mad cow disease. Bio-Rad's BSE test is used in 27 countries including Japan, Germany and the United Kingdom. More than 24 million cattle worldwide have been screened using the Bio-Rad BSE tests in more than 500 laboratories since November 2000. The Bio-Rad test currently accounts for approximately 65-70 percent of all animals screened for BSE throughout the world.

There is a great deal of confusion with regard to public understanding about how screening and testing for mad cow disease is conducted in the United States. As the world leader in all forms of testing for the family of diseases known as TSEs (Transmissible Spongiform Encephalopathies), of which BSE is one, we would like to share the benefit of our knowledge and experience with this committee.

It is important to note that in all diagnostic tests where the vast majority of results are negative (human and animal tests), the standard practice is to employ a two-step testing regime, one that links a sensitive rapid screening test with a confirmatory method. This is how our National Blood supply is kept free from hepatitis or HIV for example.

Likewise, the BSE screening process yields one of two results, "not detected" (negative) and "initially reactive" (inconclusive). It is the confirmatory step, conducted on the "initially reactive" samples that determines whether an animal is positive or negative. For example, the immunohistochemistry used by the USDA's National Veterinary Service laboratories, in Ames, Iowa is used as a confirmatory test. Therefore the widespread use of the term "false positive" in the screening process is confusing and misleading.

In layman's terms: With a screening test you get negatives and samples that need further testing. You don't get positives and you don't get false positives. It is only the confirmatory test that gives positives.

The role of the screening test is critical to providing adequate surveillance for BSE. The most important factor in selecting a rapid test for BSE is sensitivity – the ability to detect all possible positives. This is critical since tests with lower sensitivity can lead to false negatives and false negatives can go undetected by a surveillance program.

In Japan for example, a commercial test now in use in some laboratories in Europe was unable to detect that nation's first positive case (ISSN 1012-5329, Disease Information, O.I.E., September 14, 2001, Volume 14 – No. 37, page 209). Since the cow was displaying neurological symptoms, it was retested using the Bio-Rad BSE assay and other methods and found to be positive. It was later confirmed to be positive by the World BSE Reference laboratory in England. If it were not for the persistence of the officials involved with this initial case, Japan would have missed its first case of BSE and the animal would have passed into the food chain.

Independent field studies have shown the Bio-Rad BSE test to have the highest level of sensitivity and specificity of any rapid screening tests available. Bio-Rad's BSE test has been shown to be up to 30 times more sensitive than other BSE tests (European Commission DG (Sanco) XXIV evaluation, July 1999; Nature January 2001: 409: 476-477).

Using a method considered the most sensitive by all independent evaluations constitutes a highly effective rapid screening tool for BSE surveillance, one that adds to consumer and trading partner confidence.

Finally, we wish to note that all screening tests used for the detection of BSE in cattle are subject to generating inconclusive results. Some of the marketing information presented to the contrary is neither scientifically sound nor supported by the facts.

Thank you again for this opportunity to submit testimony and for allowing us to correct any misinformation that might have confused the committees.

