

**TESTIMONY OF
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UNITED STATES DEPARTMENT OF AGRICULTURE
BEFORE THE U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON AGRICULTURE AND
COMMITTEE ON GOVERNMENT REFORM
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Chairman Davis, Chairman Goodlatte, Mr. Waxman, Mr. Stenholm, and members of the Committees, it is an honor to be with you today to discuss the ongoing activities to protect public health and enhance our food and animal safety systems against Bovine Spongiform Encephalopathy (BSE).

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

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

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

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

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

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

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

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

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

In 1998, USDA asked the Harvard Center for Risk Analysis to investigate the risk of BSE in the United States. In 2001, their report was released. It noted that, because of

the actions taken over the past 15 years, the risk of BSE becoming a widespread epidemic in the United States was extremely low.

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

These included:

- An immediate ban on non-ambulatory disabled (downer) cattle from going into the food chain;
- A “test and hold” policy, which mandates that meat from cattle tested for BSE cannot enter into the food chain until test results come back negative;
- A requirement to remove specified risk materials (SRMs), which can carry the infectivity, from the food supply in order to protect public health;¹
- Enhanced requirements on the use of advanced meat recovery systems. Product produced using advanced meat recovery cannot contain spinal cord or dorsal root ganglia;

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

- A ban on the use of mechanically separated beef from the human food supply;
- And a ban on air-injection stunning.

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

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

International Guidance

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

The International Review Team's report confirmed the epidemiological investigation as well as USDA's actions announced on December 30 to further protect

human health. In briefing me on the report, Dr. Uhli Kihm, the chairman of the team, described the SRM removal as the single most important action to protect public health.

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

Enhanced BSE Surveillance

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

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

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

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

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

The comments of the Harvard Center for Risk Analysis also were supportive. “In summary,” wrote Joshua Cohen and George Gray, “we agree with USDA’s focus on testing high risk cattle.” They noted that USDA faces a challenge in drawing conclusions from its testing program for the prevalence of BSE in the normal cattle populations.

They suggested alternative approaches for consideration. USDA intends to continue consulting with them, as well as others, as we collect the data.

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

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

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

Details of this enhanced plan were made public and posted on the USDA website on March 15. In just two-and-a-half months following that announcement, USDA undertook extensive efforts to implement what amounts to a broad, new surveillance

program. I would add that our BSE response and surveillance plans have proceeded simultaneously with APHIS responses to other major animal and plant disease issues. These include avian influenza, exotic Newcastle disease, soybean rust and sudden oak death. Each one of these has also required a substantial commitment of APHIS program staff and management attention.

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

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

USDA's enhanced BSE surveillance effort would not be possible without additional testing alternatives and increased laboratory capacity to handle the volume of samples submitted as part of the program. To support this component, USDA has issued licenses or permits for five rapid BSE test kits. In addition, 12 public laboratories

strategically located across the country have been approved by USDA to support the surveillance program. These laboratories are all part of an existing network of state and federal labs that assist APHIS with animal-disease testing as needed.

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

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

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

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

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

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

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

We continue activities to inform producers, slaughter facilities, renderers and affiliated industries about our surveillance goals, and to encourage reporting of suspect or

targeted cattle on the farm or elsewhere. These activities include public service announcements, advertisements in trade publications, and presentations to veterinary schools, agricultural colleges, and local farm organizations. In addition, materials will be available on our website for livestock markets, animal health technicians and veterinarians.

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

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

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

USDA agencies are also working together to set up and conduct a quality assurance audit system. Our Agricultural Marketing Service (AMS) will begin a

nationwide evaluation of the APHIS enhanced BSE surveillance program, beginning tomorrow, July 15, at APHIS headquarters and proceeding to regional and state offices later this month. Over a four- to six-week period, AMS will conduct onsite assessments of random locations where surveillance activities occur, with a report issued within four weeks afterward. These assessments will be on-going.

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

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

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

Conclusion

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

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

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