

U.S. DEPARTMENT OF AGRICULTURE

Petition for Regulatory Action to Bar the Use)
of Spinal Cord and Columns and Other Potentially) Docket No. _____
Infective Tissue From Beef in the Food Supply)
_____)

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**

July 31, 2001

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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 systems and mechanical separation machines. This ban is necessary to ensure that central nervous system tissue, such as spinal cord and dorsal root ganglia, are not consumed by humans. In addition, we urge the U.S. Department of Agriculture to immediately amend **its** purchasing specifications for meat intended for the National School Lunch Program and other Federal Food Assistance Programs to ban **the purchase of beef containing** small bits of spinal cord.

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 tissue could cause variant Creutzfeldt-Jakob Disease (vCJD) in humans. Because vCJD is such a devastating disease, 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 advanced meat recovery (**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, central nervous system tissue, or other potentially infective materials from cattle. 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 bovine spongiform encephalopathy (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) prohibited the feeding of most types of mammalian protein to ruminants to prevent the spread of BSE among the cattle population if the disease occurs in this country. That important protection 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 U.S. Department of Agriculture (USDA) has already recognized the need for such

safeguards and issued a directive banning spinal cord tissue from the meat produced in advanced meat recovery (AMR) systems. Unfortunately, due to weak enforcement mechanisms and the impossibility of removing the dorsal root ganglia from spinal columns, that directive has proven inadequate to prevent spinal cord 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 infectious central nervous system tissue is not allowed in any beef products, including those that are purchased for National School Lunch Program and the Federal Food Assistance Programs.**

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.”¹ Prions have the remarkable ability to 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

¹Stanley B. Prusiner, “The Prion Diseases,” Scientific American online, available at <<http://www.sciam.com/0896issue/prion.html>>Internet [hereinafter cited as “The Prion Diseases”].

that the disease can show up in an individual with no apparent cause.² TSEs are characterized by a long incubation period, relatively short duration of clinical signs, and a 100% mortality rate.³

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. 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).⁴

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.⁵ 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.

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.

²The 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.

³U. 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.

⁴"The Prion Diseases."

⁵"The Prion Diseases."

Consumption of beef contaminated with BSE-infected tissue has been linked to the development of vCJD in humans.⁶ In 1996, vCJD killed ten people in Europe (principally in the U.K.); last year it killed 27.⁷ In all, about 100 people have died from the disease in Europe.⁸ No one knows how many more are already infected and will develop **and die from** vCJD, which can 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 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 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.”⁹

In July 2000, the Scientific Steering Committee (SSC) of the EU published a Geographical BSE risk assessment together with detailed assessment reports for 23 countries, including the

⁶Gerry 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*].

⁷UK 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].

⁸Monthly CJD Statistics, p.1.

⁹Testimony 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.

U.S.¹⁰ 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.¹¹

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,¹² a fact that contributed to the loss in consumer confidence in the countries where BSE has been newly discovered.¹³ 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

¹⁰European 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.

¹¹European 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, p. 4, 43, 46, available at <http://europa.eu.int/comm/food/fs/sc/ssc/out113_en.pdf>Internet.

¹²Paul 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, Appendix Table B, Measures taken to prevent the spread of bovine spongiform encephalopathy to humans, p. 16.

¹³Dagmar 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*, p. B8, April 20, 2001; 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.

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 effected 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.”¹⁴ Consumer confidence in the safety of the U.S. meat supply could plummet if it is found that Americans are eating **BSE-infected** material.

Although the USDA has tested approximately 14,000 cattle suspected of having a central nervous system disorder for BSE,¹⁵ there is always the chance that it has not tested enough. While the U.S. ban on the importation of live ruminants and most ruminant products has 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.¹⁶

It is also possible that BSE occurs sporadically in a small portion of cattle, as CJD does in the human population. If BSE were to occur spontaneously in a U.S. bovine today, this country

¹⁴Anita Manning, USA Today, “Consumers’ Fears Carry Over to Food Decisions,” *USA Today*, April 19, 2001, p. 8D.

¹⁵United States Department of Agriculture, Animal and Plant Health Inspection Service, “BSE Surveillance,” available at <<http://www.aphis.usda.gov/oa/bse/bseurvey.html>>Internet.

¹⁶For example, New Zealand is just now redesigning its certificates of origin for cattle to make them less likely to be forged. New Zealand has no known cases of BSE and as an island nation, there is an increased certainty that New Zealand’s BSE status will remain unchanged. But it is certainly possible that cattle from another country with a forged New Zealand certificate could enter the U.S., Canada, or Mexico. Personal conversation with representative of the New Zealand government, June 5, 2001.

needs to be prepared to ensure that humans aren't consuming highly infectious tissue from that animal.

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 meat-and-bone meal supplements made from rendered cows or sheep to cows or sheep.¹⁷ However, the banned mammalian meat-and-bonemeal is still on the market because it can be fed to non-ruminants,¹⁸ such as pigs and poultry.¹⁹

In a 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 different types of feed, as required by the feed ban.²⁰ 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.²¹

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.²² A clerk at

¹⁷Food 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).

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

¹⁹21 CFR § 589.2000(c).

²⁰General 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].

²¹September 2000 GAO Report.

²²"Texas Cattle are Quarantined to Determine Mad-Cow Risk," *New York Times*, January 27, 2001, p. A8.

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.²³ 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.²⁴ **Because the FDA's feed rules aren't strict enough, if one cattle 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.**

3. The U.S. Should Follow Europe in Banning Potentially Infective 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.”²⁵

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

²³Sandra Blakeslee, “Agency Clears Texas Cattle in Quarantine,” *New York Times*, January 31, 2001, p. A18.

²⁴ **Although 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.**

²⁵*Final Report of the Investigation into the North Leicestershire Cluster of Variant Creutzfeldt-Jakob*, p. 19.

stated that the infectivity of the spinal cord is not in doubt.²⁶ 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 nervous system material (such as dorsal root ganglia) with the same infectivity as the spinal cord; and any potential infectivity from bone marrow.²⁷

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.”²⁸

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

²⁶European 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].

²⁷SSC Report, Section 4, Vertebral columns, p. 8.

²⁸SSC Report, Section 4.2.1, Contamination, p.9.

to the removal of the whole vertebral column (other than the coccyx) is now appropriate.”²⁹

Subsequently, this finding that dorsal root ganglia are highly infectious has been published.³⁰

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 1989.³¹ The list of banned bovine organs and tissues was revised and expanded a number of times as new information became available.³² In 1995, the U.K. also banned the use of “the vertebral column of a bovine animal in the

²⁹SSC Report, Section 4.2.2, Dorsal root ganglia, p.9.

³⁰Spongiform 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>>.

³¹WHO Factsheet 113, p.2.

³²WHO Factsheet 113, p. 2.

recovery of meat by mechanical means.”³³

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.³⁴

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 advanced meat recovery and other systems that mechanically separate the meat from the bone.³⁵ 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 significantly reduce the amount of potentially infectious spinal cord and dorsal root ganglia that enter the human food supply.

³³British 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, advanced meat recovery systems are not in use in Europe.

³⁴The 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.

³⁵While 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.

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.”³⁶ 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**.³⁷ **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 meat, 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 skeletal muscle of livestock carcasses and parts of carcasses.”³⁸ The definition of mechanically separated beef should be changed to exclude central nervous system tissue, **including dorsal root ganglia**.

³⁶ 9 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].

³⁷ 9 CFR § 319.6.

³⁸ 9 CFR § 319.5.

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 (AMR) 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 meat from the bone. According to FSIS regulations, these machines are supposed to detach the meat without crushing, pulverizing or grinding the bone itself.³⁹ 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.⁴⁰ Advanced meat recovery systems produce a product that can be called “meat” under current government requirements.⁴¹

In July 2001 in Europe, the Standing Committee on Foodstuffs endorsed a proposal from the European Commission that “tightens up the definition of the term ‘meat’ for the labeling of pre-packed meat-based products.”⁴² The Directive restricts the definition of meat to skeletal-attached muscles, provides for the indication of the species from which the meat comes, and excludes mechanically separated meat.⁴³ But what is more important than changing the definition of “meat” is being sure that any food product, whatever the label, does not contain harmful material.

³⁹9 CFR § 301.2.

⁴⁰9 CFR § 301.2.

⁴¹9 CFR § 301.2.

⁴²European Commission Press Release, “Stricter Labeling Requirements for Sausages and Preserved Meat Products,” Brussels, July 19, 2001, available at <http://europa.eu.int/comm/dgs/health_consumer/library/press/press168_en.html> [hereinafter cited as European Commission Press Release, July 2001].

⁴³European Commission Press Release, July 2001.

AMR systems strip the 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 entering these machines. **Despite the small number of tests conducted under the directive in 1997**, there were at least six documented cases in which 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

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, p. 64-65.

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).

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

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 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 is 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

⁴⁸AMR Proposed Rule, p. 17960.

⁴⁹AMR Proposed Rule, p. 17964.

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

a. Enforcement of the FSIS 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

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.

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.

performed, the small number of laboratory samples indicates that government inspection of the bones going into AMR machines may be quite rare.

Plant enforcement information from 1997 through 2000 **supports the conclusion that few inspections are performed under the directive.** 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 were found to contain central nervous system 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 advanced meat recovery system, but spinal cord couldn't be "definitively identified" in the sample.⁵⁶

Between 1998 and 2000, fewer than 60 samples of meat were analyzed under this directive. This is a pitifully small number, considering that **45 million** pounds of beef was produced by AMR systems in just one of those years.⁵⁷ Two of those 60 samples were positive for central nervous system tissue, and peripheral nerve tissue was found in other samples as well.

⁵⁵AMR Lab Reports: Pathology Report, completed 6/3/97 by Scott Hafner, D.V.M., M.S. Diplomate, ACVP 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.

Independent testing also indicates that USDA's directive has not been fully effective. The National Cattlemen's Beef Association hired Glenn Schmidt, a meat 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 central nervous system tissue is to prohibit the use of the spinal columns and neck bones in the AMR systems.

6. The Agricultural Marketing Service Allows Spinal Cord in Meat Purchased for the School Lunch Program

USDA must review all its regulations and purchasing requirements to ensure that spinal cord and other potentially infectious material are kept out of the human food supply. Although **several fast-food restaurants** surveyed by CSPI said they would reject ground beef that included meat derived from AMR or **mechanical separation** systems,⁵⁹ USDA specifications for ground beef purchased for the Federal School Lunch Program and other Federal Food Assistance Programs do not bar AMR meat. Even more disturbing is the fact that AMS quality specifications **explicitly** permit small bits of spinal cord in beef intended for **those** programs.⁶⁰ For example, for boneless beef intended for grinding into ground beef, the presence of pieces of

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

⁵⁹**Personal conversations with representatives with McDonalds, Burger King, and Wendy's.**

⁶⁰United States Department of Agriculture, Agricultural Marketing Service, Livestock and Seed Division, Institutional Meat Purchase Specifications (IMPS), Quality Assurance Provisions and IMPS Quality Assurance Tables for Beef Items Series 100, effective June 1997 [hereinafter cited as IMPS QA Tables].

spinal cord less than 0.5 by 0.2 inches is allowed.⁶¹ Similarly, spinal cord is allowed in many other cuts of beef purchased for **those** programs, which may be destined for grinding,⁶² including carcasses,⁶³ bone-in ribs,⁶⁴ boneless ribs,⁶⁵ bone-in forequarters,⁶⁶ boneless forequarters,⁶⁷ bone-in short rib/beef bones,⁶⁸ bone-in loins,⁶⁹ boneless hindquarters,⁷⁰ boneless round,⁷¹ boneless strip loins,⁷² and boneless sirloins.⁷³ Spinal cord should not be allowed in any beef destined for the school lunch program and other federal feeding programs, **including programs overseen by other federal agencies, such as the Department of Defense, the Veterans Administration and the General Services Administration.** Other regulations should be amended to ensure that spinal cord and other potentially infectious materials are kept out of the human food supply.

III. Legal Authority

⁶¹IMPS QA Table 100 I.

⁶²Institutional Meat Purchase Specifications for Fresh Beef Products, Series 100, effective June 10, 1996, p. 47, (“Unless otherwise specified, ground beef shall be prepared from any portion of the carcass (graded or ungraded)”).

⁶³IMPS QA Table 100 A.

⁶⁴IMPS QA Table 100 B.

⁶⁵IMPS QA Table 100 C.

⁶⁶IMPS QA Table 100 D.

⁶⁷IMPS QA Table 100 E.

⁶⁸IMPS QA Table 100 G.

⁶⁹IMPS QA Table 100 K.

⁷⁰IMPS QA Table 100 L.

⁷¹IMPS QA Table 100 M.

⁷²IMPS QA Table 100 N.

⁷³IMPS QA Table 100 P.

In enacting the Federal Meat Inspection Act (FMIA), 21 U.S.C. 601 *et seq.*, 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.” 21 U.S.C. 602. The courts have agreed that the purpose of this statute is to insure high level 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”).

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”⁷⁴ 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

⁷⁴U.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, [hereinafter cited as HACCP Final Rule].

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.”⁷⁵ “Adulterated” meat includes meat that “contains any poisonous or deleterious substance which may render it injurious to health.”⁷⁶ **This permissive 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.⁷⁷ **Several consumer groups and state officials challenged USDA regulations on procedural and substantive grounds for failing to adequately assess the health effects of mechanically deboned meat. It presents issues that are highly analogous to the issues presented in this petition.** First, mechanically separated meat is comparable to the meat produced from AMR systems. In fact, AMR 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:

⁷⁵21 U.S.C. § 606.

⁷⁶21 U.S.C. § 601(m)(1).

⁷⁷*Community Nutrition Institute v. Butz*, 420 F. Supp. 751 (D.D.C. 1976).

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.⁷⁸

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.⁷⁹

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 the 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

⁷⁸420 F. Supp. 751 (D.D.C. 1976).

⁷⁹420 F. Supp. 751 (D.D.C. 1976).

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.”⁸⁰

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. In addition, 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.⁸¹ 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 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 infectious materials in the human food supply would make the meat unwholesome and adulterated. Therefore, USDA should act 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

⁸⁰U.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).

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

recognized as safe, and comes 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.”⁸² While USDA has not reached 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 that contains 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. However, that is the issue that this petition places squarely before the Secretary.**

Because it is based on quality considerations, rather than safety, the enforcement of the Directive 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 CNS material out of the human food supply.

The scientific evidence is much clearer now than when USDA’s current standards were adopted that spinal cord tissue and other central nervous system tissue in the meat supply raises food-safety concerns, as this tissue from infectious cattle could spread a transmissible spongiform encephalopathy to humans. Therefore, it is time for FSIS to implement meaningful

⁸² 62 Fed. Reg. 30935, 30949 (June 5, 1997).

and enforceable **food safety** regulations to prevent infectious 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 entered 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]."⁸³ FSIS relied upon those provisions when it promulgated its HACCP/Pathogen Reduction Rule,⁸⁴ and they are equally applicable here.

2. FSIS Should Promulgate the Requested Regulations As an Interim Final Rule Without First Completing Notice and Comment, Risk Assessment, and Cost-Benefit Analysis

Meat products contaminated with infected spinal cord tissue, brain tissue, dorsal root ganglia or other specified risk material could pose a serious, immediate threat to human health if U.S. cattle are infected with BSE. FSIS, the agency responsible for protecting consumers from hazardous meat and poultry products, has a duty to respond to the potential threat from BSE by taking *immediate* regulatory action, without pursuing an unnecessarily lengthy rulemaking process. Under ordinary circumstances, the agency must comply with procedural requirements under both the Administrative Procedures Act (APA)⁸⁵ and the USDA Reorganization Act of

⁸³21 U.S.C. §§ 463, 621.

⁸⁴HACCP Final Rule, pp. 38806-55.

⁸⁵U.S.C. §§ 551 *et. seq.*

1994,⁸⁶ including the use of notice-and-comment rulemaking and the completion of a risk assessment and cost-benefit analysis before issuance of a new rule. However, both acts provide for exceptions to those requirements for circumstances such as those present here, where the new regulations would address an imminent threat to public safety. It is critical that the **maximum** protections are in place before BSE is found **in U.S. cattle**. Any delay in rulemaking would be contrary to the public interest.

FSIS should avail itself of those statutory exceptions and promulgate the requested regulations in an expedited fashion. The agency should first adopt the regulations as an “interim-final rule,” which would become binding upon publication (or shortly thereafter), and subsequently provide for public comment and complete its risk assessment and cost-benefit analysis.⁸⁷ As explained below, FSIS is authorized to take such an approach under both the APA and the USDA Reorganization Act of 1994.

a. The Requested Regulations Satisfy the “Good Cause” Exception To the Administrative Procedure Act’s Requirement for Notice and Comment

The APA provides that full notice-and-comment rulemaking is not required when an agency “for good cause finds (and incorporates the finding and a brief statement of the reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.”⁸⁸ The good cause exception “is an important safety valve to be

⁸⁶Pub. Law. 103-354.

⁸⁷See Michael Asimow, “Interim-Final Rules: Making Haste Slowly,” *Admin. L. Rev.*, Vol. 51, (Summer 1999), pp. 703-744 (describing numerous administrative agencies’ use of interim-final rules as a pragmatic tool to “strike a compromise between a perceived need for immediate adoption of a rule and the values of public participation and regulatory analysis”).

⁸⁸5 U.S.C. § 553(b)(B).

used where delay would do real harm.”⁸⁹ According to the legislative history of the provision, “‘impracticable’ means a situation in which the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings.”⁹⁰ As one court has held, determining “impracticality” requires “analysis in practical terms of the particular statutory-agency setting and the reasons why agency action could not await notice and comment.”⁹¹

There are numerous instances in which courts have upheld an agency’s decision to invoke the “good cause” exception and issue a rule without providing for notice and comment where a delay would threaten public safety or the environment.⁹²

The rationale underlying those decisions, that compliance with time-consuming procedural requirements would “do real harm” by delaying implementation of urgently needed regulations to safeguard public health, is equally applicable here. For example, if BSE-infected cattle are discovered in the U.S. prior to the implementation of these safeguards, it would likely result in widespread public alarm because of concerns that BSE-tainted meat already may have entered the human food supply through AMR and other beef products.

⁸⁹*United States Steel v. EPA*, 595 F.2d 207, 214 (5th Cir. 1979).

⁹⁰ S. Rep. No. 752, 79th Cong., 1st Sess., at 16 (1945).

⁹¹*American Transfer & Storage Company v. ICC*, 719 F.2d 1283, 1295 (5th Cir. 1983).

⁹²*See, e.g., Hawaii Helicopter Operators Ass’n v. FAA*, 51 F.3d 212, 214 (9th Cir. 1995) (good cause exception satisfied in view of “the threat to public safety reflected in an increasing number of helicopter accidents”); *Northern Arapahoe Tribe v. Hodel*, 808 F.2d 741, 750-52 (10th Cir. 1987) (good cause exception satisfied in view of urgent need for hunting regulations where herds were threatened with extinction); *Northwest Airlines v. Goldschmidt*, 645 F.2d 1309, 1321 (8th Cir. 1981) (good cause exception satisfied in view of urgent need to allocate landing slots at major airport).

b. 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.⁹³ 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.⁹⁴

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 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 this threat constitutes the “compelling circumstances” necessary to permit FSIS to adopt the requested regulation without first completing a full regulatory analysis. FSIS instead should publish the regulations as an interim

⁹³7 U.S.C. § 2204e(b)(1).

⁹⁴7 U.S.C. § 2204e(b)(1).

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

IV. Conclusion

The recent discovery that BSE is much more widespread in Europe than previously thought makes clear that urgent precautionary measures are needed to prevent meat products contaminated with infective central nervous system 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 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.

V. Certification

The undersigned party certifies that, to the best knowledge and belief of the undersigned, 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,

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On behalf of:

American Public Health Association
Government Accountability Project

Consumer Federation of America
National Consumers League