



Center for Food and Nutrition Policy  
Virginia Tech - Alexandria

## ***Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities***

Comments to the U.S. Department of Agriculture

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The Center for Food and Nutrition Policy (CFNP) is an independent, non-profit, center chartered at Virginia Polytechnic Institute and State University. The CFNP mission is to advance rational, science-based food and nutrition policy, and it is recognized as a Center of Excellence on such matters by the Food and Agriculture Organization of the United Nations (FAO).



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Docket No. 03-0800-1  
Regulatory Analysis and Development  
PPD APHIS  
Station 3C71  
4700 River Road Unit 118  
Riverdale, MD 20737-1238

**RE: Docket No. 03-0800-1  
RIN 0579-AB73  
Bovine Spongiform Encephalopathy; Minimal Risk Regions and  
Importation of Commodities**

The Center for Food and Nutrition Policy (“Center”) of Virginia Tech—Alexandria is an independent, non-profit research and education organization that is dedicated to advancing rational, science-based food and nutrition policy. It is recognized as a Center of Excellence on such matters by the Food and Agriculture Organization of the United Nations (FAO). The Center uniquely operates like an independent “think-tank,” while maintaining its academic affiliation with a major land-grant university. The research, education, outreach, and communications activities of the Center’s faculty are conducted in a relevant, time-sensitive manner that helps inform the public policy process on food and nutrition issues.

Encompassed in the Center’s activities on food policy are its interests in regulatory issues involving food safety and security, including animal health issues. As such, the Center respectfully submits the following comments in response to the United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA / APHIS) request for comment on Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, docket no. 03-0800-1 as published in the Federal Register.<sup>1</sup>

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<sup>1</sup> Federal Register: Proposes Rules. November 4, 2003, Volume 68, Number 213, pages 62386-62405.

<http://frwebgate4.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=47660412255+0+0+0&WAIAction=retrieve>

### Overview of the Comments

On December 23, 2003, a 6 ½ year old dairy cow in Washington state was diagnosed with Bovine Spongiform Encephalopathy (BSE/Mad Cow Disease). The facts of this case have emerged rapidly since this discovery and authorities worldwide have sought greater information about this incident. The format of these comments are as of November 4, 2003; as of December 29, 2003; and as of January 5, 2004—the final date for submitting comments.

The Center recognizes the important role of USDA in: (1) protecting public and animal health; (2) assuring public confidence in our food supply; (3) safeguarding our \$1.3 trillion annual agricultural economy; and (4) maintaining our agriculture-related export and domestic markets affected by BSE. The USDA must balance competing interests, laws, regulations, and international recommendations that appear to conflict or may be based on, as yet, very limited science, especially when dealing with the emerging transmissible spongiform encephalopathy diseases (TSEs) such as Bovine Spongiform Encephalopathy (BSE / Mad Cow Disease) that presents in people as new variant Creutzfeldt-Jakob Disease (nvCJD.)

### **Comments as of November 04, 2003**

The Center began preparation of these comments on November 04, 2003, following the publication of proposed rules in the *Federal Register*. Comments on pages 1 – 6 were prepared prior to the discovery of the one cow diagnosed with BSE on December 23, 2003. Nevertheless, the comments here point to several overarching issues that were imperative before December 23, 2003 and after.

- 1. Protect our \$1.3 trillion annual agricultural economy;**
- 2. Protect public health and public confidence in the food supply;**
- 3. Protect U.S. animal populations from foreign animal diseases that infect people;**
- 4. Protect our many agriculture related export and domestic markets;**
- 5. Protect future U.S. economic interests now.**

#### **1. Protect our \$1.3 trillion annual agricultural economy.**

Our \$1.3 trillion agricultural economy bolsters our standard of living and helps to feed many other people around the world. Our cattle / beef industry amounts to \$175 billion annually. Changing the Office International des Epizooties (OIE) Code recommendations on BSE to allow Canada and other countries with BSE

to openly export cattle / beef to the U.S. may hasten our fall from the short list of countries now seen as BSE-free.<sup>2</sup> This will be economically devastating especially now when so little is known about prion diseases such as BSE.

Changing OIE Code recommendations on BSE is not just about cattle / beef and Canada, our good trading partner in agriculture. BSE is still undergoing intense scientific investigation. The only well-documented constant is that BSE wreaks economic devastation wherever it appears. To date, countries without BSE are trying to avoid economic disaster by not joining the list of those with BSE. As of March 03, 2003, the Canadian Food Inspection Agency (CFIA) listed only seven countries as being BSE-free.<sup>3</sup>

1. Argentina
2. Australia
3. Brazil <sup>(1)</sup>
4. Chile
5. New Zealand
6. Uruguay
7. U.S.

<sup>(1)</sup> Includes health certification guarantees provided by the Brazilian authorities

The USDA has already publicly breached the concern that Japan may not accept U.S. cattle / beef imports if the U.S. openly accepts cattle / beef imports from Canada and other countries currently listed as having BSE.<sup>4</sup> Indeed after the discovery of a U.S. cow with BSE, many countries closed their borders to U.S. cattle / beef.

Today, Canada is a much larger cattle / beef trading partner than is Japan. As alliances change radically with time, it seems possible that U.S. cattle / beef trading partners could change as well. Focusing on only today's largest cattle / beef trading partner threatens to trap the U.S. later when trading alliances could change.

Unless the USDA can produce overwhelming evidence that BSE is inevitable in the U.S., then the USDA should continue to do all things possible to maintain our BSE-free status. To date, the current OIE Code on BSE recommendations have served this country well.

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<sup>2</sup> CFIA List of BSE Free Countries as of 03/03/03.

<http://www.inspection.gc.ca/english/anima/heasan/disemala/recotab/bsefreeliste.shtml>

<sup>3</sup> CFIA List of BSE Free Countries as of 03/03/03.

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<sup>4</sup> Federal Register: Proposes Rules. November 4, 2003, Volume 68, Number 213, pages 62386-62405.

<http://frwebgate4.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=47660412255+0+0+0&WAISSaction=retrieve>

Sound science from reproducible, peer-reviewed research still requires many more years of study to learn: (1) the details of the pathogenesis of BSE; (2) how to effectively and efficiently destroy the BSE prions without simultaneously destroying everything else; and (3) how to develop and produce safe, effective vaccines for both people and animals. Even if USDA believes that BSE in the U.S. is inevitable, the department has an affirmative duty to take all steps possible to protect U.S. citizens and our economy until scientists learn how to defeat BSE. One step is to not implement this proposed USDA / APHIS rule change.

### **The “Precautionary Principle” and BSE in the U.S.**

It is important to distinguish trade restrictions to reduce the BSE risk from trade restrictions based on the precautionary principle. The precautionary principle is applied when no risk has been demonstrated, but there is still uncertainty in a risk assessment. For example, the precautionary principle has been invoked to restrict trade in hormone-treated beef and genetically-modified crops. In the case of BSE, the economic risks and the risks to medical products and others have been clearly demonstrated in the U.K. and other countries, even if the food safety risk was small. The economic risk is known and devastating.

Furthermore, the trade restrictions to help keep BSE out of the U.S. and the other six remaining countries listed as BSE-free are not being applied as camouflaged protectionism. Trade restrictions can be lifted as soon as Canada regains its place on the list of BSE-free trading partners in eight years.

In the alternative, the trade restrictions could be lifted as soon as scientists learn enough about prions to effectively deal with them through safe and effective vaccines for people and animals or other effective risk mitigation strategies.

## **2. Protect public health and public confidence in the food supply.**

Keeping the U.S. free from BSE directly protects public health here and abroad. BSE is hypothesized to also be transmitted through human blood and blood products. The Associated Press reported December 17, 2003, that the government of the United Kingdom (U.K.) believes that one or more people recently died in the U.K. most likely from new variant CJD (nvCJD) contracted from blood transfusions contaminated with BSE prions. The presumed incubation period in these victims is believed to have been years long, a common finding for some prion diseases. The U.K. now imports all human blood and blood products from the U.S. to avoid just such loss of human life and public confidence. Thus, the U.K. depends on the U.S. remaining BSE-free.<sup>5</sup>

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<sup>5</sup> *Donor, Recipient Die of Mad Cow Disease.* Associated Press / The Washington Post. 12/17/03.

To illustrate that BSE involves more than the cattle and beef industry:

- The U.S. does not accept blood donations from people who spent considerable time in Europe, especially from 1980 to 1996.<sup>6</sup>
- Iatrogenic nvCJD and CJD result in part from the inability to sterilize surgical instruments with prion contamination without also destroying the instruments.<sup>7</sup>
- Human tissue grafts have transmitted infectious prion diseases including BSE / nvCJD.<sup>7</sup>
- U.S. pharmaceutical companies and others rely on BSE-free raw animal products to produce both human and animal health products sold here and abroad.

Even if the OIE Code recommendations on BSE are changed, as the USDA is now championing, it will remain the sovereign decision of each country to interpret the new code as each country sees fit. OIE Code is only a guideline with no enforcement authority. That authority lies with each sovereign nation.

Member nations of the World Trade Organization (WTO) should abide by their international obligations. Several member nations of the WTO have implemented bans on cattle and beef from countries with BSE. To date, these bans have not been challenged at the WTO.

### **3. Protect U.S. animal populations from foreign animal diseases that infect people.**

The USDA has an admirable track record of keeping foreign animal diseases out of our livestock populations and away from our citizens. Historically, most of these foreign animal diseases did not infect people. BSE does.

The prions that cause BSE are hypothesized to permanently contaminate certain soils and terrains. As such, prions are similar to anthrax spores, which last essentially forever to infect later generations of susceptible animals and people. The USDA should act to limit prion contamination of U.S. soils for as long as possible. Or at least until the science of BSE is better understood and there are effective vaccines for people and animals.

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<sup>6</sup> <http://www.fda.org/opacom/factsheets/justthefacts/8bse.htm>

<sup>7</sup> <http://www.cdc.gov/ncidod/eid/vol3no2/ricketts.htm>

Unless and until there are safe and effective BSE vaccines for susceptible people and animals, the USDA should not champion changes to the OIE Code on BSE recommendations that expose the U.S. to increased risk from prions. Much of the world looks to the U.S. as a major source of BSE-free products ranging from human and animal health care products to human and pet foods.

BSE vaccine research and development is in its early stages. Every year the USDA is able to maintain our BSE-free status is one more year available in the race to develop and produce safe and effective BSE vaccines for people and animals.

#### **4. Protect our many agriculture related export and domestic markets.**

Most countries with confirmed BSE have suffered devastating economic losses from drastically reduced foreign export and domestic markets. This usually occurred along with a severe loss of consumer confidence in the safety of each country's food supply. The notable exception is that Canada seems to have lost only its cattle / beef export markets. This has cost Canada about \$20 million per day or about \$1.5 billion to date.<sup>8, 9</sup>

#### **5. Protect future U.S. economic interests now.**

If USDA believes the U.S. will be inevitably infected with BSE, then easing of OIE Code may favor the U.S. by ending some of the effective measures that have kept separate those countries with BSE from those that remain BSE-free. If the USDA aids Canada now, Canada and other countries may afford us the same consideration once the U.S. has BSE.

The U.S. has a strong interest in maintaining and supporting a science-based system of international trade in agricultural products. In our opinion, measures to reduce the likelihood that BSE will be introduced to a country are consistent with science-based, free, and fair trade in agricultural products.

This concludes the center's comments prior to December 23, 2003, when BSE was discovered in the U.S.

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<sup>8</sup> *The Spread of Mad Cow Disease.* CNN.com 12/23/03.

<sup>9</sup> *Canada Awaits Test Results on Cow.* The Washington Post. 12/30/03.

## **Addendum** **December 29, 2003**

Since the USDA first released its proposed BSE rule changes for comment, the U.S. confirmed its first case of BSE in a 6½ year-old Washington state dairy cow from Alberta, Canada. This dairy cow was imported along with hundreds of other Canadian dairy cows into the Yakima Valley in the state of Washington between 1997 and 2000.<sup>10, 11</sup> This BSE-infected dairy cow passed through many handlers and owners from birth in Alberta, Canada until its slaughter on December 9, 2003. Some U.S. consumers believe they may have eaten meat from the infected cow.<sup>12, 13</sup>

### **National Trace Back and Forward System for Cattle**

The current USDA tracking system for cattle is insufficient to guarantee success in tracing all parts of this cow and its herd mates from birth 6½ years ago to today. The U.S. already has in place a national trace back and forward program for swine. Such a system for our cattle / beef industry is long past due.

### **Meat and Bone Meal Feed Commercially Available – But Not for Cattle**

In 1993, Canada identified its first case of BSE, yet it did not ban meat and bone meal (MBM) feed for cattle until 1997. The OIE Code on BSE recommendations state that any country must have an MBM feed ban in place for at least eight years before that country is considered BSE-free. Even so, the U.S. continued to import Canadian live cattle and beef until May, 2003 when Canada's second case of BSE was identified. In coordination with this proposed USDA BSE rule change, the USDA has petitioned the OIE to change its BSE Code recommendations to allow the U.S. and other countries to accept live cattle imports as occurred before this second Canadian case of BSE in May, 2003.

The FDA banned Meat and Bone Meal (MBM) feed to cattle in 1997. Eighteen months later, the General Accounting Office (GAO) released a report that 18% of the 1,826 regulated rendering plants were unaware that a ban even existed.<sup>14, 15</sup> About 12 months after that, the GAO released a second report stating that essentially nothing had changed in rendering plant MBM feed ban compliance in the previous 12 months since its first report.<sup>16, 17, 18</sup> There is only substantial compliance with the U.S. MBM feed ban as of 2000.

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<sup>10</sup> *Sick Cow Probably Imported.* The Washington Post. 12/28/03.

<sup>11</sup> *Origin of Sick Cow Sought.* The Washington Post. 12/26/03.

<sup>12</sup> *Holstein's Origin will be Clue to U.S. Safeguards' Success.* The Washington Post. 12/30/03.

<sup>13</sup> *Sick Cow Was Old Enough to Have Eaten Now-Banned Feed.* The New York Times. 12/30/03.

<sup>14</sup> *Inspections Practices Examined.* The Washington Post. 12/25/03.

<sup>15</sup> <http://www.gao.gov>

<sup>16</sup> *Mad Cow Disease. Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts.* January, 2002

<sup>17</sup> *Too Little Regulation and Too Much Hysteria Feed Food Fears.* USA Today. 12/26/03.

The 6½ year old, Washington state dairy cow contracted BSE from consuming BSE-contaminated MBM feed either in Canada or the U.S. The 1997 MBM feed bans in each country (with limited compliance and enforcement in at least the U.S. until 2000) gave ample opportunities for this cow and others to contract BSE. Although compliance and enforcement of the MBM feed ban are both the responsibility of the FDA, presumptively the USDA was aware of the two GAO reports noting the low compliance and enforcement of the ban. USDA was BSE testing about 4,000 (only sick and/or injured) cattle out of the 37 million slaughtered annually even though the effective MBM feed ban was not followed by 20% of the renderers for the first three years until 2000. Because an effective MBM feed ban has been in place in the U.S. only since 2000, the USDA should BSE-test all cattle born before the year 2000 at slaughter.

### **“Downer Cows”**

The U.S. Congress defeated banning “downer cows” from the human food supply in December, 2003.<sup>19</sup> There are about 150,000 to 200,000 “downer cows” each year at USDA inspected slaughter facilities.<sup>20</sup>

At least one major trade association advocates sending “downer cows” through cattle slaughterhouses for human consumption because they believe that the USDA BSE testing program will otherwise miss those “downer cows” infected with BSE. USDA now BSE tests only “downer cows” and others that appear clinically ill. Some cattle with BSE are clinically normal for some time. These BSE infected cattle will not be BSE tested by the current USDA program and will enter the human food supply for domestic and export markets.

If “downer cows” with BSE enter the slaughterhouse, pass USDA antemortem inspection as this dairy cow with BSE did, and are BSE tested, then these “downer cows” will enter the human food supply before the BSE test results are available. This sequence of events occurred with the recent Washington state BSE infected dairy cow.<sup>21</sup> Some U.S. consumers complained that they believed they had consumed some this dairy cow as ground beef.

If the Washington state dairy cow had entered the Washington state slaughtering facility more than three months ago—before this facility began to participate in the USDA BSE testing program—it would have never been tested for BSE and would have entered the human food supply as a “downer cow”. This Washington state cattle facility specializes in slaughtering older dairy cows that are injured or no longer produce enough milk.<sup>22</sup>

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<sup>18</sup> *Sick Cow Was Old Enough to Have Eaten Now-Banned Feed.* The New York Times. 12/30/03.

<sup>19</sup> *Top Export Markets Slam Shut to American Beef.* USA Today. 12/26/03

<sup>20</sup> *Meat From Infirm Animals is Banned.* The Washington Post. 12/31/03.

<sup>21</sup> *As Probe of Infected Cow Spreads, So Does Worry.* The Washington Post. 12/27/03

<sup>22</sup> *We Were Lucky About One Thing.* The Washington Post. 12/25/03.

### **MBM Feeds Available to Cattle**

The recent Canadian BSE case would not have been BSE tested in the U.S. because it did not exhibit any signs of clinical neurological disease. This Canadian cow with pneumonia was instead rendered and shipped to as many as 1,800 Canadian feed outlets. MBM feeds have outlived their economic value in cattle production everywhere because of the virtually indestructible prions that cause BSE in cattle, new variant Creutzfeldt - Jakob disease in people, Chronic Wasting Disease in cervids, and other invariably fatal neurodegenerative diseases in other species.

### **BSE – Never Just a Direct Threat to Human Health**

USDA needs to focus more attention on the threat to the U.S. economy in addition to reassuring the public of the safety of the food supply. BSE directly and indirectly threatens many economic sectors, including pharmaceutical companies and other private sectors here and abroad, which depend on BSE-free raw animal products.

## **Addendum** **January 04, 2004**

### **More MBM Feeds: The FDA and The USDA**

The Associated Press reported in The Washington Post on December 31, 2003 that the FDA already plans to extend the MBM feed ban to dogs, cats, swine, and poultry in 2007.<sup>23</sup> The USDA should work with the FDA and others to effect this expanded MBM feed ban in 2004. This will close one of the lingering loopholes in both the actual safety of U.S. cattle / beef – but more importantly the perception of consumers everywhere that U.S. cattle / beef are safe.

### **BSE Testing for Cattle Born Before the Year 2000**

To date the FDA (working closely with the USDA to protect the U.S. food supply) formally banned MBM feed to cattle in 1997. The General Accounting Office (GAO) twice noted that there was no better than about 80% compliance until the year 2000. Because the U.S. has had an effective MBM feed ban since only 2000, the USDA should BSE-test every cow born before the year 2000 – about 30% of the total cattle slaughtered in 2003.

Epidemiologists can design an appropriate sampling procedure and sample size to detect the presence of BSE in any small percentage of cattle e.g., one in 100,000. Because of the nature of statistics the sample size would not need to be as large as the total population of cattle. An appropriate sampling procedure and sample size could provide an efficient and effective means to determine whether BSE exists in even a very small percentage of cattle.

However, this may not be sufficient to restore public confidence in the U.S. and globally. In order to completely restore public confidence that U.S. cattle / beef are BSE-free, USDA may need to implement testing of all slaughtered cattle that were born before the year 2000. For cattle born after 2000, a statistical testing program may be sufficient to monitor the BSE status of the U.S. cattle population.

### **Ban Each and Every “Downer Cow” from the U.S. Food Supply**

The USDA announced December 30, 2003 that it was banning all “downer cows” from the human food supply. But during a December 30, 2003 briefing, the USDA stated that some “downer cows” will still be allowed to enter the U.S. human food supply.

As recent numerous U.S. beef export bans clearly demonstrate, the perceived safety of the U.S. cattle / beef industry is as important as its actual safety. The cost / benefit analysis does not justify jeopardizing our \$175 billion U.S. cattle / beef industry to save most likely less than 10,000 “new downer cows” per year. Economically, this is unacceptable.

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<sup>23</sup> *Experts: Pets Probably Safe From Mad Cow.* Associated Press / The Washington Post. 12/31/03.

It is now time to totally shore-up our cattle / beef industry and its export markets to allow the U.S. to resume our leadership position in cattle / beef production by banning each and every “downer cow” of every description from the U.S. human food supply.

### **Summary - January 05, 2004**

The U.S. cattle / beef supply is safe, but that is not good enough in a global economy. U.S. foods must also be perceived to be safe by the world’s consumers. Only then can the U.S. continue to be a leader in agriculture and in feeding the world’s hungry.

The U.S. and the USDA have recently made substantial regulatory changes affecting our cattle / beef industry. These advances positively impact our domestic and export cattle / beef markets. We need to now go the last few yards to effectively show the world that the U.S. can completely respond to infectious disease threatening the human food supply – and – allay the prevalent and reasonable consumer fears globally concerning BSE in cattle / beef.

We can supply food products that are both safe and perceived as safe globally. The USDA must continue to take the lead and move forward on BSE regulations.

In summary, the Center for Food and Nutrition Policy at Virginia Tech urges the USDA to:

1. Not implement the proposed changes in the USDA / APHIS BSE rules;
2. Withdraw the USDA proposed changes to OIE Code recommendations on BSE that effectively liberalize cattle / beef imports from countries with BSE into the U.S.;
3. Champion a continuation of the current OIE Code recommendations on BSE at the OIE May, 2004 meeting;
4. Ban all “downer cows” without exception from the U.S. food supply;
5. Institute a national trace back and forward system for all domestic and imported cattle;
6. Work closely with the FDA to effect a total ban in 2004 of MBM feeds to any animals that could possibly enter the U.S. human food supply;

7. BSE-test all slaughtered cattle born before the year 2000;
8. Support federal funding for extensive basic and applied BSE research plus vaccine research and development for people and animals;

Respectfully submitted,



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