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COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Tom Freedman
OA/Box Number: 17557

FOLDER TITLE:

Food Safety - Mad Cow

2015-0274-S

rc1877

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

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Freedom of Information Act - [5 U.S.C. 552(b)]

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FROM: Andy Solomon

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Pages (including cover sheet) 9

Comments: _____

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DRAFT

Contact: Andy Solomon (202) 720-4623
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USDA CONTINUES EFFORTS TO PREVENT BSE

WASHINGTON, April 24, 1998--The United States Department of Agriculture has entered into a cooperative agreement with Harvard University's School of Public Health to begin an analysis and evaluation of the Department's current measures to prevent bovine spongiform encephalopathy (BSE). The two-year study will review current scientific information, assess the ways that BSE could potentially enter the United States, and identify any additional measures that could be taken to protect human and animal health.

Initiating this study is the latest step in a ten-year record of aggressive measures USDA has taken to prevent the entry of BSE into the United States. In coordination with other government agencies, the USDA BSE Working Group has been regularly reviewing the available science and implementing appropriate regulatory measures to prevent BSE. These measures include the 1989 ban of cattle and cattle products from countries where BSE has been reported, as well as an active inspection, testing, and education program.

No cases of BSE have been diagnosed in the United States.

#

DRAFT

**Backgrounder:
Harvard University-U.S. Department of Agriculture BSE Study**

The United States Department of Agriculture (USDA) is responsible for protecting both human and animal health and for ensuring the safety and security of our food supply. The Department's efforts have been effective in keeping bovine spongiform encephalopathy (BSE), a fatal neurodegenerative disease of cattle, out of the United States.

BSE was first diagnosed in 1986 in the United Kingdom. It has since affected approximately 170,000 cattle in the U.K. and other European countries. Recent scientific studies suggest that BSE may be linked through consumption of BSE-infected tissues to new variant Creutzfeldt-Jakob disease, a fatal neurodegenerative disease in humans.

USDA has taken aggressive measures to prevent the entry of BSE into the U.S. These measures include banning cattle and cattle products from countries where BSE has been reported or where adequate surveillance programs are not in place; monitoring and testing for BSE in U.S. cattle; and educating producers and the public about the disease.

USDA has entered into a cooperative agreement with Harvard University's School of Public Health to begin an analysis and evaluation of the Department's current measures to prevent BSE. Harvard University researchers will review existing science on the disease in order to:

- ▶ characterize the hazards of BSE and other transmissible spongiform encephalopathy agents to human and animal health
- ▶ assess potential pathways that BSE could enter the U.S.
- ▶ evaluate existing USDA regulations and policies
- ▶ identify any additional preventive measures that could be taken

While this study is being conducted, USDA will continue to aggressively test and monitor for BSE and will institute any preventive regulatory measures that are necessary.

DRAFT**USDA Actions to Prevent Bovine Spongiform Encephalopathy (BSE)**

- 1988** Establishes BSE Working Group to regularly review the available science and suggest appropriate regulatory measures.
- 1989** Bans the importation of all ruminants, bovine semen, embryos, and meat and bone meal from the United Kingdom (U.K.), where BSE has been officially diagnosed.
- 1990** Begins BSE educational outreach, educating veterinary practitioners, veterinary laboratory diagnosticians, industry, and producers about the clinical signs and pathology of BSE.
- Initiates an active BSE surveillance program, including histopathological examination of brain tissue of high-risk cattle.
- Initiates traceback of cattle imported from the U.K.
- 1991** Conducts BSE risk analysis.
- Enacts formal regulations to prohibit the importation of most ruminant products from any country known to have BSE.
- 1993** Expands BSE surveillance program to include examination of brain tissue from "downer" cows.
- Updates the 1991 BSE risk analysis.
- 1994** Expands diagnostic testing to include supplemental tests for abnormal prion proteins, which are indicative of BSE.
- 1996** Updates the 1993 BSE risk analysis.
- 1997** Prohibits importation of live ruminants and most ruminant products from Europe.
- Supports FDA regulation prohibiting the use of most mammalian protein in the manufacture of animal feeds given to ruminants.

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1998

Enters into cooperative agreement with Harvard University to analyze and evaluate the Department's BSE prevention measures.

**USDA-HARVARD UNIVERSITY BSE STUDY:
TALKING POINTS**

DRAFT

- **USDA policy on BSE is proactive and preventive.**
 - ▶ Since 1989, we've had an active working group monitoring BSE activities and research around the world, continually evaluating USDA's preventive program, recommending changes to enhance our prevention and surveillance efforts, and assuring that those changes take place.
 - ▶ We train veterinary practitioners and our own inspectors to recognize the symptoms of BSE.
 - ▶ We test animals suspected to have neurologic disease -- and we ensure that they don't enter the human food chain.
 - ▶ We have prohibited the importation of cattle, sheep and related animal products from countries where BSE has been detected.
- **On Friday we are announcing another step in our continuing efforts to prevent BSE.** We are asking researchers at Harvard University's School of Public Health to review current science, assess the ways BSE could potentially enter the United States, and identify any additional measures that could be taken to protect animal health and therefore the food supply.
- **USDA has conducted several BSE studies of its own.** Given the amount of new information about BSE, increased reports of the disease in Europe, and heightened public concern, **we believe a more current and comprehensive study is needed.**
- **There has never been a diagnosed case of BSE in the United States.** As part of our active surveillance and inspection program, USDA has tested brains from over 6600 domestic cattle for BSE. All have tested negative.
- **We believe this study will help us make sure that we continue to do everything we can to keep BSE from U.S. cattle and the U.S. food supply.**

FOR INTERNAL USE ONLY**USDA-HARVARD UNIVERSITY BSE STUDY:
QUESTIONS AND ANSWERS****DRAFT**

Q. Why is this study being undertaken?

A. USDA's policy on BSE is proactive and preventive. We want to continue to make sure that we are doing all we can to keep BSE from U.S. cattle and the U.S. food supply.

USDA has conducted several studies of its own about BSE. Given new information scientists have learned in the last several years, increased reports of the disease in Europe, and heightened public concern, we believe a comprehensive study by outside research experts is needed.

Q. What exactly will be studied?

A. USDA wants to make sure that we continue to do everything we can to keep BSE from U.S. cattle and the U.S. food supply. Harvard University researchers will assess potential pathways for entry of the disease into U.S. cattle or the U.S. food supply, evaluate existing policies designed to prevent this entry, and then make any recommendations that might further improve on our successful strategy.

Q. Why did USDA choose Harvard University to conduct this study?

A. To ensure that human and animal health are being protected, USDA felt current science and Department policies should be reviewed by an objective, outside party. We wanted a research partner with a reputation for excellence, visibility in the scientific and public health community, and experience with this kind of analysis.

Q. How long will the study last? How much will it cost?

A. We expect to receive a final report from Harvard researchers in about two years. The project will cost \$500,000.

Q. Is our food supply safe?

A. Yes. Americans enjoy the one of the safest, most abundant food supplies in the world.

DRAFT

Q. *Is there BSE in the U.S.?*

A. No cases of BSE have been diagnosed in the United States.

USDA has prevented the introduction of BSE with aggressive measures, including a ban on imports of cattle and meat products from the U.K. and other countries where BSE has been diagnosed. Cattle in the United States are inspected at slaughter and any animal showing signs of central nervous system disease is removed from the food chain. This study will help ensure that we are doing all we can to protect U.S. consumers and livestock resources.

Q. *If BSE has never been diagnosed in the U.S., why are we doing this study?*

A. This is another proactive, preventive step taken by USDA to protect animal health and our food supply. We want to assess any new potential pathways for entry of BSE into the U.S. -- and we want to evaluate existing regulations and policies in order to continue our effective prevention efforts.

Q. *What does USDA do to prevent BSE in U.S. cattle and the U.S. food supply?*

A. Our aggressive BSE prevention efforts lie at the core of our mission. We are dedicated to maintaining the health and safety of U.S. cattle and the food supply.

Specifically, USDA keeps cattle with nervous system symptoms out of the food supply. We have banned cattle and beef products from countries where BSE has been diagnosed -- and we recently extended our import ban to countries without adequate BSE surveillance programs.

We continue to train veterinary practitioners and our own inspectors to recognize the symptoms of BSE. And we have an active, ongoing BSE inspection and testing program.

Q. *What would USDA do if BSE were detected in the U.S.?*

A. We are optimistic that our preventive efforts will continue to be effective and there will not be a case of BSE diagnosed in the United States. However, USDA does have an emergency response plan in place in the unlikely event that a case of BSE is detected. The plan would enable USDA to rapidly identify, isolate and eliminate the source of disease in order to prevent public exposure.

DRAFT

Q. Is there a possibility that BSE exists in the U.S.?

A. We have been testing the cattle at highest risk for BSE for a decade and have never found it. USDA is committed to preventing BSE in the United States. Our surveillance system is focused on cattle, especially older animals, that show neurological symptoms. We are committed to ensuring that those cattle are excluded from the food supply. We review continuously the latest science and we continue to take aggressive surveillance, education, and prevention measures. Our cooperative agreement with Harvard University is only the most recent step we have taken to ensure we are doing all we can to prevent BSE.

Q. Do Mexican cattle pose a BSE risk?

A. We are concerned about cattle wherever they come from. That's why we require every country to meet the international standard of reporting any case of BSE. The Mexican meat that comes to this country must go through an inspection equivalent to the U.S. system.

Of course, other countries are interested in preventing BSE too. The World Health Organization includes surveillance and education as part of its ongoing efforts to control BSE.

Q. Is this study part of the President's National Food Safety Initiative?

A. The President has asked us to do all that we can to protect the food supply. While the National Food Safety Initiative includes additional resources for research, it does not specifically fund this study.

Food Safety
Mud Cow

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TALKING POINTS**

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April 24, 1998

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Fax: 456-7028

FROM: Andy Solomon

DATE: 4/24/98

Pages (including cover sheet) 11

Comments: Final BSE materials: Release
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Andy Solomon (202) 720-4623
andy.solomon@usda.gov

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No cases of BSE have been diagnosed in the United States.

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Backgrounder

Harvard University-U.S. Department of Agriculture BSE Study

The United States Department of Agriculture (USDA) is responsible for protecting both human and animal health and for ensuring the safety and security of our food supply. The Department's efforts have been effective in keeping bovine spongiform encephalopathy (BSE), a fatal neurodegenerative disease of cattle, out of the United States.

BSE was first diagnosed in 1986 in the United Kingdom. It has since affected approximately 170,000 cattle in the U.K. and other European countries. Recent scientific studies suggest that BSE may be linked through consumption of BSE-infected tissues to new variant Creutzfeldt-Jakob disease, a fatal neurodegenerative disease in humans.

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USDA has entered into a cooperative agreement with Harvard University's School of Public Health to begin an analysis and evaluation of the Department's current measures to prevent BSE. Harvard University researchers will review existing science on the disease in order to:

- ▶ characterize the hazards of BSE and other transmissible spongiform encephalopathy agents to human and animal health
- ▶ assess potential pathways that BSE could enter the U.S.
- ▶ evaluate existing USDA regulations and policies
- ▶ identify any additional preventive measures that could be taken

While this study is being conducted, USDA will continue to aggressively test and monitor for BSE and will institute any preventive regulatory measures that are necessary.

#

April 24, 1998



USDA Actions to Prevent Bovine Spongiform Encephalopathy (BSE)

- 1988 Establishes BSE Working Group to regularly review the available science and suggest appropriate regulatory measures.
- 1989 Bans the importation of all ruminants, bovine semen, embryos, and meat and bone meal from the United Kingdom (U.K.), where BSE has been officially diagnosed.
- 1990 Begins BSE educational outreach, educating veterinary practitioners, veterinary laboratory diagnosticians, industry, and producers about the clinical signs and pathology of BSE.
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- 1997 Prohibits importation of live ruminants and most ruminant products from Europe.
- Supports FDA regulation prohibiting the use of most mammalian protein in the manufacture of animal feeds given to ruminants.
- 1998 Enters into cooperative agreement with Harvard University to analyze and evaluate the Department's BSE prevention measures.



Bovine Spongiform Encephalopathy

Bovine spongiform encephalopathy (BSE), widely referred to as "mad cow disease," is a chronic degenerative disease affecting the central nervous system of cattle. The disease was first diagnosed in 1986 in Great Britain.

BSE has had a substantial impact on the livestock industry in the United Kingdom. The disease also has been confirmed in domestic cattle in Belgium, France, Ireland, Luxembourg, the Netherlands, Portugal, and Switzerland. The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is enforcing import restrictions and is conducting surveillance for BSE to ensure that this serious disease does not become established in the United States.

Clinical Signs

Cattle affected by BSE experience progressive degeneration of the nervous system. Affected animals may display changes in temperament, such as nervousness or aggression, abnormal posture, incoordination and difficulty in rising, decreased milk production, or loss of body weight despite continued appetite. Affected cattle die. The causative agent of the disease is not completely characterized, and there is neither any treatment nor a vaccine to prevent the disease.

The incubation period (the time from when an animal becomes infected until it first shows disease signs) is from 2 to 8 years. Following the onset of clinical signs, the animal's condition deteriorates until it either dies or is destroyed. This process usually takes from 2 weeks to 6 months. Most cases in Great Britain have occurred in dairy cows between 3 and 6 years of age.

Currently, there is no test to detect the disease in a live animal; veterinary pathologists confirm BSE by postmortem microscopic examination of brain tissue or by the detection of the abnormal form of the prion protein. BSE is so named because of the spongy

appearance of the brain tissue of infected cattle when sections are examined under a microscope.

History

From November 1986 (when BSE was first identified as a separate disease entity) until November 28, 1997, 169,650 head of cattle in more than 34,000 herds were diagnosed with BSE in Great Britain. The epidemic peaked in January 1993 at almost 1,000 new cases reported per week. Agricultural officials in Great Britain have taken a series of actions to eradicate BSE, including making BSE a notifiable disease, prohibiting the inclusion of mammalian meat-and-bone meal in feed for all food-producing animals, prohibiting the inclusion of animals more than 30 months of age in the animal and human food chains, and destroying all animals showing signs of BSE and other animals at high risk of developing the disease.

As a result of these actions, the rate of newly reported cases of BSE is decreasing. Currently, fewer than 100 new cases are found in Great Britain per week.

Epidemiology

There are different scientific hypotheses concerning the origins of BSE. Epidemiologic data suggest that BSE in Great Britain may have been caused by feeding cattle rendered protein produced from the carcasses of scrapie-infected sheep. Scrapie has a long incubation period—up to 60 months—and has been endemic in Great Britain for centuries. An alternate theory is that BSE had existed in undetectable levels in the British cattle population prior to 1986. The practice of using products such as meat-and-bone meal as a source of protein in cattle rations has been common for several decades. Changes in rendering operations in the early 1980's—particularly the removal of a solvent-extraction process that included a steam-heat treatment—may have played a part in the appearance of the disease and the large number of cases that developed.

There is no evidence that BSE spreads horizontally, i.e., by contact between unrelated adult

cattle or from cattle to other species. New evidence suggests that maternal or vertical transmission may occur at a very low level. This low level most likely would not perpetuate the epidemic under British farming conditions. Research continues in this area.

BSE is classified as a transmissible spongiform encephalopathy (TSE). The agent responsible for BSE and other TSE's is smaller than the smallest known virus and has not been completely characterized. There are three main theories on the nature of the agent: (1) the agent is a virus with unusual characteristics, (2) the agent is a prion—an exclusively host-coded protein that is modified to a protease-resistant form after infection, and (3) the agent is a virino—a small, noncoding regulatory nucleic acid coated with a host-derived protective protein. The BSE agent is extremely resistant to heat and to normal sterilization processes. It also does not evoke any detectable immune response or inflammatory reaction in host animals.

In cattle naturally infected with BSE, the BSE agent has been found only in brain tissue, in the spinal cord, and in the retina. Additional studies have identified BSE infectivity in the distal ileum, bone marrow, dorsal root ganglion, and trigeminal ganglion of calves that had been fed brain material from BSE-infected animals.

The presence of the BSE agent in tissues is determined by inoculating animals, usually mice, with material believed to be infected with BSE. Mouse inoculation studies take a long time (up to 700 days) to detect the agent, and failure to identify it in tissues may indicate either true absence of the agent or simply the limited sensitivity of current diagnostic methods.

Related Diseases

Specific types of TSE's include scrapie, which affects sheep and goats; transmissible mink encephalopathy; feline spongiform encephalopathy; chronic wasting disease of deer and elk; and kuru, Creutzfeldt-Jakob disease (CJD or classical CJD), new variant Creutzfeldt-Jakob disease (nvCJD), Gerstmann-Straussler-Scheinker syndrome, and fatal familial insomnia, five diseases rare in humans. Other cases of spongiform encephalopathies have been reported in Great Britain in captive wild ruminants.

On March 20, 1996, the United Kingdom's Spongiform Encephalopathy Advisory Committee (SEAC) announced the identification of 10 cases of nvCJD. These 10 cases differed from other routinely diagnosed cases of classical CJD in that they shared an early age at onset of symptoms, an unusual clinical course with psychiatric problems, an overall

prolonged duration of illness, and, under microscopic examination, different lesions in brain tissues.

SEAC concluded that, although there was no direct scientific evidence of a link between BSE and nvCJD, based on current data and in the absence of any credible alternative, the most likely explanation at that time was that the cases were linked to exposure to BSE before the introduction of a specified bovine offal (SBO) ban at slaughter in 1989. The SBO ban excluded from human consumption brain, spinal cord, and other organs with potential BSE infectivity. As of November 30, 1997, 23 confirmed cases of nvCJD have been identified.

It is important to clarify the difference between classical CJD and nvCJD. Classical CJD occurs each year at a rate of 1 to 2 cases per 1 million people throughout the world, including in the United States and other countries where BSE has never occurred and among vegetarians and meat eaters alike. Classical CJD occurs sporadically and is not linked to BSE. According to the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC), no cases of nvCJD have been found in the United States.

Research published in October 1997 found evidence to further link nvCJD to BSE. Investigators in the United Kingdom found that BSE and nvCJD are of the same "strain." In addition, classical CJD and known scrapie strains were not similar to nvCJD or BSE.

USDA Actions in Response to BSE

The United States has one of the most aggressive BSE surveillance programs in the world. BSE has not been diagnosed in the United States, and USDA has worked proactively to keep it that way. In cooperation with USDA's Food Safety and Inspection Service (FSIS), APHIS has taken stringent measures in prevention, education, surveillance, and response.

To prevent BSE from entering the country, since 1989 APHIS has prohibited the importation of live ruminants from countries where BSE is known to exist in native cattle. Other products derived from ruminants, such as fetal bovine serum, bonemeal, meat-and-bone meal, bloodmeal, offal, fats, and glands, are also prohibited from entry, except under special conditions or under USDA permit for scientific or research purposes.

On December 12, 1997, APHIS stopped issuing import permits for all live ruminants and ruminant products, including meat-and-bone meal, offals, glands, etc., from Europe until APHIS scientists can assess the disease risk and evaluate surveillance activities in individual countries. In addition to the countries already known to have BSE, these new restrictions apply to Albania, Austria, Bosnia—

Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Federal Republic of Yugoslavia, Finland, Germany, Greece, Hungary, Italy, the former Yugoslavian republic of Macedonia, Norway, Poland, Romania, Slovak Republic, Slovenia, Spain, and Sweden.

APHIS educates veterinary practitioners, veterinary laboratory diagnosticians, industry, and producers on the clinical signs and pathology of BSE.

APHIS leads an ongoing, comprehensive, interagency surveillance program for signs of BSE in the United States. APHIS veterinary pathologists and field investigators have received training from their British counterparts in diagnosing BSE. FSIS antemortem inspection procedures include identifying animals with central nervous system conditions. Animals identified with such conditions are prohibited from slaughter and referred to APHIS for review. APHIS' surveillance program is based on laboratories' histopathologically examining brains from high-risk cattle, i.e., adult cattle that exhibit clinical signs of a neurological disorder. In addition, using a technique called immunohistochemistry, scientists test brain tissues for the presence of the protease-resistant prion protein. Samples are submitted from neurologically ill cattle identified on the farm or at slaughter and from rabies-negative cattle submitted to veterinary diagnostic laboratories and teaching hospitals. As of November 30, 1997, more than 6,500 brains from the United States and Puerto Rico have been examined with no evidence of BSE or other TSE detected.

APHIS also monitors the remaining cattle imported from Great Britain and Belgium (before the bans on imports from those countries went into effect). As of January 1, 1998, of the 486 cattle imported from Great Britain between 1981 and 1989, 17 animals are still alive. The animals are quarantined and observed regularly. To date, no evidence of BSE has been detected. APHIS continues to attempt to purchase the 17 live animals for diagnostic research purposes. The five Belgian cattle imported in 1996 are currently under quarantine, and APHIS will attempt to buy these animals as well.

APHIS has also drafted an emergency response plan to be used in the event that BSE is introduced into the United States. In addition, APHIS' TSE Working Group monitors and assesses all ongoing events and research findings regarding TSE's. APHIS continually revises and adjusts prevention and diagnostic measures as it receives new information and knowledge.

As an additional preventative measure, APHIS supports the Food and Drug Administration's (FDA) regulation (effective August 4, 1997) prohibiting the use of most mammalian protein (with certain

exceptions) in the manufacture of animal feeds given to ruminants. In addition, the final regulation also requires process and control systems to ensure that ruminant feed does not contain the prohibited mammalian tissues.

Getting the Word Out

As part of its increased surveillance activities, APHIS is continuing an education effort to inform U.S. cattle producers and veterinarians about this disease. Numerous briefings have been held for industry groups. In addition to press releases and factsheets, a British videotape on BSE and an information packet were distributed to all APHIS field offices, State veterinarians, extension veterinarians, colleges of veterinary medicine, and industry groups.

For additional information, contact
USDA, APHIS, Veterinary Services
Emergency Programs
4700 Riverdale Road
Riverdale, MD 20737
Telephone: (609) 259-5825 or
(301) 734-8073.

For information about importing animals or animal products, contact

Veterinary Services
National Center for Import/Export
Animals Program
Telephone: (301) 734-8170
Products Program
Telephone: (301) 734-7885.

For public health information, contact CDC at (404) 639-3091. For food safety information, contact FSIS at (202) 205-0293 or call the USDA's Meat and Poultry Hotline at (800) 535-4555. For more information about the ruminant feed ban, call FDA's Consumer Hotline at (800) 532-4440.

Current information on animal diseases and suspected outbreaks is also available on the Internet. Point your Web browser to <http://www.aphis.usda.gov> to reach the APHIS home page.