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TO EXAMINE THE CURRENT SITUATION REGARDING THE DISCOVERY OF A CASE OF BOVINE SPONGIFORM ENCEPHALOPATHY IN A DAIRY COW IN WASHINGTON STATE AS IT RELATES TO FOOD SAFETY, LIVESTOCK MARKETING AND INTERNATIONAL TRADE

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

JANUARY 27, 2004

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TUESDAY, JANUARY 27, 2004

U.S. SENATE, COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
WASHINGTON, DC

The committee met, pursuant to notice, at 9:36 a.m., in room SR–328A, Russell Senate Office Building, Hon. Thad Cochran, [Chairman of the Committee], presiding.

Present or submitting a statement: Senators Cochran, Roberts, Coleman, Crapo, Talent, Grassley, Harkin, Leahy, Conrad, Daschle, Baucus, and Nelson.

STATEMENT OF HON. THAD COCHRAN, A U.S. SENATOR FROM MISSISSIPPI, CHAIRMAN, COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

The CHAIRMAN. Good morning. The committee will please come to order.

Today, our committee meets to conduct a hearing to review the status of the administration's response to the discovery of a case of bovine spongiform encephalopathy, or BSE, and to assess the effect BSE has had on the U.S. livestock industry and the safety of our nation's food supply.

I am pleased to welcome today the distinguished Secretary of Agriculture, the Honorable Ann Veneman, and Dr. Lester Crawford, Deputy Commissioner of the U.S. Food and Drug Administration, who are here today to discuss these issues and answer questions from the members of the Senate Committee on Agriculture, Nutrition, and Forestry.

I first wish to compliment the Secretary for the prompt, public response she organized and led at the Department of Agriculture to investigate and make available to all Americans the facts about the BSE discovery. It has been an impressive example of responsible leadership, in my opinion.

Even though the investigation continues and there are questions that are not yet fully answered, the marketplace has stabilized and there has been no public panic. Most Americans realize that we

have in place inspection and safety procedures that are effective in protecting our food supply, and in spite of the fact that we have experienced a serious disruption in the U.S. beef trade, market prices are higher than last year's levels.

We are hopeful that our trading partners around the world will apply the principles of sound science when assessing the risks to their markets of this isolated event in the State of Washington. I am convinced that it is because of the transparency, with which Secretary Veneman and others have led the effort to inform and educate the public, that there has been such high consumer confidence in American beef products.

Our committee is ready to cooperate in any way necessary to help strengthen our laws to ensure the integrity and safety of our nation's food supply and the restoration of markets for our food products.

I am pleased at this time to yield to other members of the committee for any statement that they may wish to make.

[The prepared statement for Chairman Cochran can be found in the appendix on page 58.]

Senator Baucus.

STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA

Senator BAUCUS. Thank you very much, Mr. Chairman. I thank my colleagues, Senator Allard and Senator Durbin, for taking such an active interest, and I compliment, too, as has the Chairman, Secretary Veneman. She has done a great job. It is a difficult time, to say the least, and I know how pressured she has been, but I thank you, Madam Secretary, and your people. I have a few suggestions that we can talk about when you testify, but you have done, quite a good job.

Mr. Chairman, I have a fairly lengthy statement and I don't want to take too much of the committee's time, but there are several issues that concern me. I will just talk about them very briefly.

One is the need for a trade envoy. I know that the USDA has spent a good bit of time talking to various countries, encouraging them to open up their markets to U.S. beef, but the Deputy Secretary or Under Secretary of Agriculture has a lot of other issues on their plates, to say the least. It is very important, because this is such a vital industry to America, that the United States appoint, that the President appoint a very top-level person with high prestige whose sole mission is to help work with countries and get them to reopen their markets to American beef. We need one person to work on this full time.

Second, we ought to spend a little time on the mouthing rule. I certainly understand the general point, namely if the number of teeth, the third tooth hasn't come in in 30 months, the animal is too old and more likely to be diseased and placed in the category. That is a very imperfect rule because different animals develop at different rates. We should take a hard look at that one again to make sure that we know what we are doing and we don't throw, not the baby out with the bathwater, we just don't over react with that rule.

Another is country of origin labeling. We have to get this through the Congress. I am very upset, frankly, that on this appropriations bill, the conferees put in language which delays—I think they did, I can't recall if that was put in the bill or not—and the administration has been working in conjunction with that. That is delaying the implementation of country of origin labeling. That is just wrong. That doesn't work. This is a consumer confidence matter. If consumers know that it is American beef, we have done a very good job, and as I said, you have done a good job, too, Madam Secretary, in protecting American beef and particularly the safety of American beef and we have to work very hard on that.

Animal ID is something we have to work on. I understand USDA has been working on a national system and I appreciate that. I want to talk to you, Madam Secretary, when you testify about what kind of timeline you are looking at and how that is working out.

We in Montana are very proud that we brand all of our cattle. Cattle, it is my understanding, east of the Mississippi don't. The States do not brand their cattle east of the Mississippi. We have a good system and we are very proud of it. Montana producers want to go the extra mile in making sure that our cattle are safe. That is, they like the ban on downers. They want, are very, very interested, intrigued with a national ID system. They want to find a mouthing rule that works.

It is astounding to me—I am so gratified the degree to which Montana stockgrowers have come together to make sure that all is being done to ensure that their beef is safe. I know this because we have had many meetings in Montana the last couple of weeks, in ten different communities in Montana, and this is what producers say, this is what the packers say, and this is what the consumers say. There is unanimity in being very firm but fair here and I know you have been working hard.

One final point is potential insider trading. The disease was known, it is my understanding—I might have my dates wrong, I am pulling it out of the air—about December 9 or something like that, and it was not revealed to the public for some time later. At that time, the cattle futures market fell about 15 percent. Now, there could be possible reasons why the futures market fell, but I want at some point for us to perhaps have the CFTC look at potential insider trading due to the delay between discovery of BSE and the date of announcement, which was, in my understanding, about ten or 12 days later. I may have the facts wrong, but at the very least, let us get that out and see what we can do.

Anyway, Mr. Chairman, thank you very much. This is extremely important to my people and my State and I thank all those that worked very hard to try to find a solution.

[The prepared statement of Senator Baucus can be found in the appendix on page 63.]

The CHAIRMAN. Senator Crapo.

STATEMENT OF HON. MIKE CRAPO, A U.S. SENATOR FROM IDAHO

Senator CRAPO. Thank you very much, Chairman Cochran. I appreciate the committee holding this hearing. This is a critical hearing to address the discovery of the case of BSE in a cow imported

from Canada through the State of Washington and the related food safety, livestock marketing, and international trade issues that have arisen in light of this discovery.

I would like to thank Senator Allard and Senator Durbin for being here today to discuss some of the issues that they are advocating with regard to this issue, and Secretary Veneman, Commissioner Crawford, and Dr. Torres for being here with us today, as well.

Beef cattle is my home State of Idaho's No. 1 commodity. Valued at more than $975 million annually, it is a vital part of Idaho's economy. Like all of you, I am deeply concerned with the discovery of BSE in the United States, not only for the safety of our food supply, but also for the effect that this discovery is having on the livelihood of my fellow Idahoans and our agricultural economy as a whole.

I am confident that our beef supply is safe. The precautions and safeguards we had in place worked and worked well. U.S. consumers are blessed with an extremely high quality and competitive domestic beef industry. Our cattle ranchers and processors meet rigorous safety and quality standards and we have every reason to have confidence in the continued safety of our beef supply.

Secretary Veneman, I would like to commend you and the many USDA employees for your quick and diligent response to the discovery. I also appreciate the Department's effort to work with the cattle industry, State and local governments, and others throughout this process.

So far, three of the cows from the indexed herd have been found in Idaho. Close contact with the local cattle industry has been essential and I would encourage the continued and increased communication with affected communities. In my view, more cooperation and more coordination between all interested parties is always better, and this open dialog has clearly contributed to maintaining our consumer confidence.

That having been said, as has already been raised by others, there are a number of critical issues dealing with how we should best manage this issue in this country that will be handled both here in Congress, in the Department of Agriculture, and in our respective State Departments of Agriculture as they struggle with this difficult issue.

I would like to express my support for the continued efforts to reopen our beef export markets. We all understand the importance of regaining these markets to the beef industry. Senator Baucus has already mentioned the fact that we have encouraged the establishment of a trade envoy, very specific focus in our Federal Government's efforts to make sure that these markets are reopened. Prolonged closure of our markets could have serious long-term effects that will ripple throughout our entire economy.

I commend the administration's efforts and encourage continued persistence to reopen the doors of our trading partners. We must maintain constant dialog with nations that have banned U.S. beef and continue to work to restore their faith in our beef exports so that they will terminate their bans.

Collectively, we must ensure that the proper mechanisms are in place to prevent and to respond to future cases, and as good as our

efforts were in response to this case, I am certain that we can improve our abilities.

Understandably, when incidents such as this occur, it is natural to immediately enact changes or new programs to address the issue. However, we must use a great level of caution in our pursuit of reforms and the further development and expansion of tools, such as animal identification programs. We owe it to the agricultural industry and consumers to ensure that we carefully consider all available options. Any of these reforms which we adopt must be guided by sound science. They must be flexible to take into account the needs of local communities and our private industry and not be overly cumbersome and intrusive to U.S. cattle operations or to American consumers.

Clearly, questions regarding the current and future responses to the discovery of BSE remain to be addressed. Overall, however, I have been impressed with our timely response and the continued work to address this discovery. I appreciate the administration's efforts to keep consumers and the ranching community well informed at every step in the process.

Again, I thank Secretary Veneman and the Department for their prompt response and our chairman for holding this hearing and look forward to working with you all to be sure that we are well equipped to prevent and respond to incidents of BSE. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

[The prepared statement of Senator Crapo can be found in the appendix on page 74.]

Senator Grassley.

STATEMENT OF HON. CHARLES GRASSLEY, A U.S. SENATOR FROM IOWA

Senator GRASSLEY. Thank you, Mr. Chairman, for this timely opportunity to discuss a crucial issue. The discovery of a Canadian cow carrying BSE in the United States shaved off 20 percent of the market price for live cattle and devastated our export markets within days of the announcement. While the discovery of the Canadian cow has had and will continue to have a devastating impact on cattle producers, I need to commend the Department of Agriculture for initially handling the issue well and solidifying domestic consumer confidence.

I plan to raise many questions today which seemingly might challenge the Department's recent choices, but I recognize that the U.S. Department of Agriculture has done an outstanding job and no one should question my confidence in our meat supply or my belief that we will overcome some of the issues I will raise today to further solidify consumer confidence and reopen foreign markets as quickly as possible. Thank you.

The CHAIRMAN. Thank you, Senator.

[The prepared statement of Senator Grassley can be found in the appendix on page 71.]

Senator Conrad, an opening statement? You may proceed.

STATEMENT OF HON. KENT CONRAD, A U.S. SENATOR FROM NORTH DAKOTA

Senator CONRAD. I thank the Chairman. I thank the Chairman very much for holding this hearing. I held a hearing in North Dakota on this subject and it was very interesting, the level of concern across the State with respect to the potential effect on our economy.

I just read the Washington Post this morning. I want to commend USDA for additional steps that have been taken. They are very important steps. I must say I was somewhat alarmed at our hearing to learn that we have actually been feeding poultry litter to cattle in the country. I don't know how widespread that was, but it certainly didn't make any sense to me. I am very pleased that USDA has stopped that practice. It is the right step to have taken.

In this morning's *Wall Street Journal*, there is a story headlined, "U.S. Investigates Cattle Trades," and in it, it says that Federal regulators are investigating whether some commodity traders last month had advance knowledge that the first U.S. case of "mad cow" disease was confirmed in Washington State. It goes on to say that investigators with the Commodity Futures Trading Commission are interviewing possible witnesses, reviewing documents and phone records, and examining trading patterns on the Chicago Mercantile Exchange. At issue are investors who took short positions in live cattle futures, betting on a price decline in the days just before the December 23 announcement by the Department of Agriculture Secretary.

That is a serious matter and it is something that I heard a lot about at the hearing in North Dakota, a very grave concern that there was a gap between the time we knew that that cow was diseased and the time it was reported, a gap between the time we knew that cow was from Canada and the time that that was reported, and a very serious concern that some had inside knowledge. People who raised the concern are very knowledgeable in the futures market and had been watching developments and were convinced that some had insider knowledge.

Given the very steep price decline, that is a matter that this committee simply must investigate. I have asked the Inspector General to investigate the question of a gap between what was released to the public and what we knew about the cow's origin, if there was such a gap, and how it occurred, and what the effects of it were.

Mr. Chairman, just very briefly, at the hearing in North Dakota, there were three things that came up and came up repeatedly. One was this question of a gap between the time we knew it was a cow from Canada and when that was released to the public.

The second was a livestock ID system. Last week, the committee was briefed by an organization that currently has in operation an apparently successful livestock identification system, one that is based on ear tags with computer chips. According to this organization, they could scale up a national program within 90 days provided it was funded, and they have estimated it would cost about $100 million a year.

The third issue was country of origin labeling. With USDA's December 30 announcement, it is now a given that we are going to have a national livestock identification system. Common sense

would tell us that having an ID system in place will make it much easier and much less costly to implement country of origin labeling, since under the ID system we will be tracking cattle from the farm to the processor.

A fundamental question has to be asked and answered today on the implementation of country of origin labeling. That is of deep interest to the producers of my State, and with a national identification system, which clearly is going to be required, it would appear that putting off country of origin labeling for 2 years really is not necessary and that we could speed the implementation of country of origin labeling. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Roberts.

STATEMENT OF HON. PAT ROBERTS, A U.S. SENATOR FROM KANSAS

Senator ROBERTS. Yes, thank you, Mr. Chairman. I see my colleagues, Senator Allard and Senator Durbin, eagerly awaiting to shine the light of truth into darkness, so I am going to ask that my prepared statement be part of the record, with the exception—and I have about 11 questions for the Secretary, so to move things along, I am not going to read my entire statement.

In the days after this announcement, the No. 1 priority was to maintain consumer confidence in our beef supply. Secretary Veneman and her team, along with the National Cattlemen's Beef Association and its State affiliates, really jumped on this issue and made sure the real facts and information regarding the case and the disease were provided to the American public and the press. It is in no small part due to these efforts that we have avoided a replay of the alar disaster some years ago where it cost the apple industry $600 million and they deserve a lot of credit. Television and newspaper reporting has been relatively balanced and most consumers have responded by continuing to consume beef.

I want to thank the Secretary, her team, and especially the Cattlemen's Beef Association and all their State affiliates. I will wait until the Secretary comes to respond to questions, and I thank the Chairman for holding the hearing.

The CHAIRMAN. Thank you, Senator Roberts.

[The prepared statement of Senator Roberts can be found in the appendix on page 65.]

The CHAIRMAN. Senator Harkin.

STATEMENT OF HON. TOM HARKIN, A U.S. SENATOR FROM IOWA, RANKING MEMBER, COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

Senator HARKIN. Thank you, Mr. Chairman. Again, I just ask that my statement be made a part of the record.

Just two things. USDA and FDA are to be commended for the openness and the speed with which they have responded. While both USDA and FDA's actions are a strong start, I hope that this hearing will shed light on some questions that remain unanswered.

One of those is the renewed interest in a national animal ID system. Five weeks after intensive investigation, we still have only found 28 of the 81 cows that entered the U.S. from Canada with

the infected cow, we are really going to have to look at this ID program.

Second, we need more scientific information on BSE, how ruminant feed is fed to non-ruminants, how that feed may recycle back into ruminant feed later on. I know that former Under Secretary Torres, I believe, is going to be testifying to that, and maybe Senator Allard, who is also a veterinarian, could also testify to that.

Thank you very much, Mr. Chairman, for holding the hearing.

The CHAIRMAN. Thank you, Senator Harkin.

[The prepared statement of Senator Harkin can be found in the appendix on page 61.]

The CHAIRMAN. Senator Coleman, you are recognized for any opening statement you may have.

STATEMENT OF HON. NORM COLEMAN, A U.S. SENATOR FROM MINNESOTA

Senator COLEMAN. Thank you very much, Mr. Chairman. Just briefly, I want to thank you for holding this very important hearing. I also want to thank the Secretary for being here today.

I want to echo the *Minneapolis Star Tribune* editorial of December 31, 2003, which observed, and I quote, "Agricultural Secretary Veneman and the Bush administration deserve praise for moving quickly and decisively to respond to the public health threat and to the question of worldwide consumer confidence in the safety of U.S. beef." The *Star Tribune* rightly noted that the public can take those assurances to heart, and I believe what was true before December 23, 2003, remains true today. America produces the safest, most abundant, most affordable food supply in the world, and the evidence I have seen of the continued strong consumer confidence in the United States is a testimony to that fact.

My frustration is that there are about 50 countries out there who have chosen to wall off their borders to U.S. beef. I would very much like to see us continue to move very aggressively to deal with that, using sound science and fact. That is all we are asking for, Mr. Chairman.

I have joined in a letter with Senators Baucus, Craig, Nelson, and others. We have talked about perhaps sending a high-level envoy there. I am not offering any suggestions, but I would say, and I haven't talked to him, somebody like Walter Mondale, former U.S. Ambassador to Japan, somebody of that caliber who has relations working with the Secretary. It has to be the right thing in dealing with the international community and I will certainly defer to the Secretary's judgment. We need that kind of approach, to go to folks and say, all we are asking is sound science and fact. That is what this is about.

Two other quick observations. One, a matter that was raised in the *Star Tribune* is the need for a national animal identification program, and that is important. I know my colleagues have touched upon that. Madam Secretary, I do applaud her decision on December 30, that you have begun work on the national ID program. That is helpful.

Then the last comment is the FDA decision of yesterday does raise some questions that I hope we address today. Does this announcement make our beef supply safer and by how much? Does

it do anything to reopen our markets? Again, that issue is important for me and my cattlemen. How does it impact our ability to feed animals? I look forward to hearing the answers to these and other questions.

Again, Mr. Chairman, let me thank you for your leadership in bringing this important hearing before us today. Thank you very, very much.

The CHAIRMAN. Thank you, Senator Coleman, for your comments.

Let me welcome our distinguished colleagues, Senator Durbin from Illinois, Senator Allard from Colorado. I am going to ask Senator Allard to proceed with his statement and then we will call on Senator Durbin. I hope you can limit your statements to 5 or 10 minutes at the most, if that is all right. I don't want to cut you off, but we do have the Secretary and the Food and Drug Administration Deputy Commissioner awaiting the opportunity to testify.

Senator Allard.

STATEMENT OF HON. WAYNE ALLARD, A U.S. SENATOR FROM COLORADO

Senator ALLARD. Thank you, Mr. Chairman. If you will let me know when we get to 5 minutes, I will wrap it up. I would ask that you put my full statement in the record, if you would.

The CHAIRMAN. Without objection, it is so ordered.

Senator ALLARD. Mr. Chairman, first, let me thank you for convening this timely and very important hearing. I appreciate the committee making the accommodation to allow me to appear this morning. I would also like to extend a welcome to Secretary Veneman and Dr. Crawford and also my colleague, Senator Durbin.

The level of participation in bovine spongiform encephalopathy roundtables and panels across the country, as well as the interest in this hearing, is one more sign that government, industry, and the retail sector are taking this matter very seriously and will take all necessary and reasonable measures to isolate this occurrence and prevent future incidents.

Let me start by stating that I believe U.S. beef is safe. When a single BSE-positive cow was found in Washington State, our food safety policy and safeguards worked. USDA acted quickly and effectively. Where there were room for improvements, I believe USDA seized the opportunity to make them.

Everyone may agree that we have learned a tremendous amount from this finding. Future policy recommendations will obviously need to take into account those changes that are believed necessary as a result of the recent finding, especially as we learn what worked and what did not and what we need to know in the future. We must continue to implement the requisite measures to protect our food supply, but there is no reason to question the integrity of American meat safety and the overall safety of the system.

I believe that the government is taking a hard-line stance against further occurences of BSE in the United States, as evidenced by the major announcement by the Secretary several weeks ago. While we had hoped this day would never come, it was an eventuality that we had to be prepared for.

As Members of Congress, it is our duty to help enact legislation that protects the consumer and safeguards our national food supply. However, consumer protection and national security must not stifle the ability of the agriculture industry to produce food efficiently and affordably. If they do, we will have undermined the various very goals that we were attempting to accomplish. Overburdensome rules and regulations will hinder the ability of agriculture to provide our nation with food, threatening our nation's independence and security by making us dependent on foreign nations, nations that may not place as much emphasis on safety as we in the United States do.

In simple terms, our food supply policy must avoid the pitfalls of our energy policy. We rely some 60 percent on foreign energy sources. We don't want to put ourselves in that position as far as beef and food supply.

We have had our warning and we must take it very, very seriously. If we do not, we will pay for it with the economic life of the producer and retailer. If rules are not followed, if regulations are not adhered to, no one has more to lose than those who failed to follow them. A 75 percent compliance rate when it comes to feed regulations will not afford the level of protection we need to maintain the integrity of animal health, and blatant violations are intolerable.

In the past several weeks, the USDA has taken several steps that were not necessarily embraced by all with open arms, but most agreed they were the proper response to the task at hand. We all realize that the finding of BSE is a serious challenge to consumer confidence and the industry's financial stability. Government must take strong measures to bolster confidence and ensure consumers that American beef is a safe and wholesome product. I believe Secretary Veneman took the first step with her policy announcement several weeks ago.

I believe that these actions by the Secretary will enhance the safety of the American food supply. The three major policy directives dealing with downer animals, verification, and specified risk material are a step in the right direction, but as is always the case, the devil is in the details.

As a veterinarian, I am committed to the idea that any measures imposed must be science-based. While these recent actions do have sound footing and are logical decisions given the characteristics of BSE, there is still much work to be done to protect both consumer safety and the industry.

Much work must be done on defining and identifying downer animals. This issue has been highly controversial and much discussion has taken place on the matter on Capitol Hill. Are animals with nerve damage from calving to be forbidden, or only aged and sick animals? Who will be the one to determine which case is which? These questions must be worked out at great length by those most knowledgeable about the industry and food supply. I am also hopeful that the USDA will provide my constituents with further guidance when it comes to matters like dentition and animal age verification.

In terms of verification and traceability, a true verification and identification program, perhaps using retinal scanning and other

biometric technologies would provide immediate background resources on the origin and presence of every animal leaving marketing to the retailer and the producer. In fact, Swift and Company is using just such technology in Colorado, Idaho, and Nebraska as part of the beef industry's first traceability program.

This is about tracking the cow and food health, not politics. It would provide answers in times of emergency and provide closure during the critical first hours of an epidemiological investigation. A credible identification plan must take into account identity and location, a fact that I encourage the USDA to consider when developing the forthcoming identification plans.

I would add at this time, Mr. Chairman, and I know one of the members on your committee had talked about the tag identification, I hope that the USDA in putting forth rules and regulations will allow enough flexibility that they don't let just one technology prevail, that it be open for new technologies that will be coming to us in the future so that as they are developed, they can be put to use if they are a better system.

At this time, I would ask the Chairman that the full text of a statement I entered into the Congressional Record last week on this issue be inserted into the committee's record, as well.

The CHAIRMAN. Without objection, it is so ordered.

Senator ALLARD. While such a verification program will indeed cost producers money, I believe that retail chains would eventually demand such assurances anyway. In the long run, such verification will enhance the value of the product and prove a valuable tool in domestic and international sales.

As implementation of the USDA directives moves forward, I encourage the USDA to continue working cooperatively with the beef industry. Together, we will not only improve food safety, but we can also restore access to important markets, an important component of our economy.

Food safety goes hand-in-hand with the restoration of our markets. We have all seen the list of nations that have banned U.S. beef. We must work diligently to reopen these markets and to reestablish the trust and confidence that I know the U.S. beef industry deserves. In my own State, employee hours at beef processing plants are being cut back, hurting the whole Colorado economy.

As we continue to trace back, trace forward, verify, confirm, and cull, we cannot allow nations to block our products under the guise of BSE in order to bolster their own industry or to cultivate relationships with other exporters. A sound process must be in place immediately that provides assurances to other nations about the quality and safety of the meat they receive. This must be a high priority of the Congress and administration and I intend to make sure that such discussions take place.

Thank you, and remember this. Beef is still what is for dinner. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Allard.

[The prepared statement of Senator Allard can be found in the appendix on page 88.]

The CHAIRMAN. Senator Durbin, you may proceed.

STATEMENT OF HON. RICHARD DURBIN, A U.S. SENATOR FROM ILLINOIS

Senator DURBIN. Thank you very much, Mr. Chairman and members of the committee, for your leadership in holding this hearing and my special thanks to Secretary Veneman. I want to join on a bipartisan basis in thanking her for her leadership. I am sure this was a very difficult holiday season for her, but she rose to the challenge and she rallied America to do the right thing, to move in the right direction, and that is a very, very important thing and I salute her for that.

I also want to address, though, some of the elements and questions which still remain. I wrote a letter to the Secretary a few weeks ago asking about the delay in diagnosing BSE in the cow last month in Washington State. Given the focus of this hearing, I would like to discuss some of the questions I asked.

If the inspectors recognized that the animal was uncoordinated or unable to rise on her own, why was she allowed into the human food chain at all? I am told by veterinarians that the behavior of an animal with calving paralysis and the behavior of an animal with a neurological disorder, such as BSE, is virtually indistinguishable. Why was this carcass not held until BSE test results were known? It was only after the incident that the USDA adopted a test and hold policy on all BSE-tested animals.

I also wonder why it took 13 days to obtain the presumptive positive result test for BSE. I understand immunohistochemistry analysis usually takes 5 to 7 days. As a result of the delay, the animal was processed, according to Dr. Steven Solomon from FDA, into 2.8 million pounds of consumer product, all of which were potentially contaminated.

To prevent future unnecessary delays in obtaining BSE test results, the USDA should adopt the use of rapid BSE tests on all cattle and bison presented for processing that are either suspect or over 30 months of age. If a rapid test had been used on the cow in Washington State, the results would have been known within a few hours instead of days, avoiding the need for a costly recall.

How many cattle in America have BSE? Answering that question today is similar to trying to estimate the prevalence of HIV by only testing individuals who have symptoms of AIDS. At the current level of testing, we have no real estimate of the true prevalence of BSE in America. Using rapid BSE testing on suspect and older cattle would provide critical surveillance data that could make clear whether we truly have a BSE problem in our country and demonstrate to our customers and partners around the world that they have nothing to fear.

Expanding BSE surveillance will cost money. However, a Consumer Union's poll released today shows that 71 percent of Americans who eat beef said they are willing to pay more to support testing cattle for BSE. Of these, 95 percent say they would pay an additional ten cents a pound for beef that is tested.

I introduced legislation last week that will reduce the likelihood that meat from BSE will reach the food supply. This bill, S. 2007, codifies some of the USDA's recent steps, which I applaud. It restricts the importation of more ruminant-derived materials, plugs loopholes in the current ruminant feed restrictions, requires testing

of older cattle, and expands surveillance and research for chronic wasting disease in deer and elk and Creutzfeldt-Jacob disease in people.

I reflected for a moment before this hearing, Mr. Chairman, about September 11. On September 11, 3,000 innocent Americans lost their lives. Nineteen terrorists were identified. It was one of the most tragic moments in American history.

I wondered if we would have been able to summon the will to respond had that tragedy been averted and one of those terrorists been discovered ahead of time and his plot uncovered. I wonder if we would have been able to summon the will with that warning signal to create a new coordinated Federal agency, to revise laws giving our law enforcement more authority, to confront a major industry like the airline industry about the need for more safety, and I thought about our hearing today.

We are dealing with a situation where we have a clear warning. What happened in Moses Lake, Washington, is an indication of what could happen on a much grander scale. I certainly agree with my colleague, Senator Allard, and all of you. We have the safest food supply in the world. We now have fair warning. What happened with this cow in Washington is fair warning that we need to summon the same political will as we did after September 11, to come together on a timely, bipartisan basis to look at some very troubling issues, issues which involve the role of government and the private sector, issues which really demand of us more efficient government response to make certain that we continue to have the safest food supply in the world.

I have said for many years, and I continue to say, we need a single food agency. We currently have over a dozen different agencies in our government responsible for food safety, more than 35 laws, dozens of committees with jurisdiction. Look at this issue. The feed being given to the cattle is regulated by the Food and Drug Administration. The animal is regulated by the U.S. Department of Agriculture. When we are talking about chronic wasting disease in elk and other animals, that is regulated by the Department of the Interior. Why? Why is this spread all over government? Why doesn't it come together, as we did with the Department of Homeland Security, into one science-based operation that we can turn to with confidence? That is our challenge.

Instead of a dead canary in a cage, Mr. Chairman, we have a broken down dairy cow in Washington. The message, however, is clear. The safest food supply in the world is vulnerable. Will we have the political will to make the important decisions to keep it safe? The challenge is not just to reopen our markets. The challenge is to make certain that we do everything humanly possible and scientifically sound to close the door on any unsafe food that may find its way to the tables of American families and our customers around the world. I sincerely hope on a bipartisan and timely basis we can summon the will to respond. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

[The prepared statement of Senator Durbin can be found in the appendix on page 80.]

The CHAIRMAN. There have been members of the committee who joined the hearing after opening statements have been made, but I am going to recognize them for any opening statement they wish to make. Senator Nelson.

STATEMENT OF HON. E. BENJAMIN NELSON, A U.S. SENATOR FROM NEBRASKA

Senator NELSON. Thank you, Mr. Chairman. First of all, I want to commend Secretary Veneman and her staff for responding rapidly to this beef crisis and for their efforts to work at the level necessary to deal with the issue in foreign countries.

Obviously, there are two points here to be made. Food safety is one of them, and the actions that they have taken are going to only improve the food safety issue. That deals with credibility. There has never been that much of a credibility issue with the domestic market, but the foreign markets, some of them, have taken this in a form of protectionism.

I learned a new word the other day, or some new words. Instead of over reaction, an abundance of caution. There has been an abundance of caution taken by many of the foreign countries in stopping the exports for our beef. We have to deal with exports and imports as quickly as we possibly can. I have learned a lot of new words over the year, credibility, food safety, protectionism, lost markets and delays, but the only word that we really want to focus on here today is not simply what we are doing but when will we get the export markets opened.

I have said recently that I am interested in sending a person to Mars, but I am a lot more interested right now in sending beef to Japan and all the other Asian and other markets that we have had over the years. In Nebraska, we are at risk for 21,000 jobs that will be lost if this continues over a protracted period of time. The question is, when will we get those markets reopened and what will it take?

I have joined several of my colleagues and said the administration needs a special envoy. Also the President needs to make some calls to many of the leaders of the foreign countries that are engaging in what may be protectionism or this overabundance of caution. It strikes me as odd, if my information is correct, that Mexico is denying exports of U.S. beef but permits boxed beef from Canada.

These issues have to be resolved, and the only question my cattle growers in Nebraska and the people who work in the industry that supports cattle growers in the beef industry are asking is when will this open. Nebraska beef exports during the years when I was Governor went up from $400 million to over $800 million in 7 years. I notice that they have gone up since then. Due to this crisis, they are dropping, and that is a concern that we must address here today.

I appreciate, Mr. Chairman, your calling this together, calling us together in this hearing. There is an assumption that only the Midwest deals with beef. Quite frankly, every State has a beef industry to one degree or another. It just happens that Nebraska relies significantly on this, and one out of five steaks in the United States is Nebraska beef. I could say in a partisan way, I am sorry for

those other poor four folks, but there are cattle that are grown outside of Nebraska that are pretty good, too.

We have a problem, I appreciate it, and I hope that we can get the answer to when will this protectionism, when will this embargo against United States beef be ended. That is the only question that I am interested in today because that is, in fact, the bottom line. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

[The prepared statement of Senator Nelson can be found in the appendix on page 76.]

Senator Talent, do you have an opening statement?

STATEMENT OF HON. JAMES TALENT, A U.S. SENATOR FROM MISSOURI

Senator TALENT. Just very briefly. I have one I would like to submit for the record, Mr. Chairman.

I also want to compliment the Secretary and the Department for a very quick response. The fact that consumer confidence in the food system has stayed high is a testimony to that. In a sense, we are dealing with a system that has worked in the sense that it has protected the safety of our food supply, and that is why all of us can sit here and say we have the safest food supply in the world. We do.

The question is, how can we improve the system so as to ensure that there is no leakage of confidence, if you will, that the response is so swift that confidence remains high, even when a lack of confidence might not be based on science. Also, as Senator Nelson said, no one around the world has an excuse for closing their markets to our product.

That is what I am interested in finding out. There are several aspects of the issues I want to go into with the Secretary, Mr. Chairman. I have, as I said, a statement I would like to submit for the record and I thank you for giving me an opportunity.

The CHAIRMAN. Without objection, the statement will be printed in full in the record.

The CHAIRMAN. Senator Daschle.

STATEMENT OF HON. TOM DASCHLE, A U.S. SENATOR FROM SOUTH DAKOTA

Senator DASCHLE. Thank you, Mr. Chairman. I, too, join with others in thanking you for this timely and important hearing. The article in the Wall Street Journal today again illustrates the degree to which there are still unanswered questions about what happened and why, and the more this committee can aggressively pursue all of those issues and questions, the better off our country will be.

I join with others, as I have personally, in commending the Secretary for many of the actions she has taken, one in particular. She took a little heat last week on the downer cattle decision. It was the right decision, and I told her personally and want to say publicly that I appreciate the decision she made with regard to downer cattle.

I am concerned that we are virtually the only country in the world that now have that policy. There are countries all over the

world that have the policy we once had, that we had until just recently with regard to downer cattle. A lot of that cattle comes into this country and we have no guarantee that those downer cattle ultimately don't enter into the feed and food system at some point.

That, again, is why many of us have said it is so critical for us to have country of origin labeling, so people understand that we have, as the Senator from Missouri just noted, a higher standard for safety and quality than other countries do. We threaten that quality and that safety to a certain extent when we allow downer cattle to come in without any indication that this is a foreign product.

This is yet another illustration, another argument, in my view, why country of origin labeling is so critical. In that regard, I am also curious, and I am hoping the Secretary can address somewhat of a technical intention about her intentions with regard to country of origin labeling. The law requires the regulations to be promulgated by September. The law also now stipulates, as we have deemed it to be so in the passage of the omnibus appropriations bill, not to be implemented until 1 year from now, in September of 2006. There is a distinction.

The wild and raised fish regulations will be implemented on time this September. The question is, will the regulations for all country of origin labeling be promulgated as required by law, and this is something I hope that the Secretary can clarify. If I am here, I want to be able to ask her that question.

Mr. Chairman, I would also say, as others have suggested, there are a number of other actions that ought to be taken. We ought to extend indefinitely this ban on live cattle from Canada. We ought to rescind the order on boxed beef that was made last October. I believe that we ought to have far greater effort on the prioritization for greater testing than what we have seen so far. We can do better than we are doing today on testing. We need a regimen, we need a plan, and we need to work together to see that that is achieved.

Also, Senator Nelson made a good point, one that many of us have made over a period of time. We need to send the highest-level negotiator we possibly can to these countries to tell them to open up their borders once again. There is absolutely no reason why they shouldn't be taking U.S. meat products, and beef in particular, and we need to make that point as clearly and as emphatically as we can and hopefully open those borders as quickly as we can.

We also need to deal with all of that product that is still out there, not able to penetrate those markets. We don't want it to come back here. We need to find a place for it to land. We haven't done that yet, and it is critical we find a suitable market for it.

Finally, to the point that Senator Durbin made, it is critical we consider reorganizing ourselves in this Federal Government in order to accommodate the demands, the challenges, and the extraordinary complexity that we face as a country today. We can't do that with the disjointed, bifurcated, and extraordinarily complex array of bureaucratic boxes that we have created to address this issue in the future. I hope we can work on that, as well.

This is a good start, a good hearing, an important time to have it, and I commend the Chairman for holding it. Thank you.

The CHAIRMAN. Thank you, Senator.

Senator Leahy.

STATEMENT OF HON. PATRICK LEAHY, A U.S. SENATOR FROM VERMONT

Senator LEAHY. Thank you, Mr. Chairman. I will put a long statement in the record, but I do want to thank you for having this hearing. It is extremely important and I am glad, notwithstanding the weather, that you did not reschedule it.

I want to thank Secretary Veneman, of course, for being here. She and I had a long talk about the hearing yesterday. Of course, Deputy Commissioner Crawford, Mr. Torres are coming to this hearing on the Department's response to finding the BSE-positive cow in Washington State a month ago.

At the outset, I want to recognize the Department of Agriculture and the Food and Drug Administration's action in responding to what has been a difficult time for American agriculture and American consumers. I want you to know that I believe you have taken steps in several areas that I believe are essential to prevent a serious outbreak of BSE, to be able to tame one should an outbreak occur.

As I told the Secretary yesterday, I joined with the Chairman and several others from this committee, Senator Roberts and Senator Coleman, who were in South America. This issue was raised, I believe, Mr. Chairman, at just about every single meeting we had, whether as a head of government or ministers of agriculture. I admit that some threw a little bit of crocodile tears about it, but there is no question that all of them accept the fact that American agriculture pretty well sets the standards for safety and they were asking each one of us what is going to happen next.

It is a time for us to examine the steps necessary to increase the safety of all Americans. First, I believe we need to ban downed cows from entering the human food chain. Clearly, there is already opposition to your regulation. Congress may need to act and assure these regulations are not rolled back.

I am pleased the FDA announced yesterday, just ahead of this hearing, stricter regulations on the feed we give our cows. The announcement yesterday may have been a coincidence, but the hearing encouraged them to go forward, another good reason for the hearing, Mr. Chairman. Until yesterday's announcement, FDA regulations allowed blood to be fed to cattle. There is still no restriction on rendering all parts of cattle into feed for pigs and poultry, which in turn can be entirely rendered and fed back to themselves and to cattle.

Finally, Madam Secretary, as I said to you yesterday, we have to establish a national tracking system for every cow in the United States to trace animals from birth to slaughter within 48 hours to combat animal disease outbreaks. I know USDA has indicated they may soon stop their investigation of the remaining 53 animals and cows that were imported from Canada with the infected cow because poor record keeping has limited their ability to locate these remaining cows. I know that your people have been working around the clock to try to do that. It is another example of the need for a national animal ID system.

Madam Secretary, and I will put my full statement in the record, I hope you know that all of us up here on both sides of the aisle want this to hurt. Again, Mr. Chairman, I commend you and Senator Harkin on having this hearing. Thank you for doing this.

The CHAIRMAN. Thank you, Senator.

[The prepared statement of Senator Leahy can be found in the appendix on page 78.]

The CHAIRMAN. Madam Secretary and Dr. Crawford, if you could come forward, we appreciate very much your patience and your attendance at the hearing today. The Honorable Ann Veneman is Secretary of the United States Department of Agriculture, as we know. Dr. Lester Crawford is a doctor of veterinary medicine and has a Ph.D. degree, as well. He is Deputy Commissioner of the United States Food and Drug Administration.

We have copies of statements that each witness has prepared and submitted to the committee in advance. We thank you very much for that. Those statements will be made a part of the record in full. We encourage you to make any summary comments that you think would be helpful to the committee's understanding of the issues before us and then we will have an opportunity to ask questions of each of you.

Secretary Veneman, welcome. You may proceed.

STATEMENT OF HON. ANN M. VENEMAN, SECRETARY, U.S. DEPARTMENT OF AGRICULTURE

Secretary VENEMAN. Thank you, Mr. Chairman, and thanks to all the members of the committee for the opportunity to appear here today and thank you for holding this hearing. I also want to thank you all for your kind comments about the process that USDA has gone through over the past month as we confronted this issue which we hoped we would never have to deal with.

In the interest of time, I would like to submit my comments for the record in writing, along with an attached timeline of what happened—that was included in our comments—and then just summarize and follow through on a few of the issues.

As you know, on December 23, we received word that a tissue sample taken as part of our routine surveillance system tested presumptive positive for BSE. We had in place a BSE response plan which was first developed in 1990 and has been continually updated since then to reflect the latest knowledge about the disease and the lessons learned from other countries that have had cases of BSE.

Upon hearing of the BSE find, we immediately began to implement the plan. We began an investigation to determine the origin of the cow and to identify and locate her offspring and cohorts. Ultimately, DNA tests and other documentation confirmed that the animal originated on an Alberta dairy farm.

We focused much of our efforts on 81 animals that we know came from the Canadian birth herd. International standards also tell us that animals of special significance are those born within a year before or after the positive animal. This 2-year window is based on animals that are likely to have consumed the same feed source. Given that standard, we have now determined that there are 25

out of the 81 animals that fit in that 2-year window around the birth of the indexed cow.

Based upon statistical examination of culling rates, we would have expected to find that only 11 of those 25 animals would still be found alive. In fact, we have found 14 of those 25 animals of significance. From a statistical standpoint, our tracing efforts to date have been remarkable.

All animals tested in this process so far have tested negative. Although the investigation is ongoing, given the estimates of the number culled, it is unlikely that we will find all the remaining animals. Even in the case of those animals that are not found, we would not expect them to pose a significant risk to public health or animal health.

First, we know that based on the international experience. Even at the height of the BSE in the United Kingdom, it was rare to find more than one or two positive animals in a single herd. The Harvard risk assessment also found that the risk of spread of BSE in the U.S. is very low.

Second, our protection systems, including those enhancements we announced December 30, are those which protect us from widespread cases of this disease. As part of our trace-forward of the products, we determined that high-risk products, such as brain and spinal cord, did not enter the food system. Nevertheless, we issued a recall of all of the meat that came out of that plant for the day in question.

We sent a sample of the indexed cow for confirmation to the World Organization for Animal Health Reference Laboratory in England. We decided to immediately inform the public on December 23, prior to the ultimate confirmation in England, based on our confidence in the accuracy of the test conducted by our scientists at the National Veterinary Services Laboratory in Ames, Iowa.

On December 30, 1 week after the find, I announced a series of actions to further enhance our already strong safeguards that protect the public health and animal health and to help maintain consumer confidence. These included an immediate ban on non-ambulatory or so-called downer animals from the food system and further restrictions on specified risk materials, such as brain and spinal cord tissue, from entering the food supply.

Now, at this point, I would like to answer one of the questions raised by Senator Daschle, who indicated that there wouldn't be a guarantee on downers from other countries. In fact, once we announced these regulations and then put them in the Federal Register as interim final rules on the 12th of January, we then required the same treatment or equivalent treatment from other countries and our exporting partners have now implemented the same or similar regulations to those that we announced on the 30th. We also announced on December 30 that the meat from any cattle tested for BSE will be held until a test has been confirmed negative, a so-called test and hold policy.

We were able to act quickly on these actions because of the advance planning we had undertaken after the find in Canada but before the find on December 23 in the U.S.

We also announced on December 30 that we will be expediting the implementation of a verifiable system of national animal identi-

fication, and I heard a lot of interest in that subject today. Our goal is a nationwide system that is uniform, consistent, and efficient.

In keeping with our commitment to continually review our systems, I also announced that an international panel of experts would be convened to review our investigative efforts and recommend possible further enhancements. They arrived in the U.S. last week and began that review. This international review team is a subcommittee of the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases. Our officials have had a positive exchange with them and provided all the information that they have requested. The international review team will now compile its report for submission in about 2 weeks and we look forward to their findings and their recommendations.

All of the actions that we are taking are in addition to the strong safeguards that we had in place before December 23, some of which I have already alluded to. As you may know, in November 2001, an independent risk assessment by Harvard University found that based on those existing safeguards, BSE is highly unlikely to become established in the United States should the disease be detected in our country. As a result of the Harvard analysis, we announced additional preventative actions, such as increased surveillance and the testing of certain ground beef products for central nervous system tissue.

In 2003, we asked Harvard to reassess the situation, taking into account the BSE find in Canada in May of 2003. In August, Harvard reaffirmed the findings of the initial study.

Throughout this process, we have been committed to maintaining public health, safety and consumer confidence in our systems. Some 90 percent of U.S. produced beef is consumed domestically, and all indications are that the confidence of the U.S. consumer in the safety of American beef remains very strong. We believe this is due in part to the quick and aggressive steps that we took to protect public health.

Unfortunately, most of our export markets, including our key buyers, Japan, Mexico, Korea, and others, immediately closed their markets to U.S. beef after the December 23rd announcement. The loss of exports had an immediate impact on the cattle market, resulting in an initial drop of 15 to 20 percent in cattle prices on cash and futures markets. However, prices have strengthened over the past couple of weeks and markets are now down just 5 to 8 percent from the levels prior to the BSE finding, with current cattle prices still above year-ago levels.

Regaining our export markets is a top priority for this administration. We are pleased that Poland has become the first country to reinstate imports of U.S. beef and we continue efforts with our trading partners to resume trade.

Within days of this finding, we dispatched USDA Senior Trade Advisor David Hegwood and Dr. Chuck Lambert, our Deputy Under Secretary for Marketing and Regulatory Programs, to Japan and South Korea to explain the investigation and the rigorous safeguards that we already had in place.

Earlier this month, U.S. Trade Representative Zoellick and I each had very encouraging meetings with the Japanese trade minister, and Ambassador Zoellick announced just yesterday that he

will go to Japan the second week in February to discuss the WTO and the beef issue with high-level officials in Japan.

Two weeks ago, I had a lengthy discussion with Japan's Minister of Agriculture Kamei to impress upon him the importance of finding a practical solution to allow resumption of trade and releasing into commercial channels beef that was shipped to Japan prior to December 23. The minister stated that Japan is looking forward to resuming trade.

Dr. J.B. Penn, USDA's Under Secretary for Farm and Foreign Agricultural Services, is returning this evening after leading a delegation of USDA and FDA officials, including Dr. Crawford, who came home early to be here today but was on most of the trip, and they had discussions in Japan, the Philippines, Hong Kong, and South Korea. These visits have been well received and discussions will continue following the completion of our investigation.

We have also had a team visit China to discuss our response actions. In addition, I have had numerous conversations with the ministers from Canada, Mexico, the Philippines, and others on an ongoing basis to keep them informed of our progress.

It is important to note that both Canada and the Philippines have allowed at least a portion of their markets to remain open to our beef.

Dr. Penn and Mr. Bill Hawks, Under Secretary for Marketing and Regulatory Programs, traveled to Mexico for productive discussions earlier this month. Just yesterday, I again spoke with Secretary Usabiaga, my counterpart in Mexico, and Under Secretary Hawks will be in Mexico again next week.

On January 16, I hosted a meeting of my counterparts from Canada and Mexico, Minister Speller from Canada and Secretary Usabiaga from Mexico. We agreed to develop an enhanced consultative process to facilitate a consistent North American response.

In addition, technical teams from Japan and Mexico spent several days in the United States meeting with technical experts at USDA and the Food and Drug Administration. The Japanese team also traveled to the State of Washington to review the investigation there, and the Mexicans visited processing facilities in Colorado. Another Mexican delegation has been visiting the U.S. this week.

Our efforts to restore our foreign markets continues to be a top priority and we urge our trading partners to resume trade based on sound scientific principles.

In summary, our investigation has made a lot of headway in the past 5 weeks. We have further enhanced our protection systems. Our food supply and the public health remain protected and consumer confidence in the beef supply has been maintained. We are working diligently to restore our export markets. I am very proud of the accomplishments of our very dedicated USDA team. As our efforts proceed, we will continue to provide complete and timely updates to the public.

Mr. Chairman, I want to again thank you and the members of the committee for holding this hearing today. I look forward to discussing all of these issues with the committee members. Thank you very much.

The CHAIRMAN. Thank you, Secretary Veneman.

[The prepared statement of Secretary Veneman can be found in the appendix on page 91.]

The CHAIRMAN. Dr. Crawford, you may proceed.

STATEMENT OF LESTER M. CRAWFORD, D.V.M., PH.D., DEPUTY COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. CRAWFORD. Thank you, Mr. Chairman. We appreciate the opportunity to participate in today's hearing addressing the finding of a BSE-positive cow in Washington State and activities of the Federal Government to safeguard human and animal health in the United States from BSE.

I am Les Crawford, Deputy Commissioner, Food and Drug Administration. I am pleased and honored to be here with Secretary Veneman to describe FDA's contribution to these efforts.

I also want to say, Mr. Chairman, how much we at FDA admire the latest shift that Secretary Veneman has taken. Of all the countries that have had this disease, and I believe there are about 22 now, no country has stepped forward with a more bold and aggressive program. We are very pleased to be part of that team.

Our mission is to protect the public health by assuring the safety and effectiveness of our nation's human and veterinary drugs, human biological products, medical devices, human and animal food supply, cosmetics, and radiation-emitting products. In fulfilling this mission, the agency is responsible for assuring that all FDA-regulated products remain safe and uncompromised from BSE and related diseases.

FDA has a longstanding commitment to protecting consumers from BSE. Under the Federal Food, Drug, and Cosmetic Act, FDA has used adulteration and misbranding provisions to prohibit ruminant feed from containing specified mammalian protein, and the same adulteration and misbranding provisions apply to human food. Further, for medical products that require premarket approval, such as drugs and medical devices, FDA has addressed safety concerns related to BSE through requirements of the application and approval process.

Yesterday, I am pleased to report that Secretary Thompson and FDA Commissioner Mark McClellan announced that the agency intends to issue rules to ban from human food and cosmetics and dietary supplements a wide range of material from cattle so that the same safeguards that protect Americans from exposure to BSE through meat products also apply to food and other FDA-regulated products. We are also adding a series of additional firewalls in our feed rule that will make our efforts to protect the public health even more robust.

In my testimony, I am going to briefly describe our current protections against the spread of BSE and also discuss the additional science-based steps we announced yesterday.

In 1998, the USDA commissioned the Harvard Center for Risk Analysis to conduct an analysis and evaluation of the U.S. regulatory measures to prevent the spread of BSE in the U.S. and to reduce the potential exposure of U.S. consumers to BSE. The Harvard study concluded, among other things, that even if introduced

into the United States, due to the preventative measures currently in place in this country, BSE is extremely unlikely to become established in this country.

Our existing firewalls are effective and our new ones will add even greater security and enhanced public confidence. Our existing firewalls are based on a five-prong regulatory strategy.

The first one is formed through regulations and enforcement to protect U.S. borders from potentially infective materials utilizing a regime of import controls. Major restrictions on imports were put in place by the USDA beginning in 1989 and more restrictive import controls have been introduced as we have learned more about the science of BSE and as the worldwide epidemiology has changed. FDA remains a committed partner with the Department of Agriculture and Customs and Border Protection in protecting our borders.

The second firewall is surveillance of the U.S. cattle population for the presence of BSE. Surveillance of the cattle population is the primary responsibility of USDA, and USDA has recently announced steps to increase surveillance.

The third firewall is prevention of the amplification of BSE through feed provided to cattle and other ruminants, and this responsibility falls primarily on FDA. FDA's animal feed ban regulations form the basis of this third firewall and have been cited as one of the most significant elements needed to prevent the spread of BSE in the United States. FDA implemented this rule to establish in our country feeding practices consistent with the best available science to prevent the spread of BSE throughout herds of U.S. cattle. We have taken intensive steps to get an extremely high level of compliance with this feed ban, and as a result, we have been able to work with the animal feed industry to achieve more than a 99 percent compliance rate and we intend to continue to work for full compliance.

As a result of this rule and the other firewalls that make up the U.S. framework, the risk of exposure to BSE through products FDA regulates remains extremely low in the United States.

The fourth firewall is making sure that no bovine materials that can transmit BSE will be consumed by people. Even if a BSE-positive cow made it through all of the previous firewalls, which is extremely unlikely, it would not pose any risk to people. USDA and FDA have long had steps in place to help prevent any possible exposure to BSE in bovine products. Recently, USDA announced additional major steps to prevent any of the tissues known to carry BSE from entering the beef supply as well as to restrict use of certain downer cows that might be at higher risk of carrying BSE. Yesterday, we announced comparable measures to prevent human exposure to the bovine products that potentially harbor BSE.

The fifth firewall is effective response planning to contain the potential for any damage from a BSE-positive animal if one is discovered at some point in the system. This response plan went into place immediately upon the discovery of a BSE-positive cow in Washington State on December 23. We have inspected and traced products to 22 facilities, including feed mills, farms, dairy farms, calf feeder lots, slaughterhouses, meat processors, transfer stations, and shipping terminals. We have accounted for all the high-risk

materials related to the BSE-positive cow that FDA regulates and none have gone into human or animal consumption. Moreover, FDA has conducted inspections at all the rendering facilities involved and found they were fully in compliance with our feed rule.

The goal of our firewall after firewall approach is to provide full protection of the public against BSE without adding unnecessary cost or restricting the consumption of safe beef products. Working with USDA, we intend to maintain an extremely high level of compliance with each firewall. In addition, a multi-layered approach makes sure that even if each firewall doesn't function perfectly, the U.S. consumer is nonetheless protected from exposure to the BSE-infected material.

To maximize protection afforded by the feed regulation, FDA has also developed and implemented a BSE ruminant feed ban inspection compliance program and established the goal of 100 percent compliance. FDA and its State counterparts conduct, at least annually, BSE inspections of 100 percent of known renderers, protein blenders, and feed mills processing products containing material prohibited from use in ruminant feed.

As of December 20, 2003, FDA had received over 26,000 inspection reports. The total number of inspection reports represent 13,672 firms, 1,949 of which are active and handle materials prohibited from use in ruminant feed. The 1,949 active firms that handle prohibited material have been inspected by FDA, and as of December 31, 2003, only five were found to have significant violations resulting in official action indicated. FDA is working with these firms to bring them into compliance.

In addition, FDA remains firmly committed to bringing better science to the public to provide better health protection at a lower cost. That is why a key part of our strategy involves fostering the development of better technologies to deal with the disease. To enhance the ability of our public health system to detect prohibited materials in animal feed, we will continue to support the development and testing of diagnostic tests to identify prohibited materials. As these tests are developed, FDA will evaluate the utility of such tests promptly and thoroughly.

Although the risk of exposure to BSE in the United States remains extremely low and the measures in place are working as a result of the recently discovered infected cow in the State of Washington, yesterday, we announced the following further measures. We announced that we will publish an interim final rule that will ban the following materials from FDA-regulated human food, dietary supplements, and cosmetics: Downer cattle—all bovine sources for these products must be animals that have passed USDA inspection for human food; dead cattle—these are cattle that die on the farm before reaching the slaughter plant; specified risk materials that are known to harbor the highest concentrations of the infectious agent for BSE, such as the brain, skull, eyes, and spinal cord of cattle 30 months or older; the product known as mechanically separated beef, a product which may contain SRMs. Meat obtained by advance meat recovery may be used since USDA regulations do not allow the presence of SRMs in this product.

Concerning animal feed, we announced that we will be taking the following four additional actions. First, FDA will act to elimi-

nate the present exemption in the feed rule that allows mammalian blood and blood products at slaughter to be fed to other ruminants as a protein source. Recent scientific evidence suggests that blood can carry some infectivity for BSE.

Second, FDA will also ban the use of poultry litter as a feed ingredient for ruminant animals.

Third, FDA will ban the use of plate waste as a feed ingredient for ruminants. Plate waste consists of uneaten meat and other meat scraps that are currently collected from some large restaurant operations.

Fourth, the Food and Drug Administration will act to further minimize the possibility of cross-contamination of animal feed by requiring equipment, facilities, or production lines to be dedicated to non-ruminant animal feeds if they use so-called prohibited protein.

Finally, we are increasing our inspection of feed mills and renderers in 2004. Now, 2001 base funding for BSE-related activities was $3.8 million. We shifted resources internally in 2001 and received a substantial increase from Congress in 2002. Our funded level for 2004 is $21.5 million, almost a fivefold increase over the 2001 base. We will conduct 2,800 inspections and will make our resources go even further by working with State agencies to fund 3,100 contract inspections of feed mills and renderers and other firms that handle animal feed and feed ingredients. Through partnerships with the States, FDA will receive data on 700 additional inspections, for a total of 3,800 State contract partnership inspections in 2004.

The agency looks forward to continuing to assist Congress as it evaluates the risk associated with BSE and considers science-based approaches to further strengthen regulatory protections and bolster the resources available to assure that BSE does not present a threat to human or animal health in the United States. Mr. Chairman, I thank you very much.

The CHAIRMAN. Thank you, Dr. Crawford. Thank you, Madam Secretary.

[The prepared statement of Dr. Crawford can be found in the appendix on page 118.]

The CHAIRMAN. My first question to Secretary Veneman is do you recommend any change in our food safety statutes as a result of your experience in dealing with this case of BSE?

Secretary VENEMAN. Thank you, Mr. Chairman. At this point, we have not recommended specific changes to our food safety statutes. All of the actions that we have announced thus far have been done through our existing authorities by announcing and implementing new regulatory measures. We are awaiting the results of the recommendations of the international panel that I discussed in my testimony to see if they recommend additional actions, and whether or not that would include anything that would require statutory change, I cannot predict changes at this point.

The CHAIRMAN. I wonder also whether there would be any necessity to enact new authorization for funding on a supplemental basis or in next year's budget request to enable you to discharge your responsibilities under the law in connection with this case of BSE?

Secretary VENEMAN. Mr. Chairman, we are looking at funding possibly through the CCC for moneys that we may need for 2004, particularly for animal identification. In our 2005 budget, we are also looking at enhancing measures pertaining to BSE. We will be announcing our 2005 budget next Monday, on the 2nd of February.

The CHAIRMAN. Dr. Crawford, I wonder whether or not your agency has the adequate statutory authority it needs to take the steps necessary to ensure the protection of Americans against harm from this case of BSE.

Dr. CRAWFORD. Mr. Chairman, we are evaluating that as we go forward with these new feed ban changes and we look forward to working with the Congress in terms of the authorities we have and what might be done in order to consider whether or not we need more. We don't have a position on that at this point, but we are very interested in that because we are aware of, as we expand these activities under the 1997 feed ban rule, we are going further than was anticipated then, and so that possibility certainly exists, that we will need to review the authorities.

The CHAIRMAN. In connection with the budget submission that we will be receiving, is there any need that you anticipate for a change in statutory authority for spending money by the FDA to carry out your duties in connection with this case of BSE?

Dr. CRAWFORD. No. We don't think this stresses the system in that way and we believe that we are working well with USDA and obviously it has been a coordinated approach. I have no reason to think that we need anything further.

The CHAIRMAN. Yu are both to be congratulated for the dispatch and the concentration of effort that you made to make Americans aware of this situation, to disclose the discovery of the case of bovine spongiform encephalopathy when you did and as you did. I was very impressed by the fact that you conveyed everything you were doing with full transparency to the public, engaging our trading partners around the world, too, and acquainting them with all the facts and the steps that we are taking to ensure continued safety of American beef exports. Hopefully, that will pay off for us in the decisions in the near future to continue to buy and resume purchases of American beef products.

Do you have any expectation along that line, Madam Secretary, in talking with our Trade Representative or other members of the cabinet or at the White House at the highest levels, of steps that are going to be taken to try to accelerate the purchase of U.S. beef products in the future?

Secretary VENEMAN. Again, Mr. Chairman, we have been very proactive on the trade front. As I indicated in my testimony, we immediately dispatched a team to Japan and Korea even in that week between Christmas and New Year's. We must keep in mind that this was a difficult time of the year for so many people that gave up a lot of holidays to do the right thing in terms of our response to this issue.

We then had two of our under secretaries travel to Mexico. Mexico is our No. 1 market by volume, our No. 2 by value. Japan is our No. 1 by value. Those are two of our biggest markets, along with Korea. As I indicated, we have a team that is just coming back today from Japan, Korea, the Philippines, and Hong Kong.

Ambassador Zoellick and I both had extensive meetings with the trade minister from Japan. We have had—and we continue—ongoing dialog, in person and on the telephone. We have had teams of experts from both Mexico and Japan in the United States.

We are hopeful that we can resume trade as quickly as possible. I would remind the committee, however, that in the case when we terminated all imports from Canada after their May 20 find, it took us until just the end of August to resume imports from Canada AFSU a completion of the investigation. A number of countries are looking at our actions and looking forward to the recommendations of our committee. We will review the actions that we have taken to basically mirror what we did in response to the find in Canada.

We are appreciative of the fact that Canada maintained their market open for boxed beef. This was similar to what we did in terms of opening up our market to boxed beef from Canada. The Philippines keep their market open and Poland just opened. We are seeing some progress.

We continue to work very closely and aggressively with our trading partners at every level. Ambassador Zoellick and I talk frequently about our actions and those of our team in terms of opening of trade.

The CHAIRMAN. Thank you very much.

Senator Harkin.

Senator HARKIN. Thank you very much, Mr. Chairman.

Again, Secretary Veneman, as I said in my opening statement, you have done a great job at the Department of Agriculture in responding to this and getting on top of this situation.

My line of questions is going to take a little bit different tack, and this is a question both for you, Secretary, and for Dr. Crawford, and I will ask Dr. Torres later when he comes up. I will start by just asking this question. How much increased research on BSE or TSE, the transmissible form, and prion—or "pry-on," I have heard it pronounced both ways. Maybe one of you can tell me if that is acceptable, or whatever it is. I have heard it both ways. How much increased research on BSE, TSE, prion research in general do you believe is needed now that we have experienced a BSE case in the United States and what increases in our diagnostic capacity are needed?

Secretary VENEMAN. Mr. Harkin, I don't know that I can give you a number on increases in research per se, but there is research going on not only in USDA but on the human health side in some HHS agencies, including National Institutes for Health. We are part of that coordinated process as we look to some of the kinds of research that is being done.

As you say, research is important in the case of these prion diseases, primarily because until the find in England in the 1980's or so, we really didn't know much about this disease. In many ways, we are in our infancy in some of this research. There is a lot of research being done in other countries, there is a lot of research being done in the private sector, and we are going to continue to be very proactive.

As you now, we recently made a pre-budget announcement about funding the Ames Laboratory in Iowa, and I appreciate you being with me for that announcement.

Senator HARKIN. Thank you.

Secretary VENEMAN. That is a significant amount of money that we will be asking the Congress for. That was going to be in our budget before this find. This modernization of the Ames Laboratory is very important because this is our flagship laboratory and research facility as it pertains to these prion diseases.

We will be happy to work with you and other members of the committee to look at some of these needs, but the Ames announcement is very important in this regard.

Senator HARKIN. Are you the central person, department, on this research? Is it NIH? Is it FDA? Who is coordinating all this research? Some of it is being done by you. You say some is being done in other countries, some being done in the private sector. I don't know what is being done through NIH. I am trying to find out right now. FDA may have something going on that I don't even know about. Who is coordinating all this?

Secretary VENEMAN. Well, through our research agencies, we are looking at a coordinated effort. Particularly in light of this particular find, we will strengthen the coordination and find ways to better coordinate even than what has been done in the past. As we look at all of these prion disease issues, there are still a lot of unanswered questions.

Senator HARKIN. Did you have a response to my question?

Dr. CRAWFORD. Yes. I agree with the Secretary. The disease has always been considered to be a veterinary medical disease with public health implications, so the lead for the coordination should, in my view, continue to be USDA. Now, the National Institutes of Health has conducted research on this class of diseases, as you know, for many, many years, and as a matter of fact, a worker at NIH discovered the first of these diseases in terms of what actually caused it.

On your question about the prion, the man who——

Senator HARKIN. Now wait. Secretary Veneman called it "pree-on."

Dr. CRAWFORD. Well, that is the difference between the two departments.

[Laughter.]

Dr. CRAWFORD. The man who discovered the entity does call it a "pree-on". He was on our TSE advisory committee, and I want to expand on that a little bit. The Secretary is right, as always.

[Laughter.]

Dr. CRAWFORD. There are committees that are coordinated in this way. There are research committees for the prion class of diseases in the National Institutes of Health that have representatives from the Department of Agriculture and also from FDA itself on them, and the reverse is true in USDA.

The principal one that we pay attention to is the TSE advisory committee that this Dr. Prusner used to be on. I was on before I came back to the government. It has gotten a lot of notice because it puts in the restrictions on blood donations and also the consumption of gelatin and the use of gel-caps and these kinds of things and it has a USDA representative on it and always has had as a full voting member. As a matter of fact, I believe there are more than one at the present time. The coordination is good.

I would——

Senator HARKIN. Excuse me. Let me get to my point. Do we need any increase in diagnostic capacity?

Dr. CRAWFORD. Yes. We are working on three things now. One is that our Center for Food Safety is in the final year of funding a 2-year project to develop sensors to detect abnormal prion protein in food. Work on the project should be completed in early 2004. I am sure it will branch out and we will need some more work.

There are no tests for the rapid diagnosis of new variant CJD in people. They haven't been validated. A reliable blood screening test for VCJD, the kind that occurs in people, is an extremely important goal and it hasn't been done.

FDA has conducted and supported research efforts in the process of validating a rapid DNA-based method for the detection of animal-derived materials in animal feed. We don't have that now, either. We have to depend on other means for doing it. There is a lot of work.

Senator HARKIN. That is what I assumed. One last thing is why has the U.S. chosen 30 months as the, quote, "age of concern" for defining specified risk materials while the EU has chosen an age of 12 months? Since BSE can be detected in animals younger than 30 months, how confident are scientists that there is no risk of material from cows under 30 months being ineffective? Is there a period where prions are detected in an animal but not believed to be infectious?

Secretary VENEMAN. We chose the 30-month level based upon the current international standards under the OIE. That is a regulation that is out for public comment at this point, so I assume that we may get some comments on the number of months that is in it. It is based upon the current international standard and we really do need to rely on the OIE for the basis of setting the internationally recognized scientific standards. We have tried to utilize those recommendations from the international organization as much as possible.

I might just note in response to your previous question, one other announcement that we made recently is a partnership funding on the bovine genome mapping project. We can map genomes of various animals and insects and plants, and learn a lot more about them. We are hoping that by getting bovine mapping project started, we will learn much more about this disease down the road. This will give us more of the answers to some of the research that you are talking about.

Senator HARKIN. Thank you, Mr. Chairman. I have a second round.

The CHAIRMAN. Senator Daschle, I am going to recognize you. I understand you have another commitment.

Senator DASCHLE. Thank you very much, Mr. Chairman. I would like to follow–up, if I could, with a comment you just made with regard to downer cattle, Madam Secretary. You indicated that other countries that have now exported to the United States have adopted, is it exactly the same regulations or the equivalent of our regulations? I guess there is some confusion as to what are they actually agreeing to.

Secretary VENEMAN. What we require is that they have the same or an equivalent regulation in place. This regulation obviously wasn't the normal process, where you go out for notice and public comment and as a proposed rule. I've spent a lot of time to working with other countries. We put these out as interim final rules because of the change in status of our country of now finding BSE.

We notified all of the countries that export to us. We are working with them to ensure that they have the same or equivalent regulations in place. For example, Canada did institute a downer ban mirroring what we did because they do export the boxed beef to us.

Senator DASCHLE. Do I understand you to say that all countries that are now exporting to the United States have equal or equivalent regulations with regard to downer cattle? We have 100 percent compliance?

Secretary VENEMAN. Yes.

Senator DASCHLE. How do we determine equivalency?

Secretary VENEMAN. Well, we have a team of experts in the Food Safety Inspection Service that work with our trading partners, that review regulatory requirements as well as review plants in other countries to determine that the food safety inspection process in the foreign country is indeed equal to or equivalent to that which we have in the United States. That is a requirement to ship into this country.

Senator DASCHLE. There is some form of a certification of equivalency that they have to agree to or comply with?

Secretary VENEMAN. Yes. Countries have to maintain their status as being equivalent to our system. We consistently do reviews of countries that ship to us and oftentimes we de-list plants or whole countries because they are not complying with our equivalence requirements.

Senator DASCHLE. Again, I commend you for making progress with these countries. I guess Dr. Crawford listed and you have listed other actions that the United States has taken unilaterally, and again, the point I made earlier is one that applies here. While it appears we have had good cooperation from our trading partners with regard to downer cattle, it would be great if they could also comply with these other steps we are taking.

Because of our boundaries and because of our trade practices, clearly, these steps are only so good as it applies to our domestic production. We still don't have any assurance that actions taken in other countries will preclude the problems that we are designed to address with regard to these higher safety standards without insisting that they take them, too.

Let me ask a second question with regard to the point I made in my opening remarks with regard to regulation and implementation. We are going to be implementing and promulgating the regulations with regard to raised and wild fish in September. The law requires that we also promulgate the regulations on country of origin labeling across the board in September, even though they wouldn't be implemented for another year. Is it still your intention to comply with the law in that regard?

Secretary VENEMAN. Yes. Let me address briefly the comment you made about other countries and taking equivalent actions. The action we took with regard to specified risk material mirrors the

action that Canada took following their find. We now have, at least in the U.S. and Canada, equivalent regulations with regard to specified risk materials. The conversations that I had when I hosted the meeting with my counterparts from Mexico and Canada is how do we find even more uniformity in the regulations that we promulgate on regulatory issues that would pertain to BSE?

On the issue of country of origin labeling, as you know, this was part of the Farm bill and it required basically a two-stage regulatory process. The first part was that the USDA implement voluntary guidelines or regulations on voluntary country of origin labeling. That indeed has been done and those were implemented on time.

We then began also the process of the regulatory process for the mandatory country of origin labeling regulations. We began that process within the time frame specified by the law. A proposed rule is now open for public comment. We will continue to take public comments on that.

The omnibus appropriations bill delays our implementation of that bill a 2-year period of time. This was done to provide time to look again at the statute legislatively.

The USDA has continued to follow the time frames that were specified in the law and that we have implemented the regulations according to schedule.

Senator DASCHLE. Well, the promulgation of the regulations and the implementation are two distinct actions. Do I understand then you to say that the promulgation of the regulations will be on schedule, which as I understand it is September of this year?

Secretary VENEMAN. We have continued the regulatory process. The rule is still out as a proposed rule for comment. The office of General Counsel's in USDA is looking at how to implement/promulgate in light of the language that is in the appropriations bill.

Senator DASCHLE. Mr. Chairman, I just emphasize again, that the law is very clear and I would like to follow-up later, if I could, with you with regard to the requirement that they be promulgated on time and that we understand because of the appropriations bill implementation will be postponed. If there is some confusion about that, we need to make some adjustment in whatever form required, because the law is fairly clear. I would love to get more information from you about that.

Secretary VENEMAN. We will be happy to work with you. As I said, the regulatory process is continuing as proposed at this point in time. We have not made any changes in the process. It is ongoing since the appropriations language was implemented.

Senator DASCHLE. I will not ask the question, I just ask that you answer it for the record, but I would like to know, we have about 200 million pounds of beef that was supposed to be exported and it is still on the high seas. We don't want it to come back into the domestic market. It can't go into the foreign markets because of the prohibition by most countries to accept U.S. product today. I would be interested in knowing what the Department of Agriculture may be contemplating with regard to how to deal with that product.

Mr. Chairman, I thank you for your courtesies and appreciate your answers, Madam Secretary.

The CHAIRMAN. Thank you, Senator.

Senator Roberts.

Senator ROBERTS. Thank you, Mr. Chairman, and welcome, Madam Secretary and also Dr. Crawford.

When I was turning on the heater to my car to get the ice off of the windshield this morning, I went back into the house and happened to spot television and it had something of note in regards to you. They were announcing the Academy Awards and the nominees and I understand that the nominee for the best supporting Secretary for Agriculture for the real life drama, "Beef Exports: Something Has Got to Give," and the movie, "Beef Biscuit," and "Lord of the Feedlots"——

[Laughter.]

Senator ROBERTS [continuing]. That you were the only nominee. You are probably deserving of not an Academy Award. As I say, these are real life dramas.

Second, there have been 15 Senators, maybe 16, all extolling your virtues. That is a record, more especially with a Secretary of Agriculture, on the job that you have done.

Now, Senator Leahy and I constantly get reminders, since this is televised, that there may be a glare that could be of some difficulty, so I am going to loan him this after I am through with it, but to join you in your support for consumer confidence, I have the "Beef, It's What's For Dinner" cap that I thought I would put on and then we would continue the questions, if that would be all right with you.

Secretary VENEMAN. It's fine with me.

Senator ROBERTS. Congratulations on your nominations.

Senator LEAHY. Senator Roberts, would you——

Senator ROBERTS. I am not yielding.

Senator LEAHY [continuing]. Would you put——

Senator ROBERTS. I am not yielding. We will change the hat in just a minute.

[Laughter.]

Senator LEAHY. I was going to say, putting the hat on changed the whole dynamics of the lighting in this room.

Senator ROBERTS. Yes.

[Laughter.]

Senator ROBERTS. I will just have to make this part back here a little bigger when I give it to you.

[Laughter.]

Senator ROBERTS. Secretary Veneman, it has been suggested by some—not some, a lot—that we should be testing every animal slaughtered in the United States, and I understand these arguments and it is a policy discussion. I am concerned that such suggestions may not be based on science and would result in a tremendous new burden on the industry in regards to the economy. Does the best science indicate that it is not necessary to test all animals, particularly those under 30 months, although the question by Senator Harkin was a good one? What is the estimated cost per herd and to the total market if we were to test every animal?

Secretary VENEMAN. Senator, first of all, we are testing in accordance with internationally recognized standards. The OIE has a rather complicated formula by which they identify the kinds of animals that are at highest risks and the amount of tests that you

ought to be conducting based upon the risk level of your country. That is how we have been conducting our testing program. As you know, we are going to about double our tests this year, from about 20,000 to about 40,000. Even with the 20,000, we were well in excess of OIE guidelines.

The other thing that we are doing is we are specifically asking the international committee, the review committee, to give us recommendations in terms of testing. We think it is important that we have that international committee—the experts on BSE from around the world—to give us guidance on testing. We do know that we clearly exceed what the OIE guidelines would require for testing. The OIE does not recommend the testing of every animal. They recommend a representative sample to ensure that you are able to detect the disease to a high level of confidence.

Senator ROBERTS. I understand the integration of the U.S. cattle market, but I want to relay to you a lot of concern from producers, and I am sure this is true with every beef cattle State, over this event being labeled a North American problem. Since it was obviously two cattle from Canada that were diseased, does calling it a North American problem hurt the U.S. in trying to reopen our export markets? I have been trying to think of something else we could call it other than just a Canadian problem, but I haven't been able to do that. Has that posed a problem for us? I know it has posed a problem at least in the minds of a lot of producers.

Secretary VENEMAN. Regarding the reference to this being an issue of North America—I don't know about calling it a North American problem— but the fact of the matter is there has been a lot of trade in animals and animal products in North America. We have quite an integrated market, which has been obviously disrupted by the find in Canada on May 20, 2003. Our producers do have a lot of interrelationships in terms of trading cattle back and forth among the three countries involved in North America.

That is one of the reasons we think it is important to work together on our regulatory structures. They need to be as uniform as possible in terms of what we require with regard to BSE, because we want to make sure that we all have protections in place so that this disease does not spread.

Both of these cattle, the one found in Canada in 2003 and—the one found in May, and the one found in December in the United States, which also came from Canada, both predated the feed ban. The feed ban went into effect in Canada and the U.S. in 1997. Both these cattle were born before the feed ban, which hopefully can explain how these cattle might have gotten this disease.

In terms of our trading partners, it is important to emphasize the actions that we, the United States, are taking. There are also protections in terms of uniform regulations to the greatest extent possible with our trading partners to the north and the south.

I understand the question you are raising, but it is important that we understand it in a global context, as well.

Senator ROBERTS. Prior to the discovery, and Mr. Chairman, I only have about two more questions and I apologize to my colleagues for the time, prior to the discovery of the diseased animal in Washington State, there were some international discussions and they were ongoing in regard to changes to any international

guidelines for countries that have experienced isolated cases of BSE, specifically changes that would keep an entire country's exports from being suspended in such a situation.

Are these discussions continuing on this issue or were they simply suspended with this new issue? What kind of support are we receiving from the other major beef exporting countries in this regard?

Secretary VENEMAN. I thank you, Senator, for bringing that up because the U.S., Canada, and Mexico, after the Canadian find in May, I signed a letter to the OIE asking them to look at this whole issue. When we were made aware of the find of Canada, we immediately cutoff trade because that is what our process told us to do.

What we are now learning is that we are in a situation where there was a single animal. There is a single animal here. Most of our trading partners took equivalent action, the same action as we took against Canada and we have taken against every other country where there has been a BSE find.

In light of the knowledge that we now have about the disease, what we have learned from the outbreak in Europe, from doing the Harvard risk assessment, the importance of banning ruminant-to-ruminant feeding because that is the way this disease spreads all around the world people are realizing that the trade actions that one country would take against another in the event of a single find, should be reviewed.

Clearly, when we opened up to the lowest-risk product from Canada, we were taking a step in that direction. Working with the OIE, we are asking the OIE to specifically look at this question and make further recommendations which are expected this spring.

Yes, indeed, we are working with a number of other countries around the world through the international organizations at ways to make sure that a find in a country doesn't become a major trade problem. In both Canada and the U.S. thus far, it has been a single find. When you look at the kinds of precautions that we have taken, both in terms of our feed ban as well as what we have taken in terms of the kinds of risk materials we have taken out of the food supply, we have taken the kind of precautions that protect public health and, therefore, it should not impair trade.

Senator ROBERTS. I have a question for Dr. Crawford. We have heard a lot about inspections and the current compliance rate at the feed mills in regards to feed inspections. Can you tell us what an inspection entails very briefly? For example, is any ruminant feed tested during these inspections to ensure that the meal does not include any banned material?

Dr. CRAWFORD. Yes. Essentially what we do, Senator, is we come into a plant—these are unannounced inspections—we come into the plant. We evaluate their records. We primarily want to know where they source the ingredients from and whether or not they actually are using meat and bone meal. The technical violations that have been reported in terms of getting our compliance rate up to 99 percent have generally been their inability to keep records or to keep records that satisfy FDA.

We do have—we are using microscopy now, basically using microscopes to examine the feed if we have any doubts. Just recently, we had a shipment of non-meat feed that was sent in from Canada

and we were able to detect the presence of some animal protein in there and we, of course, took regulatory action. In the plants, we do the same thing. We have a test. We want to have a better test so that we basically have a chemical test that is very fast, very accurate, rather than having to go through this laborious process of using the microscope, and we think that is not very far off.

We are able to do both things. We check the records, which is the strongest thing we have to deal with, and the second thing is that when we have doubts, we actually look at the feed samples and evaluate them for the presence of animal protein.

Senator ROBERTS. That gets back to Senator Harkin's comment in regards to research.

I am going to ask you a question that has nothing to do with BSE, Madam Secretary. It is not BSE related and it is sort of a hand grenade without a pin in it. There is another factor at play in the beef industry that should be raised. As you know, there were reports last week that the administration had decided to take sugar off the table—we have some Senators here that are very instrumental in that and I understand that—in regard to negotiations of a free trade agreement with Australia. What I want is assurance that the administration will not provide excessive concessions to other commodities, more especially beef and in reforming the Australian Wheat Board, in exchange for taking sugar off the table.

Secretary VENEMAN. Mr. Roberts, I am fully aware of the concerns that you are raising and certainly we have heard a number of the same concerns expressed in conversations that we have had with various people. I have discussed this issue on several occasions with Ambassador Zoellick. As you know, every trade agreement is a balance of give and take. The agriculture issues are particularly difficult in the Australia agreement. We are certainly not at a point yet where concessions are being given in any specific commodity. I pledge to you to continue to work closely with Ambassador Zoellick on these issues because I know of the concerns of so many people that represent agricultural interests.

Senator ROBERTS. We have a similar problem in regards to Iraq and that State Grain Board in reference to purchasing wheat from Australia to a criteria that used to be Saddam Hussein, and I understand that that has been rescinded and that the provisional government will try again to say, OK, look at all the different criteria so that you could, i.e., Iraq, purchase grain from the United States. It is in that same vein and I would expect that these negotiations with the Australians, who have been our friends, will be meaningful dialog.

Thank you, Mr. Chairman. I apologize for the time.

The CHAIRMAN. Senator Conrad.

Senator CONRAD. Thank you, Mr. Chairman.

Earlier, Madam Secretary, I attributed a decision made to ban the feeding of cow blood and chicken waste to cattle to USDA action. Apparently, it was FDA action, so I want to correct that for the record. I assume you support that move by the FDA. I do think it is—I see you nodding. It was the right move to take.

I must say, in reading what poultry litter consists of, they said it consists of bedding, spilled feed, feathers, and fecal matter swept

from the floors of chicken coops. I don't know why that was ever permitted to be fed to cattle. Do you have any idea how widespread that practice was?

Dr. CRAWFORD. We don't think it was very widespread. It obviously would occur, if it does occur, in those areas that have both a significant chicken industry or turkey industry and also cattle, and that wouldn't include very many parts of the United States. I suspect that it wasn't very widely used.

Senator CONRAD. Madam Secretary, would you agree that that is a most unwise practice and this ban is welcome?

Secretary VENEMAN. Well, I certainly agree with the ban. It has been one that has certainly gotten a lot of attention and a lot of questions have been raised about it. We have been working closely with FDA or the actions that they have decided to take and are supportive of those actions.

Senator CONRAD. Dr. Michael Hansen, a scientist at Consumers Union, said that is a good step, but it is not good enough. He said a remaining loophole is allowing rendered matter from cows to be fed to pigs and chickens, and rendered pigs and chickens to be fed back to cows. In theory, that sequence could bring the disease full circle back to cows. In Europe, cows cannot be fed any animal matter. What is your reaction to Dr. Hansen's criticism that we are still allowing something here that could cause a problem?

Dr. CRAWFORD. The actions that we take will be the subject of an interim final regulation, as you know, so they have to be under the FDA law, as you know far better than me, science-based. There has to be a risk, either an animal health risk or a public health risk, and this has to be accepted in the scientific community. That is not the case. Pigs and chickens are not known to be susceptible to BSE and so we do not believe there is a risk in terms of this, and yet it is a useful animal protein. We would respectfully disagree with Dr. Hansen.

We have discussed this with him and with Consumers Union and are aware of their disagreement with our conclusions. We will continue to discuss it with them and we also will continue to evaluate this. At the present time, the scientific consensus holds that pigs, chickens, and turkeys are not susceptible to BSE so there would be no basis for prohibiting the feeding of this material to them.

Senator CONRAD. All right. Madam Secretary, let me just ask you, in your testimony—this is on the question of whether there was a gap in the reporting of knowing it was a Canadian cow—you say, "On Saturday, December 27"—this is from your testimony, page four at the bottom—"we learned that the ear tag matched that of a Canadian cow that was exported to the U.S. We made the public announcement of that information that same day." Your testimony is on December 27, you learned that there was a Canadian tag and made the announcement that same day.

On January 10, I had a hearing in North Dakota on this question. Glen Ullin, North Dakota rancher Terry DuPong said that cattlemen knew the infected Holstein was imported from Canada days before the USDA made it public. He said the cow had a Canadian export ear tag. He is a member of R–CALF, the United Stockgrowers of America. He said the group urged USDA to make the information public to prevent the market from over reacting.

He went on to say in his testimony, that his group knew of the cow's link to Canada on December 24. The USDA did not make the announcement until December 27.

Julie Quick, a spokesman for the Agriculture Department, said her agency reported the cow was from Canada as soon as it was confirmed, but she goes on to say that the USDA knew the cow had a Canadian ear tag on December 23.

There is a discrepancy here between what she told the press in response to our hearing and your testimony here today. Can you help us understand the discrepancy?

Secretary VENEMAN. Yes, Senator. Thank you for that question. I know there has been some concern on this, and let me just run down the time line, because I do think it is important because so many questions were asked. I asked a lot of questions about this myself, and this is the information that I have been given.

When the results came back on December 23, we had with it a number of the cow but not the actual ear tag. The ear tag apparently was sent with the brucellosis sample and that was—and the tag was then destroyed. When they went to look on farm on the 24th——

Senator CONRAD. Can I just stop you there. They destroyed the tag?

Secretary VENEMAN. That is my understanding, because it went with the brucellosis sample.

Senator CONRAD. Gosh. Didn't somebody realize that is a pretty important piece of evidence as to where this cow might have come from?

Secretary VENEMAN. The brucellosis test was negative. That is standard procedure when the ear tag apparently was with the brucellosis sample. Senator, I am just going to tell you the way this has worked. Now, as we go through an animal identification system, which many people have talked about today, we are going to be looking at all of these issues. I just want to tell you what happened in this case.

On December 24, they went to the farm and they determined that the number on this tag was similar to the numbers on some other cow tags that were still on the farm, and on the back of these tags there was a reference to terminology that the Canadian Food Inspection Agency uses. Only the number, not the tag, was with the BSE sample.

As a result they immediately notified the veterinarian, Ron DeHaven's counterpart in Canada—to see if they could trace this ear tag to any Canadian cow. This was because of the similarity of number of the tag. They confirmed this. He got called at midnight on the evening of 26th/27th, and we announced it on the 27th. We had confirmation on the 27th.

I will tell you that there was some reluctance on the part of the Canadians to allow us to announce that, but for us, it was a preliminary finding. It had to be released to the public. We then said we would confirm with DNA tests. They would have preferred we waited for those DNA tests, but we knew those would take some time and we needed to let the public know of this information.

I understand what you are saying in terms of people think they knew, but there was no confirmation by tracing this at all until the 27th, and we did announce it on the same day.

Senator CONRAD. Let me just say that I don't know exactly what happened here. It adds to the confusion when your spokesperson says that USDA knew the cow had a Canadian ear tag on December 23, but officials had to follow a paper trail to say with certainty that the cow came from that country. She went on to say there was no gap in reporting. She then follows that by saying, "It took us 3 or 4 days of working with our Canadian colleagues to say, in fact, the cow did come from Canada."

The representative of R–CALF said at the hearing that the gap in reporting resulted in a worst case scenario for U.S. beef producers. He said the market value for a 1,200-pound steer dropped more than $190 by the end of the year. He is saying that the domestic cattle market received insufficient information and the international markets were equally uninformed.

I do think that is an important thing. We need to establish when, in fact, it was known that this cow carried a Canadian tag and when it was reported. I take you at your testimony that as far as you know, from what you have been able to ascertain, you learned of it on the 27th and reported it on the 27th. I would ask you to go back, if you could, to your spokesperson, Julie Quick, and ask her why she said to the press that the USDA knew the cow had a Canadian tag on December 23. If you could do that, I would be interested to know why she said that.

It is important because, obviously, the lag in information had a potential effect on markets and people took an enormous hit. When we knew it was a Canadian cow, we saw markets recover substantially, and that is the concern that people have at the Commodity Futures Trading Commission about some people knowing and other people not knowing. This is important for us to determine.

Secretary VENEMAN. I will be happy to do that, Senator, and I would also be happy to make available our chief economist to talk about how the markets reacted. You know, there are limits on how much the market can go down each day. We saw the markets go down initially, but they have started to come back up. A lot of that was based upon the market not knowing what was going to happen with consumer confidence domestically, 90 percent of our market. We saw the markets continually go down for the first few days and then they began to level off. It was market reaction that was much along the lines of what our chief economist predicted, he thought might happen if we could maintain consumer confidence domestically.

Senator CONRAD. Let me just conclude by saying the one thing I heard loud and clear at home was a deep concern about this gap and that some people had knowledge and took advantage of it in the markets and there was such a dramatic swing that there was a potential for some people to lose a lot of money, and some people, of course, did. On the other hand, there was the potential for some people who might have inside information to make a lot of money. That is the story that we see in the Wall Street Journal this morning, the suggestion that somehow, some had insider knowledge as to where that cow came from and whether or not it was diseased.

The CHAIRMAN. Thank you, Senator.

Senator Talent.

Senator TALENT. Thank you, Mr. Chairman.

I have two areas I want to get into briefly, Madam Secretary and Dr. Crawford. Let me preface it by explaining a comment I made in my brief opening statement when I said I thought what has happened shows that the system has worked, and I do think the food safety system has worked. Some may be wondering why, if we all believe that, we have all said that, well then why are we then inquiring into all these additional measures and why are you taking additional measures?

I say the system worked because the animal was identified as needing testing. She was tested on a timely basis. The risky material in the animal was not put into the food system. The disease was identified on a timely basis. Other meat that was put into the system was recalled for confidence purposes. No other animal has been identified as having BSE and no human being has contracted the equivalent.

The system worked, but I do think it is important that we make a distinction. You have two purposes. One is to protect food safety and another is to protect the markets, and to do the second, you have to create a level of confidence and take steps that may not strictly be necessary to do the first.

This leads to my first question, because the steps that were taken with regard to downers, I don't want anybody to believe that by allowing downers to go into the food system in the past we have done something that we thought subjected the food system to risk. What we are trying to do here is to create greater confidence.

The question I have for you is, if the downers cannot—the meat from the downers, the good meat, the muscle meat—cannot be put into the food system now, will the producers have the incentives to take the downers to market, to the auction barns or the processors in the first place, and if they don't, if they just destroy the animal and bury it on the ranch, are we going to be deprived of an opportunity to test an animal that may possibly have a disease we need to know about? Might the ban have a counterproductive aspect in terms of food safety if we are not careful or don't take some steps, and have you done any thinking along those lines. Then I have one other area I want to go into.

Secretary VENEMAN. Absolutely, Senator, we have very much looked at that issue. As you indicate, a number of the animals that were part of our testing of animals for BSE were those downer animals that were presented for slaughter at slaughter plants. Those are certainly not the only high-risk animals, but the reason they are being tested is because they are high-risk. Once we found a BSE-positive cow in this country, we thought it was prudent to protect the public health to take the downers out of the system. We entered a different period when we found it in this country.

We think that there are ample opportunities to get and test all of the test samples that we need, whether it is through rendering plants or through veterinarians with appropriate training and information on what to look for. The highest risk are those with some kind of central nervous system disorder and we want to make sure that veterinarians all across the country are looking for this.

A couple of years ago, we were looking at the potentially devastating impacts to cattle of foot and mouth disease. Now, that disease doesn't have any human health problem, but we were helping veterinarians all over the country understand what to look for. Likewise, we are going to be making sure that people have in mind what kinds of symptoms to look for. We are going to be testing more frequently at rendering plants, at animal food plants, at the areas where these downers are not going into human food but going in for other purposes. We are also asking our international committee of experts to give us recommendations in that regard.

As you indicate, we have done a lot of thinking on this issue. We are having a lot of discussions on this issue with everyone from State veterinarians to rendering plants to a whole variety of other interested parties.

Senator TALENT. I am certain of that. I wanted to hear from you that the issue is by no means closed in your mind or any of the ramifications of it, because I understood why you took the step. There are certain respects in which I am not satisfied with it, but all of us are continuing to look at it and will in the future.

Let me—this is switching subjects, but the national identification system that the administration is working on with industry, it is an idea whose time has come. A lot of us are reaching that conclusion. Two aspects of it. Could you compare and contrast the USAIP system with the FAIR program that are being proposed here. What are the pluses and minuses in your mind of both.

Also, the latest draft I have seen indicates that the USAIP plan would be in place sometime in 2006. Do you have any intention or desire to accelerate that schedule? Is it possible? Do you need any help from here, funding or anything like that?

Secretary VENEMAN. Those are very good questions and I appreciate the opportunity to expand a little bit more on animal ID. It is important to recognize, Senator Allard talked about a technology. USAIP is based upon a certain technology. The FAIR program is part of USAIP, but there are people that are participating in that that have different technologies.

One of the things that is becoming very clear as we look at animal ID systems and the potential for them is that we should be looking at ways not to preclude technologies but to set the standards for the information that we need to have an effective and efficient national animal ID system. That is the direction that we want to go in in terms of looking at how we structure a national animal ID system.

I have asked our chief information officer, along with our chief economist, because there are so many economic issues involved in all of this, and our general counsel, because there are legal issues, as well, to oversee the implementation process.

It is also important to recognize, I mentioned in my House hearing last week that we are getting more and more indications that other parts of the food chain are going to give incentives, for example, to have identification systems. For example, McDonald's announced in the fall, before BSE, that they would pay a premium for meat product that could be traced back to its origin of birth. We have actually talked with some producers who are getting that pre-

mium now because they have systems in place that allow them to give that kind of information to the purchaser of the product.

What we don't want to do with any kind of animal ID system is overlay several layers of requirement onto our producers. We want to have an efficient system that allows the information to be put into a nationwide system and that will be one that allows technology to develop and become more efficient with time.

Senator TALENT. Well, I agree. I am going to look more into this both personally and in the subcommittee, and I am glad you are sensitive to the fact that so many of our producers are part-time producers. In Missouri, 42 percent of our producers run fewer than 50 cows. Also that technology is evolving. We don't want to through regulations or anything freeze this into one technology and then have to go through a whole regulatory process if better technology comes along.

For so many reasons, this, the BSE, the terrorism, everything else, it is just more and more pointing me, anyway, in the direction of we are going to have to bite the bullet and have some kind of a system.

I thank you and thank you, Dr. Crawford. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Leahy.

Senator LEAHY. Thank you. Let me just follow-up a little bit on that, Madam Secretary. You and I discussed this yesterday. We talked about the program that the Holstein Association has developed in Brattleboro, Vermont, and USDA spent a lot of money with my encouragement to get them to develop that program. They have around a million bovines in over 7,000 farms, 42 States, and they know it works.

I understand your concern about mandating a particular program and then having somebody find a better one. We all do that. I look at what happened. We had 27 of the 81 cows that came from Canada were able to be identified. Senator Specter and I have introduced legislation to require USDA to do a national animal identification program.

If we go to tracking, as many of us have suggested may be the thing to do, is that system going to be mandatory or voluntary?

Secretary VENEMAN. Well, we have indicated we want a verifiable system. We first need to get——

Senator LEAHY. Let us assume we get one.

Secretary VENEMAN. Ultimately, the kind of information you will want to have fed in will probably be required after a period of time. This will allow pilot programs to demonstrate how it is going to work. We are going to need some time to phase it in to be required of all of the animals. I do think, over time, the only way it will work is if we have the requirement that everybody participate in it.

Senator LEAHY. I don't pretend to speak for the industry, but I would think that they would want a mandatory one, because the good producers, the people who have a huge amount invested in this who are being very careful, if there is such a tracking system out, they are going to use it anyway. They are going to use it because they want to sell, whether it is to McDonald's, the school

lunch program, and so on and so forth. It doesn't help them if they are then undercut by some of the smaller producers who may want to save $3 or $4 an animal to not use the tracking system.

I would think that as the major ones are going to do that so that they can point to it if something goes wrong, they are going to want everybody to be doing it, and I would think if we want to keep the kind of credibility that we have always kept of our food supply here in the United States, we would want it to be mandatory.

Secretary VENEMAN. Well, the example you use of the effectiveness of so many of these systems, particularly in the dairy industry, whether it is the Holstein Association or a number of systems that are used in dairies throughout the country that can give you the productivity of any animal, gives the producer the ability to make good, solid management decisions about certain animals. You can have a whole range of information from those kinds of technologies that are now available and that are being developed.

Senator LEAHY. I absolutely agree with that, but I would hope that this pressure to bring those together sooner than later. We have one more of these incidences and then if we tell the world we really can't track where the animal came from, you can imagine what that is going to do to our export business, what it is going to do to our internal business.

I would urge you to take whatever your target date is and look at it very carefully and see if you couldn't make it a lot quicker, because we have hundreds of millions, maybe billions of dollars at stake just for our industries.

Secretary VENEMAN. I couldn't agree with you more, Senator, and that is why, with all of the work that has gone on in the last 18 months in looking toward an animal identification system for animal health purposes, I announced on the 30th of December that we were going to make this a priority.

I would also point out that because the cow in question was in fact, a dairy cow, it did have an animal ID on it. This was one of the reasons we were able to track it so quickly. As we move forward with this process, we want to do it with as much speed as possible, but we also want to do it right.

Senator LEAHY. Of course, the other part of this, we have all expressed concern about the industry, which is a major part of our economy in this country. With the growing, actually unbelievably huge trade deficit this country now has, anything that we can export, we are very much in favor of.

We also have the other overriding—overriding—question, and that is to protect our consumers themselves, the parents who buy beef products for their children or for themselves. These are important. I have long supported Senator Akaka's Downed Animal Act. I tried to get it in the 2002 Farm bill. The administration opposed it and it did not go in there. Now we have it back. You have done it by regulation and I applaud you for that.

Does the Department have any plans to amend their Federal Register notice, I believe it was January 12, regarding the prohibition of downed animals in the human food chain?

Secretary VENEMAN. Well, we published it as an interim final rule. It is open for public comment and so it would be inappropriate for me to prejudge what the outcome of that comment period may

be. Obviously, by announcing it through an interim final rule, making it effective immediately, we thought it was the right thing to do.

Senator LEAHY. Do you have any plans to start testing downed animals on the farm? I understand there are about a million of those a year.

Secretary VENEMAN. We, again, are working with—we do already work with veterinarians and we want to enhance the understanding of our veterinarians that deal with bovines, particularly to recognize the kinds of symptoms of this disease so that we will get the kind of high-risk cattle into the testing population that we need. We will work with people at rendering plants. We already have agreements with a number of these kinds of plants where we can get animals for testing.

We are working with all of the various places where we may find the highest risk animals whether it is on the farm or in the rendering plant or other places.

Senator LEAHY. The reason I ask that, we have, what is it, 190,000 or so downed animals delivered to slaughter, but about a million more on the farm. One of the things I get thrown back, to other countries, is what they do. Japan tests 100 percent of the cattle, I am told, that enter the food chain. In the EU, they test about 25 percent of all slaughtered cattle, but they test 100 percent of those in certain high-risk categories. That is about a million cattle per month.

Now, in the U.S., we test about half of 1 percent of the cattle slaughtered. EU is testing about 500 times more than we do. UPI submitted a FOIA request to the Department of Agriculture for information. UPI is a respected major news agency. They came out with this. They said during the first 7 months of 2003, not a single cow was tested in Washington State—surprising, because the May 2003 outbreak of BSE was in Canada in the Alberta Province. The Alberta Province is about as close to Washington State as any part of Canada could be.

We found out from them having made that Freedom of Information request that fewer than 100 of the 700 plants known to slaughter cattle were tested. Some of the biggest slaughterhouses weren't tested at all. Cows in the top four beef-producing States—that is 70 percent of the cattle slaughtered in the U.S. each year—are only 11 percent of the animals screened. In some cases, we found out that the USDA veterinarians were not in charge of selecting the animals for testing, rather the plant personnel were.

Having seen that news story, does that concern you? Is USDA doing enough testing, is my basic question.

Secretary VENEMAN. Senator, as I indicated in response to a previous question about the testing, we are targeting the highest-risk populations. We are targeting the populations based upon what the international guidelines would tell us. We know that our testing far exceeds the number of tests that would be required of a country in the same or similar circumstances as the United States. We are doubling our testing this year, from approximately 20,000 animals per year to about 40,000, again, of the highest-risk animals.

It is important to recognize that we are—and I would again reiterate that we are depending upon this international committee of

experts to give us further guidance on our testing protocols and procedures.

As you indicated, Japan tests every animal. Japan tests every animal not based on a scientific analysis, but rather when they had their first find of BSE, which as the trade minister reminded me was September 10, 2001, the day before September 11, they were hit with something that devastated certainly their food sector. Their consumption of beef went down substantially. Their consumer confidence plummeted, and they really took this action to regain consumer confidence rather than as a testing protocol for highest-risk animals.

My understanding is that their testing primarily targets those animals that go into the food chain as opposed to those that may not and may be the highest-risk animals, where you might be most likely to find it. It is a different strategy with regard to testing. Ours would follow the international guidelines, which indicate that you ought to be testing high-risk populations where you might be most likely to find the disease.

We will be testing as part of the overall protocols of part of the 40,000. Some animals that are going to slaughter that are older animals, because we know that older animals do have a higher risk.

We would be happy to continue to discuss all of these issues with regard to testing with you and I would be happy to make staff available to discuss this——

Senator LEAHY. We will. You are talking about testing 40,000. We do slaughter 35 million. Let us follow-up some more on that. I will issue some questions for the record. As I said yesterday, I am pleased, when I talked to you, I am pleased with the steps you are taking. I want to tell you publicly that. I told you that privately. I want to tell you publicly.

I also—my last point—I have just been notified that the Department is going to implement a regional equity provision in the 2002 Farm bill, something I wrote into that. That was to put those areas especially along the Eastern Seaboard and others that get very little out of the Farm bill but do have major conservation programs, that you are going to be implementing that. It means about $12 million to Vermont and other traditionally underserved States in conservation funds that protect our farmland and restore our waters. That is good news and I applaud you for it.

As you have heard from what the Chairman and all the other members have said, we share your concern on this matter. We want to ensure that our consumers, our children, our other consumers are eating products that are safe. We have a well-deserved reputation for safety in the United States. We want to keep that up. We want to be able to tell our trading partners that when they buy from us, it is also safe.

Mr. Chairman, I applaud you again for having this hearing. It is one of the most important ones we will have at the beginning of our session.

The CHAIRMAN. Thank you, Senator Leahy, and for your participation in the hearing.

Senator Grassley.

Senator GRASSLEY. Thank you very much, Mr. Chairman.

I want to start with Secretary Veneman. My Midwestern common sense tells me that there is an inconsistency that I want to point out and ask you about, because we all know that there is blood in meat. We also know that milk contains blood cells and other blood proteins. Now, the U.S. Department of Agriculture readily, and rightly so, assures us about the safety of both meat as well as milk. Then on the other hand, the Food and Drug Administration less than 14 hours ago limited blood for ruminant feed. Is the FDA's position inconsistent with your position?

Secretary VENEMAN. Senator, that it is important to point out, as you did, that there is no scientific evidence that would indicate that there is any presence of the prion or that there is any problem with the muscle cuts of meat or with any milk or milk products. There is no scientific evidence that I am aware of or that I have been informed of by any of the many people I have talked to who have scientific knowledge that there is any risk with regard to these.

I don't want to speak for the science behind the FDA actions, but the fact of the matter is, that as part of the ruminant-to-ruminant ban, this was one of the gaps in the overall ruminant-to-ruminant ban that they have acted to correct.

Senator GRASSLEY. OK. Well, blood is blood, so I would ask Dr. Crawford. It is my understanding that the scientific community supports the safety of blood and blood proteins. The World Health Organization, the Food and Agriculture Organization of the United Nations, and the World Organization for Animal Health categorizes blood in a Category 4, which is tissue with no detectable infectivity.

While hypotheticals were raised to determine potential risk, the Harvard report states, and I quote, "No detectable infectivity has been found in blood or blood components of cattle infected with BSE," end of quote. It is my understanding that the Harvard report concluded that feeding bovine blood to cattle will not spread BSE. Other groups have implied that the blood proteins could have the potential to be a risk.

As you know, blood has never been found to carry BSE, so upon what scientific basis has FDA come to the decision that you announced yesterday?

Dr. CRAWFORD. The concern about blood has been changing in the last few weeks. There is a case of variant Creutzfeldt-Jacob disease in England, which is, as you know, the human form of mad cow disease, or BSE. That person did receive a transfusion from a BSE-infected patient, that is a VCJD-infected patient, and then over a period of time, in this case 6 years, the individual that received the blood did come down with the disease. They are checking very hard to be sure that that was the cause of the disease.

As you also know, the Food and Drug Administration and many other governments have limited blood donations from those individuals that lived in the United Kingdom during the time of the major outbreak, before they got it under control. We also have imposed restrictions on donations of blood from U.S. servicemen because those that served south of the Alps did receive meat from the United Kingdom during the time of the apogee of the outbreak.

We review the blood donation restrictions every 6 months with our Transmissible Spongiform Encephalopathy Advisory Committee and we adjust these on a regular basis. I must say that the new

case in England has caused shockwaves around the globe, and that is new information.

In terms——

Senator GRASSLEY. How does that comport with the decision made yesterday not to use animal blood in animal feed?

Dr. CRAWFORD. Because it means that the prions may be found in the blood. As a matter of fact——

Senator GRASSLEY. What about the blood in the meat I eat?

Dr. CRAWFORD. Well, the blood in the meat you eat is minimal compared to something like a blood transfusion or being fed a diet of blood and it is not thought to be a risk factor. In fact, there is no risk for the so-called purge that is found in meat. What we are concerned about are blood transfusions that go right into the bloodstream, into the system. We are also concerned about the consumption of blood in dairy calf replacement rations.

Senator GRASSLEY. Would that blood that is fed in replacement rations, as an example, be a higher percentage of blood in that animal's diet compared to my diet of the meat I eat?

Dr. CRAWFORD. Yes, it would be, much higher.

Senator GRASSLEY. I would like to ask Secretary Veneman about the downer issue. The ban troubles me, and I want to take my hat off as a member of the Agriculture Committee and speak to you as I do often about my concerns about international trade, because my Finance Committee deals with this. In international trade, we have always argued that standards affecting trade must be based on sound science. This means well recognized standards accepted by the scientific community.

My question is, what scientific standards are you relying on when banning all downers as opposed to being discriminating in some, like broke a leg as opposed to those that might be sick?

Secretary VENEMAN. Senator, it is important—first of all, I would like to also recognize your work on trade. You do a terrific job as Chairman of the Finance Committee, and as you know, we are very dependent upon trade as an agricultural industry in this country and we appreciate your leadership and your knowledge of both agriculture and trade.

In the situation with regard to the downers, we do know that the downers are among the highest-risk animals. Of the cattle that have been found to be infected in other countries, including in Europe, when the disease did become established, it was much more prevalent in downer animals than other animals.

Second, we have had three finds of BSE in North America the two in 2003 and one back in the early 1990's, which was a single cow that was imported from, I believe, the U.K. In all three of those cases, the animals were downer animals. One just simply had the symptoms of a broken leg.

When you make decisions about regulations, they are based upon an evaluation of the science and a determination of the risk. Given the fact that we found a case of BSE in this country, we determined that based upon the science and the risk that these animals posed—we should take them out of the food chain itself.

That is why we made the decision. It is clearly a decision that can be defended in an international setting. Certainly it doesn't

violate national treatment and I believe that any panel would support our decision in terms of the science as well as the risk.

Senator GRASSLEY. In that 1990 case, the broken leg was not the only symptom, though, was it?

Secretary VENEMAN. I am not intimately familiar. That was the symptom that I was told, in addition to the fact that the animal—the animal was tested also because it was identified as having come from the U.K., as I understand it. It was presented as a non-ambulatory broken leg cow.

Senator GRASSLEY. In regard to whether or not sound science was used, or can be used in this particular case, the United States has been so far out in front on making sure, at least since 1993 when the last WTO dealt with the sanitary and phytosanitary rules, was to make sure that we did have sound science.

The extent to which this might be questionable in this case, it puts us at a disadvantage in the arguments we have been making, particularly with Europe, on the standards that could ban genetically modified organisms or the beef hormone issue that we won the WTO case on, and also the extent to which we might be playing to the European goal in this area of their use of the precautionary standard, which to me can ignore sound science and might be a way around the sanitary and phytosanitary rules, kind of a loose science. We have to be careful that we don't get other nations encouraged to go that same direction after we have taken such a strong stand against it.

Mr. Chairman, I believe that is the end of my questioning.

The CHAIRMAN. Thank you, Senator Grassley, for your contribution to the hearing.

Madam Secretary, Dr. Crawford, thank you so much for being here and testifying before our committee today. I congratulate you again on the fine work you are doing. We commend you for your efforts and wish you the best.

Our final witness is Dr. Alfonso Torres, who is Associate Dean of Veterinary Public Policy and Executive Director of the New York State Animal Health Diagnostic Laboratory. He is a professor, as well, at the College of Veterinary Medicine of Cornell University. He served as Director of the Plum Island Animal Disease Center before working at the Department of Agriculture as the Chief Veterinary Officer.

It was at the request of Senator Harkin that we invited an outside witness, someone who is not currently employed by the U.S. Government, to give us the benefit of observations and testimony concerning BSE and our government's efforts to deal with the threat, if any, to our food supply and the effect that it may have had on our domestic beef cattle industry. Dr. Torres comes to us highly recommended because of his previous experiences and his knowledge in this area.

We have a copy of the statement which you have submitted to the committee and we will make that a part of the record in full. I would invite you to make whatever summary comments you think would be helpful to our further understanding of your assessment of the actions that our government has taken and the effectiveness of those actions. You may proceed.

STATEMENT OF ALFONSO TORRES, D.V.M., M.S., Ph.D., ASSOCIATE DEAN FOR VETERINARY PUBLIC POLICY, AND EXECUTIVE DIRECTOR, NEW YORK STATE ANIMAL HEALTH DIAGNOSTIC LABORATORY, COLLEGE OF VETERINARY MEDICINE, CORNELL UNIVERSITY, ITHACA, NEW YORK

Dr. TORRES. Thank you, Mr. Chairman, for inviting me, and Senator Harkin and members of the committee.

While we are now experiencing the impact of BSE in our country, BSE is not a new disease for us in the veterinary community. We have been following this disease since it was first recognized as a brand new one in the United Kingdom in 1986, and all the proactive regulations from the USDA and the FDA dating back to 1988 have worked well in protecting us against an outbreak of BSE.

As Secretary Veneman indicated, we have followed BSE response plans that had been in place in 1990. Thanks to that, the Federal agency has been remarkably effective in dealing with the current situation, as has been pointed out before here. Now that we have BSE in our soil, we need to modify our plans. I know that both USDA and FDA have indicated before they are doing so.

Given the nature of BSE, there are three areas that I would like to provide some comments. The first one is in the area of trade of ruminants and ruminant products. Recognizing that we have been very proactive in implementing regulatory safeguards to prevent introduction of BSE-affected animals or products containing the BSE agent, all these regulations have so far followed the scientific knowledge about this disease, which is evolving. Consequently, our policy of how to respond to BSE-affected countries needs to be also adjusted accordingly.

In the past, we had a set policy of implementing some trade embargoes on countries that had BSE regardless of how many animals or regardless of the risk factor that they had, and that needs to be modified. Actually, the Federal agencies, Secretary Veneman pointed out, are beginning to do in cooperation with trading partners and in cooperation with the OIE.

It is important to point out that our response to Canada must be different than to respond to many countries in Europe. I also want to point out that while we only have two animals, Canadian-born animals diagnosed with BSE, we still have several hundred cases of BSE every year in EU member countries. When I hear comments that France is doing more testing of that than we do, it is because they do have a lot of cases of BSE. We don't.

Our nation will not be able to overcome the restrictions that other countries have placed on our export of animals and animal products until we continue to adjust our import trade restriction to other countries in an equivalent and proportional way under similar situations. I believe that the trade restrictions imposed by many countries, as pointed out, are not science-based, and that includes boxed beef, embryos, and semen. Those should be lifted. The restrictions on live animals are going to take a little bit longer term to be lifted, until we are in a position to lift similarly restrictions in other countries.

The second point that I want to make some comments, Mr. Chairman, is in the targeted domestic surveillance. As pointed out

by previous testimony here, USDA has had an effective surveillance system to provide for an early detection of BSE in our country. The system has worked well, as demonstrated by the detection of the first BSE-affected cow in the State of Washington.

The task now is to maintain and expand an effective surveillance program in face of the recently announced USDA ban on the slaughter of non-ambulatory animals for human food. This is the segment of the cattle population that has been our best target for sampling and testing. A new system of BSE surveillance that statistically represents the entire cattle population of the U.S. and that meets international guidelines and recommendations will be a challenge. The system for transportation to and sampling at slaughter establishments that process only downer animals are not well developed at the present time.

There is a need, in my estimation, to find a safe and economically viable means to humanely slaughter non-ambulatory animals and to provide for safe disposal and sampling of on-farm dead animals. Such actions will avoid potential welfare issues of injured animals at the farm and will restore a well-established source of samples for a credible BSE surveillance at the national level that is based on sound epidemiologic science.

Animal ID is an integral component of surveillance, and while I recognize and appreciate the many efforts that USDA and the animal industries are doing in developing and implementing a national ID system, the weakness of such a system is that it is voluntary at this time. I am encouraged by the statements from Secretary Veneman and others at USDA on the acceleration of the national animal ID plans. However, I respectfully suggest that Congress, in cooperation with the USDA and the industry, needs to make this national animal ID system a mandatory program.

My final comment, Mr. Chairman, is in regard to ruminant feed bans. I applaud the efforts from the FDA in tightening enforcement of the regulations banning the feeding of ruminant proteins to cattle and the additional safeguard measures just announced. I understand the reasons for those at this point in time.

Still, the very best way to prevent the amplification and the spread of BSE from affected cattle to other animals is by preventing the use of potentially BSE-contaminated feeds for all susceptible animals. Given the fact that BSE prion agent is primarily present in relatively few tissues of the infected animal, the so-called specified risk materials, or SRM, I urge the USDA and the FDA to extend the ban on the use of SRMs from all downers and from cattle older than 30 months of age, not only for use in the human food chain, but also for use in the animal feed chain. Such action will further enhance the safety of protein supplements used in ruminant and feline diets.

This recommendation has been proposed by the World Health Organization as part of scientific measures to prevent the spread of BSE in the world. This recommendation was also made to Canada last June by the international review panel that evaluated the actions after the case in the Province of Alberta last year.

Mr. Chairman, I want to be on record to congratulate the USDA and the FDA for their effective actions following the BSE finding and announcement December 23 of last year. These actions have

maintained consumer confidence in the safety of our beef products, and while trade embargoes were to be expected in a situation like this, I hope that with continued implementation of actions as suggested today by members of the panels we will continue to enhance the defense of our nation against BSE and sustain domestic and international confidence in our animal industries and the safety of our food and feed supply.

Thank you again, Mr. Chairman, and to the committee for inviting me to testify, and I would be glad to answer any questions that you may have.

The CHAIRMAN. Thank you very much, Dr. Torres. We appreciate your attendance at our hearing and your help in our understanding of the issues involved in this BSE situation.

[The prepared statement of Dr. Torres can be found in the appendix on page 148.]

The CHAIRMAN. In your statement, you suggest that even though we have learned a lot since the outbreak of BSE in Europe, our research has some scientific gaps in it. With your experience with BSE and other diseases, can you give us your thoughts about how we could better coordinate research efforts both domestically and internationally to close those gaps?

Dr. TORRES. Yes, Mr. Chairman. Certainly this group of diseases have been difficult ones to do research on because of a number of things. One is a unique type of agent for which the technologies that we use for infectious diseases do not work. Second is a very long incubation period. Even if you were to use mice, you need to inject these mice and then wait a year and a half to 2 years to have the results. If you were to use the host species, cattle, you have to wait 4 to 7 years. Then you have to do those experiments under proper, biocontainment, isolation. It becomes very cumbersome and very difficult and expensive to do it.

There is one issue that I have to caution all of you about and that is the extrapolation of scientific information from other TSEs into BSE. Let me use an example. Variant CJD is the BSE infection in humans, but the findings of vCJD in humans could not be directly extrapolated to humans. Yes, there was a case, as pointed out by Dr. Crawford, of a transfusion that led to a vCJD case in a human, and that is because humans with vCJD have the prions in the bone marrow, which is the tissue or the organ of the body that forms blood.

That has not been determined in cattle. We have never seen prions be accumulated in the bone marrow of cattle. That is why the OIE, the WHO, and other agencies still argue that the blood of cattle is safe for consumption or for use, because there is no evidence of that in cattle. There is evidence of that in humans.

What I am trying to say is that there are a lot of gaps in research in these diseases as they apply to animals. A lot of the research, funding for research on these diseases has been directed to the human aspects of these diseases. There is very little money going to understand the effect of these diseases on the host animals themselves. We know still very little how chronic wasting disease is transmitted. We still have some gaps in the understanding of BSE in animals, especially what could happen with BSE infection in sheep, for example.

Mr. Chairman and Senator Harkin, I know that both of you are interested in this area, but when it comes down to the funding available for universities like ourselves at Cornell University to conduct animal health research, it is a very, very small portion of the pool of the money that is available to do biomedical research for human purposes to NIH, and I will argue that the biomedical sciences are as expensive whether you are working for disease in animals or in humans and I would urge the Congress to revisit the issue of funding for agricultural-based animal health and public health research.

I hope that I have answered some of your question.

The CHAIRMAN. Your mentioning the World Animal Health Organization is helpful to us. Many people have heard of the World Health Organization. It is commonly discussed in the decisions that are made by the World Health Organization.

You suggested in your statement that specified risk materials from cattle over 30 months of age should not enter the human food chain. You recommend that they should not enter the human food chain or animal feed chain and that this recommendation has been proposed by the World Health Organization. I wonder if that is the same position that the World Animal Health Organization has, or have they taken a position on that issue? You were a delegate to that World Animal Health Organization.

Dr. TORRES. Yes, Mr. Chairman. They are coordinating their recommendations to be uniform. One of the reasons why—first of all, let us keep in mind that the SRM is where the major infectivity exists. There could be 5,000 infective doses in the brain of an affected animal, 2,000 infected doses for cattle in the spinal cord of affected cattle. If you remove just brain and spinal cord, you are taking more than 80 percent of the infectivity that is in the system.

There are always leaks in the system, even though you may have a ruminant feed ban in place, there are leaks in the system as has been pointed out here before. The chicken litter feed is one of the sort of leaks of the system that have been plugged now. There are also leaks in the system of spent pet food being fed to cattle.

That is one of the recommendations, elimination of all SRMs from even the feed, is to prevent these infection materials to be available through the feed channels that perhaps accidentally could be leaked into the ruminant feed chain. That is also why FDA wants to have separate lines of production of these products, to prevent this cost-contamination. The additional removing of all SRMs even from the feed chain is going to help us to remove that risk from ruminants.

Also, we have to keep in mind that although there have been very few cases, about 100 cases of domestic cats have suffered infection of BSE. These cases have been mostly in the U.K., a few cases in other parts of Europe. The elimination of SRMs from the feed chain is an added safeguard in preventing the spread of BSE in a given country.

The CHAIRMAN. When you mention the acronym SRMs, you are referring to specified——

Dr. TORRES. Specified risk materials.

The CHAIRMAN. Specified risk materials?

Dr. TORRES. That is correct, yes.

The CHAIRMAN. With respect to the national animal identification system, do you see this as an area where the Federal Government should mandate the system, including any type of technology that should be employed, or do you see the potential for USDA to be able to use existing ID systems developed by commercial entities or State governments or breed associations?

Dr. TORRES. Mr. Chairman, as I indicated in my testimony, the national animal ID system needs to be, in my estimation, mandatory. The mandatory part will be the standardization of systems, of nomenclature and maybe computer data bases that can gather information but allow the marketplace to establish what is placed on the animal. This could be an implant, it could be an ear tag, it could be different methodologies.

What needs to be mandatory and standardized is the nomenclature system and the system to collect that information and being made available when needed. Unless we have all the systems that are compatible in the data bases, then we are not going to accomplish what we need.

It needs to be also ISO certifiable. That means that internationally, it is going to be accepted by trading partners. Some of these animals that we are going to ear tag or ID tag are going to be exported. Our system needs to be also recognized internationally. There are many, many systems that many companies are promoting now. Many of them are not ISO certifiable, and that needs to be part of the standards that are mandatory.

The CHAIRMAN. Thank you. Your presence here and your testimony has been very helpful and we appreciate your assistance to our committee.

Senator Harkin.

Senator HARKIN. Thank you, Mr. Chairman. I just wanted to get back here. I had to take a small break, but I wanted to be here for Dr. Torres' testimony, basically just to cover a couple of things with you, Dr. Torres.

I am not certain, I listened to the answer that Dr. Crawford gave to Senator Conrad, and I believe there may have been a misinterpretation or misperception from that answer. Dr. Crawford said that BSE does not manifest itself—that is the word he used—in poultry, for example. Chickens don't get BSE. Therefore, the implication was that if you feed ground up chickens, bones and everything else, to ruminants, that is no problem.

Is it not a fact, Dr. Torres, that these prions are highly indestructible molecules that can go—let us say you can take a ruminant, you can grind it up, use that as feed and feed it to poultry. If that animal is infected with those prions, that ruminant, those prions then will be picked up by the chicken. The chicken may never manifest BSE, but the prions could be there in the chicken's system. If that chicken is then slaughtered and ground up and fed back to another ruminant animal, those prions may have completed that cycle, is that not true?

Dr. TORRES. Senator Harkin, there is a need to have a certain amount of material in order to infect an animal, a bovine. Chickens——

Senator HARKIN. Do we know how much that is?

Dr. TORRES. It has been estimated to be probably a tenth of a gram or maybe less.

Senator HARKIN. A tenth of a gram?

Dr. TORRES. Or less.

Senator HARKIN. That is very small.

Dr. TORRES. It is a very small amount, yes.

Senator HARKIN. Very small.

Dr. TORRES. A very small amount.

Senator HARKIN. Thank you. I didn't want to leave the impression there that a ruminant had to eat a thousand chickens before it would ever get prions. A tenth of a gram.

Dr. TORRES. Now, if chickens, following your example, are fed materials contaminated with that prion—let us assume that that is the case.

Senator HARKIN. Yes.

Dr. TORRES. The materials are going to be passed through the gastrointestinal tract of the chicken without being destroyed because of the nature of those proteins. They are not going to be taken into the body of the chicken, nor do they have an ability to replicate or multiply or accumulate in the chicken. The only part that could be in the chicken, if it is ground up, following your example, to be used as a protein supplement for cattle, it would be whatever minute amounts are still present in the lining of the intestinal tract of that chicken fed that material.

Senator HARKIN. Let me just clear up one thing, Dr. Torres. You are saying that if a chicken eats ground up ruminant material that contains these prions, those prions cannot go beyond the gastrointestinal tract? They cannot be absorbed in the bloodstream?

Dr. TORRES. That is correct. That is what is estimated to be the case, yes.

Senator HARKIN. Estimated, or—I really want to pin you down on this, because I have heard other information that those prions may be deposited in other parts of the chicken's body, where they won't do any harm, but they are still there. Now, if I am wrong, I would like to know that.

Dr. TORRES. I don't have a recollection now of a specific scientific paper that deals with quantifying how much of this material may be absorbed in chickens or not. I am basing my answer on general principles that we know about what is absorbed from the intestinal tract of animals or not.

Senator HARKIN. OK.

Dr. TORRES. In my estimation, the amount of prion, the large molecule that the chicken may absorb into the bloodstream, will be either nil or very minute amounts.

Senator HARKIN. I need to get more information on that because it seems there is a fair amount unknown about whether those prions could deposit themselves in various parts of the chicken's body. The chicken will never manifest any illness, but the prions would be there. I need to get some more information on that because I thought these was some uncertainty regarding that, and I will have to check that out some more from scientists.

The other point, if there is that possibility, and I don't know if there is, but it seems to me that the one way to stop all this is just

to ban the feeding of any ruminant parts to any animal. Wouldn't that just stop it right there?

Dr. TORRES. Sure, or the elimination of all SRMs to get into the feed chain, what I have suggested, as well.

Senator HARKIN. Well, but that is the way it gets in the feed chain, isn't it?

Dr. TORRES. No. The SRMs are still allowed to go into the feed chain. Now, that feed cannot be fed to ruminants, but can be fed to other animals, chickens, pigs, and so forth.

Senator HARKIN. Right.

Dr. TORRES. If you were to eliminate all SRMs from the feed chain——

Senator HARKIN. Yes.

Dr. TORRES [continuing]. Then you remove the majority of the potentially infectious agent from the feed chain, period, whether it is fed to chickens——

Senator HARKIN. The majority or all of it?

Dr. TORRES. Well, there is still some residue, but if you eliminate the SRMs, you are eliminating 90 percent plus of all infectious, or all tissue that potentially could contain the prion agent of a ruminant.

Senator HARKIN. Those prions in a bovine animal, in a steer, cow, whatever, those prions actually could also attach themselves to nearby tissues of the spinal column, for example, along the ribs.

Dr. TORRES. Well, that is—Mr. Harkin, there are some ganglions, some nearby ganglions. As the nerves exit the spinal cord——

Senator HARKIN. Right.

Dr. TORRES [continuing]. There is a ganglion there. That is called a dorsal ganglia. They are part of the SRM definition. If you remove all SRMs, you are removing that nerve tissue that is there as the nerves exit the spinal cord through the muscle to the ribs.

Senator HARKIN. These prions could not attach themselves to anything beyond that that we know of?

Dr. TORRES. These prions are associated with nerve cells. Most of our nerves in the body are not the cells. The cells are in the spinal cord, the brain, or the ganglia. What we have in our tissues is just the extensions of those cells but not the nucleus of the cell and that is where the prions are. The nerve tissue, pure nerve tissue that may be in a muscle mass, does not contain the prions.

Senator HARKIN. I see. Is it my understanding that some countries, Japan, France, I don't know how many, have actually banned all feeding of ruminant feed to anything?

Dr. TORRES. That is correct, and part of that is because the systems, as I understand, of rendering and processing, they have plants that process and render ruminants or non-ruminant species in the same plant. The possibility of cross-contamination for them is quite high. The FDA has implemented rules that separate the production lines of ruminant feed from other lines that produce feed for other species. It is a little bit different systems in how the rendering unit is organized, as I understand, why some countries have banned all ruminant feeding to other animals versus ourselves doing the ruminant-to-ruminant feed ban.

Senator HARKIN. My last question would be this. I was told the other day that France inspects more animals in 1 month than we

do in a decade. I saw your testimony as I was walking out of my office that you said, of course, they have BSE. They have more BSE. That is why they do more testing. I understand that.

Is there not a quick—test right now that other countries have adopted, which before any slaughtered animal goes to market, there is a test done and then the animal is released to go to market based upon that test, and that test only takes a couple days, maybe, two or 3 days, less than that, maybe. I don't know. What can you tell us about that as a possibility of perhaps ensuring the public that the meat they eat contains absolutely none of these prions?

Dr. TORRES. Senator Harkin, there are a variety of diagnostic tests for prions, BSE or chronic wasting disease or the like. The majority of the tests are very good for surveillance but they are not intended, many of them, to be for food safety purposes, and there is a difference there. These tests, only they take the positive animal when the animal is just a few months or a few weeks before the animal becomes clinical. We cannot detect animals that may have the prions in their tissues too much before the animal becomes clinical.

The feeling is that many of these tests are very good for surveillance, targeting the high-risk population like we have been doing here in the past, the downer animals and the like. Testing animals older than 30 months of age makes sense.

Testing animals below that age, 24 to 30—I know that you asked that question because there are differences in establishing when there is sufficient prion accumulated in an animal for that animal to be infectious to others. Experiments were done using mice, but now they are getting the results after 4 to 7 years of the same experiments doing calves and the data looks a little different. There is a range between 24 to 30 months. Some countries have elected to take 24 months, but most countries have elected to take 30 months. Testing eventually 30 months of all the animals, the test becomes more valid for food safety purposes than testing animals lower than that age.

Senator HARKIN. Lower than that age, those prions could still be there. They may not manifest themselves in any illness or anything like that, but they would still be there.

Dr. TORRES. It appears, Senator, that the accumulation of these prions in the SRM tissues of the animal, affected animal, increases exponentially with time. Prior to that age, even if the animal were to be incubating the disease, the scientific community estimated that those animals do not pose a risk for human or animal safety because there is not enough material there to infect other animals.

Senator HARKIN. How about to infect humans?

Dr. TORRES. Less likely. The human infective dose, although it is not established because nobody has done the direct experiment, but is estimated to be maybe a thousand or more fold greater than the dose used for infecting cattle. Every time that you jump species, the infective dose increases dramatically. The amount to infect a human is many, many folds, a thousandfold or more, greater than the amount that is used or needed to infect cattle.

Senator HARKIN. Yes, but we really don't know the answer to that and that is why more research is needed on this.

Is there any difference between poultry and swine? When swine eat ruminant parts and stuff, could these prions then be ingested and find their way to other parts of the swine rather than.

Dr. TORRES. I am not aware, Senator Harkin, of swine being, first, susceptible to these diseases, or——

Senator HARKIN. I know it is not susceptible to disease. I am just talking about eating ruminant parts, having those prions attach themselves or get in the blood stream and settle in various other parts of the swine's body that may either be consumed by humans or may be consumed by other ruminant animals as feed later on.

Dr. TORRES. Yes. I am not aware of the swine to be accumulating these prions in their tissues——

Senator HARKIN. OK.

Dr. TORRES [continuing]. Enough to pose any human or animal health hazard.

Senator HARKIN. OK. You are not aware that that is possible. Thank you. That was very informative. I appreciate it very much, Dr. Torres. Thank you.

The CHAIRMAN. Thank you, Senator Harkin.

Thank you, Dr. Torres, for your participation in our hearing. We have had a very successful hearing today. We had the full participation of the members of the committee and we have been enlightened and better advised because of the fact that we have had our witnesses before us today.

Congratulations again to the Department of Agriculture and the Food and Drug Administration for the expeditious effort that they have put forward in containing and explaining and helping to reassure not only the consuming public here in the U.S. about the BSE and what the threats are and the lack of threats to our food supply, and also to re-establish and restore markets for our beef cattle industry and our beef products around the world. This has been a very constructive hearing.

The hearing is now adjourned.

[Whereupon, at 12:54 p.m., the committee was adjourned.]

APPENDIX

JANURAY 27, 2004

Chairman Cochran
Opening Statement
Committee on Agriculture, Nutrition, and Forestry
BSE Hearing
Tuesday, January 27th, 9:30 am

Good Morning. This hearing of the Senate Committee on Agriculture, Nutrition, and Forestry will come to order. The purpose of today's hearing is to examine the current situation regarding the December 23rd discovery of a case of bovine spongiform encephalopathy, or BSE, in a dairy cow in Washington state as it relates to food safety, livestock marketing and international trade issues. We are pleased to begin our hearing today with testimony from two members of the Senate with interest in this subject. Senator Richard Durbin from Illinois and Senator Wayne Allard from Colorado will comprise our first panel. Senator Allard is one of two veterinarians serving in the Senate. Our second panel will consist of the Honorable Ann Veneman, Secretary of the U.S. Department of Agriculture, and Dr. Lester Crawford, Deputy Commissioner of the U.S. Food and Drug Administration. In addition, we will hear testimony from Dr. Alphonso Torres, the Assistant Dean of the Cornell University College of Veterinary Medicine.

The discovery of the BSE-positive cow has reaffirmed the effectiveness of the surveillance and food safety procedures in place by the Department of Agriculture and the Food and Drug Administration, and I commend them for having a good contingency plan in place to deal with this discovery. U.S. beef remains very safe, and consumer confidence in our nation's food supply remains strong.

The discovery has had other effects. After the initial announcement, cattle prices experienced a decline of about 15 to 20 percent in futures and cash markets, but now appear to be stabilizing, with today's prices remaining above last year's levels.

On the international trade front, discovery of BSE has caused major disruption to U.S. beef trade. Even though about 90 percent of our beef production is consumed domestically, the 10 percent that is exported is significant – it equated to over two and a half billion pounds last year at a value of about 3.8 billion dollars. Unfortunately, after the December 23rd announcement, most of the countries that import beef from the U.S. stopped immediately, including Japan, South Korea, and Mexico, which account for 80 percent of our beef exports. It is

absolutely vital that we resume exporting as soon as possible. However, I understand that the process for opening markets will be an uphill battle. I hope these countries negotiate in good faith and apply the principles of sound science when assessing the risk to their market. I was very pleased to see that several members of USDA's trade team, and personnel from FDA, immediately departed for Asia to expedite this process. In addition, I was pleased to learn of your visit with your North American counterparts, and look forward to hearing more on how the established consultative mechanism with Mexico and Canada will work.

Secretary Veneman has handled the situation with speed and transparency, and has led the effort to quickly inform and educate the public, which has resulted in continued high consumer confidence in the domestic beef market.

I also applaud Secretary Veneman and Dr. Crawford for their efforts to further strengthen the safety net that protects our food supply, the details of which we anticipate hearing today.

Statement of Senator Tom Harkin (D-IA), Ranking Member Senate Committee on Agriculture, Nutrition and Forestry January 27, 2004

"Thank you, Mr. Chairman, and thank you for calling this hearing to review the U.S. response to a Washington State cow that tested positive for Bovine Spongiform Encephalopathy (BSE). This hearing also raises a more global issue: a real world test of our ability to respond to an animal disease emergency that points out both strengths and areas for improvement in our system.

"USDA and FDA are to be commended for the openness and speed with which they have responded. Their actions are a significant reason that consumer confidence in our food supply has remained strong. Still, this case points out that we absolutely must do everything we can to make sure our agricultural health and food safety systems are ready to identify and respond swiftly to an outbreak of disease, whether natural or intentional. While I think USDA's and FDA's actions are a strong start, I hope this hearing will shed light on some questions that remain unanswered.

"Building and maintaining consumer and customer confidence is vital to ensuring markets remain open to our beef products. In a little more than a month, we have already seen the economic impact of losing beef export markets. About $200 million worth of product shipped overseas prior to December is now in limbo, with no countries in the region willing to accept it.

"Facing dim prospects for exports, many beef packing plants are cutting their hours of operation and laying off hundreds of workers, including at plants in Council Bluffs, Tama, and Denison, Iowa. Although the health risk to humans from a single mad cow case is negligible, we are nonetheless seeing real human impacts from this incident. I can only hope that once our investigation is complete, and all appropriate action taken to safeguard against BSE, that our trading partners will reopen their markets expeditiously.

"To resume trade and ensure consumer confidence it is important that we reexamine our BSE surveillance strategy to make sure we are detecting any cases of BSE that might be present in the U.S. and taking appropriate action to address them. Ideally, we should be able to work with the OIE and our trading partners to come to generally agreed upon standards for testing to help facilitate the reopening of foreign markets to our beef exports.

"We need to make sure testing capacity is adequate for animal and plant diseases across the country. I am very pleased that the Administration has proposed $178 million in additional funds for the animal disease facilities in Ames that are vital for the study of diseases such as BSE. My hope is that Congress will quickly move forward with that funding, hopefully by June when design will be far enough along that construction could begin.

"Our critical front line defense against BSE is enforcement of FDA's feed regulations, and we need to make absolutely sure those regulations are being effectively enforced. That is why Chairman Cochran, Senator Durbin and I requested last year that the General Accounting Office audit FDA's enforcement program to ensure that compliance with the feed regulations has improved.

"The discovery of BSE has also renewed interest in a National animal identification program to track the movement of livestock in this country. After 5 weeks of intensive investigation, we have located only 28 of the 81 cows that entered the U.S. from Canada with the infected cow. If we had an animal id system, USDA could have located those cattle in a matter of hours, or at the longest, days.

"In addition to an animal identification program, I think the Administration needs to seriously consider implementing a better traceback system for human food products. It still takes far too long to recover contaminated food products, if they are recovered at all. I have proposed legislation in the past that would give both USDA and FDA new tools to help prevent and recover contaminated products. I will reintroduce this legislation during this session of Congress and I hope this administration will reconsider its support.

"Thank you again, Mr. Chairman, and I look forward to the testimony of our witnesses."

Statement by Senator Max Baucus
Agriculture Committee Hearing
BSE
January 27, 2004

Thank you Mr. Chairman. Secretary Veneman, Commissioner Crawford, Dr. Torres, Senator Durbin, and Senator Allard, thank you for testifying today.

The discovery of a BSE infected dairy cow from Canada in Washington state presents a serious challenges to our nation's cattle industry. The actions the USDA and Congress take in response to this case will have long standing effects on Montana cattle producers and it is imperative that we do things right.

The United States continues to have the safest food supply in the world. I had a steak for dinner last night and I didn't think twice.

It is important to respond to the BSE case on two fronts. 1) We must maintain consumer confidence; and 2) we must re-open our export markets for beef.

I applaud the Secretary's actions and I support the USDA's ban on downer cattle, the prohibition of high-risk byproducts from entering the food supply, and the new practice of preventing the carcasses of BSE tested animals from entering the food supply until the test comes back negative.

I also commend Commissioner Crawford and the FDA for their actions regarding the banning of certain types of animal feed. It is imperative that we close any loopholes that may allow banned ruminant byproducts from entering ruminant feed.

These actions reinforce and reassure American and International consumers that our already safe food supply is now even safer.

Last week, members of my staff toured 10 towns in Montana and held listening sessions on BSE. Producers echoed their support for the ban on downed animals.

Before the ban a high percentage of animals tested for BSE were downer animals. I would like to hear from Secretary Veneman on USDA's plans to test cattle for BSE and USDA's plans to collect high-risk downer cattle for testing. I would also like to hear if USDA has any plans to compensate producers for healthy cattle who may break a leg during transit to a slaughtering facility and can therefore not enter the food chain.

As I mentioned before, I also support the prohibition of specified risk materials from animals over 30 months of age from entering the food supply. I do, however, have serious concerns about the implementation of the rule—specifically with the determination of age by the "mouthing" test.

Packers are discounting cattle over 30 months of age by about 15% and that adds up to approximately $200 per animal. That's adds up quickly to substantial amounts for Montana producers.

USDA's rule instructs packers to determine the age of cattle by counting the number of teeth. According to this method, two teeth indicate a cow under thirty months of age. A third tooth would indicate a cow over thirty months of age. This method is not exact and the age can be off by as much as one year. This means that a 20 month old cow could be mistaken for over 30 months and the producer would receive the 15% discount on that cow.

Two-hundred dollars is a lot of money to lose because of an inaccurate and unscientific method of determining the age of cattle. I urge the Secretary to look into alternative methods of determining age.

I would like to touch on the issue of trade for a moment. Behind me is a poster illustrating the countries that have banned U.S. beef products. Ten percent of United States beef products are exported. That might not seem like a lot, but the effect of the bans on U.S. beef caused cattle prices to decrease by 15-20 percent. As the Secretary will note in her testimony, prices increased recently and are now just 5 to 8 percent below what they were before the discovery of the BSE infected cow. Demand is high and supplies are tight, but supply will increase in a few months when more cattle go to market and it is imperative that we re-open our export markets to absorb this increase in supply.

I applaud the US Department of Agriculture's efforts to negotiate with our trading partners. Earlier this month I sent Secretary Veneman a letter requesting that a special envoy be appointed to work with our trading partners to re-open their markets to U.S. beef. USDA officials have done a commendable job negotiating with Japan, South Korea, and Mexico, but the people currently doing the negotiating also have many other hats to wear. I think it is important that a person be appointed to negotiate with our trading partners who can focus solely on the goal of re-opening our export markets.

I'd like to make one last comment—on consumer confidence. Confidence is achieved by being informed. U.S. consumers know that the United States has the safest food supply in the world. That knowledge has helped keep consumer confidence in beef at all time highs. Consumers know that U.S. beef is safe and they want to know where their food comes from. It is imperative that country-of-origin labeling be implemented immediately. It must be done in a simple and cost effective manner. Country-of-origin labeling will give consumers the information they need to make important choices at the grocery store and our cattle producers will be rewarded by their selection.

Secretary Veneman, Deputy Commissioner Crawford, I stand ready to work with you and my colleagues to maintain consumer confidence and re-open our markets. It is important to implement new safeguards with common sense and not knee-jerk reactions. It is imperative that whatever changes made do not overburden our cattle producers. I look forward to working with USDA and my colleagues to make sure we do things right.

Thank you Mr. Chairman.

Statement by Senator Pat Roberts
Senate Agriculture Committee
Hearing on the BSE case in Washington State
Washington, DC
January 27, 2004

Thank you Mr. Chairman, and welcome Secretary Veneman, Commissioner McClellan and Dr. Torres. I look forward to hearing each of your's testimony on this most critical issue.

Mr. Chairman, I joined everyone in being stunned when this announcement was made by Secretary Veneman on December 23. While it was certainly not completely unexpected, it is the announcement that we had all hoped would never come.

The announcement sent particular shock waves through Kansas where cattle and beef production represents nearly a $5 billion/yr industry, with $1 billion of that value being exported overseas.

While the loss of export markets and the sudden drop in cattle prices was expected, the total impact of this event has been tempered by the outstanding efforts of Ann and her team down at USDA.

Mr. Chairman, in the days after this announcement, the number one priority was maintaining consumer confidence in the beef supply. Ann and her team, along with the National

Cattlemen's Beef Association and its state affiliates, jumped on this issue and made sure the real facts and information regarding the case and the disease were provided to the American public and the press.

It is in no small part due to these efforts that we have avoided a replay of the Alar disaster we had with apples in the early 90s.

Rather, television and newspaper reporting has been relatively balanced and most consumers have responded by continuing to consume beef.

Mr. Chairman, without the tireless efforts of many that gave up their holidays with their friends

and families on behalf of the United States beef producers and cowboys, this industry could have been decimated. Let me assure all of you that many thank you for your efforts.

Mr. Chairman, as we continue these efforts, it is also important that we reopen our international markets and continue to base all our decisions on sound science.

As we now know, this was not a cow of United States origin. Thus, we should not be subjected to the same international blockade that has met Canadian beef shipments since last May. I know that

Secretary Veneman and the Administration are working hard in this area, and I look forward to hearing an update on these activities.

Mr. Chairman, let me close by saying that in all the years I have served on both the House and Senate Agriculture Committees, I believe this is the most serious issue to ever face United States agriculture.

The future of the entire beef industry and much of the American agriculture economy is at stake. As such, there will certainly be times where we may have disagreements on the proper course of action as

we move forward. However, it is my hope that we and our colleagues on both sides of the aisle can keep this from becoming a political issue.While it may make for good sound bites, it is not good for the beef industry or the country.

I look forward to working with you, our colleagues, and Secretary Veneman to ensure we take the proper steps and make it through this difficult time.

Thank you.

Statement of Senator Chuck Grassley
Before the Senate Ag. Committee hearing on BSE
January 21, 2004

Mr. Chairman, thank you for this timely opportunity to discuss a crucial issue. The discovery of a Canadian cow carrying BSE in the United States shaved 20% off of the market price for live cattle and devastated our export markets within days of the announcement by USDA.

While the discovery of the Canadian cow has had and will continue to have a devastating impact on cattle producers, I need to commend the Department of Agriculture for initially handling the issue well and solidifying domestic consumer confidence.

I plan to raise many questions today which will seemingly challenge Sec. Veneman's recent choices, but I recognize that USDA has done an outstanding job and no should question my confidence in our meat safety or my belief that we will overcome some of the issues I will raise today to further solidify consumer confidence and re-open foreign markets as quickly as possible.

With that disclaimer, I want to know things like how USDA approximately doubled the participation levels of Fed Cattle and Feeder Cattle in the Livestock Risk Protection program on December 23rd? Is it true that LRP for cattle was left open for a couple hours after you announced the positive cow? I won't condemn those that got in after the fact, I'm interested for those that didn't get ***home insurance after the house was on fire.*** Who is accountable for the inequity?

90% of our beef export markets have closed according to NCBA. Immediately re-opening these markets is crucial. No one has offered intellectual resistence or criticized the bi-partisan letter I co-signed along with 9 other senators calling for a special envoy, so why hasn't one been appointed yet?

USDA decided not to educate the public about the differences between lame and sick cattle, why did they make that choice?

Given the fact that we seemingly try to base all trade-related decisions on sound science, and USDA's Agriculture and Food Safety Inspection Service sent letters to 10 exporting nations explaining beef exports would be blocked without compliance, we need to know what science we are relying on behind the decision to ban all downers.

I am also interested in how Secretary Veneman came to the decision to ban all downers. I requested last Friday that Sec. Veneman write a letter or memo explaining her thought process coming to this decision. My office was informed yesterday she decided not to respond to my request.

I requested that explanation because I want to know who's advise was following. I realize that everyone with an interest in this issue likely reached out to Secretary Veneman or her advisors, but I have been led to believe that on the 30th of December she changed at least one key position shortly before her press conference.

I have been told Secretary Veneman went from a "hold and test" policy to and outright ban of downers. If that correct, would it be reasonable for folks to believe that she changed her mind?

I will also be following this line of questioning because I have obtained a memo from a major exporter laying out policy recommendations. This information, along with many other sources of information was seemingly persuasive to Secretary Veneman.

My fear is that while USDA has clearly solidified public opinion, Secretary Veneman has caused a potential trade problem. As the Chairman of the Senate Finance Committee and a farmer dependent on trade, this concerns me.

At the staff level the international community has already reached out to my office and questioned the scientific basis for Secretary Veneman's current position on downers. While I expect acceptance and compliance of this new standard by importers, I worry that other countries will now choose to develop their own standards, which could be thinly guised trade barriers, with which we will be forced to comply.

We must lead by example in the international trade arena. Our actions, more than our words, will influence opinion. Those that make these decisions must surround themselves with our foremost experts on many issues, including trade. This decision, both the perceived process and ultimate position concern me.

My final point will be that currently USDA policy condemns all downers delivered to federally inspected facilities. Because of this policy, no farmer is going to pay 70 cents to $1.50 per hundred-weight to deliver cattle that won't be purchased.

Ultimately, Secretary Veneman's policy discourages the delivery of downer cattle to federally inspected facilities. Is that good policy? What happens when farmers start burying sick and lame cattle in the cow-calf pasture? Could this be a potential health risk?

I doubt this was Secretary Veneman's intention, but it's become her reality.

Mr. Chairman, thank you again for this timely hearing and the opportunity to work with you to remedy some of the issues that will be raised today.

Statement of Senator Mike Crapo
Senate Agriculture Committee
January 27, 2004

Thank you Chairman Cochran, Senator Harkin. I appreciate the Committee holding this hearing to address the discovery of a case of bovine spongiform encephalopathy (BSE) in a cow imported from Canada to Washington state and the related food safety, livestock marketing, and international trade issues that have arisen in light of this discovery. I'd like to thank Senator Durbin, Senator Allard, Secretary Veneman, Commissioner Crawford, and Dr. Torres for being here with us today.

Beef cattle is my home state of Idaho's number one commodity. Valued at more than $975 million annually, it is a vital part of Idaho's economy. So like all of you, I am deeply concerned with the discovery of BSE in the U.S. not only for the safety of our food supply but also for the effect this discovery is having on the livelihood of my fellow Idahoans and our agricultural economy as a whole.

I am confident our beef supply is safe. The precautions and safeguards we had in placed worked. U.S. consumers are blessed with an extremely high quality and competitive domestic beef industry. Our cattle ranchers and processors meet rigorous safety and quality standards, and we have every reason to have confidence in the continued safety of our beef supply.

Secretary Veneman I would like to commend you and the many USDA employees for your quick and diligent response to the discovery. I also appreciate the Department's efforts to work with the cattle industry, state, and local governments throughout this process. So far, three of the cows from the indexed heard have been found in Idaho. Close contact with the local cattle industry has been essential, and I would encourage the continued and increased communication with affected communities. In my view, the more cooperation and coordination between all interested parties the better. This open dialogue has clearly contributed to maintaining consumer confidence.

Additionally, I would like to express my support for continued efforts to reopen our beef export markets. I know that you understand the importance of regaining these markets to the beef industry. Prolonged closure of our export markets could have serious long-term effects that will ripple throughout our entire economy. I commend the Administration's efforts and encourage continued persistence to reopen the doors of our trading partners. We must maintain constant dialogue with nations that have banned U.S. beef and continue to work to restore their faith in our beef exports so that they will terminate their bans.

Collectively we must ensure that the proper mechanisms are in place to prevent and respond to future cases. Understandably, when incidents such as this occur, it is natural to immediately enact changes or new programs to address the issue. However, I believe we must use a great level of caution in our pursuit of reforms and the further development and expansion of tools such as animal identification programs. We owe it to the agricultural industry and consumers to ensure that we carefully consider all available options. Any reforms must be guided by sound science, flexible to take into account the needs of local communities and private industry, and not be overly cumbersome and intrusive to U.S. cattle operations.

Clearly, questions regarding current and future responses to the discovery of BSE remain to be addressed. Overall, however, I have been impressed with your timely response and continued work to address this discovery. I appreciate the Administration's efforts to keep consumers and the ranching community well informed at every step in the process.

Again, I thank you for your diligence, and I look forward to continuing to work with you to ensure that we are well equipped to prevent and respond to incidents of BSE.

Statement of E. Benjamin Nelson
Committee on Agriculture Hearing
1/27/04

Mr. Chairman, I want to thank you for holding this very important hearing. I would also like to thank the Secretary for coming to the committee today to review and examine the current situation regarding the discovery of a case of bovine spongiform encephalopathy (BSE or mad-cow disease) in a dairy cow in Washington State last month. This has been an extremely busy time for you, your colleagues and staff at the United States Department of Agriculture (USDA), Madame Secretary, and therefore I appreciate your commitment to appear before this committee today.

Since the detection of BSE in Washington State on December 23, 2003, the beef industry in the State of Nebraska has felt the ramifications of this discovery in the form of falling prices and closed borders from key trading partners. I have been in close contact with a number of constituents and members of the industry in my state as we have followed the investigation into the history and extent of BSE in this case. But the real focus of my state is on the approximately $27 million per day in lost revenue the imposition of import bans have cost US producers.

In general, consumer confidence in our food supply and food safety systems remains high. As a result, beef producers have regained some price footing in the market. To this date, cattle prices have declined in the range of 16-18 percent since the discovery of BSE. While prices paid for slaughter cattle dropped from 91 cents/per pound in December to 75 cents/per pound in early January, as of last week, prices had bounced back to 86 cents/per pound. Moreover, cattle entering feedlots also dropped in price but rebounded, starting at 99 cents/ per pound in December, falling to 86 cents/per pound early this month and driving back up to 90 cents/per pound. Overall, low cattle supplies and strong demand from Americans for steaks and hamburger are helping stabilize beef prices.

However, I am concerned with the beef industry's ability to maintain these levels and fully recover from the BSE incident as long as critical export markets such as Japan, South Korea and Mexico, remain partially or completely closed to U.S. beef. Although I am aware of delegations from the USDA making outreach to Japan and Mexico, I feel there should be greater efforts being made in this area. The beef markets in Japan, Korea, and Mexico are of specific concern to the State of Nebraska and its over $700 million in annual red meat exports.

On January 7, 2004, I joined several of my colleagues in sending you a letter requesting the appointment of a special envoy to maintain persistent and productive dialogue with our trading partners and with any other country that is considering imposing a similar import ban. Our belief is that a special envoy, empowered to negotiate directly with trading partners around the world, would send a strong signal that the U.S. has placed its commitment to working in a science-based manner to re-open trade as a top priority. Now that USDA has confirmed through DNA testing that the BSE-infected cow was born on a dairy farm in Alberta, Canada, I believe our government should be moving expediently in contacting the governments of these trading partners in order to reassure them of the safety and quality of US beef, while most importantly encouraging them to reopen their markets to trade as soon as possible. As of today, I have yet to receive a response to this letter, nor any indication that USDA has any interest in exploring this option. Therefore, I encourage you to please discuss or revisit this topic with your colleagues and provide us with your opinion on this suggestion.

Nebraska is a national leader in a beef industry which provides $11.5 billion worth of economic benefit to the state and its citizens, and a total of $175 billion worth of economic stimulus on a national basis. Furthermore, the cattle ranches and farms in Nebraska play a central role in its history and heritage. As you can understand, this matter is of critical importance to the State of Nebraska on many levels. The effects of the slowdown in trade are already being felt in Nebraska. Recently, Morrell cut 50 jobs in Fremont, Nebraska, and Ernie Goss, a Creighton University economics professor, has estimated that Nebraska could lose up to 21,000 jobs if Asian countries maintain their embargo on beef. The State of Nebraska cannot accept this as a potential outcome of this occurrence of BSE in the United States. Therefore, until its satisfactory resolution, I will be constantly working to bring an end to this national crisis and I stand ready to assist the Administration and USDA in any way I can to further promote that effort.

With the start of the second session of the 108th Congress, I believe the timing of today's hearing is not only appropriate and necessary, but the first of a series of hearings this committee should dedicate to this issue over the coming weeks and months. Madame Secretary, I applaud your hard work and dedication in responding to this difficult situation in a professional and timely manner, and I commend you for your efforts in restoring consumer confidence in the safety of the U.S. food supply. I look forward to a continued level of coordination and communication between USDA and the Congress as we work together in finding a resolution to this matter.

(FOR THE RECORD)
Statement of United States Senator Patrick Leahy
at the Senate Agriculture Committee Hearing on Mad Cow Disease

January 27, 2004

I would like to thank Secretary Veneman and Deputy Commissioner Crawford for coming to the Committee today for this very important hearing on the Department's response to the finding of a BSE positive cow in Washington State one month ago. At the outset I would like to recognize the Department of Agriculture's actions in responding to what has been a difficult time for American agriculture and American consumers.

On December 25, 2003, a case of Bovine Spongiform Encephalopathy (BSE), more commonly known as "Mad Cow Disease," was diagnosed in a single nonambulatory dairy cow that had been slaughtered in Washington State. This cow belonged to a herd of 81 dairy cows that was imported from Alberta, Canada. Thankfully, there is no evidence that public health has been affected. However, U.S. cattle producers immediately faced a significant drop in market prices across the country, and a tremendous loss in the export market (hundreds of millions of dollars have already been lost from this approximately $3 billion per year market). The potential for a much greater loss still looms – it has been estimated that the May, 2003, BSE outbreak in Alberta cost Canada's beef exporters more than $1.9 billion.

For more than a decade, the United States has had in place a surveillance program for BSE. However, it is now clear that we must move beyond surveillance and toward prevention in order to protect not only the public health, but the financial health of our domestic industry. Early this year USDA appropriately instituted several well reasoned first steps that begin to institute a system to prevent BSE in our country. In particular I applaud the Department's decision to ban nonambulatory animals, or downers from the human food supply. Both the infected Holstein in Washington State and the Canadian BSE discovery earlier this year were downers. For years I have joined with Senator Akaka in attempting to restrict downers from the human food supply, thus I am pleased the Department reversed course and will now implement the Downed Animal Protection Act that was contained in the 2002 Farm Bill for cattle.

It is clear to me that the Department, in conjunction with the Food and Drug Administration, must now take additional steps to protect American animal agriculture, food safety, public health, and economic health. I applaud the Food and Drug Administration's announcement yesterday to implement stricter regulations on the feed we give our cows. I believe both Departments must now solidify their regulatory actions. Some have already begun to attack the interim final rules, but it is critical that we protect public health by permanently banning downers from the food supply.

In addition, the BSE discovery has demonstrated the need for a national individual animal identification system in this country. While the positive cow in

Washington State had an old-fashioned ear tag which helped to determine the animal's origin, at present there is no mandated national system of tracking animal movements. Unfortunately, over one month after the discovery of BSE only 27 of the 81 cattle that came from Canada have been located.

Since 1998 I have been proud to work with the Department and the Holstein Association in Brattleboro, Vermont in creating a candidate national animal identification program. The Holstein Association's pilot program, partially funded with assistance from USDA, is a precursor to a national animal identification program that will electronically identify individual animals and track their movements from birth to slaughter within 48 hours. To date Holstein's pilot program has proven its electronic animal tracking capabilities with close to a million bovines enrolled from over 7000 farms in 42 states.

The Department has laid the groundwork of a national system with the work of the National Institute for Animal Agriculture and through their work with the Holstein Association. However I am concerned about the timeline for action. The Department's only public plan to begin a national animal identification system states that it will not be off the ground until mid 2006, a timeframe that I believe must be expedited. That is why I, along with Senator Specter, introduced S. 2008, the National Farm Animal Identification and Records Act which is based on the Holstein Associations pilot project. This legislation would establish a uniform national electronic animal identification program to trace animals from birth to slaughter, within 48 hours, in order to combat animal disease outbreaks.

Additionally USDA's BSE testing program must be examined. The Department's announcement to approximately double the number of animals tested is welcome. I believe the Department must also examine their existing authority to begin testing animals on the farm (as recommended in the Harvard Center for Risk Analysis 2001 study), especially since approximately 1 million bovine die on farms and therefore never present as downers. Many have called for 100% testing, or at least for a substantial increase to ensure a higher statistical confidence level than the Department's current targeted surveillance program. I look forward to hearing more form the Secretary on this issue and hope in the future the Committee will seek outside testimony from experts in the testing field.

Madam Secretary I thank you for joining us today and again I would like to commend you and your Department for the leadership on this issue. While we may not agree on every point, I look forward to working with you to ensure the United States continues to develop a BSE protection program to ensure to protect American producers, food safety, and public health.

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Written Statement
Senator Richard J. Durbin

Senate Agriculture, Nutrition and Forestry Committee
Hearing on BSE

January 27, 2004

Mr. Chairman, thank you for holding this hearing on a topic that has severely undermined our beef export markets and shaken consumer confidence in the safety of our food supply.

Two weeks ago I wrote a letter to USDA Secretary Veneman expressing my concerns about the chronology of events that led to the diagnosis of BSE in a Holstein cow last month in Washington State.

I am still waiting for a response. Given the focus of this hearing, I would like to discuss some of the questions I posed two weeks ago.

Test and Hold Policy

The USDA has a long-standing policy prohibiting the processing of cattle with neurological signs for any use. The Washington cow was sampled for BSE testing because she was, according to the USDA, showing signs of calving paralysis. However, calving paralysis is by definition a neurological disease.

The inspectors at the Washington plant were correct in singling out this animal for BSE sampling, but why was the carcass not held until the results were known? If the inspectors recognized that the animal was uncoordinated or unable to rise on her own, why was she allowed into the human food chain at all?

If the USDA inspector had followed basic USDA guidelines prohibiting the processing of cattle with neurological signs, the carcass would not have found its way into the consumer product pipeline.

Turn Around Time for Test Results

I also wonder why it took so long to obtain the presumptive positive results from the BSE tests. I understand that immunohistochemistry analysis usually takes only five to seven days. Because the animal was not considered a priority, the results took 13 days.

As a result of the delay, the animal was processed, according to Dr. Steven Solomon from FDA, into 2.8 millions pounds of consumer products, all of which were potentially contaminated with BSE.

Need for Increased Surveillance

How many cattle in America have BSE? We are hopeful that there was only this one isolated case but the truth is that we don't know because we test so few animals. Answering that question today is similar to trying to estimate the prevalence of HIV infection in people by only testing individuals who have symptoms of AIDS. At the current level of testing, we have no real estimate of the true prevalence rate of BSE in our country.

The USDA should adopt the use of rapid BSE tests and implement a "test and hold" protocol for dealing with not only suspect animals such as the one in Washington, but also all cattle and bison presented for processing that are over 30 months of age.

Using the rapid BSE tests on this additional group of older animals would provide critical surveillance data that then could be used to determine a true prevalence rate of BSE in the United States and make clear whether we truly have a BSE problem in our country. If a rapid test had been used on the cow in Washington State, the results would have been known within a few hours instead of days, avoiding the need for a costly recall of contaminated food and consumer products.

I understand that the OIE is considering the adoption of test protocols that would require the United States to accumulate 450 points to retain our country's "minimum BSE risk." Testing downer cattle and those exhibiting neurological signs is the backbone of the OIE test point system.

Since the USDA's enactment of the ban on processing downer animals, there is currently no system in place to consistently reach those animals that OIE considers to be so important for testing. Although this system is still only a proposal, it points out the fact that, if we are not routinely testing high risk cattle, we may have to dramatically expand our testing for BSE and provide a mechanism through which non-ambulatory and neurological animals can be tested.

National Ruminant ID System

The case of the Washington BSE cow demonstrated another long-standing deficiency in our livestock disease control system: the lack of a uniform livestock ID system.

If we had in place an effective and efficient way to trace back animals with reportable or zoonotic diseases, we would not still be scrambling to find all of the cattle that had contact with the BSE positive cow. We have been talking about developing a national ruminant ID program for many years. It is now time to implement a system that can track an animal back to its herd of origin within 48 hours.

Need for BSE and Other Prion Disease Legislation

Mr. Chairman, our country has been blessed with the safest and most abundant food supply in the world, but we can do better. The events surrounding the diagnosis of the first Mad Cow case in Washington State demonstrate that improvements are possible.

My thoughts about how to improve matters are reflected in legislation I introduced that will reduce the likelihood that meat from a contaminated cow will reach the food supply and expand our understanding of the many prion diseases that affect both humans and animals. This bill, S. 2007, known as the BSE and Other Prion Disease Prevention and Public Health Protection Act, codifies some of USDA's recent steps, requires more aggressive testing of older cattle and expands surveillance for Chronic Wasting Disease (CWD) in deer and elk and Creutzfeldt-Jakob disease (CJD) in people.

Here are some of the major provisions of S. 2007 are listed below:

Better surveillance: The bill requires the use of rapid BSE tests for all cattle and bison over 30 months of age and for all sheep, goats, deer and elk over 12 months of age. Rapid tests can provide results the same day that they are taken instead of taking the current five to seven days. Although most sampling and testing for BSE will occur through USDA inspectors at slaughterhouses, the bill also provides for on-farm testing of non-ambulatory animals. In addition, all ruminants of any age exhibiting neurological symptoms would be tested.

All tested animals will be held until the results of the test are known rather than being released into the food supply and consumer product system, as was the case in Washington. An expensive and time-consuming recall of products will be avoided.

The bill also requires the development of a mandatory ruminant identification program to allow for trace back of diseased animals to their farm of origin within 48 hours after diagnosis. This is significant not only for BSE but for other reportable illnesses such as brucellosis, tuberculosis and foot and mouth disease.

The measure also regulates expanded coordination of testing for CWD in farm-raised and wild deer and elk. To support expanded ruminant testing for prion diseases, the bill calls for the expansion of the national animal health laboratory network to include state and university veterinary diagnostic laboratories.

Similarly, the bill expands the sampling of suspected cases of human CJD through the National Prion Disease Pathology Research Center at Case Western Reserve University.

Targeting Risk Materials: The bill updates and expands the definition of BSE specified risk materials and bans the use of such materials from cattle over 30 months of age for any use.

Importation of ruminant-based products: The bill expands the list of imported ruminant derived products that must be labeled for contents and country of origin and bans the importation of products containing ruminant-derived materials from countries identified as at-risk for BSE transmission.

Feed Ban: The bill closes loopholes in the USDA rules on recycling pet food and poultry litter back into ruminant feed. The legislation requires FDA to develop a database for handlers of livestock, renderers and feed mills and feed blenders.

Mr. Chairman, we currently have only a limited understanding of prions and the diseases that they cause. To understand how these significant and challenging misfolded bits of protein can affect us, we need better data. We need data on which to base sound policy for our public health, for our animal health and for the safety of our food supply. USDA's response to this problem will not give us that clear picture.

We need to take every reasonable step to ensure that we do not introduce infective material through importation or through feeding our ruminant animals contaminated feed. An expanded testing program will only demonstrate to our trading partners that they have nothing to fear in buying our meat products if the tests are negative.

Need for a Single Food Agency

As I have been watching all of the news stories about the recent discovery of BSE in the United States, I cannot help but revisit a problematic issue that I have focused on for several years. Our Federal food safety system is divided between at least a dozen Federal agencies that implement more than 35 different food safety statutes. This system of divided responsibility creates a regulatory system that is duplicative, costly and unduly complex. I can only wonder whether the investigation of the BSE positive cow in Washington would have been handled differently if we had a single agency responsible for the safety of the American food supply.

Over the past 25 years, the General Accounting Office and other organizations, such as the National Academy of Sciences, have issued report after report describing the problems with Federal food safety oversight and the need for a single food agency. These organizations have made many recommendations for change, yet no changes have been made.

I have introduced legislation in both the 106th and 107th Congresses to create a single food safety agency, and will be reintroducing this legislation soon. The creation of a single food safety agency is long overdue. We need one agency solely responsible for the safety of the food supply without the burdens of promoting meat products throughout the world. It's time to finally move forward.

Let's stop discussing the need for a single food safety agency and actually take the necessary steps to make it happen.

I want to urge my colleagues to join me in both of these efforts to strengthen consumer confidence in the safety of our food supply. The BSE and Other Prion Disease Prevention and Public Health Protection Act can provide the public with the confidence that our beef and venison is safe to eat and can assure our trading partners that we are aggressively addressing BSE surveillance in the United States. The creation of a single food safety agency will also set the course for a food safety system that is efficient, effective, and based on the latest science. I look forward to working with each of you as we continue to ensure the American food supply remains the safest in the world.

RICHARD J. DURBIN
ILLINOIS

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January 8, 2004

The Honorable Ann Veneman
Secretary
United States Department of Agriculture
14th Street and Independence Ave, SW
Washington, DC 20250

Dear Secretary Veneman:

I am extremely concerned about the chronology of events that led to the diagnosis of BSE in the Holstein cow in Washington State last month.

According to the USDA website, the animal was slaughtered on December 9, 2003, at which time the brain samples were taken. The USDA website states that the samples were not considered a "high priority" since the animal was, according to the USDA website, not showing neurological signs. The samples were included in the normal queue at the National Veterinary Services Laboratory (NVSL) for testing.

However, the history of the animal indicates that the animal was suffering from calving paralysis, which is by definition a neurological disease. Calving paralysis occurs when the obturator nerves that innervate the inner thighs are damaged during the passage of the calf through the birth canal. With obturator (calving) paralysis, the animal is unable to rise or can do so only with the assistance of hobbles. Medical professionals have advised me that the symptoms of calving paralysis are virtually indistinguishable from the symptoms of BSE.

When the sample was finally processed and a presumptive diagnosis made on December 22, 2003, thirteen days had passed and meat and meat by-products from the animal had been distributed throughout many western states and Guam.

According to the USDA website, a recall of the products from the BSE positive animal was not enforced until December 24, 2003.

A number of questions arise:

1) a) Who decided that the animal was not exhibiting neurological signs? b) Is calving paralysis not considered a neurological disease by USDA? c) Do USDA inspectors have special clinical knowledge that allows them to differentiate the symptoms of calving paralysis from those almost identical symptoms of BSE? d) If

not, why was this animal not identified as a BSE suspect and her samples given priority status?

2) a) Why did it take so long to obtain the presumptive positive result? I understand that immunohistochemistry analysis usually takes only five to seven days. Even though the sample was not prioritized and took two days just to reach the NVSL, why did it take at least thirteen days to get results? b) On which date did the NVSL first have a positive result for BSE?

3) a) Were any of the rapid screening tests used on this animal on December 9, 2003 or afterward? b) If so, what were the results and when were they finalized?

4) Why was a recall order on meat and meat by-products from this animal not issued until 48 hours after the diagnosis?

Thank you for your cooperation in this matter. I look forward to your prompt reply and would appreciate a response no later than January 16th.

Sincerely,

Richard J. Durbin
United States Senator

STATEMENT OF US SENATOR WAYNE ALLARD BEFORE THE SENATE COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY ON THE DOMESTIC DISCOVERY OF BOVINE SPONGIFORM ENCEPHALOPATHY

Mr. ALLARD. Mr. Chairman, first, let me thank you for convening this timely and important hearing. I appreciate the committee making the accommodation to allow me to appear this morning. Madam Secretary, Commissioner McClellan and Senator Durbin, welcome. The level of participation in BSE roundtables and panels across the country, as well as the interest in this hearing, is one more sign that government, industry and the retail sector, are taking this matter very seriously and will take all necessary and reasonable measures to isolate this occurrence and prevent future incidents.

Let me start by stating that U.S. beef is safe. When a single, BSE positive cow was found in Washington State, our food safety policy and safeguards worked. USDA acted quickly and effectively. Where there were room for improvements, I believe USDA has seized the opportunity to make them.

I think everyone will agree that we have learned a tremendous amount from the single finding. Future policy recommendations will obviously need to take into account those changes that are believed necessary as a result of the recent finding, especially as we learn what worked, what did not, and what we need to know in the future. We must continue to implement the requisite measures to assure further protection of the food supply, but there is no reason to question the integrity of American meat safety and the overall safety of the system.

I believe that the government is taking a hardline stance against further incidence of BSE in the United States - as evidenced by the major announcement by the Secretary several weeks ago. While we had hoped this day would never come, it was an eventuality that we had prepared for.

As members of Congress, it is our duty to help enact legislation that protects the consumer and safeguards our national food supply. However, consumer protection and national security must not stifle the ability of the agriculture industry to produce food efficiently and affordably. If they do, we will have undermined the very goals that we were attempting to accomplish. Over-burdensome rules and regulations will hinder the ability of agriculture to provide our nation with food, threatening our nation's independence and security by making us dependent on foreign nations - nations that may not place as much emphasis on safety as we in the United States do.

In simple terms, our food supply policy must avoid the pitfalls of our energy policy - we cannot afford to rely on other nations to provide us with food - we must produce it ourselves. I shudder at the thought of having 67 percent of our food supply shipped in from friend and foe - we must do all we can to avoid such an extreme circumstance.

While the government has taken strong steps to contain the present incidence and to prevent future occurrences, I cannot emphasize enough the enormous burden of responsibility that rests with the agriculture industry. We have had our warning - we must take it very, very seriously. If we do not, we will pay for it with the economic life of the producer and retailer. If rules are not followed, if regulations are not adhered to, no one has more to lose than those who failed to follow them. Even a 75 percent compliance rate when it comes to feed regulations will not afford the level of protection we need to maintain the integrity of animal health. And blatant

violations are intolerable.

In the past several weeks, the USDA has taken several steps that, while not necessarily embraced by all with open arms, were received by an overwhelming majority of the industry as the proper response to the task at hand. We all realize that the finding of BSE is a serious challenge to consumer confidence and the industry's financial stability and that the Government must take strong measures to bolster confidence and ensure consumers that American beef is a safe and wholesome product.

I believe Secretary Veneman took that first step with her policy announcement several weeks ago. Given the urgency caused by the discovery of BSE in the United States, I believe that these actions by the USDA will enhance the safety of the American food supply. The three major policy directives dealing with downer animals, verification, and specified risk material, are a step in the right direction - but, as is always the case - the devil remains in the details.

As a veterinarian, I am committed to the idea that any measures imposed must be science-based. While these measures do have sound footing and are logical decisions given the characteristics of BSE, there is still much work to be done. Much work must be done on defining and identifying "downer" animals. This issue has been highly controversial and much discussion has taken place on the matter on Capitol Hill. Are animals with nerve damage from calving to be forbidden? Or only aged and sick animals? Who will be the one to determine which case is which? These are the questions that must be worked out - at great length - by those most knowledgeable about the industry and food safety. I am also hopeful that the USDA will provide my constituents with further guidance when it comes to matters like dentition and animal age verification.

In terms of verification and traceability, a true verification and identification program - perhaps using retinal scanning and other biometric technologies - would provide immediate background resources on the origin and presence of every animal, leaving marketing to the retailer and the producer. It would provide answers in times of emergency and provide closure during the critical first hours of an epidemiological investigation. A credible identification plan must take into account identity and location - a fact that I encourage the USDA to consider when developing their forthcoming identification plans. At this time, I would ask the Chairman that the full text of a statement I entered into the Congressional Record last week on this issue, be inserted into the committee's record as well.

While such a verification program will indeed cost producers money, I believe that retail chains would eventually demand such assurances anyway. In the long run, such verification will enhance the value of the product and prove a valuable tool in domestic and international sales.

As implementation of the USDA directives moves forward, I encourage the USDA to continue working cooperatively with the beef industry. Together, we will not only improve food safety, but we can also restore access to important markets, a critical component of our economy.

Food safety goes hand in hand with the restoration of our markets. We have all seen the list of nations that have banned US beef. We must work diligently to reopen these markets and to reestablish the trust and confidence that I know the US beef industry deserves. As we continue to traceback, traceforward, verify, confirm and cull, we cannot allow nations to block our products under the guise of BSE in order to bolster their own industry or to cultivate relationships with other exporters. A sound process must be put in place immediately that

provides assurances to other nations about the quality and safety of the meat they receive. This must be a high priority of the Congress and Administration and I intend to make sure that such discussions take place.

Thank you and remember, this: Beef: It's still what's for dinner!

TESTIMONY OF

THE HONORABLE ANN M. VENEMAN

UNITED STATES DEPARTMENT OF AGRICULTURE

BEFORE THE U.S. SENATE

COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY

JANUARY 27, 2004

Mr. Chairman and members of the Committee, thank you for the opportunity to appear today to discuss the recent BSE-positive cow found in Washington State, and our response.

I have appreciated the conversations that I have had with many of you during the last month. Your input and comments are extremely valuable as we continue to work through this situation.

Response actions on and after December 23rd

On December 23rd, we received word that a tissue sample taken as part of our routine surveillance system had tested presumptive positive for BSE. While that was only five weeks ago today, in some ways it seems much longer, especially when you consider all that has transpired.

We had in place a BSE response plan, which was first developed in 1990, and has been continually updated since then to reflect the latest knowledge about the disease, as well as

lessons learned from other countries that have had cases of BSE. Upon hearing of the BSE find, we immediately began to implement that plan.

We began an epidemiological investigation to determine the origin of the cow and to identify and locate her offspring and cohorts. We also began the process of tracing the meat forward and learned that, while the meat from this cow went into the food supply, the high-risk products, such as brain and spinal cord, did not enter the human food system.

We feel very confident that the meat that did enter the food supply posed virtually no risk to public health. However, in an abundance of caution, we traced the meat from the animal and issued a recall of the product. Also, consistent with our response plan, we sent the tissue sample for confirmation to the World Organization for Animal Health (OIE) reference laboratory in Weybridge, England.

We also decided to immediately inform the public. I felt then and still feel very strongly that we have an obligation to the American public and to our industry to be as transparent, timely and accurate as possible in our communication efforts.

Upon learning of the presumptive positive, I asked our scientists how confident they were of the preliminary results. When our experts said they were very confident in the accuracy of the tests conducted by our scientists at the National Veterinary Services Lab in Ames, Iowa, we made the information public on December 23rd – the same day I learned of the presumptive positive test result – even though the lab in England had not yet verified our findings.

After the announcement, we began daily briefings that were broadcast live via our website and, in some cases, broadcast live on network and cable television so that those who were interested could hear the latest updates. From December 24th through New Year's Eve, some 100,000 people viewed our briefings via the web and thousands more participated through an interactive phone line.

When considering actions to be taken following the find, I repeatedly asked myself and staff three questions: First and foremost, what, if any, additional actions need to be taken to further protect public health; second, what additional actions, if any, need to be taken to prevent potential spread of disease in the cattle herds; and third, how can we best maintain consumer confidence in our safe beef supply.

On December 30th, one week after the find, I announced a series of actions to further enhance our already strong safeguards. These included an immediate ban on non-ambulatory (downer) animals from the food system and further restrictions on specified risk materials – such as brain and spinal cord tissue – from entering the food supply. We also announced that meat from cattle tested for BSE will be held until the test has confirmed negative. The measures were published on January 12th as interim final rules.

We were able to act so quickly because of the advance planning we had undertaken. After the find in Canada, and prior to the find in Washington State, we had been working on new regulations on specified risk materials, so much of the regulatory analysis had already been

completed. In addition, we said that we will maintain an aggressive surveillance system by doubling the number of animals tested and continuing to target high-risk animals.

We also announced that we will be expediting the implementation of a verifiable system of national animal identification. Currently, many animals can be identified through some system of animal ID. In fact, the BSE-infected cow in Washington had an animal ID, which has greatly facilitated the traceback.

Significant work to develop such a system has already been accomplished. Over the past 18 months, USDA has worked with the National Institute for Animal Agriculture, and state and industry groups, to identify national standards for an animal identification system that will enhance the speed and accuracy of our response to animal disease outbreaks. I have asked USDA's Chief Information Officer to make it a top priority to develop the technology architecture necessary to implement an effective and verifiable system throughout the United States. Our goal is to achieve a uniform, consistent, and efficient national system.

On Saturday, December 27th, we learned that the ear-tag matched that of a Canadian cow that was exported to the U.S. We made the public announcement of that information that same day, and further announced we would be confirming through DNA testing. On January 6th, the DNA result, along with other records and documentation, allowed the U.S. and Canada to confirm that the cow originated on an Alberta dairy farm.

In keeping with our commitment to continually review our systems, I also announced on December 30th that an international panel of experts would be convened to review our investigative efforts. They have been asked to make recommendations for possible further enhancements to our systems, including recommendations on changes to our current surveillance systems, in light of the current situation. This team will be composed of the same experts who reviewed the Canadian situation, with the addition of an OIE expert. They arrived in the U.S. last week to begin conducting their review.

We are also in the process of approving so-called "rapid tests" for BSE. On January 9th, we announced that APHIS would begin formally accepting license applications for BSE rapid test kits. These tests, among other things, are less specific than the immunohistochemistry (IHC) test that USDA has designated as its official test for BSE, but can produce results for screening purposes more quickly. Internationally, the IHC is considered the "gold standard" diagnostic test method.

APHIS is now reviewing and responding to the data submissions, physically inspecting the facilities where these test kits would be produced, and actually testing these kits at the National Veterinary Services Laboratories in Ames, Iowa.

Two weeks ago, on January 13th, I traveled to Ames, Iowa, to visit with our scientists at the National Veterinary Services Laboratory, to get a sense of how the testing process currently works, listen to their views about revisions to our testing program, and discuss what additional resources they need to get their jobs done.

As you all know, the National Centers for Animal Health in Ames are the linchpin in our animal health infrastructure. We have world-class scientists there, and they need world-class facilities. That is why I was pleased to announce last week that the President's 2005 Budget – which will be formally announced in early February – will include $178 million to complete the renovation of the USDA campus in Ames, which houses a critical mass of APHIS' diagnostics and veterinary biologics laboratories, as well as ARS researchers.

When completed, the campus will be the most modern and best-equipped animal disease diagnostic and research facility in the world. If approved by Congress, these funds will allow us to fully complete this project by the end of 2007 under an accelerated contracting and construction schedule.

All the actions that we are taking are in addition to the strong safeguards we had in place before December 23rd. Since the discovery of BSE in the United Kingdom in the mid 1980s, the United States has been very proactive in implementing measures to guard against BSE. We have continually reviewed the scientific research, conducted risk assessments and strengthened our protective measures accordingly.

As you know, USDA requested Harvard University to conduct an independent risk assessment to evaluate preventative measures already in place and to identify additional actions that should be taken to minimize the risk of BSE. After three years of extensive data gathering and analysis, the results were released in November 2001. At that time, Harvard found that the BSE is highly

unlikely to become established in the United States, should the disease be detected in our country. As a result of the Harvard analysis, we announced additional preventive actions, such as increased surveillance and the testing of certain ground beef products for central nervous system tissue.

In 2003, we asked Harvard to reassess the situation, taking into account the BSE find in Canada in May. In August, Harvard reaffirmed the findings of the initial study that systems already in place would prevent BSE from spreading if it were found in the United States. Harvard also concluded that even if infected animals or ruminant feed material entered the U.S. animal agriculture system from Canada, the risk of it spreading extensively within the U.S. herd was very low.

Impact on domestic and export beef markets

Throughout this process, we have been committed to maintaining public health safety and consumer confidence in our systems. Some 90 percent of U.S.-produced beef is consumed domestically, and all indications are that the confidence of the U.S. consumer in the safety of American beef remains very strong. Retailers and food service outlets are reporting virtually no adverse effects on consumer demand as a result of the BSE finding. We believe this is due in part to the quick and aggressive steps the Administration has taken to protect public health.

Unfortunately, most of our export markets, including our key buyers – Japan, Mexico, Korea and others – immediately closed their markets to U.S. beef after the December 23rd announcement.

In 2003, the quantity of U.S. beef exports is estimated at 2.6 billion pounds, accounting for 10 percent of U.S. beef production. The value of our exports of beef, veal and variety meats is estimated at about $3.8 billion for 2003, and we exported another $65 million in live cattle. The products that otherwise would have been exported in 2004 now must be absorbed in the domestic market.

The loss of exports had an immediate impact on the cattle market, resulting in an initial drop of 15 to 20 percent in cattle prices on cash and futures markets. However, prices have strengthened over the past two weeks. Markets are now down just 5 to 8 percent from the levels prior to the BSE finding, and current cattle prices remain above year-ago levels.

Regaining our export markets is a top priority for the Administration. We are pleased that Poland has become the first country to reinstate imports of U.S. beef. The conditions our trading partners impose on us for re-opening trade must reflect what science tells us. We know that the risk to public health from BSE is extremely low in countries that have no or low incidence in cattle, and that also have appropriate mitigation measures in place.

The United States is leading the effort to ensure that the international response to BSE is science-based. After the find in Canada last May, we reacted exactly the way countries are now treating the United States – we shut off all beef and cattle imports from Canada. However, after conducting a complete and thorough investigation into the incident, and evaluating the additional

safeguards Canada made to its already strong system, we allowed trade in low-risk products to resume in late August.

The United States reviewed the scientific evidence and determined that imports of boneless beef from animals under 30 months of age and other low-risk products could safely resume. The U.S. decision was consistent with international scientific standards that allow for trade to resume when a country has taken the necessary actions to prevent the spread of BSE.

Last fall we published a proposal to extend the trading, to allow live animals and certain other products to enter the United States. The comment period on that rule closed January 5th. In light of the finding in Washington State and the origin of the cow, we will consider the next steps on this proposal after our investigation is complete, and determine how to obtain further public comment on that proposal, or if we need to revise the original proposal.

In addition, together with Canada and Mexico, we have asked the OIE to clarify its guidelines regarding trade among countries with BSE so that science guides the actions of all countries. We expect the OIE to issue an updated chapter on BSE in the spring.

U.S. beef is safe for consumers in the United States and around the world, and we are urging our trading partners to base their decisions on science. Since December 23rd, we have worked continually to inform our trading partners about the case, the steps we are taking to investigate the situation, and the additional safeguards we have implemented.

Within days of the finding, we dispatched USDA's senior trade advisor, David Hegwood, and Dr. Chuck Lambert, Deputy Undersecretary for Marketing and Regulatory Programs, to Japan and South Korea to explain the investigation and the rigorous safeguards that we already had in place.

Earlier this month, U.S. Trade Representative Zoellick and I each had very encouraging meetings with the Japanese trade minister. Two weeks ago, I had a lengthy conversation with Japan's Minister of Agriculture Kamei. I impressed upon him the importance of finding a practical solution to allow resumption of trade and releasing into commercial channels the considerable quantity of beef shipped to Japan prior to December 23rd.

Minister Kamei stated that Japan is looking forward to resuming trade. Dr. J.B. Penn, USDA Under Secretary for Farm and Foreign Agricultural Services, has now traveled to Hong Kong and South Korea after being in Japan, leading a delegation of USDA and FDA officials to further engage the Japanese in discussions to reopen that important market to our beef. Additional discussions will continue within the next few days.

In addition, I have talked with ministers from Canada, Mexico, the Philippines and others on an ongoing basis to keep them informed of our progress. We have been quite pleased with the reactions of both Canada and the Philippines. Both countries have allowed at least a portion of their markets to remain open to our beef.

Dr. Penn and Mr. Bill Hawks, USDA Under Secretary for Marketing and Regulatory Programs, traveled to Mexico for productive discussions, and other U.S. officials discussed these issues in China, as well.

On January 16th, I met with my counterparts from Canada and Mexico, Minister Speller and Secretary Usabiaga, to discuss the need to enhance and coordinate a consistent North American response to the animal health and trade issues that BSE raises. We agreed to develop an enhanced consultative process led by senior officials in each of our respective departments to facilitate these efforts. The work is already underway, and we expect the officials to meet within the next 30 days.

In addition, technical teams from Japan and Mexico spent several days in the United States, meeting with technical experts at USDA and the Food and Drug Administration. The Japanese team also traveled to the State of Washington to review the investigation there, and the Mexicans visited processing facilities in Colorado.

USDA staff at U.S. embassies abroad continue to inform foreign governments of actions taken and reassure them of the safety of our beef. In addition, we held a briefing two weeks ago for all foreign embassies, to keep them informed of new developments in the BSE investigation and to respond directly to their questions.

Our efforts to restore our foreign markets continue to be a top priority, and we urge our trading partners to resume trade based on sound scientific principles.

Our investigation into the case in Washington State is ongoing. In just the past five weeks, we have made a great deal of progress in both the traceback and the trace-forward from the infected animal. Our investigators have worked hand-in-hand with the State of Washington and other States, as well as with Canadian authorities.

Because of our advance planning and our continuous review of our BSE risk-mitigation measures – and particularly the intensive review we have undertaken since the Canadian case in May – we were able to respond very quickly and effectively to the BSE find in Washington State.

We are continuing to trace the other animals that came across the border with the infected cow and are finding and testing those animals. To date, all animals tested have been negative for BSE. We have implemented significant policy changes and had numerous meetings with our international counterparts. We have worked to be as transparent in our processes as possible, and provided updated information as quickly as possible.

I am very proud of the accomplishments of our dedicated USDA team, many of whom are with us today, including Under Secretary Hawks, Under Secretary Murano, and Chief Economist Keith Collins. I would like to especially recognize our chief veterinarian, Ron DeHaven, for his extraordinary work throughout this process.

We will continue to provide timely updates to the public as information is available. We have also included as an attachment to my testimony a timeline of events relating to this incident. We will continue to update this on our website as appropriate.

Mr. Chairman, again, thank you very much for holding this hearing today. We appreciate the opportunity to inform the agricultural community and the broader public of the actions we have taken. 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 for dialogue on these issues that this hearing affords us. I would be pleased to take any questions you have at this time.

BSE Chronology

December 9, 2003	A non-ambulatory dairy cow believed to be about 4-1/2 years old arrives at Verns Moses Lake Meats, a slaughter plant in Moses Lake, WA; the animal's condition is attributed to complications from calving. Consistent with USDA's standard testing protocols for BSE, samples are taken from the animal and all potential high-risk material (central nervous system tissue) is diverted out of the human food supply and into rendering.
December 11	Samples from the animal arrive at USDA's National Veterinary Services Laboratories (NVSL) in Ames, IA. Because the animal had no neurological signs at slaughter, it was not considered to be a higher priority for BSE and the samples were placed in the normal queue for testing. The meat from the cow, which was part of 10,410 pounds of product, is shipped to Midway Meat Company in Centralia, WA.
December 12	After the meat in question was further processed at Midway Meat Company, the product was distributed to two Federal establishments: Interstate Meat Distributors in Clackamas, OR and Willamette Valley Meats in Portland OR. Product was then shipped to approximately 42 additional locations.
December 22	Preliminary test results are positive for BSE; NVSL conducts further testing.
December 23	Further test results are positive for BSE. Secretary Veneman announces a "presumptive positive" case for BSE. A sample from the animal is hand-carried to the United Kingdom for final confirmatory testing at the BSE world reference laboratory in Weybridge, England. APHIS' epidemiological investigation begins. Quarantine placed on herd in Mabton, WA, in which the index animal had last resided. USDA's Food Safety and Inspection Service initiates a Class II recall of meat (10,410 pounds) from the group of 20 animals slaughtered on December 9 at Verns Moses Lake Meats. Interstate and Willamette begin notifying their consignees of recall-related products.

BSE Chronology

December 24	USDA determines disposition of three calves from index animal: one died shortly after birth in October 2001. One is a yearling heifer and is in the index herd in Mabton, WA, which is under State quarantine. The third is the most recently born calf, a bull calf, and is in a herd in Sunnyside, WA, which is placed under State quarantine
	Twenty-three countries, including Japan, Canada, and Mexico, institute bans on U.S. products.
	UK world reference laboratory confirms USDA diagnosis of BSE.
December 25	Traceback of index animal continues. It is believed likely that the index animal was purchased into Mabton herd from a dairy cattle finishing farm in Mattawa, WA. The other, less likely, possibility is that it came from an area livestock market.
	FSIS continues to coordinate the recall, obtain distribution information, and collect additional information. FSIS finds that Interstate Meat Distributors sold product to an additional nine businesses in Oregon and Washington. Willamette Valley Meats sold product to an additional 33 businesses in Oregon, Nevada, Idaho, Washington, and California.
December 26	USDA's traceback investigation indicates that the affected cow was likely imported from Canada in 2001 and that she was likely 6-1/2 years old, rather than 4-1/2 years old as the last owner's records had indicated. Investigative efforts continue and involve Canadian officials.
	USDA team departs Washington for Japan to pursue trade talks.
	FSIS continues effectiveness checks and issues Export Alert and Export Notice, notifying inspectors and industry of bans or restrictions placed on U.S. beef imports by additional countries.

BSE Chronology

December 27

USDA's Food Safety and Inspection Service (FSIS) determines that two tertiary cosignees (the customers of Williamette Valley Meats) of the recalled beef products had limited further distribution to four other states, including Alaska, Montana, Hawaii and Idaho, as well as the U.S. territory of Guam. These areas are in addition to the primary distribution in Oregon and Washington, with some product shipped to Nevada and California. FSIS continues to trackback the distribution of any recalled meat to ensure compliance with the recall.

Traceback of the index animal continues. USDA is also continuing to trace the 73 other cows that came in the same shipment.

December 28

USDA determines that records obtained from the owner of the index animal correspond with Canada's records indicating that this animal was approximately 6 ½ years old at the time of slaughter. USDA is working with Canada to conduct DNA tests to verify that the correct animal has been identified.

Tracebacks of the index animal, along with the 73 other cows from the same shipment, continues. USDA identifies 8 additional cows from the same herd in Canada as the index cow that may have entered the United States. USDA begins tracing these animals.

FSIS determines that the recalled meat products were distributed to 42 locations from Interstate Meats and Willamette Valley Meats, with at least 80 percent of the products distributed to stores in Oregon and Washington. FSIS is verifying that these 42 distributors, along with the original distributors, are complying with requirements to notify their customers.

BSE Chronology

December 29

Agriculture Secretary Ann Veneman announces additional safeguards to bolster the U.S. protection system against BSE and to further protect public health:

- downer cattle and specified risk material and tissues will immediately be banned from the human food chain
- skull, brain, trigeminal ganglia, tonsils, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle over 30 months of age and a portion of the small intestine of cattle of all ages are now considered specified risk materials and are prohibited from entering the human food supply
- any normal cattle, if they are targeted for BSE surveillance testing at slaughter, will no longer be marked as "inspected and passed" until confirmation is received that the animals have, in fact, tested negative for BSE
- dorsal root ganglia, clusters of nerve cells connected to the spinal cord along the vertebrae column, in addition to already-prohibited spinal cord tissue, will be prohibited in products labeled as "meat"
- the air-injection stunning of cattle will be prohibited
- mechanically separated meat in human food will be prohibited
- USDA will begin immediate implementation of a verifiable system of national animal identification.

Traceback of the index animal continues. USDA continues working closely with Canadian officials to conduct DNA testing of the index cow.

Through the traceback of the index animal, USDA determines that 82 cattle (including the positive cow) were cleared for shipment into the United States. USDA is verifying the actual number that entered the United States and the location of each animal. Initial information from Canada suggested only 74 of the 82 cattle on the health certificate were shipped to the United States. However, since USDA cannot rule out the possibility that the other eight also came across the border, USDA is looking at import/export records, as well as on-farm records, for all remaining 81 cattle.

FSIS determines that all forward movement of product in distribution has stopped. FSIS also determines the following:

- 10,410 pounds was distributed by Verns; Approximately 31,000 pounds, containing product from Verns, was distributed by Interstate and Willamette.
- Affected product totals less than 50,000 pounds.
- Montana received less than 69 pounds of product.
- Product may never have been distributed to Hawaii and Guam.

- Product was shipped to 2 locations in Alaska but it is a negligible amount.
- California received 14% of the product. Product was distributed to 6 WinCo supermarkets in California. The supermarket chain has notified all customers of the recall and FSIS has completed effectiveness checks.
- Nevada received 2,000 pounds of trim from Interstate, which went on to be ground into 13,000 pounds of product and distributed to 180 restaurants, the majority of which are located in Nevada, and to several restaurants in California.
- Oregon and Washington – the product was distributed to major supermarkets within both States. The supermarkets have notified their customers of the recall.

December 30

USDA continues to work with Canadian officials to verify the traceback of the index animal. USDA is working with Canada to conduct DNA tests in both countries. Testing is expected to begin this evening and results could be available as early as next week.

Through the traceback investigation, USDA learns that the Canadian health certificate, dated August 28, 2001, lists 82 eartag numbers from cattle that were part of a herd dispersal in Alberta, Canada. One of those eartag numbers matches that number on the BSE-positive cow. Nine of the 82 are part of the index herd in Washington State. Currently, USDA has information that suggests that 81 of the 82 animals crossed the border into the United States. However, since USDA cannot rule out the possibility that all the animals came into the United States, USDA is looking at import/export records, as well as on-farm records, for all remaining 72 cattle.

USDA announced its intent to have an international team of experts review the Department's investigation and make recommendations following the completion of the epidemiological investigation. The team will be similar to the group that conducted such a review in Canada. Members of this team are: Dr. Ulrich Kihm, President and CEO, Safe Foods Solutions, Bern, Switzerland; Dr. Dagmar Heim, TSE Coordinator, Federal Veterinary Office of Switzerland; Dr. William Hueston, Director, Center for Animal Health and Food Safety, University of Minnesota; and Dr. Stuart MacDiarmid, Principal Advisor, Zoonoses and Animal Health, New Zealand Food Safety Authority, New Zealand.

BSE Chronology

December 31

USDA confirms that 81 of the 82 animals listed on the Canadian health certificate, which includes the eartag number for the index cow, entered the United Sates through Oroville, WA, on September 4, 2001.
USDA has 11 of the 82 cattle definitely accounted for including:
· One is the index cow
· Nine are those known to be in the index herd
· One animal is on the Mattawa premises
· Also, USDA believes one animal may still be in Canada
Tracebacks of the other 70 animals continue. USDA has good leads on the whereabouts of many of these animals.
USDA announces that three facilities are under hold orders during the epidemiological investigation. The first facility is the index herd, while the second is a nearby facility that has the index cow's recently born bull calf. The third facility is a dairy operation in Mattawa where one animal from the original herd of 82 is located.

USDA and Canadian officials continue DNA tests to determine the identification of the index animal. Two USDA epidemiologists are in Canada to assist with the testing, while two Canadian epidemiologists are in the United States to assist with the DNA testing.

USDA is working closely with industry to reposition its efforts to collect samples of high-risk animals for BSE surveillance testing on farms, at rendering facilities, and other locations.

January 2

USDA announces the decision to depopulate the bull calf operation in Sunnyside, Washington, that includes a calf born to the heifer infected with BSE prior to the heifer's slaughter this past December. There are approximately 450 cattle on the premises, and operations will proceed this week but will likely be dependent on weather conditions in the Mabton area. The calves will be transported to a currently unused slaughter facility.

USDA will have animal care experts on hand at both the farm where the calves will be loaded and at the slaughter facility to ensure humane treatment of the animals. The animals will be euthanized according to American Veterinary Medical Association animal welfare euthanasia guidelines. No products from any of the slaughtered animals will enter the human food chain, nor will products be rendered.

A USDA team departs Washington for Mexico to pursue trade talks.

USDA and Canadian officials continue DNA tests to determine the identification of the index animal. Test results

	are expected sometime this week.
	USDA has 11 of the 82 cattle that were listed on the Canadian health certificate, including the index cow, definitely accounted for. USDA believes that one of the animals is still in Canada. Tracebacks of the other 70 animals continue. USDA has good leads on the whereabouts of many of these animals.
	FSIS continues recall activities. FSIS advises FAS that initial results of BSE recall effectiveness checks indicate that no implicated product was exported.
January 5	USDA announces that DNA evidence now helps to verify—with a high degree of certainty—that the BSE positive cow found in Washington State originated from a dairy farm in Alberta, Canada.
	USDA depopulates the bull calf operation outside Sunnyside, WA. Approximately 450 calves are transported from the farm to a designated slaughter facility and euthanized according to American Veterinary Medical Association humane guidelines. USDA officials secure the animal carcasses overnight.
	Other elements of the investigation, including animal tracebacks, continue on both sides of the border and may provide additional information. This includes the cattle feed investigation in Canada as well as the additional DNA testing.
January 6	USDA disposes of the carcasses of the depopulated calves by landfill. None of the carcasses entered the human food supply chain or were rendered.
	USDA locates another animal that came into the United States with the index cow, which is also located in a Mattawa, WA dairy herd. USDA has 12 of the 82 cattle listed on the Canadian health certificate definitely accounted for including: · The index cow · Nine known to be in the index herd · Two animals on a Mattawa premises
	USDA also believes that one of the animals listed on the health certificate remained in Canada and did not enter the United States. Tracebacks of the other 69 animals that entered the United States continues. USDA has good leads on the whereabouts of many of these animals.
	A Japanese delegation arrives in the United States to participate in trade talks.

BSE Chronology

January 7

USDA finishes disposal of the carcasses of the depopulated calves by landfill. None of the carcasses entered the human food supply or were rendered.

FSIS has submitted three rules and one notice for publication in the Federal Register on Monday, January 12, 2003. The rules and notice are:

- An interim final rule declaring that the Specified Risk Materials, the skull, brain, trigeminal ganglia, tonsils, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle 30 months of age or older, and the small intestine of all cattle are specified risk materials, and prohibited in the food supply. These prohibitions will be effective immediately upon publication in the Federal Register.
- An interim final rule expanding on the prohibition of central nervous system tissues in advanced meat recovery products.
- A final rule to prohibit air injection stunning.
- A notice announcing that FSIS inspectors will not mark ambulatory cattle that have been targeted for BSE surveillance testing as "inspected and passed" until negative test results are obtained.

January 8

USDA announces it will begin accepting license applications for BSE tests. Heretofore, USDA's Center for Veterinary Biologics has been accepting and reviewing data from companies that have various rapid tests, but has not formally accepted applications for licensing.

USDA announces it will soon begin to remove a limited number of cows from the index herd in Mabton, Washington. At this time, USDA will most likely remove approximately 130 animals from this herd that contains approximately 4,000 dairy cows. To summarize results thus far from the epidemiological investigation:
Of the 81 cows that came from Canada with the positive cow:
. One is the positive cow
. Two are under a hold order at a premises in Mattawa
. USDA believes 7 may have gone to another dairy and is working to determine if those animals are still there
. Nine are in the index herd
. Potentially some of the remaining cows that came in that shipment are on the index premises, but at this time the identity of these animals has not been confirmed.

BSE Chronology

January 9	USDA personnel begin a selective depopulation of the index herd. Nine animals from the index herd are transported, humanely euthanized, and sampled.
January 10	FSIS' new rules on product holding, specified risk material, advanced meat recovery, and air injection stunning become effective. USDA has traced a third animal to the herd in Mattawa, Washington. Two animals were previously traced to this herd. The three animals in the Mattawa herd will be removed.] A declaration of extraordinary emergency, signed by Secretary Veneman, is published in the Federal Register. This declaration of extraordinary emergency authorizes the Secretary to (1) hold, seize, treat, apply other remedial actions to, destroy (including preventative slaughter), or otherwise dispose of, any animal, article, facility, or means of conveyance if the Secretary determines the action is necessary to prevent the dissemination of BSE and (2) prohibit or restrict the movement or use within the State of Washington, or any portion of the State of Washington, of any animal or article, means of conveyance, or facility if the Secretary determines that the prohibition or restriction is necessary to prevent the dissemination of BSE.
January 12	USDA has confirmed that one animal has gone to a dairy in Quincy, Washington. USDA believes that as many as seven animals may have been sent to this facility; we are working to confirm how many may remain at this facility. The State has placed a hold on this facility in order to aid the investigation. Selective depopulation of the index herd continues. USDA plans to transport, humanely euthanize, and test approximately 130 animals in the index herd.
January 13	Selective depopulation of the index herd continues. To date, 89 animals from the index premises have been euthanized and tested. Results of the tests will be reported as soon as they are available.

BSE Chronology

January 14	USDA's investigation on the 81 cows that came from Canada continues. Five additional animals have been located at a facility located in Connell, Washington. The State has placed a hold on the facility in order to facilitate the investigation. In total, 19 of the 81 cows that came from Canada have been located. Selective depopulation of the index herd, which began on Saturday, January 10, is expected to be completed today. USDA plans to transport, humanely euthanize, and test a total of 129 animals in the index herd. To date, 119 animals from the index premises have been euthanized and tested. To date, 28 samples have completed testing; results have been negative.
January 15	USDA locates 3 animals that are part of a group of 17 heifers originally dispersed from the Canadian source herd in August 2001. The 3 animals were mentioned by Canada's chief veterinarian during the January 6, 2004, technical conference call with USDA's Dr. Ron DeHaven. The 17 animals are separate from the 81 animals that arrived in the United States from Canada along with the index animal. The 3 animals were found at the Quincy, Washington, dairy where 1 of the 81 animals has also been located. APHIS continues to work to determine whether the remaining 14 animals entered the United States. Delegations from Mexico and Canada meet with USDA officials in Washington, D.C. to discuss issues related to BSE.
January 16	USDA begins selective depopulation operations on the facility in Mattawa.

BSE Chronology

January 17	USDA's investigation on the 81 cows that came from Canada continues. Three additional animals are located at a facility in Tenino, Washington, and one additional animal is found in Connell, Washington. Washington State places a hold on the Tenino facility in order to facilitate the ongoing investigation. In total, 23 of the 81 cows that came from Canada have been located. USDA completes the selective depopulation of 129 animals from the index herd. To date, 30 samples from the index herd have completed testing; results have been negative for BSE.
January 18	USDA completes selective depopulation operations on the facility in Mattawa, Washington. To date, USDA has transported and sampled a total of 39 animals from this facility. To date, 121 samples taken from the depopulated index herd have completed testing; results have been negative for BSE.
January 19	USDA completes selective depopulation operations on the facility in Mattawa, Washington. To date, USDA has transported and sampled a total of 39 animals from this facility. To date, 121 samples taken from the depopulated index herd have completed testing; results have been negative for BSE.
January 20	USDA personnel locate another animal that is part of a group of 17 heifers originally dispersed from the Canadian source herd in August 2001. The animal was found at a Boardman, Oregon, facility. It is not unusual for an epidemilogical investigation to cover multiple States. These 17 animals were mentioned by Dr. Brian Evans, Chief Veterinary Officer for Canada, in the January 6, 2004, technical briefing and are not part of the original 81 animals. APHIS investigators have now located four from this group of 17. Three others were located at the Quincy facility. Investigators are still determining whether the remaining 13 animals entered the United States. Selective depopulation operations on the facility in Mattawa and the index herd have been completed. USDA has

transported and sampled a total of 39 animals from the Mattawa facility and 131 animals from the index premises. To date, 129 samples from the index herd have completed testing; results have been negative for BSE. Results from the Mattawa herd are not yet available.

Senior U.S. government officials continue talks with trading partners and this week are meeting with officials in Japan, the Philippines, Hong Kong and South Korea to discuss BSE related issues.

January 21

USDA has transported and sampled a total of 39 animals from the Mattawa facility and 131 animals from the index premises. All these samples have been tested and the results were negative.

January 22

USDA has located three additional animals at a facility in Burley, Idaho. The state has placed this facility on hold. These animals are part of the group of 81 cattle that came from Canada.

In total, 27 of the 81 cattle that came from Canada have been located:

- One of the 81 was the positive cow.
- Three have been located in a facility in Burley, Idaho.
- One has been located at facility in Moxee, Washington.
- Three have been located at a facility in Tenino, Washington.
- Six have been located at a facility in Connell, Washington.
- One has been located at a dairy in Quincy, Washington.
- Three are at a facility in Mattawa, Washington.
- Nine were in the index herd.

The Canadian Government announced that they are modifying their import standards to allow certain imports from the United States. Products that will be allowed include:

- boneless beef of cattle under 30 months of age subject to the development of certification procedures;
- cattle imported for immediate slaughter;
- Bovidae and things derived from them imported for medical use, scientific research or zoological

collections;*
- embryos from the family Bovidae;
- animals and things carrying an animal pathogen imported into Canada under an import permit;
- products of a rendering plant imported into Canada under an import permit issued after December 25, 2003;
- meat and meat products originating in Argentina, Australia, New Zealand, Chile, Uruguay, or Brazil that are processed in the US;
- meat and meat products originating in Argentina, Australia, New Zealand, Chile, Uruguay, Canada or Brazil that are in transit in the US;
- transhipments through Canada to communities where only practical water/land route is through Canada.

The international review team, comprised of Dr. Ulrich Kihm, President and CEO, Safe Foods Solutions, Bern, Switzerland; Dr. Dagmar Heim, TSE Coordinator, Federal Veterinary Office of Switzerland; Dr. William Hueston, Director, Center for Animal Health and Food Safety at the University of Minnesota; Dr. Stuart MacDiarmid, Principal Advisor, Zoonoses and Animal Health, New Zealand Food Safety Authority, New Zealand; and Danny Matthews, TSE program coordinator for the United Kingdom, begin their assessment of the scope and thoroughness of the epidemiological investigation.

January 24

The international review team completes its assessment of the epidemiological investigation. USDA expects the results of the assessment in the near future.

January 25

USDA's investigation into the 81 cattle that came from the United States continues. At this time, 28 of these animals have been identified:

- 1 is the BSE-positive cow
- 9 were located in the index herd in Mabton, Washington
- 3 were located at a facility in Tenino, Washington
- 6 were located at a facility in Connell, Washington
- 1 is located at a facility in Quincy, Washington
- 3 were located at a facility in Mattawa, Washington
- 1 is located at a facility in Moxee, Washington
- 3 are located at a facility in Burley, Idaho (1 of which recently died)
- 1 is located at a facility in Othello, Washington

USDA is focusing the remainder of its epidemiological investigation on 25 of the 81 animals also born into the birth herd of the index animal. Of these animals, 14 of the 25

(including the BSE-positive cow) have been definitively identified.

Depopulation Summary:

- A cumulative total of 449 animals have been depopulated from the bull calf raising premises outside of Sunnyside, Washington.
- A cumulative total of 131 at-risk animals have been depopulated from the index premises in Mabton, Washington.
- A cumulative total of 39 animals have been depopulated from the facility in Mattawa, Washington.
- A cumulative total of 15 animals have been depopulated from the facility in Connell, Washington.
- A cumulative total of 20 animals have been depopulated from a facility in Boardman, Oregon.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT

BY

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DEPUTY COMMISSIONER OF FOOD AND DRUGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE

THE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

UNITED STATES SENATE

JANUARY 27, 2004

RELEASE ONLY UPON DELIVERY

Introduction

Mr. Chairman, Members of the Committee, thank you for the opportunity to participate in today's hearing on measures taken by the Federal government to safeguard human and animal health in the United States from Bovine Spongiform Encephalopathy (BSE) and the response to the finding of a BSE-positive cow in the State of Washington. I am Dr. Lester M. Crawford, Deputy Commissioner, Food and Drug Administration (FDA or the Agency).

The mission of FDA is to protect the public health by assuring the safety and efficacy of our nation's human and veterinary drugs, human biological products, medical devices, human and animal food supply, cosmetics, and radiation emitting products. In fulfilling this mission, FDA is the Agency responsible for assuring that all FDA-regulated products remain safe and uncompromised from BSE and related diseases. Many FDA-regulated products contain bovine ingredients, for example, heart valves, ophthalmic devices, dental products, wound dressings, injectable drugs, vaccines, soups, gravies, sausage casings, and animal feeds.

FDA has long been actively involved nationally and internationally in efforts to understand and prevent the spread of BSE. FDA collaborates extensively with the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS) within the U.S. Department of Agriculture (USDA), Customs and Border Protection (CBP), the Environmental Protection Agency (EPA), other Federal agencies, state and local jurisdictions, and with affected industries and consumer groups. Many of these activities fit within the framework of the Department of Health and Human Service's (HHS or the Department)

Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy (BSE/TSE) Action Plan, which was released in August 2001. This collaboration over many years has enabled FDA to strengthen safeguards for FDA-regulated products and to respond quickly and effectively to the first case of BSE within the U.S.

Executive Summary

The mission of the Agency is to protect the public health by assuring the safety and efficacy of our nation's human and veterinary drugs, human biological products, medical devices, human and animal food supply, cosmetics, and radiation emitting products. In fulfilling this mission, FDA is the Agency responsible for assuring that all FDA-regulated products remain safe and uncompromised from BSE and related diseases.

BSE is a progressive neurological disorder of cattle that results from infection by an unconventional transmissible agent, and was first diagnosed in the United Kingdom (U.K.) in 1986. Many FDA-regulated products contain bovine ingredients, for example, heart valves, ophthalmic devices, dental products, wound dressings, injectable drugs, vaccines, soups, gravies, sausage casings, and animal feeds and thus must be taken into consideration as part the effort to prevent infectivity by BSE.

FDA has a longstanding commitment to protecting consumers from BSE by following multiple measures designed to safeguard FDA-regulated products from possible contamination by the BSE agent. Under the Federal Food, Drug, and Cosmetic (FD&C) Act, FDA has the authority to prevent the adulteration and misbranding of FDA-regulated products. Further, for medical products that require pre-market approval (e.g., drugs under Section 505 and medical devices under Section 513 of the FD&C Act), FDA has addressed safety concerns related to BSE through requirements of the application and approval process.

The U.S. employs a robust multi-layered approach to preventing the introduction and amplification of BSE. While the goal of this approach is to achieve an extremely high level of compliance with each preventative measure, this multi-layered approach is designed to protect the U.S. consumer from exposure to the BSE infective material, and to date this approach has been working. Since 1989, USDA has prohibited the importation of live animals and animal products from BSE-positive countries. Since 1997, FDA has prohibited the use of certain mammalian proteins in the manufacture of ruminant feed. FDA continues to implement policies to keep safe all FDA-regulated products, including food, food ingredients, dietary supplements, drugs, vaccines, and cosmetics from risk of any BSE-contaminated bovine material. As a result of these multiple regulatory safeguards, the risk of exposure to BSE through products, FDA regulates remains extremely low in the U.S.

FDA's 1997 animal feed regulation forms the basis of the Agency's efforts to prevent the spread of BSE through animal feed. This rule prohibits the use of most mammalian protein in the manufacture of animal feeds for ruminants. FDA implemented this rule to establish in our country feeding practices consistent with the best science and epidemiological knowledge known at the time to prevent the spread of BSE throughout herds of U.S. cattle. A risk assessment sponsored by USDA and conducted by the Harvard Center for Risk Analysis, released in November 2001, identified FDA's feed ban as one of the primary safeguards against the spread of BSE in U.S. cattle.

To maximize protection afforded by the feed regulation, FDA has developed and implemented a BSE/Ruminant Feed Ban Inspection compliance program and established the goal of 100 percent compliance. FDA's strategy for achieving uniform compliance with the feed rule focuses on three areas: education, inspection, and enforcement. FDA and its state counterparts conduct, at least annually, targeted BSE inspections of 100 percent of known renderers, protein blenders, and feed mills processing products containing material prohibited from use in ruminant feed. Compliance by these establishments with FDA's feed rule is estimated to be at better than 99 percent. As of December 20, 2003, FDA had received over 26,000 inspection reports (6,404 for Fiscal Year 2003). The majority of these inspections (around 70 percent) were conducted by state officials for FDA, with the remainder conducted by FDA officials. The total number of inspection reports represents 13,672 firms, 1,949 of which are active and handle materials prohibited from use in ruminant feed. The 1,949 active firms that handle prohibited material have been inspected by FDA and, as of December 31, 2003, only five were found to have significant violations, resulting in official action indicated (OAI). FDA is working with these firms to bring them into compliance.

On December 23, 2003, FDA was notified by USDA of a presumptive-positive finding of BSE in a cow in Washington State. FDA immediately initiated its BSE Emergency Response Plan. As part of the plan, FDA has been coordinately closely with USDA so that we can effectively investigate this BSE case, trace the various products involved, and take the appropriate steps to protect the public. FDA investigators and inspectors located the high risk material rendered from the infected cow, and the rendering plants placed a hold on the rendered material, which is being disposed of appropriately. I am happy to report that all of the establishments inspected by FDA during the course of the investigation were in compliance with the feed ban. In addition, to help address the concerns of foreign governments and restore confidence in American products, FDA has participated, along with USDA, in numerous meetings and consultations with foreign governments since USDA surveillance found the BSE-positive cow.

In addition to new policies and regulations, new knowledge and tools gained through applied research can greatly help us to be more effective in our regulatory mission, such as protecting the country from BSE. Several of FDA's Centers, as well as many private laboratories, academic institutions, and other Federal agencies (most notably NIH) are also involved in significant research activities relating to TSEs. Basic areas requiring research include: increasing our understanding of prions, learning how prions are transmitted within a species and potentially between species, developing diagnostic tests for humans and animals, developing detection methods for use on regulated products, developing methods to increase

or eliminate infectivity, and designing new treatments. We are optimistic about the promise of new technologies, such as better methods to quickly distinguish the species of proteins and sensors to detect abnormal prions in food. Development of these technologies can contribute significantly to the effort to prevent the spread of BSE and must be considered carefully when evaluating potential regulatory changes to address BSE.

At the time that FDA implemented the feed rule in 1997, the Agency also recognized that evolving, complex scientific and public health issues, particularly regarding BSE required the Agency to continue to assess and scrutinize the rule to ensure its integrity as a firewall against the potential for spread of BSE. To further explore ways the animal feed regulation could be improved in November 2002, FDA published an advance notice of proposed rulemaking (ANPR) soliciting information and views from the affected industries and the public on some potential changes to its current feed regulation, including ways that the animal feed regulation could be strengthened. Although the risk of exposure to BSE in the U.S. remains extremely low and the measures in place are working, as a result of the recently discovered infected cow in the state of Washington, the Agency is evaluating the appropriateness of additional science-based measures to further strengthen our current protections.

Yesterday, Department Secretary Tommy Thompson and FDA Commissioner Mark McClellan announced several additional public health measures to further strengthen the current robust safeguards that help protect Americans from exposure to the agent that causes BSE and help prevent the spread of BSE in U.S. cattle. These measures relate to both protections for foods intended for human consumption as well as additional measures to strengthen FDA's 1997 final rule regulating animal feed. With respect to human foods, FDA announced that it will extend to FDA-regulated foods, dietary supplements and cosmetics, restrictions on using specified risk materials that would complement the recent USDA announcements. Concerning animal feed, the Agency announced a series of measures designed to lower even further the risk that cattle will be purposefully or inadvertently fed "ruminant" proteins, including, eliminating an exemption in the feed rule that allows mammalian blood and blood products at slaughter to be fed to ruminants as a protein source; banning the use of "poultry litter" as a feed ingredient for cattle and other ruminants; prohibiting the use of "plate waste" as a feed ingredient for ruminants, including cattle; and taking steps to further minimize the possibility of cross-contamination of animal feed via equipment, facilities or production lines.

Finally, FDA is increasing its inspections of feed mills and renderers in 2004. Our 2001 base funding for BSE-related activities was $3.8 million. We shifted resources internally in 2001 and received a substantial increase from Congress in 2002. Our funded level for 2004 is currently approximately $21.5 million, almost a five-fold increase over the 2001 base. FDA will itself conduct 2,800 inspections and will make its resources go even further by working with state agencies to fund 3,100 contract inspections of feed mills and renderers and other firms that handle animal feed and feed ingredients. Through partnerships with states, FDA will also receive data on 700 additional inspections, for a total of 3,800 state contract and partnership inspections in 2004. These inspections would include 100 percent of all known renderers and feed mills that process products containing prohibited materials.

The Agency looks forward to continuing to assist Congress as it evaluates the risks associated with BSE, identifies opportunities to promote technologies that will detect and prevent the spread of BSE, and considers science-based approaches to further strengthen regulatory protections and bolster the resources available to assist Federal, state, local and private efforts to assure that BSE does not present a threat to human or animal health in the U.S.

Background on Bovine Spongiform Encephalopathy (BSE)

BSE is a progressive neurological disorder of cattle that results from infection by an unconventional transmissible agent, and was first diagnosed in the U.K. in 1986. It belongs to a family of diseases, transmissible spongiform encephalopathies (TSEs), a group of transmissible, slowly progressive, degenerative diseases of the central nervous systems of several species of animals.

The vast majority of BSE cases have been reported in the U.K., where more than 183,000 cases in more than 35,000 herds have been reported through the end of November 2003. The U.K.-BSE epidemic peaked in January 1993 at nearly 1,000 new cases per week. The original source of the BSE outbreak is uncertain, but may have resulted from the feeding of scrapie-containing sheep meat-and-bone meal to cattle. Scrapie is an endemic spongiform encephalopathy and has been widespread in the U.K., where the rendered carcasses of livestock (including sheep) were fed to ruminants and other animals until 1988, as a protein-rich nutritional supplement. It appears likely that changes in the rendering process in the U.K. that had taken place around 1980 allowed the etiologic agent in infected carcasses to survive, contaminate the protein supplement, and infect cattle. There is strong evidence and widespread agreement that the outbreak was amplified by feeding rendered bovine meat-and-

bone meal to young calves. BSE has a prolonged incubation period in cattle, ranging from two to eight years, with a mean of five to six years.

Outside of the U.K., 22 other countries, mostly in Europe, have reported cases of BSE in indigenous cattle to the World Organisation for Animal Health (known as the O.I.E.). Other countries may be considered at risk because of an inadequate surveillance program, a lack of information on which to make a risk assessment, or the potential for exposure to BSE.

Related Diseases

TSEs also include "scrapie" in sheep and goats, "chronic wasting disease" (CWD) in deer and elk, feline spongiform encephalopathy, transmissible mink encephalopathy, and, in humans, kuru, Gerstmann-Straussler-Scheinker syndrome, fatal familial insomnia, and Creutzfeldt-Jakob disease (CJD or "classical" CJD) and variant CJD, which was first reported in the U.K. in 1996. TSEs are not known to infect non-mammalian species.

Classic CJD occurs throughout the world, including the U.S., at a rate of about one case per million people. The median age at death in the U.S. of patients with classic CJD is 68. Most cases of CJD are considered sporadic, a small number are familial associated with a gene mutation, and a small number are iatrogenic, resulting from the accidental transmission of the causative agent via contaminated surgical equipment, or as a result of cornea or dura mater transplants, or the administration of human-derived pituitary growth hormones.

Variant CJD (vCJD) is a distinct variant from classic CJD and is strongly believed to have been acquired from eating food products containing the BSE agent. The absence of confirmed cases of vCJD in geographic areas free of BSE supports this conclusion, and the interval between the period for initial extended exposure of the population to potentially BSE-contaminated food and the onset of initial vCJD cases, approximately ten years, is consistent with known incubation periods for CJD. Experimental studies on monkeys and mice, as well as additional laboratory studies of infecting prions from vCJD patients and BSE-infected animals, also support such a relationship. The incubation period for vCJD in humans is unknown, but is at least five years and could extend up to 20 years or longer.

As of December 1, 2003, a total of 153 vCJD cases had been reported worldwide, 143 of the cases occurring in the U.K. The low number of vCJD cases relative to the number of cases of BSE in the U.K. indicates that a substantial species barrier protects humans from widespread illness. There are no cases of vCJD having been contracted in the U.S. The only person diagnosed with vCJD while living in the U.S. is a U.K. citizen believed to have acquired the disease while living in the U.K.

Legal and Regulatory Framework for FDA Protections

FDA has a longstanding commitment to protecting consumers from BSE by following multiple measures designed to safeguard FDA-regulated products from possible contamination by the BSE agent. Under the FD&C Act, FDA has the authority to prevent the

adulteration and misbranding of FDA-regulated products. For example, FDA has used provisions in Section 402(a) (the food adulteration provisions) and Section 403(a) (the food misbranding provisions) of the FD&C Act to prohibit ruminant feed from containing certain protein derived from mammalian tissues. These same adulteration and misbranding provisions apply to human food. Further, for medical products that require pre-market approval (e.g., drugs under Section 505 and medical devices under Section 513 of the FD&C Act), FDA has addressed safety concerns related to BSE through requirements of the application and approval process. Additionally, when material from the one BSE-positive cow in the U.S. was traced to renderers, FDA advised those firms that this material could not be used as an animal feed because it was adulterated under Section 402(a)(5) of the FD&C Act because it was, in part, the product of a diseased animal. Under section 801 of the FD&C Act, FDA may refuse admission of imported food and certain other products that appear to be in violation of the FD&C Act. Furthermore, under Section 701(a), FDA may promulgate regulations for the efficient enforcement of the FD&C Act. For example, under Section 701(a) and other sections, FDA promulgated its "animal feed" rule (Title 21, *Code of Federal Regulation* (CFR) section 589.2000) to prohibit ruminant feed from containing certain protein derived from mammalian tissues. In addition, under the Public Health Service Act, FDA is authorized to make and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the U.S. or between states.

Preventing the Spread of BSE: FDA Protections

FDA and other Federal agencies have had preventive measures in place to reduce the U.S. consumer's risk of exposure to any BSE-contaminated meat and food products for a considerable time. Since 1989, USDA has prohibited the importation of live animals and animal products from BSE-at risk countries. Since 1997, FDA has prohibited the use of certain mammalian proteins in the manufacture of ruminant feed. FDA continues to implement policies to keep safe all FDA-regulated products, including food, food ingredients, dietary supplements, drugs, vaccines, and cosmetics from risk of any BSE-contaminated bovine material. As a result of these multiple regulatory safeguards, the risk of exposure to the BSE agent through products FDA regulates remains extremely low in the U.S. In 1998, USDA commissioned the Harvard Center for Risk Analysis to conduct an analysis and evaluation of the U.S. regulatory measures to prevent the spread of BSE in the U.S. and to reduce the potential exposure of U.S. consumers to BSE. The Harvard study concluded, among other things, that even if introduced in the U.S., due to the preventive measures currently in place in the U.S., BSE is extremely unlikely to become established in the U.S.

The U.S. employs a robust approach to preventing the introduction and amplification of BSE, and the prevention of introduction and amplification of BSE has been described as consisting of five separate firewalls. Our existing firewalls are based on a four-pronged regulatory strategy:

- Our first firewall is formed through regulations and enforcement to protect U.S. borders from potentially infective materials utilizing a regime of import controls. USDA, beginning in 1989, enacted major restrictions on imports, and more restrictive import controls have been introduced as we have learned more about the science of BSE and as the worldwide epidemiology has changed. FDA remains a committed partner with USDA and CBP in protecting our borders.

- The second firewall is surveillance of the U.S. cattle population for the presence of BSE. Surveillance of the cattle population is the primary responsibility of USDA, and USDA has recently announced steps to increase surveillance.

- The third firewall is prevention of the amplification of BSE through feed provided to cattle and other ruminants, and this responsibility falls primarily on FDA. FDA's animal feed ban regulations form the basis of this third firewall and have been cited as one of the most significant elements needed to prevent the spread of BSE in the U.S. We have taken intensive steps to get an extremely high level of compliance with this feed ban. As a result, we have been able to work with the animal feed industry to achieve more than a 99% compliance rate – and we intend to continue to work for full compliance.

- The fourth firewall is making sure that no bovine materials that can transmit BSE be consumed by people. So even if a BSE-positive cow made it through all of the previous firewalls, which is extremely unlikely, it would not pose any risk to people. USDA and FDA have long had steps in place to help prevent any possible exposure to BSE in bovine products, and recently USDA announced additional major steps to prevent any of the tissues known to carry BSE from entering the beef supply, as well as to restrict use of certain "downer" cows that might be at higher risk of carrying BSE. FDA will be taking comparable measures to prevent human exposure to the FDA-regulated bovine products that might potentially harbor BSE.

- A fifth firewall is effective response planning to contain the potential for any damage from a BSE positive animal, if one is discovered at some point in the system. This urgent response plan went into place immediately upon the discovery of a BSE-positive cow in Washington State on December 23, 2003. We have inspected and traced products at 22 facilities, including feed mills, farms, dairy farms, calf feeder lots, slaughterhouses, meat processors, transfer stations, and shipping terminals. We have accounted for all the products related to the BSE-positive cow that FDA regulates, and none have gone into human or animal consumption. Moreover, FDA has conducted inspections at all the rendering facilities involved, and found they were fully in compliance with our feed rule.

The goal of our firewall after firewall approach is to provide full protection of the public against BSE without adding unnecessary costs or restricting the consumption of safe beef products. FDA and USDA intend to maintain an extremely high level of compliance with each firewall. In addition, our multi-layered approach makes sure that even if each firewall doesn't function perfectly, the U.S. consumer is, nonetheless, protected from exposure to the BSE infective material.

FDA's Feed Rule: Substances Prohibited From Use in Animal Feed

Rendered feed ingredients contaminated with the BSE agent are believed to be the principal means by which BSE is amplified in cattle populations. To help prevent the establishment and spread of BSE through feed in the U.S., FDA implemented a final rule that prohibits the use of most mammalian protein in the manufacture of animal feeds for ruminants. This rule, 21 CFR 589.200, became effective on August 4, 1997. Mammalian proteins exempted from the rule are blood and blood products, gelatin, inspected meat products that have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings), milk products (milk and milk proteins), and any product whose only mammalian protein consists entirely of porcine or equine protein. Fats and oils, such as tallow, do not fall within the current feed rule because they are not protein.

FDA implemented this rule to establish in our country feeding practices consistent with the best science and epidemiological knowledge known at the time to prevent the spread of BSE throughout herds of U.S. cattle. A risk assessment sponsored by USDA and conducted by the

Harvard Center for Risk Analysis, released in November 2001, identified FDA's feed ban as one of the primary safeguards against the spread of BSE in U.S. cattle.

To maximize protection afforded by the feed regulation, FDA has developed and implemented a BSE/Ruminant Feed Ban Inspection compliance program and established the goal of 100 percent compliance. FDA's strategy for achieving uniform compliance with the feed rule focuses on three areas: education, inspection, and enforcement.

A strong inspection presence can be considered the backbone of FDA's strategy for achieving compliance with the feed rule. FDA and its state counterparts conduct, at least annually, targeted BSE inspections of 100 percent of known renderers, protein blenders, and feed mills processing products containing material prohibited from use in ruminant feed. Compliance by these establishments with FDA's 1997 feed rule is over 99 percent. FDA has prioritized the inspection process so that any firms found to be out of compliance in their last inspection will be promptly re-inspected. In addition, FDA will conduct for-cause inspections where evidence dictates, e.g., as a result of a sampling assignment. FDA and the states also conduct inspections of selected processors that are not using prohibited material to ensure compliance with the regulation by this segment of the industry.

Inspections conducted by FDA or state investigators are classified to reflect the compliance status at the time of the inspection based upon the objectionable conditions documented. These inspection decisions are reported as OAI, Voluntary Action Indicated (VAI), or No Action Indicated (NAI).

- An OAI inspection classification occurs when significant objectionable conditions or practices were found and regulatory sanctions are warranted in order to address the establishment's lack of compliance with the regulation. An example of an OAI inspection classification would be findings of manufacturing procedures insufficient to ensure that ruminant feed is not contaminated with prohibited material. Inspections classified with OAI violations will be promptly re-inspected following the regulatory sanctions to determine whether adequate corrective actions have been implemented.

- A VAI inspection classification occurs when objectionable conditions or practices were found that do not meet the threshold of regulatory significance, but do warrant advisory actions to inform the establishment of findings that should be voluntarily corrected. Inspections classified with VAI violations are more technical violations of the ruminant feed rule such as minor record-keeping lapses and conditions involving non-ruminant feeds.

- A NAI inspection classification occurs when no objectionable conditions or practices were found during the inspection or the significance of the documented objectionable conditions found does not justify further actions.

As of December 20, 2003, FDA had received over 26,000 inspection reports (6,404 for fiscal year 2003). The majority of these inspections (around 70 percent) were conducted by state officials for FDA, with the remainder conducted by FDA officials. The total number of inspection reports represents 13,672 firms, 1,949 of which are active and handle materials prohibited from use in ruminant feed. These firms, which may be in more than one category,

include renderers, licensed feed mills, feed mills not licensed by FDA, protein blenders, and others (such as ruminant feeders, on-farm mixers, pet food manufacturers, animal feed salvagers, distributors, retailers, and animal feed transporters). The 1,949 active firms that handle prohibited material have been inspected by FDA and, as of December 31, 2003, only five were found to have significant violations, resulting in OAI. FDA is working with these firms to bring them into compliance.

To be transparent about inspection results, FDA has recorded inspectional findings in a newly designed FDA BSE/Ruminant Feed Inspection Database available on FDA's website. The database is dynamic, with new information being entered on a continual basis. Each entry in the database represents the results of the most recent inspection.
FDA also conducts sampling of feed and feed ingredients in the marketplace as an additional tool to target firms for inspection. This type of sample analysis is being done using feed microscopy as the method for detecting prohibited materials. Other methods, such as polymerase chain reaction (PCR), are being validated for additional analytical use.

Enforcement is an important component of the compliance strategy. FDA pursues enforcement actions when we find knowing or intentional non-compliance, or if repeated inspection and educational efforts are ineffective in assuring compliance. Our first action of choice will ordinarily be a Warning Letter, which notifies responsible parties of a violation or violations and asks for a response within a certain time frame explaining corrective actions taken. When it is consistent with the public protection responsibilities of FDA and the nature of the violation, it is our practice to afford individuals and firms an opportunity voluntarily to

take appropriate and prompt corrective action. The Agency has additional, more stringent enforcement tools available when our notification to the company of documented violations does not lead to compliance with the FD&C Act, including product seizure, injunction, and prosecution.

As of January 1, 2004, FDA has issued 63 Warning Letters and has one court ordered Permanent Injunction since the BSE feed rule went into effect. Also, 47 firms recalled 280 products during the same time period; 12 of the recalls were in 2003.

Education has been, and continues to be, a critical component of our compliance strategy. Providing clear guidance and information on FDA's requirements and regulations is vital to help assure compliance. FDA has provided and sponsored many educational services and forums, including nationwide seminars, CD-ROM training, teleconferences, guidances targeted for different segments of the animal feed industry, guidance for Federal and state inspectors, and a variety of published articles. The Agency has met with many industry trade groups to discuss coordination of educational efforts with affected parties, and we expect to continue an open dialogue, seeking suggestions for types of educational approaches, sharing resources, and keeping the industry updated on new developments or problem areas that arise.

Import Controls

To minimize the risk of the introduction or spread of BSE we also must have strong enforcement measures to protect our borders. FDA's Import Program is responsible for

coordinating the import of products potentially infected with or at high risk of infection with the agent associated with BSE. Operationally, FDA's Import Program provides for the review of information about FDA-regulated products offered for entry into the U.S. and the opportunity for physical examination of the products. FDA uses this information to determine whether a product is subject to refusal of admission.

In protecting the borders from potentially unsafe products, FDA works closely with USDA and CBP to ensure a coordinated and efficient BSE import control strategy. This tri-agency cooperative effort has led to a multi-layer review process whereby each agency utilizes the strengths of its particular entry procedures to produce a composite system that is considerably more robust than any one component. BSE import activities are reviewed and coordinated by an inter-agency workgroup composed of representatives from FDA, CBP, and USDA/APHIS. In fact, on February 5, 2002, with APHIS, FSIS, Canadian Food Inspection Agency (CFIA), Health Canada, and state participation, FDA conducted a simulation exercise involving the importation of potentially BSE-contaminated product and subsequent regulatory follow-up.

FDA uses Import Alerts to disseminate information regarding problems or potential problems with imported products. Import Alerts recommend that field offices examine, sample, or detain and, if warranted, refuse admission of the product in question. These Import Alerts are made available on FDA's website. With respect to its import alerts on BSE, FDA coordinates closely with APHIS and its prohibitions on the importation of products related to BSE concerns. An alert may cover an individual manufacturer, supplier, or a particular product from an entire country. Import Alerts also may be issued as a follow-up to an

inspection, when it is determined that a manufacturer is in violation of good manufacturing practice requirements.

FDA has in place several import alerts targeting BSE. Import Alert 17-04, first issued in October 1994, allows detention, without physical examination, of bulk shipments of high-risk bovine tissues and tissue-derived ingredients from BSE-at-risk countries. Import Alert 99-25, first issued in January 2001, allows detention without physical examination of animal feed, animal feed ingredients, and other products for animal use from countries identified by USDA as BSE-positive or BSE-at-risk when processed animal protein is declared in the ingredients or when FDA sampling and analysis finds the presence of undeclared animal protein. Import Alert 71-02, issued in October 2003, calls for detention without physical examination of products of specific firms located in USDA-listed BSE-positive or BSE-at-risk countries, which have been identified through FDA sampling and analysis, as importing products containing animal protein. These import alerts are continuously updated as new countries are listed by USDA as either BSE-positive or BSE-at-risk, or to make other appropriate changes.

FDA's Response to the Identification of a BSE-Positive Cow in Washington State

On December 23, 2003, at approximately 3:00 pm, the Agency's Office of Crisis Management (OCM) was notified by USDA's APHIS of a presumptive-positive finding of bovine spongiform encephalopathy (BSE) in a "downer" cow slaughtered on December 9, 2003, at a USDA-inspected slaughter facility in Washington State.

FDA had in place its Bovine Spongiform Encephalopathy Emergency Response Plan that describes the roles and activities of each of the Agency components involved in managing this kind of emergency. This plan had been tested several times in tabletop and simulated incidents that actively involved state, Federal, and Canadian counterparts. The plan has been in place since 2001 and has been revised in response to the incident exercises conducted by FDA.

As provided in the Emergency Response Plan, OCM's Emergency Operations Center (EOC) is the single point of coordination for FDA's response to a BSE emergency. FDA's EOC maintains contact with HHS Secretary's Command Center (SCC), CDC's EOC, USDA/FSIS Office of Food Security and Emergency Preparedness, and other EOCs, as appropriate.

At the time of notification by USDA of the presumptive case of BSE, FDA's OCM initiated its BSE Emergency Response Plan and activated FDA's EOC. Various FDA headquarters and FDA center offices were immediately notified in accordance with the plan, as well as the FDA Seattle District Office (SEA-DO).

FDA responsibilities include conducting inspections and investigations to determine where any animal by-products went and ensuring that they did not enter commerce contrary to provisions of the FD&C Act and other statutes enforced by FDA.

On the same day FDA was notified of the presumptive case of BSE by USDA, FDA's SEA-DO dispatched five investigative teams to investigate various facilities suspected of being either a source or recipient of affected material.

An aggressive schedule of inspections and investigations was pursued by FDA which enabled FDA to announce in December 27, 2003, that its investigators and inspectors from the states of Washington and Oregon had located the high risk material rendered from the one cow that had tested positive for BSE in Washington State and that the rendering plants that processed this material had placed a hold on the rendered material. The firms, located in Washington State and Oregon, assisted and cooperated fully with FDA's investigation.

FDA advised the involved renderers on acceptable methods of disposing of material, such as landfill (coordinating with state and local officials and EPA), incineration, digestion, or conversion to a fuel/industrial source. Disposal of the meat and bone meal on hold has begun.

Communications, of course, have played a critical role in many aspects of the incident response. Late on December 23, 2003, FDA's headquarters and district staff participated in a teleconference with APHIS and Washington State officials to ensure a coordinated response to the incident. FDA, CDC, Department of Defense, and FSIS continued to participate in APHIS-initiated interagency calls throughout the response to the incident.

FDA also has kept affected industries and State counterparts informed and up-to-date. On December 23, 2003, FDA's Center for Food Safety and Applied Nutrition (CFSAN) advised Washington State milk cooperatives that there was no known risk of BSE transmission from milk. The scientific data indicate that milk from BSE cows does not transmit BSE.

In responding to the BSE incident, FDA inspected and traced products at many different facilities, including renderers, feed mills, farms, dairy farms, calf feeder lots, slaughterhouses, meat processors, transfer stations, and shipping terminals. Notably, inspectors found no deviations from FDA's feed rule.

Working with Foreign Governments

FDA officials regularly meet with representatives of foreign governments and international organizations on many levels and on many issues of common interest, including BSE. Immediately after the announcement on December 23, 2003, of a BSE-positive cow in the U.S., various foreign governments closed their markets to U.S. beef. Since that time, FDA officials, working closely with USDA officials, have been involved in numerous meetings and consultations with representatives of foreign governments to help address concerns and restore confidence in American products. For example:

- FDA representatives met with Japanese officials from the Ministry of Agriculture, Forestry, and Fisheries, the Ministry of Health, Labor, and Welfare, the Food Safety Commission and the Japanese Embassy on January 9, 2004, to discuss BSE control measures in animal feed and food additives.

- FDA representatives met with numerous foreign attaches at USDA on January 12, 2004, to discuss FDA's Center for Veterinary Medicine measures to prevent BSE in animal feeds.

- FDA representatives met in separate meetings on January 13, 2004, with officials from the CFIA and from Mexico's Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación to discuss current feed safety measures to prevent BSE in the U.S.

- The Ministers of Agriculture of the U.S., Mexico and Canada met on January 16, 2004, to coordinate ongoing interagency efforts towards expediting increased harmonization through a consultative process among the countries. I accompanied Secretary of Health and Human Services Tommy G. Thompson, at this meeting that resulted in a proposal to establish a Coordinating Committee on BSE to facilitate collaborative effort.

- Additionally, last week I visited with Japanese and Korean officials, as part of the U.S. Government's delegation to discuss scientific and trade implications of the U.S. BSE case. The delegation also included senior scientific, regulatory, and trade officials from USDA, and the U.S. Trade Representative.

Research

Several of FDA's Centers, as well as many private laboratories, academic institutions, and other Federal Agencies (most notably NIH) are involved in significant research activities relating to TSEs. Basic areas requiring research include: increasing our understanding of prions; learning how prions are transmitted within a species and potentially between species; developing diagnostic tests for humans and animals; developing detection methods for use on regulated products; developing methods to increase or eliminate infectivity; and designing new treatments.

Most people envision research as being applied by medical practitioners to diagnose and treat disease. Applied research also is critical in a regulatory environment, where knowledge and tools gained through applied research can help us to achieve our mission more effectively and more efficiently.

Taking one example pertinent to BSE, current rendering processes do not completely inactivate the BSE agent. Advances in technology that could distinguish between BSE-infected and non-infected cattle, or that could completely inactivate the BSE agent in feed components may allow for exemptions to the feed regulations for those renderers and feed manufactures who apply these technologies.

Discussed below some examples of research on BSE and vCJD that could have significant regulatory implications and benefit:

- FDA's CFSAN is in the final year of funding a two-year project to develop sensors to detect abnormal prion protein in food. Work on the project should be completed in early 2004, and will result in a report on the usefulness of the sensors for detecting TSE agents in finished food products.

- No tests for the rapid diagnosis of vCJD have been validated as either sufficiently specific or sensitive to be used to screen the blood supply. A reliable blood-screening test for vCJD is an extremely important goal and is currently the object of considerable research activity.

- FDA has conducted and supported research efforts in the process of validating a rapid-DNA based method for detection of animal derived materials in animal feed and feed ingredients. As a part of this research effort, FDA has developed a Polymerase Chain Reaction probe to determine the animal species of origin from which feed ingredients were derived.

FDA remains firmly committed to bringing better science to the public, to provide better public health protection at a lower cost. That's why a key part of our BSE strategy involves fostering the development of better technologies to deal with BSE. To enhance the ability of our public health system to detect prohibited materials in animal feed, FDA will continue to

support the development and testing of diagnostic tests to identify prohibited materials. As these tests are developed FDA will evaluate the utility of such tests promptly and thoroughly, so that there will be a quick and reliable method of testing animal feeds for prohibited materials.

Additional Measures to Bolster Protections Against BSE

FDA implemented the feed rule in 1997 based on the best information obtainable on the science and epidemiology of BSE at the time. The Agency also recognized that evolving, complex scientific and public health issues, particularly regarding BSE and vCJD, required the Agency to continue to assess and scrutinize the rule to ensure its integrity as a firewall against the potential for spread of BSE.

The Agency held a public hearing in October 2001 to solicit information and views on its present animal feed regulation. FDA requested information and views from individuals and organizations on the present rule and whether changes in the rule or other additional measures were necessary. The Agency was particularly interested in soliciting comments and views from individuals, industry, consumer groups, health professionals, and researchers with expertise in BSE and related animal and human diseases. The Agency specifically invited comments, both oral and written, on 17 questions about ways the rule and its enforcement might be improved to achieve its original objectives of preventing the establishment and amplification of BSE in the U.S. Transcripts of the hearing were then made publicly available with access through FDA's website.

Soon after the public hearing, the USDA released the Harvard Center for Risk Analysis's findings on the impact of various risks and potential pathways for exposure of U.S. cattle and U.S. citizens to the BSE agent. This assessment of the situation in the United States concluded that, due to control measures already in place, the risk to U.S. cattle and to U.S. consumers from BSE is very low. The model also demonstrated that certain new control measures could reduce the small risk even further.

To further explore ways the animal feed regulation could be improved in November 2002, FDA published an ANPR soliciting information and views from the affected industries and the public on some potential changes to its current feed regulation, including ways that the animal feed regulation could be strengthened. Information and comments were sought on the following five aspects of the BSE feed regulation: feasibility and impacts of excluding high risk materials, such as brain and spinal cord, from rendered animal products; use of poultry litter in cattle feed and impacts of banning such use; impacts of introducing new labeling requirements for pet food; methods to prevent cross-contamination between prohibited and non-prohibited material; use of plate waste in ruminant feed and impacts of eliminating such use.

Yesterday, we announced that we will be taking several additional steps to further strengthen the current robust safeguards that help protect Americans from exposure to the agent that causes BSE and help prevent the spread of BSE in U.S. cattle. These measures relate to both protections for foods intended for human consumption as well as additional measures to

strengthen FDA's 1997 final rule regulating animal feed. Many of these steps were raised in the November 2002, ANPR, as well as at the public meeting. With respect to human foods the Agency announced it will be extending to FDA-regulated foods, dietary supplements and cosmetics, restrictions on using specified risk materials that would complement the recent USDA announcements. Concerning animal feed, the Agency announced a series of measures designed to lower even further the risk that cattle will be purposefully or inadvertently fed "ruminant" proteins, including, eliminating the existing exemption in the feed rule that allows mammalian blood and blood products at slaughter to be fed to ruminants as a protein source; prohibiting the use of "poultry litter" as a feed ingredient for cattle and other ruminants; banning the use of "plate waste" as a feed ingredient for ruminants, including cattle; taking further steps to minimize the possibility of cross-contamination of animal feed via equipment, facilities or production lines; and evaluating additional mechanisms to enhance the ability of our public health system to detect prohibited materials in animal feed utilizing diagnostic tests.

In addition, FDA intends step up its inspections of feed mills and renderers in 2004. FDA is increasing its inspections of feed mills and renderers in 2004. Our 2001 base funding for BSE-related activities was $3.8 million. We shifted resources internally in 2001 and received a substantial increase from Congress in 2002. Our funded level for 2004 is currently approximately $21.5 million, almost a five-fold increase over the 2001 base. FDA will itself conduct 2,800 inspections and will make its resources go even further by working with state agencies to fund 3,100 contract inspections of feed mills and renderers and other firms that handle animal feed and feed ingredients. Through partnerships with states, FDA will also

receive data on 700 additional inspections, for a total of 3,800 state contract and partnership inspections in 2004. These inspections would include 100 percent of all known renderers and feed mills that process products containing prohibited materials.

Conclusion

FDA has an enormous responsibility in assuring that the products the Agency regulates which contain bovine materials are safe and uncompromised by BSE or other TSEs. FDA's principal line of defense in meeting this responsibility is to cut-off all avenues for the possible spread of BSE through U.S. cattle herds. Our most powerful tool in preventing the spread of BSE in U.S. cattle herds is effective enforcement of the Agency's feed ban restrictions as part of a multi-layered set of firewalls put in place as part of the U.S. Government's comprehensive BSE prevention program.

To date, a rigorous program of education, inspections, and enforcement education have enabled us to fulfill our responsibilities as part of the U.S. plan for preventing the spread of BSE. Although the risk of exposure to BSE in the United States remains extremely low and the measures in place are working, as a result of the recently discovered infected cow in the state of Washington, the Agency will be taking additional science-based steps to further strengthen our current protections.

FDA looks forward to continuing to assist Congress as it evaluates the risks associated with BSE, identifies opportunities to promote technologies that will detect and prevent the spread

of BSE, and considers science-based approaches to further strengthen regulatory protections and bolster the resources available to assure that BSE does not present a threat to human or animal health in the U.S.

Thank you for the opportunity to testify today.

Testimony of
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College of Veterinary Medicine
Cornell University

Before the United States Senate
Agriculture, Nutrition and Forestry Committee
January 27, 2004

Mr. Chairman, Senator Harkin, and members of the Committee, I am honored to have been invited to testify on the impact of the discovery of the first case of bovine spongiform encephalopathy (BSE) in the United States.

I am a Professor at the College of Veterinary Medicine at Cornell University where I serve as Associate Dean for Veterinary Public Policy, and as the Executive Director of the New York State Animal Health Diagnostic Laboratory. Prior to my return to academia two years ago, I had the privilege to serve our nation through eleven years of service in the U.S. Department of Agriculture where I was very much involved with activities related to the protection of our nation against the incursion of foreign animal diseases. I was Director of the Plum Island Animal Disease Center before serving USDA as the Chief Veterinary Officer. During 2001, I had the opportunity of working very closely with Secretary Veneman in our efforts to prevent the entry of foot-and-mouth disease into the U.S., while the world witnessed outbreaks of this disease in Europe and South America. I was one of the lead participants at USDA in preparing a comprehensive report to this Senate Committee as part of the Animal Disease Risk Assessment, Prevention, and Control Act of 2001 (P.L. 107-9), which was concerned with the plans of Federal agencies to defend our country against foot-and-mouth disease and BSE. I also served as the U.S. delegate to the World Animal Health Organization (OIE) in matters related to international standards for the trade of animals and animal products. These activities provided me with the opportunity to participate with other Federal officials in international trade negotiations, also related to our import and export of animals and animal products. Those previous experiences at USDA, and my current activities provide the foundation for my following comments on the current situation that we are facing regarding BSE.

While we are newly experiencing the impact of BSE in our country, BSE is not a new disease to us in the veterinary community. We have been following this condition since its first recognition as a brand new disease in the United Kingdom in 1986. As you know, BSE is a slow progressive disease that affects the central nervous system of cattle, invariably leading to their death. BSE is one member of a larger family of similar diseases that affect both animals and humans. These are known as the Transmissible Spongiform Encephalopathies (TSEs), including Kuru and Classical or Sporadic Creutzfeldt-Jacob Disease (CJD) in humans; Scrapie in sheep; Chronic Wasting Disease

(CWD) in deer and elk; and Mink Transmissible Encephalopathy (TME). The initial lack of scientific knowledge about BSE led to some erroneous conclusions, particularly in predicting the potential public health risks of BSE. First thoughts were, because Scrapie has not been a human health hazard for over two centuries, that BSE would be the same. Today, we know that that is not the case. The proteinaceous infectious agent, or prions, associated with BSE can infect humans with the development of a neurological condition that bears some similarities to the Classical or Sporadic CJD. The human manifestation of BSE came to be known as Variant CJD (or vCJD). BSE is also known to have infected a variety of ruminant zoo animals, as well as domestic and wild cats (Feline Spongiform Encephalopathy), primarily in the UK, when those animals consumed feeds containing parts of cattle that died of BSE. Today, as a result of intensive international research on BSE and its causative agent, we know a great deal more about how the disease is transmitted, how the disease is diagnosed, and which tissues of an affected animal contain the infectious agent. We also know much about the physical and chemical resistance of the prion agent to inactivation and destruction. Still, there are many scientific gaps in regard to this disease and its unique type of agent.

Typical of all TSE diseases, BSE has a very long incubation period. From infection to the time the animal develops clinical signs could be a lapse of four to seven years. We know that in cattle, the BSE agent accumulates in the brain, eyes, tonsils, spinal cord, trigeminal and dorsal root ganglia, and the intestines, particularly in those animals older than 24 to 30 months. These tissues are known as the Specified Risk Materials or SRMs. We know that, because the prion agent is resistant to industrial rendering conditions, rendered protein products that contain SRMs from BSE-affected cattle are the main source of infection, if other cattle ingest such materials. BSE is not a contagious disease and therefore no direct transmission occurs from animal to animal. There is some possibility of vertical transmission from cow to its calf offspring. However, semen or embryos from affected animals do not transmit the disease. It is also known that the prion agent of BSE is not shed in the milk, nor it is present in the muscle meat of affected animals.

The proactive regulatory actions of the USDA initiated in 1988, combined with the regulatory actions from the FDA that started in 1997, have worked well in protecting us against a major outbreak of BSE. If there has been one disease that has provided a model for how to plan ahead for the day that a disease may be detected, it is BSE. Since 1990 there has been a federal response plan for BSE. Thanks to that, the federal agencies have been remarkably effective in dealing with the current situation, and I congratulate my colleagues at both USDA and the FDA for their response to this crisis. While the Federal BSE Plan has been effective, now that we have identified the first case of BSE on our soil, the plan needs to be modified. Both USDA and FDA are doing so.

Given the nature of BSE, there are three areas where interventions can make a significant difference: (1) restrictions on trade of ruminants and ruminant products; (2) a targeted domestic surveillance program; and, (3) a ruminant feed ban.. These three elements relate to preventing the introduction animals or risk materials into the US; detection of cases

with traceability of other potentially infected animals; and prevention of the amplification of the agent/disease within the US. I will concentrate my comments on these three areas.

Trade of ruminants and ruminant products: The US has been at the vanguard in implementing regulatory safeguards to prevent the introduction of BSE affected animals or animal products containing the BSE-agent. US actions so far have reflected the evolutionary state of scientific knowledge about this disease, and need to be continuously revised and adjusted to match actual risks. Our policy of a universal set trade response to any country having BSE cases in their territory, no matter how many clinical cases or the level of BSE risk factors they may have, needs to be modified. Federal agencies are beginning to do so, particularly after the discovery of the first case of BSE case in a Canadian-born animal earlier last year. Our trade embargoes to BSE-affected countries like Canada must be different than our response to many countries in Europe. There have been only two cases of BSE detected in Canadian-born animals. In contrast, there are still several hundred cases of BSE every year in EU Member countries. I am aware of the efforts of the USDA in working with the OIE and many trading partners in developing a framework for trade in ruminants and ruminant products that is proportional to the comprehensive risk of BSE in each country. I encourage the USDA and the US Trade Representative to continue to work in this regard. Our nation will not be able to overcome the restrictions that other countries have placed on our animal and animal exports until we adjust our trade restrictions to other countries in an equivalent and proportional way under similar situations.

Targeted domestic surveillance program: The USDA has had an effective surveillance system to provide an early detection of BSE in our country. The system worked well, as demonstrated by the detection of the first BSE-affected cow in the State of Washington. The decision to target non-ambulatory or downer animals as the highest risk population in the US was proven to be correct. The task now is to maintain and expand an effective surveillance program in the face of the recently announced USDA ban on the slaughter of non-ambulatory animals for human food. This segment of the cattle population has been our best target for sampling and testing. A new system for BSE surveillance that statistically represents the entire cattle population of the US, and that meets international guidelines and recommendations, will be a challenge. The systems for transportation to, and sampling at, slaughter establishments that process downer animals for animal feed are not well developed at the present time. While the actions of the USDA in banning the downer animals from entering the human food chain are understandable, there is a need to find a safe and economically viable means to humanely slaughter non-ambulatory animals, and to provide for safe disposal and sampling of on-farm dead animals. Such actions will avoid potential welfare issues with injured animals at the farm, and will restore a well-established source of samples for a credible BSE surveillance at a national level that is based on sound epidemiologic science.

An effective surveillance program would require the ability to trace animals at any location and at any point in time. The need for having an effective national animal identification system is well demonstrated by the difficulties in tracing the animals that were imported from Canada with the BSE-affected cohort cow. That task is even more

daunting given the long incubation period of BSE, requiring the back tracing of the entire life of animals through multiple owners and locations. While I recognize and appreciate the many efforts of the USDA and the animal industries in developing and implementing a national animal ID system, the weakness is that such a system is a voluntary effort at this time. I believe the US now requires a mandatory national animal ID system. Technologies are already available and pilot projects, such as the National Farm Animal Identification and Records (FAIR) Project funded by Congress in the recent past, have demonstrated the utility of an ISO-certified radio frequency ID (RFID) system that is cost effective and reliable. Other ISO-certifiable technologies are also available. I am encouraged by recent statements from USDA on the acceleration of the national animal ID plans. However, I respectfully suggest that Congress in collaboration with the USDA need to make this national animal ID system a mandatory program.

Ruminant feed bans: I applaud the efforts of the FDA in tightening enforcement of the regulations banning the feeding of ruminant proteins to cattle. The very best way to prevent the amplification and spread of BSE from affected cattle to other animals is by preventing the use of potentially BSE-contaminated feeds for susceptible animals. Given the fact that the BSE prion agent is primarily present in the SRMs, I urge the USDA and the FDA to ban the use of SRMs from all downers and from cattle older than thirty (30) months of age. These materials should not enter the human food chain or the animal feed chain. Such action will further enhance the safety of protein supplements used in ruminant and feline diets. I believe the confidence in the safety of our beef industries with our trading partners will be increased if such actions are implemented. This is not a new drastic recommendation. It has been proposed by the World Health Organization as part of scientific measures to prevent the spread of BSE in the world. This recommendation was also made to Canada last June by the international review panel that evaluated their actions after the BSE case in the Province of Alberta last year. I encourage the USDA, the FDA and Congress to consider the implementation of these actions as the next measures in continuing to enhance our safeguards against BSE.

Mr. Chairman, I congratulate the USDA and the FDA for their effective actions following the BSE finding announced on December 23, 2003. These actions have maintained consumer confidence in our beef products. While the trade embargoes were to be expected in a situation like this, I hope that, with the implementation of further actions as suggested; we would continue to enhance the defense of our nation against BSE, and sustain domestic and international confidence in our animal industries and the safety of our food and feed supply.

Thank you again to the Committee for inviting me to testify on this important national issue, and I will be glad to respond to any questions you may have for me at this time.

DOCUMENTS SUBMITTED FOR THE RECORD

JANUARY 27, 2004

BIOMETRICS - THE TECHNOLOGICAL ADVANCEMENT IN ANIMAL IDENTIFICATION

Mr. ALLARD. Mr. President, it has been brought to my attention that the Department of Agriculture has put for comment their rules and regulations on animal identification, in particular beef. It's not unusual that by the time federal agencies in today's environment get around to issuing their rules and regulations, or by the time Congress passes legislation, our technology has moved so quickly that those provisions become outdated. I'm concerned this could be happening with the Department of Agriculture promulgating rules on the Radio Frequency Identification Tag (RFID) in United States Animal Identification. It has an internal code structure that identifies a specific bovine, but if something happens to the tag, there is no way of re-establishing the animal's identification. That is, there is no way of re-establishing the animal's identification unless another form of permanent identification is obtained. That is why it is so important to discuss the use of biometrics in animal verification, and more specifically, to fully explore the use of retinal scanning for identification purposes.

It is my understanding that the rules and regulations may exclude the use of retinal scanning because the rules that the USDA is considering do not address or allow the use of a "secure permanent identifier," or at the least, they could be interpreted to discourage its use. I have personally viewed such retinal scanning technology and believe that it can be a practical way to identify individual animals, or lots of animals, and that this technology should not be put at a disadvantage because of a policy position by the Department of Agriculture.

With the December 23rd discovery of a cow infected with Bovine Spongiform Encephalopathy (BSE) the United States faced a real life test of our animal identification and tracking system. Identification of livestock is very advanced in the United States, but even with our system, it took days to track that BSE-infected cow to Canada.

As part of our efforts to confront, control and eliminate the risk of BSE and to address future animal health emergencies, we should consider putting into place systems that can easily and rapidly identify an animal and tell us where it has been. It must be able to tell us what animals it has been in contact with and where those contacts are now. The system should do this rapidly, securely and without error.

I commend the efforts of the USDA and industry who have been working together for some time to design a national animal identification plan. During the intervening period, new technologies have continued to emerge. As the USDA looks at implementing a national animal identification plan, it is important that we utilize the best of today's technologies. For instance, a primary objective of this plan, as proposed, is to trace any animal within 48 hours. With the technology available to us in this country, we can be looking at systems that can locate animals in minutes - not hours - with great accuracy.

To assure the American public and our export customers that we have not lost track of any animals, the US Animal Identification Plan should allow use of a secure, tamper resistant image of the animal's retinal vascular pattern that is more unique than a human fingerprint. Retinal scanning identifies the animal, not the identifier. The majority of the other animal identification systems work on the basis of adding an identifier to the animal, such as a visual or electronic marker or tag and then recording that identifier. Identifiers like this can be lost or changed and are not secure. Some estimates put livestock tag loss in the range of 5-8% - an unacceptable scenario when considering the ramifications that this could mean to the beef industry.

I hope that the national animal identification plan does not preclude the use of new technologies introduced since the plan's inception, especially when these technologies exceed the proposed plan's performance objectives. Several U.S. companies are not waiting for the USDA , but are rapidly installing retinal imaging technology in their own plans to significantly improve their ability to track livestock. These companies should not be forced to also adopt a poorer performing technology because the plan mandates a certain, specific technology.

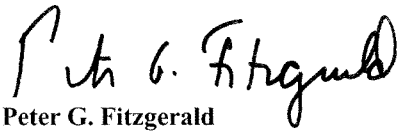
It is critical that the plan's systems be audited for performance and reliability to verify that they are actually working. We must be able to measure and document how many animals are misidentified or lost. Since retinal scanning technology uses secure, tamper resistant, retinal patterns, it is currently the only available method against which to verify the performance of any tag-based system.

We should be using the most current technology available - the Global Positioning System (GPS). By linking the Global Positioning System to a secure identifier such as a retinal scan, the time, date, and location of the animal can be captured when the eye is scanned proving beyond a doubt that "this animal was at this place at this time." Furthermore, the use of GPS coordinates provides USDA with the means to audit and verify the accuracy of any identification numbering system.

The United States has the most competitive livestock sector in the world. But we are at risk of falling behind countries in Europe, South America, as well as, Australia and New Zealand, nations that are all exploring more modern technologies for identifying and tracking livestock. Not only can the U.S. take a leadership role in this area, we can take identification and traceability "off the table" as a possible trade barrier by introducing technologies that leapfrog existing country requirements.

I would like to close by reminding my colleagues that it is only when you combine identity with location do you get traceability. And in order to build a secure, tamper-resistant system to trace livestock, you must begin with a secure, tamper resistant identifier. I believe we have the technology to do this in a practical, economically feasible way that will allow United States producers to meet the concerns expressed by our trading partners when managing diseases like "mad cow disease." I believe retinal scanning combined with the GPS system can be the most practical option if the policy of this country is to require an identification system of each animal or even for tracing batches of live animals because it is technology that can be easily used in the field and is very accurate, reliable, and precise.

Thank you, Mr. President.



Statement of Senator Peter G. Fitzgerald
U.S. Senate Committee on Agriculture, Nutrition, and Forestry
Tuesday, January 27, 2004

In the mid-1980s, European researchers made a frightening discovery. Humans could contract a deadly neurological disease -- Creutzfeldt-Jakob Disease (CJD) from simply eating animal tissue infected with mad cow disease or BSE (bovine spongiform encephalopathy). Since this revelation, around 150 people have died from the disease.

One of the more worrisome aspects of this disease is that it isn't caused by a bacillus or a virus, but by a mutated enzyme, known as a prion, that is almost impossible to eradicate. Prions can be cooked, boiled, frozen, or even dissolved in acid, but they emerge as deadly as before.

On December 23, 2004, the U.S. Department of Agriculture (USDA) announced that the agency had confirmed the first case of BSE in a cow in the United States. This announcement sent a shock wave through the beef industry. Forty of our trading partners banned the import of U.S. beef and domestic prices fell.

Today, a little over a month after this case of BSE was confirmed, our markets have stabilized. I commend the USDA for its expeditious response to the discovery and its implementation of increased safety standards to help ensure that no BSE prions enter our food supply.

On December 30, 2003, the agency took several steps to help protect the meat supply. Later, on January 26, 2004, the Department of Health and Human Services (HHS) followed suit by implementing additional safeguards.

While these are steps in the right direction, I urge the USDA and HHS to continue efforts to eliminate the threat of the BSE prion entering the human food chain. I further urge the agency to intensify its work to re-open foreign markets to U.S. beef.

Our nation's food is perhaps the safest in the world. The USDA must remain committed to ensuring that it becomes even safer.

Opening Statement
Senator Debbie Stabenow
January 27, 2004
Agriculture Committee

Thank you Chairman Cochran and Senator Harkin for convening today's hearing on BSE or Mad Cow Disease. Like all of us, I have been extremely concerned about the detection of Mad Cow in the U.S. Food Supply. I am pleased that we are focusing the committee's attention on this critical issue today.

There are currently 5,000 beef and dairy farmers in the state of Michigan. Since the discovery of Mad Cow on December 23, our beef producers have experienced a 20 percent loss in market price. In the past, Michigan beef producers have profited from access to international markets. But those markets have now been closed to U.S. beef. In order for our producers to survive this crisis, these international markets must be re-opened.

I believe that in order to regain the trust of our trading partners, we must take steps to strengthen our of food safety programs. I support the mandatory implementation of an animal identification program. I believe this is a first step to ensuring the safety of our food supply.

I also support the implementation of country of origin labeling that was initially pasted in the 2002 Farm Bill. Consumers have both a right and a need to know their food source. The U.S. has a reputation of high food safety standards. Country of Origin labeling will enhance this reputation and help re-open foreign markets that have currently closed its doors to U.S. beef.

Although the USDA estimates that the price for country of origin labeling is excessive, a recent report by the General Accounting Office (GAO) refuted the $582 million to $3.9 billion price tag attached by USDA. The safety of our food supply is invaluable, and any remaining gaps in our food supply must be closed.

I want to commend Secretary Veneman and the Department of Agriculture for there quick and diligent work in ensuring the safety of the U.S. beef supply. I am confident that the USDA is working diligently to ensure that the first U.S. case of Mad Cow is also its last.

I would like to welcome all of today's witnesses and I look forward to their testimony.

Supplemental Answer
By Dr. Alfonso Torres
To a question by Chairman Cochran during the hearing on Bovine Spongiform Encephalopathy at the US Senate Agriculture before the United States Senate Agriculture, Nutrition and Forestry Committee on January 27, 2004

Chairman Cochran asked:
"You recommend that specified risk materials from cattle over 30 months of age should not enter the human food chain or animal food chain, and that that recommendation has been proposed by the World Health Organization. What is the position of the World Organization for Animal Health (OIE) on this recommendation?"

My supplemental answer is:
The WHO makes a blanket recommendation of excluding SRMs in food or feed. On the other hand, the World Organization for Animal Health (OIE) recommends banning SRMs from food, feed, cosmetics and other uses by degree of risk, and the age of animals at the time of slaughter (Animal Health Code - Article 2.3.13.19).

At the highest risk category (countries with many cases of BSE), the OIE recommends the removal of all SRMs (including intestines and few other risk tissues) from cattle over 6 months of age.

In countries in the moderate risk category the OIE recommends the removal of SRMs (not including intestines) from cattle over 6 months of age.

In countries with minimal BSE risk (such as is the case in the US at this time), the OIE recommends the removal of SRMs (not including intestines) from any cattle over 30 months of age.

Thus, my recommendation combines the OIE recommendation for countries of low BSE risk with the mandatory elimination of SRMs from downers, as banned by the USDA. None of these risk materials should be used for human food or for animal feed.

QUESTIONS AND ANSWERS

JANUARY 27, 2004

COMPLETION OF BSE INVESTIGATION AND LIFTING OF IMPORT BANS

Senator Crapo Question: So far, three cows from the indexed heard have been found in Idaho. This is obviously of great concern to Idaho cattle operations, and they are dependent on timely and accurate information provided by USDA and the State. It would be of great assistance to them to have an understanding of the timeline expected for completion of the investigation and lifting of export bans.

Is there an estimate of when we can expect these to occur?

Answer: USDA has engaged in many bilateral approaches to get our most important export markets open again. I have personally addressed the issue of lifting export bans with my counterparts from Japan, Mexico, and Canada. I have sent high-level delegations to Japan, Korea, Mexico, China, Hong Kong, and the Philippines and we have maintained daily contact with officials in Canada. In addition, we have hosted teams from the government and private sector from Japan and Mexico and expect a Korea team come to the United States. Markets in Canada, the Philippines, and the Bahamas remain open to U.S. beef products.

We are in daily discussions with Mexican officials and we are working on ways to address their requests for assurances. We continue to work with officials in Japan, Korea, and other markets to get them to open their markets to U.S. beef.

Cattle operators can get up-to-date BSE information from USDA's special BSE website: http://www.aphis.usda.gov/lpa/issues/bse/bse.html

BSE SPECIAL ENVOY

Sen. Baucus Question 1, 2: Secretary Veneman, 10 percent of our beef market—worth over $3 billion was exported in 2003. Since December 23rd, live cattle prices have dropped 15-20%. As you said, prices are on the rise and domestic demand has remained high and has prevented further price decreases in the market. In a few months, however, when our cattle producers begin bringing more cattle into the market, our U.S. beef supply will increase and it will be imperative that we re-open our export markets to maintain current prices.

I commend USDA officials' efforts to negotiate with Japan, South Korea, Mexico and Canada to re-open these markets. I do, however, feel it is necessary to appoint a special envoy, whose primary duty is to work with our trading partners to re-open these markets. USDA officials have many hats to wear and a special envoy would be able to focus solely on opening our beef export markets. I, along with 13 other Senators sent you a letter on January 7, requesting USDA to appoint such an envoy. Do you plan to appoint a special trade envoy to work with our trading partners on BSE related issues? If not, why?

Answer:

- Regaining our export markets is a top priority for the Administration. USDA has taken extraordinary steps to reassure our trading partners of the safety and wholesomeness of U.S. beef and re-open our foreign markets.

- Within days of the initial BSE finding, USDA began engaging our most important export markets. We have sent high-level delegations to Japan, South Korea, Mexico, China, Hong Kong, and the Philippines and maintained daily contact with officials in Canada. I have personally addressed these issues with my counterparts from Japan, Mexico, Canada, and the Philippines.

- To complement high-level bilateral discussions, we have hosted technical teams from the government and private sector from Japan and Mexico. In addition, USDA staff at our overseas embassies have continuously advised foreign governments of the actions we have taken and reassured them of the safety of our beef.

- Please be assured that USDA has committed and will continue to commit the resources and energy necessary at all levels to resolve this situation and resume normal trade. Our efforts to restore our foreign markets and resume trade based on scientific principles have been proactive, aggressive, and ongoing.

- Your suggestion to dedicate a special envoy is one we will certainly consider as USDA presses forward with all of the resources we can bring to bear in this endeavor.

Sen. Baucus Question: How long will it take for countries to lift their bans on U.S. beef?

Answer: USDA officials continue to provide U.S. trading partners and international animal health officials with information regarding the steps we have taken in response to the detection of a single case of BSE. We believe sound science is the basis for trade agreements with foreign countries, and we are pressing our case through the World Organization for Animal Health (OIE) and directly with our trading partners so that safe trade of U.S. beef can resume.

In response to recommendations we received from an international panel of experts and to further assure our trading partners of our very low BSE risk, we have developed an outline for an intensive national BSE surveillance plan. The goal of the new plan is to test as many cattle in the targeted high-risk population as possible in a 12-18 month period, and then evaluate future actions based on the results of this effort. The plan also incorporates random sampling of apparently normal, aged animals at slaughter. More intensive surveillance will allow us to refine our estimates of the level of disease present in the U.S. cattle population and provide consumers, trading partners, and industry better assurances about our BSE status.

We do not have a set timeline of when all markets will open again to U.S. beef and beef products. However, we are pleased to announce that on March 3, 2004, Secretary Javier Usabiaga of Mexico announced that he was reopening the border to U.S. beef products.

Sen. Baucus Question: What kind of timeline are you envisioning for an animal identification system and what would this system look like? What actions are you taking to ensure that cattle producers are not overburdened by the costs of a national ID system?

Answer: At the present time, USDA is focused on identifying the requirements and proper architecture for a national animal identification system, and then delivering this system in a cost-effective manner. USDA believes that with proper funding, plus the support from Congress, states, and industry, a system can begin deployment in fiscal year 2004. Every effort is being taken in the design of this system to ensure it is technology neutral, cost-effective, and does not place an undue cost burden on a producer. The USAIP plan is a strong component of the USDA approach. Consideration is being given as to ways to integrate premises that treat branded animals into the national system.

MOUTHING RULE

Sen. Baucus Questions 3, 4:

The United States has the safest food supply in the world and these additional protections will make our food supply even safer. I appreciate your actions to safeguard our nation's food. I am concerned, however, about USDA's decision to determine the age of cattle by "mouthing". Using this method, a cow with three teeth would be considered over 30 months old and a cow with two teeth would be considered under 30 months old. I grew up on a ranch and I know that this method of determining the age of cattle is not exactly based on science. It is possible for a cow under 30 months to have four teeth.

Packers are discounting cattle over 30 months by 15%. This adds up to about $200 per animal. That adds up quickly to real dollars. There is too much at stake to risk inaccuracy in determining the age of cattle. Why was the mouthing method chosen to determine age? Are you exploring other methods to determine the age of cattle? I encourage you to look at alternatives to determining the age of cattle.

Answer: On January 12, 2004, FSIS issued an interim final rule declaring that skull, brain, trigeminal ganglia, eyes, portions of the vertebral column, spinal cord and dorsal root ganglia of cattle 30 months of age and older, and the distal ileum of the small intestine and tonsils of all cattle are specified risk materials, thus prohibiting their use. The same day, FSIS issued FSIS Notice 5-04 to provide guidance to Veterinary Medical Officers (VMOs) for the procedures for determining whether cattle presented for slaughter are 30 months of age and older.

When cattle are presented for slaughter, VMOs must first examine establishment documents that report the age of the cattle. Such documents include a verification letter, birth records, or other form of documentation. If the VMOs conclude that the records are accurate and reliable, then they will be accepted as verification of the age of the cattle. However, if there is no documentation, or if the VMOs find significant reasons to question the validity of the records, then the VMOs will verify the age of the cattle through dental examination. Thus, the dental examination is a secondary means of age determination, used only as a last resort. In cases in which the dental exam must be used, VMOs are to consider cattle to be 30 months and older when the dentition of the cattle shows that at least one of the second set of permanent incisors has erupted.

USDA recognizes that the permanent incisors in cattle may in some cases erupt sooner than 30 months of age, but the Department has determined that the described dentition procedure will be most protective of public health. In our Interim Final Rule, we requested comment on this issue. We will evaluate these comments, including any alternatives suggested, prior to finalizing the rule. We will accept public comments on the Interim Final Rule until May 7, 2004.

COUNTRY OF ORIGIN LABELING

Sen. Baucus Question 5, 6: Maintaining consumer confidence in beef is of the utmost importance. Country-of-origin labeling is an important marketing tool for cattle producers and an invaluable informational tool for consumers. What is USDA doing regarding the implementation of this law? Do you anticipate USDA making any changes to the current rules?

Answer: On January 27, 2004, President Bush signed the fiscal 2004 Omnibus spending bill which, among other provisions, delays implementation of mandatory country of origin labeling (COOL) for all covered commodities except wild and farm-raised fish and shellfish until September 30, 2006.

USDA is currently in the rulemaking process. The comment period for the proposed rule which was published in the Federal Register on October 30, 2003, ended on February 27, 2004. USDA is evaluating all of the comments received and will make changes to the proposal as appropriate.

ANIMAL IDENTIFICATION SYSTEM

Sen. Baucus Question 7: Secretary Veneman, I understand that USDA has been working on implementing a national animal ID system. What kind of timeline are you envisioning for such a system and what would such a system look like? Also, what actions are you taking to ensure that cattle producers are not overburdened by the costs of a national ID system? Montana utilizes branding laws to trace animals. This system is highly effective for our state and I encourage USDA to allow this system to be integrated into any national animal ID system that is put in place.

Answer: At the present time, USDA is focused on identifying the requirements and proper architecture for a national animal identification system, and then delivering this system in a cost-effective manner. USDA believes that with proper funding, plus the support from Congress, states, and industry, a system can begin deployment in fiscal year 2004. Every effort is being taken in the design of this system to ensure it is technology neutral, cost-effective, and does not place an undue cost burden on a producer. The USAIP plan is a strong component of the USDA approach. Consideration is being given as to ways to integrate premises that treat branded animals into the national system.

By technology neutral we mean that the system requirements will be such that all existing forms of effective identification technologies and new forms of technologies that may be developed in the future may be utilized. We expect that identification technologies used will be worked out through cooperative agreements with producers, states and others, rather than having one entity dictate a specific technology for all market participants. Producers, working with state animal health officials and others, can work out the most cost-efficient technology to use for their region and types of operations. Consideration is being given on ways to integrate premises identification in states with branded animals into the national standards and repositories. This would be addressed in the cooperative agreements with USDA.

Livestock Risk Protection (LRP)

Senator Grassley's Question: How is it that we approximately doubled our participation with Fed Cattle and Feeder Cattle in the Livestock Risk Protection program on the day of your announcement? Is it true that LRP for cattle was left open for a couple hours after you announced the positive cow?

Answer: The coverage prices offered under the LRP plan of insurance are determined using a methodology that looks at the Chicago Mercantile Exchange (CME) futures contract prices for live cattle and feeder cattle prior to and following the end of insurance date. The methodology then projects what the price is expected to be on the date at the end of insurance. The rating methodology assumes an implied volatility in market prices of 12.5 to 17 percent for feeder cattle and 13 percent for fed cattle (based on historic prices.) If the market is limit down, the LRP policy says that there may be no sales the next day. This is because when the market price is artificially stopped (futures limit down), the futures market no longer reflects the actual cash market, which can adversely effect actuarial soundness.

Coverage prices (the expected price at the offered coverage levels (95-70%)) and rates, are calculated daily and sales begin the following day. Therefore, on December 23, coverage prices were based on market information from December 22. The BSE announcement was made after market hours on the 23rd. At that point producers had a reasonable expectation that prices would decrease sharply the following day. Since the December 22 price was determined before the BSE announcement and producers had a reasonable expectation that the LRP coverage price would be significantly higher than the CME contract price, there was a sales surge.

After Secretary Veneman announced the BSE finding on December 23, 2003, RMA responded with a review of the terms of the Livestock Risk Protection (LRP) Insurance Policy, the potential impact on the LRP insurance plan and rate structure and, in consultation with USDA's Office of General Counsel, determined that the risks were excessive and suspended sales of the product. This was accomplished in approximately 2 hours after the BSE announcement. During a subsequent briefing of these events on December 24, the FCIC Board of Directors affirmed its belief that RMA acted quickly and responsibly to the announcement.

During the 2-hour period the amount of LRP Fed and Feeder cattle coverage in force (liability), increased from $58.6 million to $127.3 million.

Sen. Harkin Question 1, 2, 3: The United States currently utilizes a targeted screening program for BSE that focuses on testing nonambulatory cattle or cattle exhibiting neurological disease. Considering that a BSE–positive cow may not necessarily show clinical symptoms, and may not be a downer animal, how can we be confident we would not miss an asymptomatic, BSE-positive cow. What prevalence of BSE is our testing system currently designed to catch, and what prevalence should it be targeted at? Has USDA considered testing regimes that will ensure that we have a handle on the actual prevalence of BSE in the United States? Given that the United States very likely has a much lower prevalence of BSE in its cattle herds than the United Kingdom or European Union, how many cows should we be testing to make sure that we could find the disease if it were here? Forty thousand, 100,000 or every cow over a certain age as some others have suggested?

Answer: USDA, in cooperation with the Food and Drug Administration, has developed an outline for a new intensive national BSE surveillance plan. Previous targeted surveillance efforts were designed to detect BSE in the adult cattle population at the level of at least one infected animal per million adult cattle with a 95 percent confidence level. The goal of the new plan is to test as many cattle in the targeted high-risk population as possible in a 12-18 month period, and then evaluate future actions based on the results of this effort.

The key to surveillance is to look where the disease is going to occur. There is significantly better chance of finding the disease if you look within the targeted high-risk population. In Europe, where 9 million "apparently healthy" animals were tested from January-December 2003, there were 274 positive animals (a percentage of 0.003). In comparison, Europe found 307 positive animals in the suspect population, a percentage of 11, and 780 in the at-risk population, a percentage of .05. (At-risk population includes fallen stock and emergency slaughter).

Having said this, the USDA plan also incorporates random sampling of apparently normal aged animals at slaughter. More than 86 percent of all adult cattle processed annually are slaughtered in 40 plants; random sampling efforts will be focused on these plants. We plan on testing at least 20,000 BSE slaughter samples from healthy, aged bulls and cows.

More intensive surveillance will allow us to refine our estimates of the level of disease present in the U.S. cattle population and provide consumers, trading partners, and industry better assurances about our BSE status. Testing will be conducted at USDA's National Veterinary Services Laboratories and at participating contract laboratories. As an example, if a total of at least 268,444 samples is collected from the targeted population, this level of sampling would allow USDA to detect BSE at a rate of 1 positive in 10 million adult cattle (or 5 positives in the entire country).

Sen. Harkin Question 4: Secretary Veneman, USDA has proposed to ban the use of AMR on parts of cattle that might contain SRMs, basically the head and spinal column of cattle over 30 months of age. How will USDA ensure that companies do not use AMR or SRMs from cattle over 30 months of age? Would this require segregation of cattle by age? If USDA finds central nervous system tissue in a beef product, how would USDA verify it came from an animal under 30 months of age?

Answer: FSIS is requiring federally-inspected slaughter establishments that slaughter cattle to segregate cattle 30 months of age and older from younger cattle. A plant may choose not to segregate cattle, however; the plant would then have to treat all cattle as if they were over 30 months of age, and thus could not produce beef AMR product. Slaughter facilities must also determine how they will determine the age of cattle, such as through records and dentition. Establishments must incorporate these procedures into their Hazard Analysis and Critical Control Point (HACCP) plans or in their Sanitation Standard Operating Procedures (SOP) or other prerequisite program.

When cattle are presented for slaughter, FSIS Veterinary Medical Officers (VMOs) must first examine establishment documents that report the age of the cattle. Such documents may include a verification letter, birth records, or other form of documentation. If the VMOs conclude that the records are accurate and reliable, then they will be accepted as verification of the age of the cattle. However, if the VMOs find reason to question the validity of the records, or if there are no records, then they must verify the age of the cattle through dental examination. Thus, the dental examination is a secondary means of age determination.

Under the Interim Final Rule, all Federal establishments that utilize AMR systems must now have written procedures that include testing of product to ensure that there is no central nervous system tissue or excess bone solids and bone marrow. Establishments may have their procedures included in their Hazard Analysis and Critical Control Point (HACCP) plans or Sanitation Standard Operating Procedures (Sanitation SOPs) to include controls to ensure that products do not contain prohibited materials.

Any AMR product containing central nervous system tissue from cattle of any age is considered misbranded. In addition, any AMR product produced that contains specified risk material from cattle over 30 months of age is considered inedible and cannot be used for human food. If these materials are inadvertently used in an AMR system, the product will be considered adulterated. If FSIS sampling shows that prohibited tissues are present in AMR products, then inspection program personnel will initiate enforcement actions that may include retention of the product, withholding the marks of inspection and/or suspension of the assignment of inspection program personnel. Neither the product nor the equipment can be used until satisfactory corrective action has been taken. Inspection personnel will also conduct follow-up sampling. If the establishment has distributed the sampled product then a recall will be initiated. If the establishment has not distributed the sampled product then inspection personnel will verify any action taken to correct the problem.

Sen. Harkin Question 5: Is meat containing central nervous system or brain tissue from cattle over 30 months of age going to be considered adulterated, or just mislabeled, as is the current practice?

Answer: Pursuant to FSIS regulations, specified risk material from cattle 30 months of age and older is considered "inedible." Based on the Federal Meat Inspection Act, such product will therefore be considered adulterated, as it is unfit for human food.

Sen. Harkin Question 6, 7: With USDA's ban on downer animals, some have questioned how USDA is going to ensure that cattle exhibiting neurological symptoms or are nonambulatory get tested—since they can no longer be brought to slaughter. How and when will APHIS assure that animals with neurological symptoms and downer animals will be tested?

Answer: Throughout our surveillance program, APHIS has continued to work with facilities other than federally inspected slaughter establishments as part of our targeted efforts. This has included working with renderers, salvage slaughter facilities (i.e., not slaughtered for human consumption) and other animal disposal industries. We will build on these efforts to ensure that we maintain access to our targeted surveillance population.

Samples will be collected at any of the following sites as necessary:

- State or Federally inspected slaughter establishments
- Custom exempt slaughter establishments.
- On-the-farm.
- Rendering facilities.
- Landfills
- Veterinary diagnostic laboratories.
- Animal feed slaughter facilities, i.e. pet food plants.
- Public health laboratories – Rabies negative cases.
- Veterinary clinics or other sites that accredited veterinarians might utilize.

Veterinary Services' officials across the country will work closely with their State counterparts to build on existing relationships at these locations so that we can obtain the necessary samples.

Payment for services will help cover additional costs incurred by producers and the industries participating in our surveillance program. For example, costs for transporting an animal or carcass to the collection site from a farm, slaughter establishment, etc. may be reimbursed, or disposal expenses for "suspect" cattle that test non-negative or that can't be rendered may also be covered. Other expenses may also be addressed in the program.

Sen. Harkin Question 8: Will State Agriculture Departments and State Veterinarians get the support they need to assist USDA in a broader testing program?

Answer: USDA will be working with State officials, veterinary organizations, producers and affiliated industries to ensure that we achieve our surveillance goals. State animal health officials will be an important part of this effort and will be provided support as necessary. Sampling will be conducted by authorized State or Federal animal health or public health personnel, accredited veterinarians, and trained State or APHIS contractors. Scientists with our National Veterinary Services Laboratories will train collectors in how to obtain a sample, package it, and ship it to a laboratory for testing. Available training materials including videos, CDs, and manuals will also be provided. In addition, necessary safety equipment, such as gloves and protective clothing will be supplied along with sampling supplies.

State veterinary diagnostic laboratories that participate in this intensive surveillance effort will be contracted on a fee-for-service basis. Laboratories will be selected based on a number of criteria, including the geographic location and whether the lab currently contracts with APHIS for chronic wasting disease or scrapie testing. State-of-the-art equipment, such as robotics systems, will be purchased for a limited number of laboratories that test high numbers of samples.

IMPORT BANS AND FOREIGN TEAM VISITS

Sen. Harkin Question 9: How many countries that have imposed beef import bans, and how many have sent or plan to send teams to the United States to look into our investigation? How do you plan to handle these requests?

Answer: Fifty-five countries have imposed import bans on various types of U.S. beef products. To date, only Japan and Mexico have sent teams to the United States. We expect that a Korean team will also visit the United States soon. Requests for team visits are being handled through a partnership between private sector and government agencies, including USDA's Foreign Agricultural Service (FAS), Animal and Plant Health Inspection Service (APHIS), and Food Safety Inspection Service (FSIS).

In addition to the teams coming to the United States, we have sent high-level delegations to Japan, Korea, Mexico, China, Hong Kong, and the Philippines and maintained daily contact with officials in Canada.

BEEF EXPORT VERIFICATION (BEV)

Sen. Harkin Question 10: Last summer, in response to Japanese concerns about the presence of Canadian beef and cattle in the United States, USDA established a voluntary program for meat packers to identify and segregate U.S. beef for shipment to Japan, called the Beef Export Verification program, or BEV. If the government of Japan continues to insist on 100 percent testing of our cattle for BSE, would it be feasible to incorporate such testing within BEV?

Answer: Expanding the Beef Export Verification program (BEV) to include 100 percent testing of cattle for BSE is something that would have to be looked into further. As USDA has stated, and an international panel on BSE concluded, testing of all cattle is not scientifically justified.

ELIGIBILITY FOR TRADE ADJUSTMENT ASSISTANCE

Sen. Harkin Question 11: Would workers at beef packing plants who lost their jobs due to closed export markets be eligible for help under Trade Adjustment Assistance programs?

Answer: Under the Trade Adjustment Assistance for Farmers Program administered by USDA, only producers of agricultural commodities (in their raw or natural state) are eligible for program benefits; therefore, packing plant workers would not qualify.

In addition, the Trade Act of 2002 stipulates that prices must be at least 20 percent below the previous five year average price and that imports contributed importantly to the decline in price.

Sen. Harkin Question 12: As to the animal identification program, I would like to ask a couple questions related to how the program would affect smaller, independent producers. One of my main concerns is that the program might encourage vertical coordination because retailers or processors might require proprietary systems. If this scenario occurs, then once the farmer chooses to set up his farm for one processor, he may essentially foreclose possibility to sell to other processors. Does this suggest that a uniform system across the industry would be the best approach?

Answer: USDA's goal is to create an effective, uniform, consistent, and efficient national system. We believe this goal can be achieved by adhering to several key objectives.

First, the system should allow producers, to the extent possible, the flexibility to use current systems or adopt new ones. Producers should not be burdened with multiple identification numbers, systems, or requirements. Second, this flexibility can best be achieved by having a system that is technology neutral, so that all existing forms of effective technologies and new forms of technologies that may be developed in the future may be utilized. We expect that technologies used will be worked out through cooperative agreements with producers, states and others, rather than having one entity dictate a specific technology for all market participants.

Third, the national identification system should use and build upon the excellent data standards developed by the U.S. Animal Identification Plan. Provisions to ensure data confidentiality are an essential part of this objective.

One fundamental requirement should be uniform data standards that would allow the producer to identify cattle in a variety of ways, leverage existing operations when possible, and only pass data to a National Repository, or service provider, not require an interface with the next premises. The next premises would need to record the id on each animal, or collect the data from the previous premises, then also pass to the National Premises or Service Provider.

It is important to note that in many cases, a premium is being paid to producers for the providing data on the details of the animal's production.

Fourth, the system must not preclude producers from being able to use it with production management systems that respond to market incentives. We want a system that will be compatible with the alternative management programs now being used to improve animal health and quality.

Fifth, the architecture for the national identification system must be designed so that the system does not unduly increase the role and size of the government.

Sen. Harkin Question 13: Also concerning smaller farmers, as you have developed this program, have you considered ways to make sure that smaller producers are not disproportionately affected by the program? For instance, if the program requires high fixed costs for farmers, such as readers or database resources, have you considered trying to help farmers with those costs?

Answer: USDA's interests are in setting information standards, developing a database system to which states and other entities can readily connect, and receiving data from these entities. One of our objectives is to be flexible and enable producers to use existing systems for animal identification to the extent possible. We also desire to be technology neutral so that producers, working with state animal health officials and others can work out the most cost-efficient technology to use for their region and types of operations. Many issues must be resolved before we can accomplish the task of implementing a national identification program. We will continue to work with the nation's producers, industry, and the Congress to address all the issues associated with the program.

Sen. Harkin Question 14, 15: Does USDA have any concerns that downed animals will not be disposed of properly? Is there an animal disease risk if farmers start trying to dispose of more downers on their farms rather than taking them to rendering? How would USDA address such a risk?

Answer: USDA has been examining the risk of animal disposal as part of our overall approach to BSE. Specifically for BSE, there is not a significant animal disease risk if producers decide to bury an animal on their farm rather than taking it to rendering. BSE is transmitted through feed, so burial would prevent any transmission. USDA continues to work with our colleagues in FDA, EPA and State and local agencies to ensure adequate disposal options are available as necessary.

COUNTRY OF ORIGIN LABELING (COOL)

Sen. Harkin Question 16, 17:

Secretary Veneman, you have expressed at least your qualified support for an animal identification program because you believe that government health officials will need to have herd-location information should a disease outbreak occur. Yet USDA has expressed that it wants the country of origin labeling program to be delayed, as it was under the 2004 omnibus appropriations bill.

Could you explain why it is advisable for the government and much of the meat industry to know the origin of their livestock and meat, while you don't think that consumers should have that knowledge?

Answer: A comprehensive animal identification program will help to speed response times in the event of an intentional or unintentional animal disease outbreak, which will greatly aid government health officials to minimize negative impacts on animal and human health. As mandated by Congress, the Country of Origin Labeling program will not accomplish this task. I do not oppose consumers having country of origin information, but I see no compelling reason to make such marketing information mandatory. Knowledge of the origin of animals used to produce meat products already could be provided through the market place if consumers were willing to pay the price premiums that would be necessary. This has not happened. To impose a requirement that such information be conveyed when the costs of doing so exceed the benefits seems inconsistent with observed consumer behavior.

Sen. Harkin Question 18:

Secretary Veneman, you have mentioned that country of origin labeling is a targeted retail marketing tool, not a food safety or animal health program. I think everyone would agree with you on that point. USDA appears to be embracing an animal identification system, but continue to downplay the importance of country of origin labeling. Would you prefer there was an animal ID system in the U.S. rather than country of origin labeling?

Answer: These two programs serve vastly different purposes. Given that country of origin labeling is strictly a marketing tool whereas an animal ID system enhances our ability to stop the spread of animal diseases, I do believe the implementation of an animal ID system is more critical.

Sen. Harkin Question 19:

You have stated that you supported the delay in country of origin labeling in order for Congress to make some refinements to the law. Do you consider animal ID to be one of those refinements to the COOL law?

Answer: The purpose of a national ID system is fundamentally different from mandatory COOL.A national ID system addresses public health and animal health risks. Country of Origin Labeling is marketing program.

Sen. Harkin Question 20: Why has the U.S. chosen 30 months as the "age of concern" for defining Specified Risk Materials while the EU has chosen an age of 12 months?

Answer: The U.S. chose 30 months as the "age of concern" because this is consistent with Office International des Epizooties (OIE) Standards, based upon a country's perceived level of risk associated with the prevalence of BSE in that country. Furthermore, following the U.S. BSE finding, I directed an international team of experts to review U.S. actions. The report indicated that the U.S. ban on specified risk materials (SRM) from cattle over 30 months of age removes the highest risk tissues from the human food supply and is in accordance with international standards.

Sen. Harkin Question 21: Since BSE can be detected in animals younger than 30 months, how confident are scientists that there is no risk of material from cows under 30 months being infective?

Answer: FSIS considered extensive data from studies done in the United Kingdom, as well as the findings of the BSE risk assessment conducted by Harvard University, to determine which cattle parts should be removed from the human food supply. Data on the age distribution of clinical cases of BSE in the field reported in the U.K. indicate that clinical BSE disease has rarely been reported in cattle younger than 30 months of age. Of the cattle that developed clinical BSE in the field, only 0.01% were less than 30 months of age. In addition, scientific evidence demonstrates that a feed ban is critical for preventing exposure to BSE-infected materials. The U.S. would not expect cattle under 30 months of age to demonstrate BSE infectivity because the U.S. has had a feed ban in place for almost seven years.

Following the U.S. BSE finding, I directed an international team of experts to review U.S. actions. The report indicated that the U.S. ban on specified risk materials from cattle over 30 months of age removes the highest risk tissues from the human food supply and is in accordance with international standards.

Sen. Harkin Question 22: Is there a period where prions are detectable in an animal, but not believed to be infectious?

Answer: This is a difficult question to answer, as there are still many unknowns in reference to BSE and other TSEs. For example, there are still differing theories about the nature of causative agent of BSE, which is yet to be fully characterized. The prion theory is the most widely accepted at this point in time. Similarly, while there has been a significant amount of research on different aspects of tissue infectivity, there has not been a specific study conducted that directly examines all links between a detectable presence of prions and its relationship to infectivity.

There are a lot of unknowns that relate to the issue of what tissues might be infectious and when. For example, research has demonstrated that as little as 0.01 grams of infected bovine brain tissue can cause disease when fed directly to a calf. However, no similar information is known on the amount of infected bovine brain tissue that would cause disease in humans, although it is assumed to be at least 10,000 times more than that for cattle.

As another point, the research that forms the basis of the definition of SRMs did not identify prions in these tissues. Instead, it actually demonstrated infectivity – these tissues caused disease when given to other animals. Other tissues demonstrated no infectivity, and therefore are assumed to be lower or negligible risk for transmission of disease.

Senator Harkin Question 23:

Does the Animal Health Protection Act provide the Federal government the authority to enforce animal feed restrictions (including the imposition of monetary penalties), since violation of feed ban restrictions presents a risk to the health of livestock?

Answer: The current feed ban was issued as a regulation by the Food and Drug Administration (FDA) under its authorities in the Federal Food, Drug, and Cosmetics Act (FDCA). Since this regulation was issued under the FDCA, USDA would not have the authority to enforce these specific regulations.

The Animal Health Protection Act provides the Secretary with the authority to carry out operations and measures to detect, control, or eradicate any livestock pest or disease. Under this law, the Secretary may also prohibit or restrict the importation, entry, or interstate movement of any animal, article, or means of conveyance to prevent the introduction into or dissemination within the United States of any livestock pest or disease. An article is defined as any pest or disease or any material or tangible object that could harbor a pest or disease.

While USDA might be able to issue regulations over animal feed under its authorities in the Animal Health Protection Act, FDA has the expertise on animal feed, as well as an established system to inspect feed mills and other persons in the animal feed distribution chain. As the agency with regulatory authority over food for animals, it is appropriate for FDA to continue to address the BSE issues related to animal feed. USDA supports FDA's efforts to enforce the feed ban, on of the critical safeguards in our BSE prevention strategy.

BSE TESTING

Sen. McConnell, Question 1: In your testimony, you mentioned the development of rapid BSE tests for cattle. Given the volume of the cattle that we consume, what is the potential cost of such tests should they be required for all cattle slaughtered in the United States?

Answer: It is important to clarify the objective of our BSE testing program. USDA's testing is for the purpose of disease surveillance. The BSE surveillance testing program gauges animal health by identifying the statistical likelihood that the disease is present in the United States.

Under our new surveillance plan, USDA plans to test as many cattle in the targeted high-risk population as possible in a 12-18 month period, and then evaluate future actions based on the results of this effort. The plan also incorporates random sampling of apparently normal, aged animals at slaughter. More than 86 percent of all adult cattle processed annually are slaughtered in 40 plants; random sampling efforts will be focused on these plants.

More intensive surveillance will allow us to refine our estimates of the level of disease present in the U.S. cattle population and provide consumers, trading partners, and industry better assurances about our BSE status. Testing will be conducted at USDA's National Veterinary Services Laboratories and at participating contract laboratories. As an example, if a total of at least 268,444 samples are collected from the targeted population, this level of sampling would allow USDA to detect BSE at a rate of 1 positive in 10 million adult cattle (or 5 positives in the entire country).) with a 99 percent confidence level. This is greater than the standard of one positive in one million with a 95 percent confidence level. We also plan on testing at least 20,000 BSE slaughter samples from healthy, aged bulls and cows.

The international standard setting organization—the World Organization for Animal Health—recognizes that focusing all BSE surveillance efforts on testing apparently healthy animals is not the most efficient or effective method of actually finding disease.

The cost for a rapid test kit is up to $25 per test. With an excess of 35 million animals slaughtered each year, the approximate cost for the test kits alone would be $875 million. However, there are other costs involved in testing the animals. These costs include sample collection, shipping, handling, processing, lab support, equipment, disposal, etc. Because of these other costs, we have estimated that the total cost of testing would be $175-$200 for each animal. Thus our total cost of testing every animal would be between $6 billion and $7 billion. In addition to Federal costs, the private sector would also incur $x/substantial/additional costs to accommodate USDA test and hold requirements.

We must also clarify that BSE testing in and of itself does not ensure food safety; rather, it is the removal of specified risk materials from the human food chain, along with the other safeguarding measures administered by USDA's Food Safety and Inspection Service that provide the greater assurances of food safety. The specified risk material ban greatly minimizes the potential for human exposure to those materials that studies have demonstrated may contain the BSE agent in infected cattle.

Sen. McConell Question 2: Shortly following the finding of BSE in Washington state, you issued a number of interim final rules aimed at further protecting the food supply and ensuring trading partners that the United States was doing all it could to safeguard the food supply. The regulations call for many changes in the processing of cattle. How will these interim rules affect trade with other countries who produce and export beef into the United States? Will they be required to meet these new standards? How much time will be given to these countries for them to comply?

Answer: Meat and poultry products imported into the U.S. must meet all safety standards applied to foods produced in the U.S. The new regulations related to the December 2003 discovery of a cow with bovine spongiform encephalopathy (BSE) must also be addressed by exporting countries. While foreign food regulatory systems do not need to be identical to the U.S. system, all foreign countries wishing to import meat, poultry, or egg products into the U.S. must employ equivalent measures that provide the same level of protection against food safety hazards.

Ten countries currently export beef to the U.S., including Argentina, Australia, Brazil, Canada, Costa Rica, Honduras, Mexico, Nicaragua, New Zealand, and Uruguay. The Food Safety and Inspection Service (FSIS) sent letters to each of these countries regarding the new BSE-related regulations. All 10 countries have responded as to how they will adopt these or equivalent measures. FSIS will verify implementation during onsite audits of the countries this year.

Sen. McConnell BSE Test, Question 3: Regarding the prohibition of downer cattle in the food supply, if there is no market for non-ambulatory livestock, is it not possible that animal disease and infection may go unnoticed simply because these animals will never be presented to USDA veterinarians. Had non-ambulatory livestock been prohibited from the food supply prior to the finding of this case, how likely would this case of BSE have been discovered? Is the USDA considering compensating producers for bringing in downed cattle as a means of encouraging producers to bring cattle in to be inspected?

Answer: Throughout the history of our surveillance program, APHIS has worked to obtain samples from the targeted animal population, wherever these animals may be located. In order to obtain the samples, APHIS has worked with facilities other than federally inspected slaughter establishments as part of BSE surveillance efforts. These facilities included renderers, salvage slaughter facilities (i.e., not slaughtered for human consumption) and other animal disposal industries.

Under our new surveillance program, we will build on these efforts to ensure that we maintain access to our targeted surveillance population.

Samples will be collected at any of the following sites as necessary:

- State or Federally inspected slaughter establishments
- Custom exempt slaughter establishments.
- On-the-farm.
- Rendering facilities.
- Landfills
- Veterinary diagnostic laboratories.
- Animal feed slaughter facilities, i.e. pet food plants.
- Public health laboratories – Rabies negative cases.
- Veterinary clinics or other sites that accredited veterinarians might utilize.

Veterinary Services' officials across the country will work closely with their State counterparts to build on existing relationships at these locations so that we can obtain the necessary samples.

Payment for services will help cover additional costs incurred by producers and the industries participating in our surveillance program. For example, costs for transporting an animal or carcass to the collection site from a farm, slaughter establishment, etc. may be reimbursed, or disposal expenses for "suspect" cattle that test non-negative or that can't be rendered may also be covered. Other expenses may also be addressed in the program.

Sen. McConnell Question 4: Regarding the creation of an Animal ID system, the Commonwealth of Kentucky has invested significant resources in the development of an Animal ID system. I am concerned that there may be some efforts to force a particular tracking technology on producers that may impose further cost on cattle producers in Kentucky who have already taken proactive measures to track cattle using state funds. Can you provide any assurance that the plan will recognize these efforts and remain technology neutral?

Answer: One the key outcomes in the approach that USDA is taking in design of an Animal ID system is the system should be technology neutral without adding extra expense on a producer or state. One fundamental criterion is the core element should be uniform data standards rather than a technology of collecting the data. This would allow the producer to id cattle in a variety of ways, and only pass data to the National Repository not to the next premises. The next premises would need to record the id on this animal, or collect the data from the previous premises.

USDA is examining an approach that would allow states to leverage the investment they have made, and allow them to interface with a national premises and animal identification system. The states would need to conform to data standards that are a key element of the national system.

Sen. McConnell Tobacco Question 5: The Agricultural Adjustment Act of 1938 (1938 Act), authorizes the Secretary of Agriculture to adjust the burley quota formula total up or down by three percent. Why was no adjustment made to the statutory formula total for the 2004 burley quota.

Answer: This decision not to add 3 percent to the quota formula total was based on several items. First, the 1938 Act as amended, limits the reduction in adjusting reserve stocks to the greater of 35 million pounds or one-half of the amount the loan inventory exceeds the mandated reserve stocks level. This year the loan stocks on hand in producer loan associations exceeded the 50 million pound mandated level by 74 million pounds, but by law the reduction was limited to 50 percent of that figure or 37 million pounds. Therefore the quota formula exceeds actual demand by 37 million pounds prior to any adjustment. Additionally, we are concerned that the 3 percent discretionary increase would in the future increase the amount of tobacco received by the tobacco loan associations and this in turn would lead to an increase in the no net cost fee.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Thad Cochran
Chairman
Committee on Agriculture, Nutrition, and Forestry
United States Senate
Washington, D.C. 20510-6000

Dear Mr. Chairman:

Thank you for your correspondence of February 12, 2004, in which you requested responses to questions submitted by Senator Tom Harkin and other questions submitted by Senator Charles E. Grassley. The questions relate to the January 27, 2004, hearing held to examine the situation regarding the discovery of a case of bovine spongiform encephalopathy (BSE) in a dairy cow in Washington State.

We have restated the questions and responded below.

Questions Submitted by Senator Tom Harkin for the Food and Drug Administration (FDA or the Agency):

1. **The expert panel convened to review Canada's response to BSE recommended that Canada ban from its feed and food supply all SRMs from cattle over 30 months of age, and Dr. Torres recommends the same in his testimony. In light of Secretary Thompson's announcement yesterday regarding expanding the feed ban, has FDA considered banning SRMs from cattle over 30 months of age for use in food or feed? If so, what decision has FDA reached?**

As Secretary Thompson also announced on January 26, 2004, the Department of Health and Human Services (HHS) intends to ban from human food (including dietary supplements) and cosmetics a wide range of bovine-derived material including specified risk materials (SRMs) for cattle 30 months or older. FDA continues to consider whether the Agency should take any additional measures to address the risk of BSE in the U.S.

2. **Some scientists have raised the question of whether there is a risk from cattle consuming feed derived from swine and poultry that were fed ruminant protein, and in fact some countries have gone so far as to ban the feeding of any animal protein to livestock. Some have banned only SRMs from being fed to animals.**

- **What do you believe the risk to be of feeding cattle byproducts derived from swine and poultry under our current regulations?**

- **Is there general scientific consensus that there is or is not a significant risk?**

We believe that there is good scientific agreement that feeding swine or poultry-derived protein to ruminants is not a concern because challenge studies have shown their tissues do not contain detectable infectivity. There is no evidence from the scientific literature that a natural transmissible spongiform encephalopathy (TSE) exists in pigs (or poultry or fish). Scientific studies have shown that pigs are not susceptible to BSE after they have been fed large amounts of BSE positive material. There is also no evidence to date that pigs, challenged orally, harbor the BSE agent in their tissues.

The available observations in pigs are in contrast to the susceptibility of cattle to oral infection with less-than-gram quantities of BSE-affected brain and to the major feed-borne cattle epidemic in the UK. The primary concern with feeding porcine or poultry-derived protein to ruminants is the possibility that ruminant feed could be cross-contaminated during feed manufacture and distribution by swine and poultry feed that may contain prohibited protein. Under the 1997 rule, firms are required to maintain written plans that specify their procedures for separating products that contain prohibited mammalian protein from other products.

3. **How does FDA ensure that ruminant and non-ruminant feed do not get mixed up at the farm level? Does FDA monitor this? Who is FDA relying on to assure compliance?**

To prevent feed containing prohibited material from being inadvertently fed to ruminants, the current BSE feed regulation requires that feed containing prohibited material be prominently labeled with the caution statement, "Do Not Feed To Cattle Or Other Ruminants." FDA and its state partners concentrate most of their inspection resources on feed manufacturers, who are at the top of the supply pyramid, to ensure compliance with the regulation. However, the Agency and their state partners conduct some inspections at the farm level. Results of on-farm inspections are included in the inspection database.

While all firms in the non-manufacturing categories have not been identified or inspected, FDA and state authorities have conducted thousands of inspections that are representative of these operations. The Agency and their state partners have conducted over 4,500 inspections alone at farms that feed ruminant animals. We are also expanding our state contract inspections to allow states to conduct more on-farm inspections. In addition, whenever we are at a ruminant feeder for other reasons (e.g., illegal tissue residue), we confirm compliance with the BSE feed ban, and we may, and do, conduct on-farm inspections as follow-up to violative inspections at feed mills. FDA continues to believe that focusing inspectional/enforcement resources at the feed manufacturing end is the best way to assure that prohibited material does not reach ruminant animals and that education is the best way to reach ruminant feeders. Extensive educational efforts, by both government authorities and

industry groups for each of the industry segments, have been an important tool in promoting compliance with the regulation.

Questions Submitted by Senator Tom Harkin for FDA and the U.S. Department of Agriculture (USDA):

1. **Why has the U.S. chosen 30 months as the "age of concern" for defining SRMs while the EU has chosen an age of 12 months?**

   - **Since BSE can be detected in animals younger than 30 months, how confident are scientists that there is no risk of material from cows under 30 months being infective?**

   - **Is there a period where prions are detectable in an animal, but not believed to be infectious?**

While FDA collaborates closely with USDA, we believe this question is best answered by USDA as they take the lead role in protecting the U.S. from foreign animal diseases and for surveillance of the cattle population.

2. **Does the Animal Health Protection Act provide the Federal government the authority to enforce animal feed restrictions (including the imposition of monetary penalties), since violation of feed ban restrictions presents a risk to the health of livestock?**

We believe that this question is best answered by USDA because the Animal Health Protection Act is a USDA authority.

Questions Submitted by Senator Charles E. Grassley for the FDA:

1. **No scientific studies have been published reporting the presence of BSE infectivity in blood from BSE infected cattle. Dr. Crawford, you indicated that BSE infectivity is present in bovine blood. Where is the data that demonstrates the presence of BSE infectivity in beef blood?**

Transfusion studies in sheep indicate that in this animal model the BSE agent can be transmitted by blood. FDA is using this model as a basis for the determination not to allow ruminant blood to be fed to ruminant animals.

2. **A sheep is different from a cow. Tissue distribution of Scrapie infectivity in sheep is different from BSE infectivity distribution in cattle. Just because a**

blood transfusion from a BSE infected sheep transmitted BSE to another sheep does not mean that blood from a BSE infected cow contains the infective agent. Is that not correct?

FDA is using the sheep transfusion model as a basis for its decision not to allow ruminant blood to be fed to ruminant animals, because transfusion studies comparable to the sheep transfusion studies have not been performed in cattle.

3. **The scientific community recognizes that it can not be concluded transfusion with blood from a pre-clinical vCJD donor actually infected the second patient with vCJD. It is possible that both patients contracted the disease by consuming BSE infected meat or by other means of exposure. The FDA's policy is to base regulations on sound science. This policy change appears to be based upon speculation rather than science; can you explain?**

There is a small theoretical possibility that the blood recipient (the second variant Creutzfeldt –Jakob Disease (vCJD) patient) contracted the disease by some exposure other than the transfusion. However, the likelihood of such transmission is estimated to be extremely small; between one in 15,000 and one in 30,000. The fact that the recipient was older than all the other patients with vCJD except one – and in an age group that has thus far been almost completely spared from vCJD – is of special concern.

FDA strongly believes that to continue to protect the public health, the prudent and responsible presumption must be that, unless and until additional scientific evidence suggests otherwise, the blood recipient died with transfusion-transmitted vCJD. The United Kingdom (UK) Transfusion Medicine Epidemiology Review (TMER) was established specifically to detect evidence of blood-borne spread of vCJD. A total of 48 recipients received blood components from donors who later were diagnosed with vCJD. Of these 48 recipients, ten recipients have been under observation for more than five years since receiving a unit from a donor later diagnosed with vCJD. One of these ten has already died of vCJD. FDA is presuming that the second vCJD patient (the blood recipient) contracted the disease from blood due to the following factors: (i) the relatively small number of recipients under surveillance by the TMER has already yielded one vCJD case in only a few years; (ii) the incubation periods of TSE infections in humans can be extremely long (occasionally more than 30 years); and (iii) infectivity has often been detected in blood during asymptomatic incubation periods of animals with a number of TSEs, including BSE. Unfortunately, there is no laboratory test that can definitely establish the source of the recipient's infection- blood-borne, food-borne, or other.

4. **The three-year study by the Harvard Center for Risk analysis assumed that bovine blood contained BSE infectivity below the level of detection of the assays that have been used. When this assumption was included in the model, the practice of feeding blood to cattle did not result in the spread of BSE. In fact, it only contributed an average of 0.11 new cases over a 20-year period. Why is**

the FDA banning the feeding of bovine blood products when the Harvard Risk Assessment clearly showed that this practice would not spread BSE?

FDA believes that it is prudent to take new actions to manage the risks of BSE because of the two cases of BSE found in North America and new evidence of infectivity in blood of other species. The 0.11 new BSE cases from blood predicted by the Harvard risk assessment applies to the base case scenario of ten infected animals. Yet bovine blood products are often fed to young animals that may have the greatest risk of acquiring BSE.

5. **Dr. Crawford referred to the "Buffy Coat" (White Blood Cells) as the likely source of BSE infectivity in bovine blood. The FDA has published a tolerance for Somatic Cells (primarily White Blood Cells) in Grade "A" milk. The FDA allows 750,000 somatic cells/ml of milk. Spray Dried Plasma and Spray Dried Serum products are the primary bovine blood products used in calf supplements which have the majority of the White Blood Cells removed (typically <100 cells/ml remain). A child consuming an 8 oz. glass of milk will consume 1,000 times more white blood cells than a calf consuming a milk replacer supplemented with Spray Dried Plasma or Spray Dried Serum. If BSE infectivity is in the white blood cells, doesn't this suggest BSE infectivity is in milk?**

   - **Would the FDA allow bovine blood fractions to be fed to calves if they contain levels of White Blood Cells that are equivalent to that of Grade "A" milk?**

TSE infectivity has been demonstrated in blood but has not been demonstrated in milk. In addition to the infectivity in the buffy coat, a significant percentage of infectivity in blood is found in the plasma. A comparison of the risks to humans from Grade A milk and risk to calves from milk replacers is not valid because of the species barrier and because infectivity in milk has not been demonstrated for any of the TSE diseases.

6. **Dr. Crawford stated that bovine blood contains BSE infectivity. If BSE infectivity is in bovine blood, doesn't this suggest BSE infectivity is in beef meat?**

In the 1997 feed ban, FDA prohibited the use of mammalian protein in ruminant animal feed except those proteins for which there was scientific evidence showing negligible risk of infectivity, such as milk, blood, and gelatin. In light of the recent studies in sheep that demonstrated transmission of scrapie and BSE infectivity via blood, the Agency is now concerned that blood could contain low levels of infectivity that might be capable of transmitting the disease within the same species. Due to the added protection of a species barrier, such low levels of infectivity would not likely be capable of transmitting disease to humans via blood in meat.

7. **Bovine globulin protein (bovine blood fraction) is being effectively used to control the spread of Johne's in dairy calves. This is an important animal disease that has been linked to Crohn's disease in humans. There are no alternatives to the control of this disease without the use of bovine globulin protein. Why would the FDA ban the use of an effective product that is being used to control an important animal and human health disease because of a theoretical reduction in risk of the BSE?**

If FDA determines that a medical treatment need outweighs the risk associated with the use of a specific product, it could permit the use of the product. Alternately, another product such as the purified immunoglobulin fraction could be used in place of the cruder bovine globulin protein preparation.

8. **Dr. Crawford referred to the "Buffy Coat" (White Blood Cells) as the likely source of BSE infectivity in bovine blood. Commercially available spray dried bovine plasma, serum or globulin protein are isolated from whole bovine blood by centrifugation which removes both the red and the white blood cells. Why wouldn't the FDA consider these blood-derived proteins to be safe?**

The blood-derived proteins referenced in the question might not be safe because of the potential for lysis during the centrifugation process of white blood cells and red blood cells. The lysis could lead to contamination of the spray-dried blood with prions, if they were present in the white blood cells. Several experimental studies have demonstrated that about half the infectivity of TSE agents in whole blood can be found in plasma. This infectivity would still be present in the plasma products after removal of red cells and white cells.

Thank you again for contacting us regarding BSE. If we can be of further assistance, please let us know.

Sincerely,

Michael Eck

for Amit K. Sachdev
Associate Commissioner
for Legislation

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