

CSPI

CENTER
FOR SCIENCE
IN THE
PUBLIC INTEREST

Publisher of *Nutrition Action Healthletter*

RECEIVED
FBI DOCKET ROOM
01 AUG -9 PM 4:18

August 9, 2001

The Honorable Ann Veneman
Secretary of Agriculture
U.S. Department of Agriculture
14th Street and Independence Ave., SW
Washington, DC 20250

Dear Secretary Veneman:

Enclosed is our petition for regulatory action to bar the use of spinal cord and columns and other potentially infectious tissue from beef in the human food supply. We appreciate your prompt response to our letter last week on beef intended for the school lunch program and I look forward to working with you and your staff to resolve the concerns that we have outlined in this petition.

Very truly yours,



Caroline Smith DeWaal
Director, Food Safety Program

cc. Kevin Herglotz
Curt Mann
Tom Billy
Maggie Glavin

Tel: (202) 332-9110
Fax: (202) 265-4954
Home Page: www.cspinet.org
E-mail: cspi@cspinet.org

Suite 300
1875 Connecticut Avenue, N.W.
Washington, DC 20009-5728

Michael F. Jacobson, Ph.D.
Executive Director

U.S. DEPARTMENT OF AGRICULTURE

Petition for Regulatory Action to Bar the Use)
of Spinal Cord and Columns and Other Potentially)
Infectious Tissue From Beef in the Human Food)
Supply)
_____)

Docket No. _____

Submitted by the

Center for Science in the Public Interest

On Behalf of:

**American Public Health Association
Consumer Federation of America
Government Accountability Project
National Consumers League
Safe Tables Our Priority**

August 9, 2001

Michael F. Jacobson, Ph.D.
Executive Director
Caroline Smith DeWaal
Director, Food Safety
1875 Connecticut Ave., N.W.
Suite 300
Washington, D.C. 20009
202-332-9110

August 9, 2001

Secretary of Agriculture Ann Veneman
U.S. Department of Agriculture
14th Street and Independence Ave., SW
Washington, DC 20250

CITIZEN PETITION

The Center for Science in the Public Interest (CSPI) and fellow Safe Food Coalition members -- the American Public Health Association, the Consumer Federation of America, the Government Accountability Project, the National Consumers League, and Safe Tables Our Priority -- urge the Food Safety and Inspection Service (FSIS) to require meat processors to ban the use of the spinal columns and neck bones of cattle in advanced meat recovery (AMR) systems and mechanical separation machines. This ban is necessary to ensure that spinal cord, dorsal root ganglia, and other central nervous system tissue are not consumed by humans. We also urge the U.S. Department of Agriculture (USDA) to amend all relevant regulations and purchasing requirements to ensure that Americans are not consuming potentially infectious materials.

Scientists have documented that if a cow has bovine spongiform encephalopathy (BSE), consuming small portions of its brain, spinal cord and other central nervous system (CNS) tissue could cause variant Creutzfeldt-Jakob Disease (vCJD) in humans. Because vCJD is such a devastating disease and the CNS tissue from even a single BSE-infected animal could potentially infect hundreds of people, there is an overwhelming

need to institute all reasonable public health precautions to prevent vCJD in the event that U.S. cattle are infected with BSE.

I. Action Requested

We request that FSIS issue a regulation banning beef slaughter and processing operations from using spinal columns and neck bones in AMR or other systems that mechanically separate meat from bones. In addition, USDA should fully evaluate its regulations and buying specifications to determine what other food products might contain brain tissue, spinal cord, or other potentially infectious materials from cattle.¹ Meat products containing these ingredients should be banned or produced differently to assure their safety. Those actions would help prevent contamination of the food supply with the infective agent that causes BSE, if U.S. cattle have BSE.

BSE is a neurologic disease in cattle that has become a major public health concern because it may cause a form of Creutzfeldt-Jakob Disease (CJD), called variant Creutzfeldt-Jakob Disease (vCJD), in humans. Both of those diseases are degenerative neurological diseases that cause devastating symptoms and are always fatal. Many governments, including the U.S. government, have implemented safeguards to prevent BSE from infecting their cattle herds. Although BSE has never been documented in U.S. cattle, the Food and Drug Administration (FDA) has prohibited the feeding of most types of mammalian protein to ruminants to prevent the spread of BSE among the cattle population as a precaution in case one or more cases of BSE are already in this country.

¹As an example, CSPI recently wrote the Secretary concerning our discovery that USDA specifications for many types of beef purchased for the Federal School Lunch Program and other Federal Food Assistance Programs explicitly permit small bits of spinal cord in beef intended for those programs. By letter on August 8, 2001, Secretary Veneman told CSPI that “[t]his particular purchase specification appears unnecessary and has no practical effect given the FSIS requirements already in place, therefore, the reference is being eliminated.”

That important protection, if properly enforced, could help to prevent any undiscovered cases of BSE from spreading through the U.S. cattle population.

However, sufficient protections are not given to human consumers of beef products. A fire wall is needed to prevent any potentially BSE-infected tissue from entering the human food supply. The USDA has already recognized the need for such safeguards and issued a directive banning spinal cord tissue from the meat produced in AMR systems. Unfortunately, due to weak enforcement mechanisms and the near-impossibility of removing the dorsal root ganglia from spinal columns, that directive has proven inadequate to prevent spinal cord, dorsal root ganglia, and other potentially infective central nervous system tissue from entering the human food supply. Therefore, we request that USDA regulations be amended to require that spinal columns and neck bones of cattle do not enter AMR systems. In addition, USDA regulations and purchasing requirements should ensure that spinal cord and other potentially infective tissue is not allowed in processed beef products.²

II. Scientific Justification

Both CJD and BSE belong to a family of neurologic diseases that are called transmissible spongiform encephalopathies (TSEs) because they can be passed from one organism to another and cause the brain to become riddled with holes. TSEs are caused by “proteinaceous infectious particles” or “prions.”³ Prions have the remarkable ability to

²The intent of the regulatory review should be to identify places where potentially infective spinal cord or CNS material is entering the food supply in a hidden form, as in ground meat or other processed products. We are not seeking, at this time, a ban on the sale of intact meat products where adhering spinal cord or other CNS material is visible and avoidable, as with T-bone steaks.

³Stanley B. Prusiner, “The Prion Diseases,” Scientific American online, available at <<http://www.sciam.com/0896issue/prion.html>>Internet [hereinafter cited as “The Prion Diseases”].

induce other proteins to become deformed. Prions are unusual disease-causing agents because they are extremely difficult to destroy. Many cases of human TSEs, including 90% of CJD cases, are sporadic, which means that the disease can show up in an individual with no apparent cause.⁴ TSEs are characterized by a long incubation period, relatively short duration of clinical signs, and a 100% mortality rate.⁵

TSEs have been documented in a wide variety of species, including sheep (scrapie), cattle (BSE), deer (chronic wasting disease or CWD), mink (transmissible mink encephalopathy or TME), cats (feline spongiform encephalopathy or FSE), and others. Scrapie, CWD, and TME have been reported in the U.S. The following prion diseases have been recognized in humans: Kuru, Gerstmann-Straussler-Scheinker Syndrome, Fatal Familial Insomnia, Creutzfeldt-Jakob disease (CJD) and variant Creutzfeldt-Jakob disease (vCJD).⁶

1. The Human Disease, vCJD, is Devastating and Justifies Strong Precautionary Public Health Measures

CJD is a sporadic disease that has been said to strike about one person in a million annually.⁷ In the 1990s, a new variant of CJD emerged in the United Kingdom. Unlike the sporadic form of the disease, which seldom strikes those under age 50, vCJD occurs primarily in young men and women.

⁴The World Health Organization, "Bovine Spongiform Encephalopathy (BSE)," Fact Sheet No. 113, (Revised), December 2000, p. 3, available at <<http://www.who.int/inf-fs/en/fact113.html>>Internet, [hereinafter cited as WHO Factsheet 113].

⁵U. S. Department of Health and Human Services, "FDA Proposes Precautionary Ban Against Ruminant-to-Ruminant Feedings," *HHS News*, P97-1, January 2, 1997, p. 1.

⁶"The Prion Diseases," pp. 2-3.

⁷"The Prion Diseases," p. 2.

People diagnosed with vCJD may show a variety of symptoms. They may suffer from leg pain and difficulty walking, hallucinations, and they may lose the ability to see, speak, or feed themselves. Other symptoms include crying, screaming, memory loss, and a general degradation of mental functioning. This new form of CJD is a devastating disease that is invariably fatal.

Consumption of beef contaminated with BSE-infected tissue has been linked to the development of vCJD in humans.⁸ In 1996, vCJD killed ten people in Europe (principally in the U.K.); last year it killed 27.⁹ In all, about 100 people have died from the disease in Europe.¹⁰ No one knows how many more are already infected and will develop and die from vCJD, which appears to take at least five to ten years to emerge.

2. BSE-Infected Cattle Could Be Entering the Human Food Supply in the U.S.

a. USDA Can't Guarantee That U.S. Cattle Are BSE-free

Although no case of BSE has ever been identified in U.S. cattle, it is possible that the disease could have escaped detection and be present currently somewhere in the country or that it could in the future spread to the U.S. At a Senate hearing on April 4, 2001, Dr. William Hueston, D.V.M., Ph.D., Professor and Associate Dean of the

⁸Gerry Bryant and Philip Monk, *Final Report of the Investigation into the North Leicestershire Cluster of Variant Creutzfeldt-Jakob*, April 4, 2001 [hereinafter cited as *Final Report of the Investigation into the North Leicestershire Cluster of Variant Creutzfeldt-Jakob*].

⁹UK Department of Health. "Monthly Creutzfeldt-Jakob Disease Statistics," July 2, 2001, p.1., available at <<http://www.doh.gov.uk/cjd/stats/jul01.htm>>Internet [hereinafter cited as Monthly CJD Statistics].

¹⁰Monthly CJD Statistics, p.1.

Virginia-Maryland Regional College of Veterinary Medicine, said that “the possibility of a case of BSE in the U.S. could not be completely excluded.”¹¹

In July 2000, the Scientific Steering Committee (SSC) of the European Commission published a Geographical BSE Risk Assessment together with detailed assessment reports for 23 countries, including the U.S.¹² The risk assessment classified countries into four levels, with countries at level one being unlikely to have BSE-infected cattle to countries at level four having confirmed cases of BSE. The U.S. was ranked as level two, meaning that the presence of BSE in this country is unlikely but not excluded.¹³ Therefore, it is appropriate to take precautionary measures to protect the human food supply.

Recent developments demonstrate why such measures are appropriate. BSE was recently discovered in several European countries that previously had no documented BSE cases. Before October 2000, certain high-risk organs and tissues (called “specified risk materials” or “SRM”) were used in the human food chain in the European Union,¹⁴ a fact that contributed to the loss in consumer confidence in the countries where BSE has

¹¹Testimony of William D. Hueston, DVM, Ph.D., concerning Bovine Spongiform Encephalopathy (aka Mad Cow Disease): Are Our Precautions Adequate? Before the Subcommittee on Consumer Affairs, Foreign Commerce and Tourism of the Committee on Commerce, Science and Transportation, United States Senate, April 4, 2001, p.3.

¹²European Commission Press Release, “Scientists Publish Final Conclusions on Geographical BSE Risk,” Brussels, August 1, 2000, available at <http://europa.eu.int/comm/dgs/health_consumer/library/press/press66_en.html>Internet.

¹³European Commission, *Report on the Assessment of the Geographical BSE-Risk (GBR) of the United States of America*, July 2000; European Commission, *Final Opinion of the Scientific Steering Committee on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR)*, adopted on July 6, 2000, pp. 4, 43, 46, available at <http://europa.eu.int/comm/food/fs/sc/ssc/out113_en.pdf>Internet.

¹⁴Paul Brown, Robert G. Will, Raymond Bradley, David Asher, and Linda Detwiler, “Bovine Spongiform Encephalopathy and Variant Creutzfeldt-Jakob Disease: Background, Evolution, and Current Concerns,” *Emerging Infectious Diseases*, Vol. 7, No. 1, January-February 2001, p. 16 (Appendix Table B).

been newly discovered.¹⁵ The discovery of BSE in countries that may not have had enough safeguards to prevent high-risk materials, like brain and spinal cords, from entering the human food supply shows that it is imperative to exclude those high risk organs and tissues from the human food supply well before the first case of BSE is discovered in this country to protect public health and consumer confidence.

Consumer confidence in this country has already been affected by BSE. A Porter Novelli poll of 815 people living in the U.S. found that “14% said they had changed their food purchasing or family dining habits based on news about mad cow disease and foot-and-mouth disease.”¹⁶ Consumer confidence in the safety of the U.S. meat supply could plummet if it is disclosed that USDA-inspected beef and meat products may contain BSE-infected material.

Although the USDA has conducted BSE tests on approximately 14,000 cattle suspected of having a central nervous system disorder,¹⁷ out of hundreds of millions of cattle slaughtered since 1989, this along with other controls is only enough to say the disease is not rampant in the U.S. and not enough to say it is not present at low levels.

While the U.S. ban on the importation of live ruminants and most ruminant products has

¹⁵Dagmar Heim, “The European Situation,” American Meat Institute Foundation BSE Briefing March 23, 2001; Alan Travis, “Europe’s BSE Fear Deepens as UK Stays Calm,” *Guardian Unlimited*, January 15, 2001, available at <<http://www.guardianunlimited.co.uk/bse/article/0,2763,422384,00.html>>Internet; Devon Spurgeon, “McDonald’s First-Quarter Net Fell 16% Due to Concerns About Mad-Cow Disease,” *Wall Street Journal*, April 20, 2001, p. B8; James Meikle, “BSE Panic Spreads Across Europe: First Cases Reported in Germany and Spain Amid Calls for UK Ban on French Beef,” *The Guardian*, November 25, 2000, available at <<http://www.guardian.co.uk/Print/0,3858,4096355,00.html>>Internet.

¹⁶Anita Manning, USA Today, “Consumers’ Fears Carry Over to Food Decisions,” *USA Today*, April 19, 2001, p. 8D.

¹⁷United States Department of Agriculture, Animal and Plant Health Inspection Service, “BSE Surveillance,” available at <<http://www.aphis.usda.gov/oa/bse/bsesurvey.html>>Internet.

been in effect for years, covering first the U.K. and then all of Europe, there is always a chance, in today's global marketplace, that an infected animal may have entered the U.S. under false pretenses, or that infected product may have entered the animal feeding system prior to 1997.

It is also possible that BSE occurs sporadically in a small portion of cattle¹⁸, as CJD does in the human population. If BSE were to occur spontaneously in a U.S. bovine today, this country needs to be prepared to ensure that potentially highly infectious material is not allowed to contaminate batches of meat, with the potential of exposing a huge number of consumers.

b. The Mammalian-to-Ruminant Feed Ban Has Too Many Loopholes and is Not Adequately Enforced

In 1997, the Food and Drug Administration (FDA) prohibited farmers from feeding cows and sheep meat-and-bone meal supplements made from rendered cows or sheep.¹⁹ However, the banned mammalian meat-and-bonemeal is still on the market because it can be fed to non-ruminants,²⁰ such as pigs and poultry.²¹

In a recent survey of feed mills and renderers, FDA found that more than 20 percent had no system in place to prevent commingling and cross-contamination of

¹⁸Food and Drug Administration, "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed," Proposed Rule, *Federal Register*, Vol. 62, No. 2, (1997), p. 555 (later codified at 21 CFR §589.2000).

¹⁹Food and Drug Administration, "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed," Final Rule, *Federal Register*, Vol. 62, No. 108, (1997), pp. 30936-30970 (codified at 21 CFR §589.2000).

²⁰21 CFR § 589.2000(a)(7), "Ruminant includes any member of the order of animals which has a stomach with four chambers...).

²¹21 CFR § 589.2000(c).

different types of feed, as required by the feed ban.²² And 85 feed plants out of over 400 surveyed did not label their feed with information about which animals it was and, more importantly, was not intended for, as required by the 1997 feed ban.²³

This gap in protection made headlines in January 2001, when a Texas feedlot inadvertently fed meat-and-bone meal intended for pigs and poultry to more than 1,200 cattle.²⁴ A clerk at Purina Mills in St. Louis had mistakenly mixed the pig-and-poultry supplement into the company's cattle feed. Although the meal was produced in the U.S. from presumably BSE-free cattle, Purina Mills purchased the animals to keep their meat out of the food supply.²⁵ Clearly, that episode demonstrates that the feed ban is not trustworthy enough to safeguard the public. According to Stephen Sundlof, head of FDA Center for Veterinary Medicine, other breaches like this have occurred.²⁶ Because the FDA's feed rules aren't strict enough, if one cow in the U.S. has BSE, there is an increased likelihood that it could spread to other cattle. Therefore, it is risky for Americans to be consuming the central nervous system tissue of cattle.

²²General Accounting Office. Report to the Honorable Richard J. Durbin, United States Senate. "Food Safety Controls Can Be Strengthened to Reduce the Risk of Disease Linked to Unsafe Animal Feed," September 2000 [hereinafter cited as September 2000 GAO Report].

²³September 2000 GAO Report.

²⁴"Texas Cattle are Quarantined to Determine Mad-Cow Risk," *New York Times*, January 27, 2001, p. A8.

²⁵Sandra Blakeslee, "Agency Clears Texas Cattle in Quarantine," *New York Times*, January 31, 2001, p. A18.

²⁶Although it is beyond the scope of this petition, the FDA should consider banning the use of meat-and-bone meal in all types of animal feed.

3. The U.S. Should Follow Europe in Banning Potentially Infectious Cattle Parts from the Human Food Supply

Scientists believe that BSE can be transmitted to humans through beef contaminated with BSE-infected tissue and cause vCJD. In perhaps the most definitive example, an investigation of a cluster of vCJD cases in Leicestershire, England, “demonstrated an association with beef consumption, purchased from butchers where there was a risk of cross-contamination of beef carcass meat with bovine brain, and the development of vCJD.”²⁷

A 1997 WHO document listed the brain and spinal cord as the most infectious tissues in scrapie-infected sheep and BSE-infected cattle. Subsequently, the European Commission’s Scientific Steering Committee (SSC) published a Listing of Specified Risk Materials (SRM) that stated that the infectivity of the spinal cord is not in doubt.²⁸ The SSC also listed the bovine brain, eyes, spinal cord and dorsal root ganglia, dura matter, pituitary, skull and vertebral column, and lungs as being high-risk material for the transmission of BSE.

The SSC report discusses three issues relating to whether vertebral columns can be used in the human and animal food chains: the potential contamination of the vertebral columns by spinal cord during the course of its removal; the presence of coexisting

²⁷*Final Report of the Investigation into the North Leicestershire Cluster of Variant Creutzfeldt-Jakob*, p. 19.

²⁸European Commission, Listing of Specified Risk Materials: a scheme for assessing relative risks to man. Opinion of the Scientific Steering Committee adopted on 9 December 1997 (Re-edited version adopted by the Scientific Steering Committee during its Third Plenary Session of 22-23 January 1998), available at <http://europa.eu.int/comm/food/fs/sc/ssc/out22_en.pdf>Internet [hereinafter cited as SSC Report].

nervous system material (such as dorsal root ganglia) with the same infectivity as the spinal cord; and any potential infectivity from bone marrow.²⁹

The report states that contamination of the vertebral column by spinal cord “can be expected under most practical slaughterhouse circumstances...the SSC advises the removal of the vertebral columns from all older animals even when the presumed infective spinal cord has been removed.”³⁰

The SSC report says, “new (unpublished) evidence shows that the dorsal root ganglia – sited within the general structure of the vertebral column – should be considered as having an infectivity for BSE equivalent to that of the spinal cord....The dorsal root ganglia cannot be removed without extreme difficulty. This therefore means that a precautionary proposal relating to the removal of the whole vertebral column (other than the coccyx) is now appropriate.”³¹ Subsequently, this finding that dorsal root ganglia are highly infectious has been published.³²

Starting in the 1990s, public health officials all over Europe began to recognize the need to prevent potentially infectious brain and spinal cord materials from entering the human food supply. Great Britain banned some “specified bovine offal” from the human food chain beginning in 1989.³³ The list of banned bovine organs and tissues was

²⁹SSC Report, Section 4, Vertebral columns, p. 8.

³⁰SSC Report, Section 4.2.1, Contamination, p. 9.

³¹SSC Report, Section 4.2.2, Dorsal root ganglia, p. 9.

³²Spongiform Encephalopathy Advisory Committee, Report to Ministers: A Review of Infectivity in Bone Marrow and Dorsal Root Ganglia in Cattle Infected With BSE, November 1998, available at <<http://www.maff.gov.uk/animalh/bse/bse-publications/seac-30nov1998.html>>Internet.

³³WHO Factsheet 113, p. 2.

revised and expanded a number of times as new information became available.³⁴ In 1995, the U.K. also banned the use of “the vertebral column of a bovine animal in the recovery of meat by mechanical means.”³⁵

The countries of Europe have recently instituted widespread precautions to protect consumers. In February of this year, as a result of the SSC opinion, the European Commission required the removal of the vertebral column from all carcasses from cattle over 12 months and also outlawed the production of all mechanically-recovered meat that comes from cattle or sheep.³⁶

To minimize the risk of BSE entering the human food supply, USDA should adopt precautions similar to those adopted in Europe to keep spinal columns and neck bones out of AMR and other systems that mechanically separate the meat from the bone.³⁷ These precautions are essential to protect both public health and consumer confidence in the event that BSE is present but undetected in U.S. cattle. In addition, the USDA should ban the use in human food of all bovine specified risk materials, as identified and updated by the World Health Organization. Such restrictions would

³⁴WHO Factsheet 113, p. 2.

³⁵British Ministry of Agriculture, Fisheries and Food. The Specified Bovine Offal (Amendment) Order, 1995 No. 3246 [hereinafter cited as Specified Bovine Offal (Amendment) Order 1995]. To the best of our knowledge, AMR systems are not in use in Europe.

³⁶The European Commission, Health and Consumer Protection Directorate-General Press Release, “Commission approves further protection measures against BSE,” Brussels, February 7, 2001, p. 3, available at <http://europa.eu.int/comm/dgs/health_consumer/library/press/press106_en.html>Internet.

³⁷While removing the most infectious tissues from the human food chain is critical, this precaution should not replace efforts to ensure that U.S. cattle are BSE-free.

significantly reduce the amount of potentially infectious spinal cord and dorsal root ganglia that enter the human food supply.

4. FSIS Regulations Permit Mechanically Separated Beef To Contain Spinal Cord

Currently, a product labeled as “mechanically separated beef” may contain spinal cord as long as the product is not labeled as “meat.”³⁸ As spinal cord is a high-risk tissue for the transmission of BSE, this regulation should be repealed or amended to explicitly ban spinal cord and dorsal root ganglia from the human food supply.

Mechanically separated beef may legally constitute up to 20 percent of the meat portion of a food product.³⁹ Meat industry officials, however, have told CSPI that they are not aware of any beef processors currently producing mechanically separated beef. Regardless of whether anyone is currently producing mechanically separated beef, it is inappropriate to have an existing regulation that allows spinal cord tissue of cattle to legally enter the human food chain. USDA regulations must be changed in recognition of the fact that the spinal cords and dorsal root ganglia of cattle could potentially contain the infectious BSE agent and should be excluded from the food supply. For mechanically separated beef, the best way to do this is by banning bovine spinal columns and neck bones from entering those systems.

Mechanically separated beef is defined as “any finely comminuted product resulting from the mechanical separation and removal of most of the bone from attached

³⁸9 CFR § 319.5; U.S. Department of Agriculture, FSIS Directive 7160.2, “Meat” Prepared using Advanced Mechanical Meat/Bone Separation Machinery and Meat Recovery Systems, 1997 [hereinafter cited as FSIS Directive 7160.2].

³⁹9 CFR § 319.6.

skeletal muscle of livestock carcasses and parts of carcasses.”⁴⁰ The definition of mechanically separated beef should be changed to exclude spinal cord, dorsal root ganglia, and other central nervous system tissue.

5. The Products of Advanced Meat Recovery Systems Could Contain Potentially Infectious Tissue

If undetected BSE exists in the U.S., or occurs here in the future, advanced meat recovery systems could also produce meat capable of transmitting the disease to humans. AMR machines take bones with attached muscles and nerves and put them through a device that removes the soft tissue from the bone. According to FSIS regulations, those machines are supposed to detach the meat without crushing, pulverizing or grinding the bone itself.⁴¹ Bones must emerge from those machines essentially intact and in natural conformation so that they are recognizable, i.e., comparable to those resulting from hand-deboning.⁴² AMR systems produce a product that can be called “meat” under current government requirements.⁴³

AMR systems strip any soft tissue from the bones that enter the equipment. If bits of spinal cord remain attached to the spinal column or neck bone that enters these machines, that soft tissue may be incorporated into the meat that is produced.⁴⁴ USDA inspector reports provide clear evidence that spinal cords attached to spinal columns are

⁴⁰9 CFR § 319.5.

⁴¹9 CFR § 301.2.

⁴²9 CFR § 301.2.

⁴³9 CFR § 301.2.

⁴⁴B.P. Demos and R.W. Mandigo, “Chemistry and Composition of Mechanically Recovered Beef Neck Bone Lean,” Journal Series, Nebraska Agricultural Research Division, Paper No. 10997, pp. 64-65.

entering these machines. For example, the Government Accountability Project obtained, through the Freedom of Information Act, at least six inspection reports from 1997 that noted that inspectors saw bovine spinal cord material entering the AMR systems.⁴⁵

A proposed rule to narrow the definition of “meat” and otherwise tighten regulations defining the product of AMR systems has been pending since 1998.⁴⁶ This rule was drafted to address quality issues, such as economic adulteration. It still has not been finalized despite letters from the National Consumers League and the Safe Food Coalition urging the USDA to take action.⁴⁷ The proposed rule itself says “in view of the concerns about possible incorporation of spinal cord and bone marrow in products resulting from advanced meat/bone separation machinery, the Agency has determined that it should not delay action on this matter.”⁴⁸ Unfortunately, delay it has.

While citing the need for prompt action, this proposed rule nonetheless perpetuates the myth that spinal cord in the beef supply is not a public health issue. It specifically states, “the amendments that FSIS is proposing to increase the assurance that

⁴⁵USDA response to Government Accountability Project FOIA Request #97-501, AMR Lab Reports, [hereinafter cited as AMR Lab Reports]: Domestic Chemical Lab Analysis by R. Trudeau, D.V.M. for sample taken on 5/23/97, Internal Lab No. A39557, Serial No. 728124; Pathology Specimen Submission by Barbara Porter, D.V.M. on 7/14/97, Internal Lab No. A40179, Serial No. 104017 and USDA FSIS Process Deficiency Record No. 309-97, 7/14/97; Pathology Specimen Submission for sample taken on 8/7/97, Internal Lab No. A40579, Serial No. 108899, Pathology Specimen Submission by John A. Best, Jr., D.V.M. on 4/17/97, letter to USDA-FSIS-Eastern Lab from John A. Best, Jr., D.V.M. dated 4/16/97, Internal Lab No. A38869, Serial No. 075297; Domestic Chemical Laboratory Report by R. Trudeau, D.V.M. on 6/3/97, Internal Lab No. A39706, Serial No. 900755; Pathology Specimen Submission for sample taken on 8/8/97, Internal Lab No. A40580, Serial No. 108900.

⁴⁶U.S. Department of Agriculture, Food Safety and Inspection Service, Proposed Rule, “Meat Produced by Advanced Meat/Bone Separation Machinery and Recovery Systems,” *Federal Register*, Vol. 63, No. 70, (1998), pp. 17959-17966 [hereinafter cited as AMR Proposed Rule].

⁴⁷Safe Food Coalition, Letter to Secretary Glickman at the USDA Re: Advanced Meat Recovery Systems Proposed Rule, March 1999.

⁴⁸AMR Proposed Rule, p. 17960.

products marketed as meat do not include spinal cord are not intended as a response to concerns that some have expressed about spongiform encephalopathies. Available data indicate that the United States is bovine spongiform encephalopathy (BSE) free.”⁴⁹

However, in light of the recent discovery of BSE in several countries that were previously thought to be BSE-free, and other evidence that suggests there is a risk of BSE existing in or entering the United States, it is imperative that FSIS ensure that Americans are not consuming the parts of cattle that are most likely to be infectious. As spinal cords and dorsal root ganglia from infected cattle are highly infectious, AMR systems provide the single best opportunity for BSE-infected material to enter the food supply today. And this meat may be used in several staples of the American diet, like hot dogs, hamburgers and sausages.

Meat produced by AMR systems enters a variety of products. According to a report prepared on behalf of the meat industry, “a high proportion of the product (beef) is blended with other meat while a smaller portion is sold as stand alone product for uses such as jerky, taco meat or pizza toppings.”⁵⁰ In 1998, approximately 70% of the total fed cattle and hogs and 60% of the dairy cows slaughtered in 1998 were processed through the AMR system⁵¹ and AMR systems produced 45.3 million pounds of beef

⁴⁹AMR Proposed Rule, p. 17964.

⁵⁰Sparks Companies, Inc. Advanced Meat Recovery Systems - An Economic Analysis of Proposed USDA Regulations, July 1999, p. 10 [hereinafter cited as Sparks Report].

⁵¹Sparks Report, pp. 9-10.

product.⁵² Those 45 million pounds of AMR product may be mixed with hundreds of millions of pounds of other meat.

FSIS's enforcement of its Directive banning spinal cords in AMR equipment has been inadequate. In 1997, following a request by the Center for Science in the Public Interest,⁵³ the USDA directed its employees to periodically check the spinal columns going into the AMR systems to ensure that plant employees are "completely removing spinal cord from neck and/or back bones before the bones enter the [AMR] system."⁵⁴ In addition, inspectors were instructed to send suspect product to a USDA lab for testing if they thought plant employees were not adequately removing the spinal cord. However, FSIS employees can take no other action to prevent this meat from being sold to the public.

Evidence to date suggests that sampling of AMR meat under the Directive is rarely performed, in part because the USDA has determined that the presence of spinal cord in meat is not a food-safety violation. While food-safety inspection tasks are assigned more frequently, the AMR checks are considered quality-control checks, which are principally the responsibility of the industry. While CSPI has no evidence of how frequently these checks are actually performed, plant enforcement information on the number of samples analyzed since 1997 indicates that government inspection of the bones going into AMR machines may be quite rare.

⁵²Sparks Report, p. 10.

⁵³Center for Science in the Public Interest, Letter to Secretary Glickman and Administrator Billy, January 7, 1997.

⁵⁴FSIS Directive 7160.2.

FSIS data from the first six months after the directive took effect indicates that inspectors submitted laboratory samples of AMR product less than three dozen times. Of 34 product samples taken from April-September 1997, only about 14 were samples of beef, and the rest were samples of pork. Of the beef samples, three (21%) were found to contain CNS tissue.⁵⁵ Inspection reports from 1997 also indicate that even when inspectors witness spinal cord entering the AMR system, it is not always detected in laboratory testing. On three occasions, an inspector witnessed beef with attached spinal cord entering the AMR system, but spinal cord couldn't be "definitively identified" in the sample.⁵⁶

Between 1998 and August 2001, 99 samples were analyzed under this directive. This is a pitifully small number, considering that 45 million pounds of beef paste was produced by AMR systems in just 1998.⁵⁷ Out of these 99 samples, nine were positive for CNS tissue, and peripheral nerve tissue was found in other samples as well.

Independent testing also indicates that USDA's directive has not been fully effective. The National Cattlemen's Beef Association hired Glenn Schmidt, a meat

⁵⁵AMR Lab Reports: Pathology Report, completed 6/3/97 by Scott Hafner, D.V.M., M.S. Diplomate, A.C.V.P. Internal Lab No. A39557, Serial No. 728124; Pathology Report, completed 8/4/97 by S. Mark Hall, D.V.M., Ph.D. Internal Lab No. A40179, Serial No. 104017 and USDA FSIS Process Deficiency Record No. 309-97, 8/14/97; Pathology Report, completed by Scott Hafner, D.V.M., M.S. Diplomate, A.C.V.P., Internal Lab No. A40579, Serial No. 108899.

⁵⁶AMR Lab Reports: Pathology Specimen Submission by John A. Best, Jr., D.V.M. on 4/17/97, letter to USDA-FSIS-Eastern Lab from John A. Best, Jr., D.V.M. dated 4/16/97, and Pathology Report completed 4/25/97 by Mary T. Sutton, D.V.M., M.S., Internal Lab No. A38869, Serial No. 075297; Domestic Chemical Laboratory Report by R. Trudeau, D.V.M and Pathology Report completed 6/10/97 by S. Mark Hall, D.V.M., Ph.D., Internal Lab No. A39706, Serial No. 900755; Pathology Specimen Submission for sample taken on 8/8/97 and Pathology Report completed 8/15/97 by Scott Hafner, D.V.M., M.S. Diplomate, A.C.V.P., Internal Lab No. A40580, Serial No. 108900.

⁵⁷Sparks Report, p. 10.

scientist from Colorado State University, to test meat at eight major AMR plants.

Although Schmidt did not give CSPI his test results, he told us that he is finding spinal cord in some of his samples.⁵⁸

This evidence demonstrates that FSIS's directive is not sufficient to protect consumers if BSE is present in or spreads to U.S. cattle. The best way to ensure that AMR meat is free of CNS tissue is to prohibit the use of the spinal columns and neck bones in the AMR systems.

III. Legal Authority

In enacting the Federal Meat Inspection Act (FMIA),⁵⁹ Congress gave USDA broad power to prevent the introduction of adulterated meat and poultry into commerce. The FMIA is premised on a congressional finding, among other things, that “[i]t is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled and packaged.”⁶⁰ The courts have agreed that the purpose of this statute is to ensure high levels of cleanliness and safety of meat products. *See, e.g., Original Honey Baked Ham v. Glickman*, 172 F.3d 885, 887 (D.C. Cir. 1991) (stating that the FMIA has a purpose of ensuring that “meat . . . products are ‘wholesome [and] not adulterated,’ all to the end of protecting the ‘health and welfare of consumers’ and the market for wholesome and unadulterated products”).

⁵⁸Personal e-mail correspondence between Glenn Schmidt and David Schardt, CSPI Associate Nutritionist, April 17-18, 2001.

⁵⁹21 U.S.C. 601 *et seq.*

⁶⁰21 U.S.C. 602.

The Secretary's authority to take action to protect the public is clear. The meat and poultry inspection statutes mandate federal regulatory oversight of "unusual intensity and comprehensiveness"⁶¹ and provide the Secretary with broad authorities to implement rules assuring that the United States meat supply is safe.

1. Section 606 of the Federal Meat Inspection Act Requires FSIS to Consider Food Safety Issues, Not Just Quality Issues

The Federal Meat Inspection Act instructs the Secretary to perform inspections on all meat prior to sale and to mark it "inspected and passed" if it is "found to be not adulterated."⁶² "Adulterated" meat includes meat that "contains any poisonous or deleterious substance which may render it injurious to health."⁶³ This statutory language gives the Secretary authority to proactively prevent injury to human health by ensuring the safety of the meat supply. Thus, the Secretary need not wait for an outbreak of BSE or vCJD in the U.S. to take appropriate steps under the law since the authority to regulate is not based on a finding of actual harm.

In *Community Nutrition Institute v. Butz*, the district court held that USDA must consider not just the quality effects, but also the health impact of bone fragments in mechanically separated (or "deboned") meat.⁶⁴ Several consumer groups and state officials challenged USDA regulations on procedural and substantive grounds for failing

⁶¹U.S. Department of Agriculture, Food Safety and Inspection Service, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule," *Federal Register*, Vol. 61, No. 144, (1996), p. 38851.

⁶²21 U.S.C. § 606.

⁶³21 U.S.C. § 601(m)(1).

⁶⁴*Community Nutrition Institute v. Butz*, 420 F. Supp. 751 (D.D.C. 1976).

to adequately assess the health effects of mechanically deboned meat. The case presents issues that are highly analogous to the issues presented in this petition. First, mechanically separated meat (MSM) is comparable to the meat produced from AMR systems. In fact, AMR systems are just the next generation of the equipment. Second, bone fragments, like spinal cord, are a constituent of cattle, but not of meat. Third, bone fragments can -- but do not always -- pose a risk to human health. In the era of bovine spongiform encephalopathy, that is also the case with spinal cord.

In the court's own words:

As to the more health-related aspect of adulteration (§ 601(m)(1)), however, it is likely that the Secretary's approval of the use of MDM (mechanically deboned meat) in this regulation will be found clearly erroneous. . . . In order for the Secretary to approve the use of MDM as he has done in this regulation, therefore, he is required by law to have made a determination that there is no substantial possibility that the presence of bone particles in a concentration of .45% in processed products containing MDM could harm the health of those ingesting the products. It is not at all clear that the Secretary has made such determinations with the required thoroughness.⁶⁵

The same is true of USDA's regulations on spinal cord in the AMR/MSM systems: The agency has looked at only the quality aspects of meat or meat product produced by those systems and has failed to consider whether spinal cord in the meat could harm those ingesting it. It is clear that USDA has not made these determinations with the "required thoroughness" the law demands.⁶⁶

⁶⁵420 F. Supp. 751 (D.D.C. 1976).

⁶⁶420 F. Supp. 751 (D.D.C. 1976).

2. Meat Containing Spinal Cord is “Adulterated” Because it is Unsound, Unhealthful, Unwholesome or Otherwise Unfit for Human Food

The definition of “adulteration” found in FMIA section (601)(m)(3) provides that meat is adulterated if the Secretary finds that the meat is “for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food.” This gives the Secretary broad discretion to determine the safety and quality of meat as conditions change, including conditions involving animal health. Indeed, the Secretary has used this discretion in the past to address similar situations. In 1988, for example, FSIS issued a new regulation for the disposition of the thyroid glands under the authority of section 601(m)(3) and based on “an outbreak...associated with consumption of beef products made from trimmings containing cattle thyroid glands.”⁶⁷

In light of recent science, bovine spinal cord and other potentially infectious material must be considered unwholesome and unfit for human consumption. Until the 1980's, BSE was unknown. Until 1996, it was not known that BSE could be transmitted through the food chain to humans. Therefore, regulations were adopted that allowed MSM products to contain spinal cord material.⁶⁸ Today, we know better. The science and experience of the last 10 years have demonstrated that BSE is not just an animal-health concern, but a significant human-health concern as well. Meat that contains spinal cord is, in fact, unsound, unhealthful, unwholesome, and unfit for human food. We urge the Secretary not to wait for an outbreak of BSE before instituting precautions to protect

⁶⁷U.S. Department of Agriculture, Food Safety and Inspection Service, “Disposition of Livestock Thyroid Glands and Laryngeal Muscle Tissue,” *Federal Register*, Vol. 53, (1988), p. 45888 (Final Rule; codified at 9 CFR § 310.15).

⁶⁸9 CFR § 319.5; U.S. Department of Agriculture, FSIS Directive 7160.2.

the human food supply. It is time for the Department to amend its regulations and buying specifications to address the human-health implications of BSE.

Recent scientific disclosures about BSE support the notion that the presence of bovine brain, spinal cord and other potentially infective materials in the human food supply would make the meat unwholesome and adulterated. Therefore, USDA is compelled under the FMIA to prevent these agents from entering the human food supply.

Under comparable facts, the FDA has found that bovine material should be banned from animal feed. The FDA determined that this material is no longer generally recognized as safe, and therefore must be regulated under their food additive approval provisions. FDA said in that rulemaking, that: “the act as a whole and the 1958 Food Additive Amendment in particular were intended to give FDA the tools to prevent harm to the public health before it occurred.”⁶⁹ While USDA has never adequately addressed the question of whether bovine SRM materials are adulterants, the agency has exercised its authority to exclude it from certain meat food products. In 1997, FSIS recognized that spinal cord in the meat product of AMR systems raised a quality issue and required the industry to remove the spinal cord from the bony spinal columns before they entered AMR systems. In fact, FSIS based the Directive 7160.2 on its finding that product containing spinal cord does “not come within the definition of “meat” in 301.2(rr)(2) of the regulations.” This finding constitutes a labeling determination, as FSIS has attempted to avoid the safety questions surrounding spinal cord in the human food supply. Now these safety questions are placed squarely before the Secretary.

⁶⁹62 Fed. Reg. 30935, 30949 (June 5, 1997).

Because FSIS's directive on AMR was based on quality considerations, rather than safety, its enforcement has been minimal. As discussed above in section II.5.a., both government testing and private testing have shown that the Directive has not been not fully effective in keeping spinal cord and other infective material out of the human food supply. USDA must utilize a stronger public-health approach to ensure that AMR meat does not provide a disease pathway for BSE.

The scientific evidence is much clearer now than when USDA's current standards were adopted that spinal cord tissue, dorsal root ganglia, and other CNS tissue in the beef supply raises food-safety concerns, as this tissue from infected cattle could spread a transmissible spongiform encephalopathy to humans. Therefore, it is time for FSIS to implement meaningful and enforceable food-safety regulations to prevent BSE from entering the U.S. food supply. Even though BSE has not been found in U.S. herds, precautions are needed to protect the public's health and consumer confidence in the event that the disease already exists undetected in our herds or in the future enters the U.S. through imported cattle.

In addition to the foregoing provisions of the FMIA, the statute also contains a general provision that supports the actions requested in this petition, granting the Secretary broad authority to promulgate rules and regulations "necessary to carry out the Act[s]."⁷⁰ FSIS relied upon those provisions when it promulgated its HACCP/Pathogen Reduction Rule,⁷¹ and they are equally applicable here.

⁷⁰21 U.S.C. § 621.

⁷¹HACCP Final Rule, pp. 38806-55.

3. The Requested Regulations Present a Situation In Which Regulatory Analysis is “Not Practicable Because of Compelling Circumstances” Under the U.S. Department of Agriculture Reorganization Act of 1994

Under § 2204e of the USDA Reorganization Act of 1994, USDA must complete a risk assessment and cost-benefit analysis for each proposed major regulation that relates to human health, safety, or the environment.⁷² That section does provide an exception, however: when a risk assessment and cost-benefit analysis is “not practicable because of compelling circumstances,” an explanation can be provided in lieu of a full analysis.⁷³

USDA’s Office of Risk Assessment and Cost-Benefit Analysis, which has been in operation for six years, has yet to exempt a proposed rule from the regulatory-analysis requirement. Nevertheless, CSPI and other co-signers to this petition believe that the rulemaking requested in this petition readily satisfies the exemption. The public-health threat that would be posed by BSE-infected meat products presents the “compelling circumstances” needed to justify the promulgation of regulations without undertaking a full risk assessment and cost-benefit analysis. In addition, two elements of the risk analysis are impossible to determine: First, the percent, if any, of infected livestock, and second, the cost to the production system if BSE is found.

CSPI and the other co-signers contend that the potential for BSE to be found in U.S. cattle constitutes the “compelling circumstances” necessary to permit FSIS to adopt the requested regulation without first completing a full regulatory analysis. FSIS instead

⁷² 7 U.S.C. § 2204e(b)(1).

⁷³ 7 U.S.C. § 2204e(b)(1).

should publish the regulations as an interim final rule and provide an explanation for its rulemaking as contemplated under § 2204e(b)(1) of the USDA Reorganization Act.

IV. Conclusion

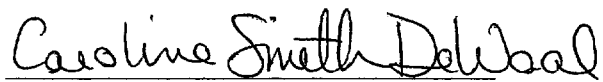
While BSE has never been found in U.S. cattle herds, the recent discovery that BSE is much more widespread in Europe than previously thought makes clear that precautionary measures are needed to prevent meat products contaminated with infective tissue from ever posing a serious health threat. Unfortunately, the existing regulatory system does not minimize that threat.

USDA should act immediately to eliminate meat containing spinal cord and other potentially infective material from the school lunch program and other federal feeding programs. Second, USDA should develop and enforce regulations that ban potentially infective tissues from the human food supply, including meat produced by the MSM and AMR systems. CSPI and the co-signers to this petition urge the agency to take that step without further delay, before the first “mad cow” is discovered in the U.S. Protecting the human food supply after BSE is discovered would be like locking the barn door after the cows have already left.

V. Certification

The undersigned party certifies that, to her best knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



Caroline Smith DeWaal
Director, Food Safety Program*

On behalf of:

American Public Health Association
Government Accountability Project
Safe Tables Our Priority

Consumer Federation of America
National Consumers League

* Leora Vegosen provided invaluable research and other assistance in the preparation of this petition.