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FSIS Docket Room
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Karen Egbert

Re: Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States; FSIS Current Thinking On Measures That Could Be Implemented To Minimize Human Exposure to Materials That Could Potentially Contain the Bovine Spongiform Encephalopathy Agent, Docket No. 01-027N

The Food Safety and Inspection Service (FSIS) is seeking comment on two documents: (1) FSIS's current thinking on additional measures that should be considered to minimize human exposure to materials that may contain the Bovine Spongiform Encephalopathy (BSE) agent if it were to be introduced in the United States (hereafter "Current Thinking paper"),[1] and (2) an "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States," prepared by the Harvard Center for Risk Analysis and the Center for Computational Epidemiology at Tuskegee University (hereafter "Risk Analysis").[2]

The Center for Science in the Public Interest (CSPI) and fellow Safe Food Coalition members -- American Public Health Association, Consumer Federation of America, and

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[1] USDA, Food Safety and Inspection Service, *Current Thinking On Measures That Could Be Implemented To Minimize Human Exposure To Materials That Could Potentially Contain The Bovine Spongiform Encephalopathy Agent* (Jan. 15, 2002).

[2] Harvard Center for Risk Analysis, Harvard School of Public Health and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States* (Nov. 26, 2001).

National Consumers League – welcome the opportunity to comment on these documents. CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by 800,000 subscribers to its *Nutrition Action Healthletter.*

Scientists have documented that if a cow has BSE, consuming small portions of its brain, spinal cord and other central nervous system (CNS) tissue could cause human cases of variant Creutzfeldt-Jakob Disease (vCJD), a devastating disease invariably causing death.[3] The CNS tissue from even a single BSE-infected animal could potentially infect hundreds of people so 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. The need for greater public health protection is further heightened by recent research showing that the prions causing BSE may accumulate in muscle tissue of mice.[4]

A joint consultation of the World Health Organization (WHO), UN Food and Agriculture Organization (FAO), and Office International des Epizooties (OIE) have recommended that countries should not become complacent about their risk from BSE. "The extremely low initial incidence and limited clustering of BSE cases, protracted latency and non-specific nature of the early clinical signs of Bovine Spongiform Encephalopathy tend to mask the severity of the problem."[5]

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[3] Paul Brown, et al., *Bovine Spongiform Encephalopathy and Variant Creutzfeldt-Jakob Disease: Background, Evolution, and Current Concerns*, 7 Emerging Infectious Diseases (Jan.-Feb. 2001), pp. 6, 10 [hereinafter Brown, et al., *Bovine Spongiform Encephalopathy and Variant Creutzfeldt-Jakob Disease*].

[4] Sandra Blakeslee, *Research Leads to Call for Quick Testing of Mad-Cow-Infected Animals*, New York Times (March 19, 2002), at D7; *Risk of mad-cow proteins in muscle tissue*, USA Today (March 20, 2002), at 8D.

[5] WHO Press Release, *Joint WHO/FAO/OIE Technical Consultation on BSE: Public Health, Animal Health and Trade* (14 June 2001).

Before October 2000, certain high-risk bovine organs and tissues (called "specified risk materials" or "SRM") were used in the human food chain in the European Union.[6] The discovery of BSE in countries where there are insufficient safeguards to prevent high-risk materials, like brain and spinal cords, from entering the human food supply caused consumer confidence to plummet. Therefore, to protect public health and consumer confidence, 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.

Although the USDA and Food and Drug Administration (FDA) have taken stringent precautions to prevent mad cow disease from infecting our animal population, they have been less proactive in protecting human food. More must be done to protect American consumers from the risk BSE poses in the food supply and from the crisis in confidence that has emerged in Europe in recent years.[7] A recent report by the General Accounting Office (GAO) has found that "[t]he continuing absence of BSE in the United States today cannot be sufficiently ensured by current federal prevention efforts."[8] Therefore, we urge FSIS to move expeditiously from the thinking to the action stage and propose and adopt all measures necessary to further minimize the threat that BSE may pose to U.S. cattle and, ultimately, to the public health.

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[6] Brown, et al., *Bovine Spongiform Encephalopathy and Variant Creutzfeldt-Jakob Disease*, at p. 16 (Appendix Table B).

[7] Dagmar 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 (Jan.15, 2001), available at <*http://www.guardianunlimited.co.uk/bse/article/0,2763,422384,00.html*>; Devon Spurgeon, *McDonald's First Quarter Net Fell 16% Due to Concerns About Mad-Cow Disease*, Wall Street Journal (Apr. 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 (Nov. 25, 2000), available at <*http://www.guardian.co.uk/Print/0,3858,4096355,00.html*>.

[8] General Accounting Office, Report to Congressional Requesters, *Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts*, GAO-02-183 (Jan. 2002), at p. 10 [hereinafter GAO, *Mad Cow Disease*].

COMMENTS ON RISK ANALYSIS

The Risk Analysis is intended to predict the potential for BSE to become a major public health threat in the United States. It uses a probabilistic simulation model and assumptions based on an evaluation of U.S. measures intended to prevent the spread of BSE to animals and humans if it were to arise in this country. Based on the model, the Risk Analysis has concluded that the United States is highly resistant to the introduction of BSE or a similar disease, and that if it were introduced, it would be eliminated within 20 years.[9] While the Risk Analysis presents a comprehensive overview of the sources of BSE infectivity, U.S. cattle slaughter practices, and the regulatory measures designed to prevent the entry and spread of BSE in this country, it appears that some of the assumptions result in an underestimation of the actual risk of BSE in U.S. cattle and, ultimately, to the public's health.

1. Current Testing May be Inadequate To Reveal Potential Cases

According to the Risk Analysis, "BSE has not been detected in the U.S. despite 12 years of active surveillance of high-risk animals."[10] Although the number of cattle brains examined annually in the United States through its active surveillance system exceeds the OIE standard,[11] this number is minimal compared to the number of cattle slaughtered each year. Approximately 37 million cattle are slaughtered in the United States each year, but the brains from only 22912 cows were tested in the 12 years between May 10, 1990 and February 28, 2002.[12] While the

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[9] *Risk Analysis*, Executive Summary, at p. i.

[10] *Risk Analysis*, Executive Summary, at p. iii.

[11] Office International des Epizooties, *Surveillance and Monitoring of Bovine Spongiform Encephalopathy*, <*http://www.oie.int/eng/normes/mcode/A_00154.htm*>.

[12] USDA, Animal and Plant Health Inspection Service, *BSE Surveillance*, <*http://www.aphis.usda.gov/oa/bse/bsesurvey.html*>.

USDA has announced that it intends to increase testing of cattle for BSE – from 5000 cattle tested in 2001 to 12,500 in 2002 – this level of testing still may not be sufficient to detect BSE if it exists in U.S. cattle.

Some European countries that thought they were at low risk for BSE suddenly discovered an increased incidence in their herds or saw their first cases in native cattle when they implemented more systematic testing, including testing of all bovines over 30 months intended for human consumption and compulsory testing of all bovines presented for emergency slaughter.[13] For instance, in November 2001, Irish authorities reported a sudden increase in findings of BSE cases. Fifty three cases were diagnosed in that month alone – the highest monthly figure ever – bringing the total number of BSE cases to over 220 for the year through the end of November, compared to 149 for all of year 2000. The government attributed this increased number of positive findings to the fact that over 600,000 animals were tested as part of its active surveillance system.[14] Likewise, findings of BSE in France increased as a result of wide-scale BSE testing.[15]

According to the USDA, cattle less than 20 months old make up approximately 88 percent of the slaughter population in this country.[16] While BSE has not been diagnosed in cattle

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[13] Official Journal of the European Communities, Court of Auditors, *Special Report No. 14/2001, Follow up to Special Report No 19/98 on BSE, together with the Commission's replies* (2001/C 324/01), at pp. 2, 11 (finding the number of BSE cases is likely to have been under-reported in the past, and that the increased number of BSE cases reported recently is due to better surveillance with the introduction of compulsory epidemiological surveillance in 1998 and the use of rapid diagnostic BSE tests) [hereinafter Court of Auditors, *Special Report No. 14/2001*]. *See also* FDA Backgrounder, *BSE: Background, Current Concerns, and U.S. Response* (Mar. 1, 2001).

[14] Consumers' Association, *BSE Monthly Report* (Dec. 2001), p. 7.

[15] Court of Auditors, *Special Report No 14/2001*, at p. 10.

[16] USDA, APHIS, *Backgrounder on USDA's BSE Surveillance* (July 2001), at p. 2, <http://www.aphis.usda.gov/oa/bse/bsesurv.htm> [hereafter APHIS, *Backgrounder on USDA's BSE Surveillance*].

less than 20 months old,[17] the risk that a cow may be infected increases with its age. Under the testing regime currently conducted by the Animal and Plant Health Inspection Service (APHIS),

- only a sampling of cattle that are nonambulatory or show signs of neurologic disease are tested,
- there is no mandatory testing on cattle over 30 months slaughtered for human consumption, and
- only a small sample of cattle that die on the farm are tested.

As a result, the current testing program may be inadequate to detect latent BSE in U.S. cattle. In addition, the European Commission's SSC has found that there is some possibility that BSE-infectivity entered this country via cattle imports from the United Kingdom and was recycled to domestic cattle so that there could be cases present at levels below the low detection level of the surveillance in place.[18]

Moreover, the rapid post-mortem tests currently in use only identify the presence of the BSE agent near the end of the incubation period for animals that are already clinically ill and do not identify pre-clinical cases at earlier stages of incubation. These tests are approved for use on animals over 30-months old and are not deemed reliable for animals under that age.[19] Even then, the European Commission's Scientific Steering Committee (SSC) has cautioned that the tests are not a fail-safe procedure, and that false negatives will give false reassurances concerning the absence of BSE when it may in fact be present.[20] Accordingly, the Risk Analysis should be more

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[17] APHIS, *Backgrounder on USDA's BSE Surveillance*, at p. 2.

[18] European Commission, *Final Opinion of the SSC on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR)*, adopted on July 6, 2000 [hereafter European Commission, *Final Opinion of the SSC on GBR*], at p. 46.

[19] Court of Auditors, *Special Report 14/2001*, at p. 11 n.(1).

[20] Consumers' Association, *Monthly BSE Report* (Jan. 2001), <*http://www.which.net/campaigns/bse/jan01/sc_news.html*>.

conservative in its assumptions concerning the ability of the current testing program to detect BSE in U.S. cattle.

2. Assumptions Concerning Feed Ban Compliance Are Too Optimistic

Since 1997, the FDA has imposed a ban on protein products derived from mammalian tissues, with certain exceptions, in ruminant feed.[21] The Risk Analysis concludes that "the U.S. appears very resistant to a BSE challenge, primarily because of the FDA feed ban, which greatly reduces the chance that a sick animal will infect other animals."[22] Although the Risk Analysis acknowledges uncertainty about feed ban compliance rates and the effectiveness of the feed ban in preventing the spread of BSE should it exist in the United States, the feed ban is being inadequately enforced and the assumptions concerning feed ban compliance are too optimistic.[23]

The prohibited material, including meat-and-bone-meal (MBM), can still be fed to non-ruminants such as pigs, horses and poultry. While there is no evidence that pigs and poultry get BSE-like diseases from their food, processing ruminants into animal feed opens the door for banned material to inadvertently be fed to cattle. A July 2001 review of the origin of BSE by an independent review committee commissioned by the United Kingdom (UK) agreed with the BSE Inquiry's earlier finding that MBM made from offal of BSE-infected cattle was so infective that accidental contamination of cattle feed with pig or poultry feed containing MBM was a significant factor which continued to spread BSE after the UK ban on the use of MBM in cattle feed.[24]

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[21] 21 C.F.R. § 589.2000.

[22] *Risk Analysis*, at p. 97.

[23] *Risk Analysis*, at p. 97.

[24] Gabriel Horn, et al., Independent Review Committee, *Review of the Origin of BSE*, commissioned by the UK Minister of Agriculture and the Secretary of State for Health, published by Department for Environment, Food &

A December 14, 2001 report by the FDA's Center for Veterinary Medicine (CVM) indicates that 264 firms recently inspected throughout various regions of the country are still not in compliance with one or more requirements of the feed ban -- over four years after its implementation.[25] Of these, at least 205 handle both prohibited material and non-prohibited material. Of the 205, at least 79 were cited for failure to have adequate systems in place to prevent commingling. These data, however, do not reveal the size of the firm cited or the volume of prohibited material handled. In addition, 159 of the firms were cited for failing to properly label their feed with the cautionary statement, thus raising the risk that prohibited material could be inadvertently fed to ruminants.[26]

These ongoing violations suggest that the FDA's campaign to educate all sectors of the animal feed industry on the requirements of the rule has not resulted in full compliance, and that firms handling prohibited material are still failing to maintain separation of prohibited and non-prohibited material.[27] Moreover, the GAO has found serious deficiencies in the FDA's

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Rural Affairs (July 5, 2001), at p. 10, *<http://www.defra.gov/animalh/bse/bseorigin.pdf>* [hereafter *Review of the Origin of BSE*>.

[25] FDA, Center for Veterinary Medicine, *Most Recent BSE Inspections, Firms Not in Compliance* (Dec. 14, 2001), *<http://www.fda.gov/CVM/efoi/BSEinspectnotcompl121401.xls>.*

[26] In the period between February 20, 2001 and December 31, 2001, FDA issued warning letters to approximately 47 companies for violations of various aspects of the rule. See FDA, *FOIA Warning Letters Search, <http://www.fda.gov/foi/warning.htm.>* A review of these letters shows a range of violations, including use of common equipment to manufacture cattle feed and swine feed containing MBM (Warning Letter 01-ATL-39); failure to flush out equipment used to mix feeds containing prohibited protein materials prior to mixing feeds that are not formulated with prohibited protein material (Warning Letter CIN-WL-01-7208); lack of written procedures for cleaning out or flushing equipment after mixing feeds containing prohibited material (WL-CIN-8669-01; Warning letter 01-ATL-39); failure to specify the amount of flush required (Warning letter MIN 01-57); failure to flush incoming receiving pit conveyor systems and ingredient storage bins after the receipt of ruminant meat and bone meal (Warning letter CIN-7703-01); and failure to separate the receipt, processing, and storage of product containing prohibited material from non-prohibited material (Warning Letter SEA 01-75).

[27] In response to an FDA request for comments on whether it should amend the ruminant feed ban, 66 Fed. Reg. 50,929 (Oct. 5, 2001), CSPI has commented that, among other things, FDA should require dedicated facilities for the manufacture, storage and distribution of prohibited animal protein.

enforcement strategy for feed ban compliance, including a lack of hierarchy of enforcement actions, criteria for actions to be taken, time frames for firms to correct violations and time frames for follow-up inspections to confirm that violations have been corrected.[28]

In addition, feed mills, which comprise the largest number of establishments producing animal feeds, are not licensed or registered by the FDA (unless they produce medicated feed products). Although there are an estimated 6,000-8,000 mills not licensed by the FDA, the agency has admitted that it does not know the exact number.[29] As a result, there could be a substantial number of such mills that have not been subject to inspection and whose compliance status is not known.

Until the FDA implements additional controls – including a mandatory registration system for all feed mills producing prohibited material, mandatory separation and dedicated facility requirements for all establishments manufacturing, storing and distributing both prohibited and non-prohibited materials, compulsory notification requirements where ruminant feed containing prohibited material has been distributed or sold without proper labeling, and an improved enforcement strategy -- the risk that prohibited materials could inadvertently be fed to cattle is magnified and should be adequately accounted for in the BSE risk assessment.

3. The Risk That Imported MBM And Meat By-Products From Infected Cattle Could Have Entered The U.S. May Be Higher Than Predicted

In December 2000, APHIS adopted a prohibition on the import of all rendered animal protein products from Europe. However, between 1989 and 1997, before the European Union banned export of feed containing animal products, the United States imported at least 9,500

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[28] GAO, *Mad Cow Disease*, at p. 24.

[29] FDA, Center for Veterinary Medicine, *CVM Update, Ruminant Feed (BSE) Enforcement Activities* (Oct. 30, 2001), at 2.

metric tons of cattle and livestock feed from Europe, including **336 metric tons** from Great Britain.[30] While this is only a small proportion of U.S. feed imports, it means that there is a real possibility that U.S. cattle have consumed the prohibited feed. According to the European Commission's SSC, the import of one ton of meat-and-bone meal from the United Kingdom may pose the same challenge (in terms of a country's geographic risk from BSE) as the import of one live animal.[31]

The Risk Analysis concludes that "past MBM imports pose little risk of exposing U.S. cattle to BSE."[32] That analysis, however, appears to have focused solely on the risk of mammalian proteins entering from the United Kingdom. The Court of Auditors of the European Union recently issued a report finding, among other things, that poor surveillance and poor implementation of the mammalian MBM feed ban in most of its member states, as well as poor controls over trade in MBM and animal feed, may have contributed to the spread of BSE to other Member States, preventing it from being eradicated.[33] According to the report, the fact that cattle in Europe with BSE have been born after the 1994 mammalian MBM feed ban "provide[s] evidence that the ban has not been properly implemented and controlled, and there is evidence from FVO [Food and Veterinary Office] inspections of lack of controls on trade in MBM."[34]

In December 2001, Austria reported its first case of BSE, although it has banned feeding

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[30] Alejandro E. Segarra and Jean M. Rawson, CRS Report for Congress, *Mad Cow Disease: Agriculture Issues* (Mar. 12, 2001), at pp. 2-3.

[31] European Commission, *Final Opinion of the SSC on GBR*, at p. 10.

[32] *Risk Analysis* at p. 23.

[33] Court of Auditors, *Special Report 14/2001*, at p. 17. According to the Report, inspection reports between 1998 and 2000 found a significant risk of contamination of ruminant feed with mammalian MBM in most member states.

[34] Court of Auditors, *Special Report 14/2001*, at pp. 2, 17.

of meat and bone meal to cattle and sheep since 1990.[35] Until that time, Austria had been classified as risk category 2 (BSE unlikely but not excluded) - the same category as the United States.[36] While the transmission source is not confirmed, it is speculated that the cause of the BSE transmission was **imported** meat-and-bone meal (MBM) that was illegally fed to cattle or imported calf milk replacer that had beef tallow as an ingredient.[37]

The Joint WHO/FAO/OIE Technical Consultation on BSE has noted that identification in 2000 of BSE in native-born cattle in European countries previously thought to be free of BSE has led to increased concern about the extent of the BSE epidemic. The committee has emphasized the global risk, stating that "[t]he concern extends beyond Europe, partly as a result of uncertainty about risks that may result from past international trade of cattle and cattle products from BSE-affected countries."[38] The General Accounting Office recently documented an example of this risk to the United States, noting that a shipment of animal feed identified as originating in Canada was discovered on inspection to have actually originated in Switzerland.[39]

Over the past 20 years the United States has imported approximately 23 million pounds of inedible meat by-products, including MBM, 101 million pounds of beef and 24 million pounds

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[35] Center for Emerging Issues, *Bovine Spongiform Encephalopathy, Austria*, Impact Worksheet, Dec. 18, 2001, [hereinafter CEI, *Bovine Spongiform Encephalopathy, Austria*], <*http://www.aphis.usda.gov/vs/ceah/cei/bse_austria1201.htm*>. In January 2001, Austria began testing all cattle over 30 months for BSE.

[36] European Commission, *Final Opinion of the SSC on GBR*, at pp. 30, 44.

[37] CEI, *Bovine Spongiform Encephalopathy, Austria*.

[38] Office International Des Epizooties, Joint WHO/FAO/OIE Technical Consultation on BSE: public health, animal health and trade, *Conclusions and key recommendations* (11-14 June 2001), at p. 2.

[39] GAO, *Mad Cow Disease*, at p. 19.

of beef products from countries where BSE was later found.[40] While this represents only a small fraction of total imports in each category, given BSE's long incubation period, "the possibility that some contaminated animals or products have entered the United States cannot be ruled out.[41]

In addition to underestimating the possibility that past shipments of contaminated feed or beef products have entered this country, the Risk Analysis has ignored the fact that BSE-risk material may still be entering the United States through international bulk mail. According to the GAO, of 116,000 packages screened at one inspection facility in New Jersey between May and October 2001, USDA inspectors found that 570 of them contained one or more at-risk beef or beef-derived products.[42] For these reasons, the Risk Analysis is too optimistic in estimating the risk of BSE in this country.

3. <u>The Swiss Simulation Model Demonstrates That the Risk Is Underestimated</u>

To test the plausibility of the model used to quantify the impact of introducing BSE into the U.S. cattle population on both animal health and on potential human exposure to contaminated food products, the risk assessors modeled a BSE outbreak that occurred in Switzerland. The model predicted that an average of approximately 480 cattle would become infected and that 170 of these would develop clinical signs of the disease.[43] However, as of the publication of the Risk Analysis in November 2001, the Swiss had detected 398 animals with clinical signs of BSE.[44] As a result, it appears that the model may predict less than 50% of the

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[40] GAO, *Mad Cow Disease*, at p. 14.

[41] GAO, *Mad Cow Disease*, at p. 14.

[42] GAO, *Mad Cow Disease*, at p. 18.

[43] *Risk Analysis*, at p. 92.

[44] *Risk Analysis,* Executive Summary, at iii. This number appears to be an update of the number reported in the "Results" section of the Risk Analysis, which indicates that the Swiss had reported 324 animals with clinical

actual risk to U.S. cattle. Although the Risk Analysis describes this as only a "modest underprediction,"[45] it clearly shows that the risk assessment lacks a conservative public health approach as we have already documented.

COMMENTS ON FSIS'S CURRENT THINKING PAPER

FSIS has indicated that it is considering a number of options that could be implemented to minimize human exposure to materials that could potentially contain the agent that causes BSE. While adoption of these proposals would represent some incremental progress in controlling for BSE, they do not adequately protect the public should BSE be discovered in U.S. cattle.

Option 1 - Treatment of High-Risk Tissue

According to FSIS, it will consider classifying certain bovine tissues as Specified Risk Materials (SRMs) and prohibit their use for human food. These include the brain and spinal cord from cattle aged 24 months and older and downer cattle, regardless of age.[46] Additionally, any materials, including edible meat, that have been cross-contaminated with bovine brain and spinal cord from downer cattle and cattle aged 24 months and older would be prohibited for human food.

- **FSIS Should Expand the List of SRMs from Downer Cattle and Cattle Older than 12 months**

    1. The entire head and vertebral column of downer cattle and cattle older than 12 months should be designated SRM

According to the FAO, specified risk materials, including the spinal cord, brain, eyes,

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signs between 1990 and 2000. *Risk Analysis*, at p. 92.

[45] *Risk Analysis*, at p. 93.

[46] FSIS, *Current Thinking*, at pp. 8-9.

tonsils, and parts of the intestines account for over 95% of BSE infectivity.[47] In experimentally-infected cattle, the distal ileum, bone marrow, dorsal root ganglion, and trigeminal ganglion also have been found to be infective. Transmission of vCJD to humans from infected cattle most probably results from consumption of beef products contaminated by bovine central nervous system and related spinal tissue – tissues carrying the highest level of BSE infectivity.[48]

The European Commission's SSC has listed the bovine brain, eyes, spinal cord and dorsal root ganglia, dura matter, pituitary, skull and vertebral column, and lungs as the highest risk materials for the transmission of BSE.[49] The dura mater, pituitary, skull, and vertebral column were moved up from lower categories of infectivity because of the possibility of their contamination by tissues of higher infectivity (such as the brain and spinal cord) during slaughter and their inclusion of dorsal root ganglia.[50]

We agree with FSIS that the brain and spinal cord from downer cattle -- regardless of age should be designated as SRMs and prohibited for use as human food. However, the list of SRMs from downer cattle should be expanded to include the entire head as well as the vertebral column since downer cattle in Europe have been shown to have a higher incidence of BSE.[51]

In addition, FSIS should designate the entire head, spinal cord and vertebral column of

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[47] Food and Agriculture Organization of the United Nations, *Mad cow disease: FAO recommends precautions* (8 February 2001), at p. 2 <*http://www.fao.org/news/2001/010202-e.htm*>.

[48] TSEAC Background Document, *Bovine Brain, Spinal Cord, and Other Neurological Tissue in Foods, Drugs, and Cosmetics for Human Use*, p. 1.

[49] European 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*> [hereinafter cited as European Commission, *Listing of Specified Risk Materials*].

[50] European Commission, *Listing of Specified Risk Materials*, at pp. 1, 2.

[51] FSIS, *Current Thinking Paper*, at p. 6.

cattle over 12 months – not 24 months – as SRM. While the majority of European BSE cases have occurred in cattle over 24 months of age,[52] it is assumed that most infection with the BSE agent happens close to birth. The SSC has concluded that the age of an animal represents a good approximation of the potentially possible incubation stage and its infective load.[53] Since there is currently no test to determine whether a cow is incubating BSE, designating the entire head, spinal cord and vertebral columns of all cattle over 12 months of age would significantly reduce the likelihood that a BSE-infected cow ever enters the food chain.

A report by the SSC has discussed 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.[54] The report found that contamination of the vertebral column by spinal cord "can be expected under most practical slaughterhouse circumstances . . . ."[55]

In addition, the SSC has reported that "new 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

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[52] In Europe, approximately 99.95% of the over 180,000 BSE cases have occurred in animals over 30 months of age. European Commission, Health and Consumer Protection Directorate-General, Press Release, *Commission approves further protection measures against BSE* (Brussels, 7 February 2001), at p. 1 [hereafter EU, *Commission approves further protection measures against BSE*], *<http://www.europa.eu.int/comm/dgs/health_consumer/library/press/press106_en.html>*.

[53] European Commission, *Final Opinion on the Geographical Risk of BSE*, at p. 33.

[54] European Commission, *Listing of Specified Risk Materials*, Section 4, Vertebral columns, at p. 8.

[55] European Commission, *Listing of Specified Risk Materials*, Section 4.2.1, Contamination, at p. 9.

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."[56] By removing the vertebral column, the dorsal root ganglia would be removed as well.

Based on this evidence, the SSC recommended that the vertebral column should be removed in bovines aged over 12 months where there are question marks over the effectiveness of the ban on the feed of MBM and "whenever it cannot be demonstrated that the animal is unlikely to be incubating BSE . . . ."[57] In February 2001, the European Commission approved removal of the vertebral column from all cattle over 12 months.[58]

While BSE has not been identified in this country, the Risk Analysis has recognized that implementation of a ban on specified risk material, *e.g.* spinal cords, brains, and vertebral columns, from the human and animal food chains has a "dramatic effect" on potential human exposure or the spread to cattle, reducing the predicted number of BSE cases in cattle by 80% and the potential human exposure by 95%.[59] Accordingly, as a precautionary action, FSIS should classify the heads, spinal cords, and vertebral columns of all downer cattle and cattle over 12-months as SRM since these cattle have the highest risk for being infected with BSE,

2. The intestines of cattle of all ages should be designated SRM

FSIS also has indicated it may consider designating the intestine from all cattle regardless of age as an SRM. We support this action since BSE has been found to be infective in the small

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[56] European Commission, *Listing of Specified Risk Materials*, Section 4.2.2, Dorsal root ganglia, p. 9. This preliminary finding that dorsal root ganglia are highly infectious was subsequently published. *See* Spongiform Encephalopathy Advisory Committee, *Report to Ministers: A Review of Infectivity in Bone Marrow and Dorsal Root Ganglia in Cattle Infected with BSE* (Nov. 1998).

[57] EU, *Commission approves further protection measures against BSE.*

[58] EU, *Commission Approves further protection measures against BSE.*

[59] *Risk Analysis*, at pp. iv & 96.

intestine (distal ileum) of calves from 6 to 22 months post-infection.[60] Because infectivity of the intestine is presumed to apply to animals immediately after they have consumed infective material, the European Commission's SSC has recommended, as a precautionary measure, that the intestine should be considered infective in cattle of all ages.[61]

3. FSIS should ban the use of air-injected and pneumatic stun guns

In its Current Thinking paper, FSIS has stated that it is considering banning the use of air-injected stun guns for knocking cattle unconscious in slaughterhouses. While it appears that few, if any, U.S. commercial slaughter facilities still use pneumatic-powered air-injection stunners, FSIS should act to adopt a prohibition on both pneumatic-powered air-injection stunners and pneumatic-powered stunners (PPS) in beef slaughter plants to reduce the risk of cross-contamination of heart muscle by CNS tissue.

The SSC has found that penetrative stunning methods, particularly pneumatic stunners that inject air, create a risk of cross-contamination of displacing brain tissue to the lungs, heart, and blood.[62] A study by researchers at Colorado State University at fifteen beef slaughter plants in the western and central United States has shown that 12% of the hearts of cattle killed with pneumatic-powered stunners in three plants where the PPS was used contained detectable clots. Where pneumatic-powered air injection stunners were used, 33% of the hearts examined

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[60] European Commission, *Listing of Specified Risk Materials*, at pp. 7-8.

[61] European Commission, *Listing of Specified Risk Materials*, at pp. 7, 11-12.

[62] European Commission, Health & Consumer Protection Directorate-General, Scientific Steering Committee, *Preliminary Scientific Opinion and Report on Stunning Methods and BSE Risks* (adopted by SSC at its meeting of 6-7 September 2001), at pp. 2, 3, 8, 19 [hereinafter European Commission, *Preliminary Report on Stunning Methods*].

contained large clots. In addition, large segments of spinal cord were detected in two hearts.[63]

Therefore, FSIS should take action to ban both air-injected pneumatic stunners and pneumatic powered stunners. Taking such action is particularly important since heart can be consumed individually as a variety meat or as a component in hot dogs or other products.[64]

- **FSIS Should Not Allow SRMs From Downer Cattle That Test Negative For BSE To Be Allowed In the Human Food Chain**

FSIS has indicated that it may consider permitting downer cattle to be used for human food without restrictions on the use of certain materials designated as SRMs if the establishment can demonstrate that an animal's non-ambulatory condition is not associated with BSE.[65] We strongly oppose this option and urge FSIS to ban the use of SRMs from downer cattle in human food regardless of test results.

The SSC has found that even if the result of a rapid test is negative it cannot be concluded that the animal (including the brain) is devoid of detectable infectivity.[66] FSIS itself has recognized that, given the limitations of the diagnostic tests currently available, "certain tissues of cattle infected with BSE may contain the BSE agent before a diagnostic test could indicate that the animal has BSE."[67]

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[63] G.R. Schmidt, et al., Research Note, *Potential for Disruption of Central Nervous System Tissue in Beef Cattle by Different Types of Captive Bolt Stunners*, Colorado State University, at p. 2.

[64] FSIS, Consumer Education and Information, *Focus on Hot Dogs* (Slightly Revised May 2000).

[65] *Current Thinking Paper,* at p. 7.

[66] European Commission, *Preliminary Report on Stunning Methods*, at p. 17.

[67] *Current Thinking Paper,* at p. 8.

Because European surveillance data have shown that downer cattle have a higher incidence of BSE,[68] and there is no currently validated test to demonstrate conclusively that a downer (or any other) cow is not infected with BSE, the entire head and spinal and vertebral columns from all downer cattle should be designated as SRM and prohibited in human food – regardless of test results.

■ **Additional Measures Are Needed To Protect The American Public**

1. FSIS Should Designate Additional Materials As SRM

APHIS has reported confirmed cases of scrapie, a Transmissible Spongiform Encephalopathy (TSE), in sheep and goats in the United States.[69] While there is no evidence that scrapie can cross the species barrier, FSIS should designate the brains in sheep and goats as SRMs to assure that they do not enter the human food chain. According to a report by the Working Group of the EU's Scientific Steering Committee on the Origin of BSE in the United Kingdom, "it is no longer possible to exclude an unmodified scrapie agent as the agent responsible for BSE."[70]

2. FSIS Should Establish a Maximum Slaughter Age for Cattle for Human Food or, Alternatively, Test All Cattle Over 30 Months Intended for Human Consumption

FSIS should consider establishing a maximum age at which cattle can be slaughtered for human food. According to the SSC, the infective load of animals below 24 months of age is in general "very much lower than it would be possible for an animal of 60 months, assuming that

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[68] *Current Thinking Paper*, at p. 6.

[69] USDA, Animal and Plant Health Inspection Service, *Bovine Spongiform Encephalopathy (BSE)*, <*http://www.aphis.usda.gov/oa/bse*>.

[70] *Review of the Origin of BSE*, at pp. 5, 12.

both were infected shortly after birth."[71] Therefore, FSIS should consider implementing a ban on slaughter for human food of cattle older than 30 months or, alternatively, testing all cattle over 30 months intended for human consumption.

3. FSIS Should Implement a Trace-back Program

FSIS should implement a trace-back regime in the event that BSE-contaminated beef is ever discovered in the United States. While livestock producers frequently identify their animals with ear tags, tatoos, or other devices, FSIS only requires establishments to maintain the identity of the carcass through the time of the post-mortem examination and inspection program personnel to collect IDs associated with animals suspected of a reportable disease.[72]

However, because an animal could already be processed into meat before it is determined that the animal has been infected with BSE, FSIS must have the ability to trace contaminated meat back, not just to a particular slaughterhouse or supplier, but to a specific animal and herd of origin as quickly as possible. Such a traceback regime could be accomplished through implementation of computerized recordkeeping and/or barcode requirements. In fact, the Japanese have recently announced that they will be testing a computerized system whereby retail customers can confirm the origin of the beef they are purchasing.[73]

4. FSIS Should Promulgate Safe Handling, Storage and Disposal Regulations of SRM

FSIS should put into place a program to address the control of SRM, including its safe handling, storage and transport, from the point where it is removed from the cattle to the point of

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[71] European Commission, *Final Opinion of the SSC on GBR*, at p. 33.

[72] 9 C.F.R. § 310.2.

[73] Joshua Lipsky, *Japanese to Test System to Identify Beef Origin* (Feb. 19, 2002), <*http://www.meatingplace.com/meatingplace/Daily News/News.asp?ID=8829*>.

destruction. Standards on the handling of specified risk materials are necessary to ensure that BSE-infected animals and tissue that is more likely to carry the BSE agent stay out of the human food and animal feed chains.

Among other things, FSIS should require that specified risk material removed from cattle be permanently stained or otherwise marked to assure that it is disposed of properly and not inadvertently used for rendered products. Another component of an effective control program would include a record-keeping system to be able to trace the movements of SRM. In addition, FSIS should act now to establish requirements for additional testing and ultimate disposal of any cow suspected of having BSE.

Option 2: Meat Recovery Systems

FSIS has indicated it may prohibit the use of the vertebral column from all downer cattle regardless of age, and "consider" prohibiting the use of the vertebral column from other cattle populations, including all cattle aged 24 months or older, as a source material in meat recovery systems that use pressure to separate beef meat or beef products from bone. If, however, the vertebral column of downer cattle and cattle older than 12 months is designated as SRM, then it could not be used in advanced meat recovery systems under any circumstances. Beyond that, the use of the vertebral column from <u>all</u> cattle – not just downer and older cattle -- should be banned in advanced and mechanical meat recovery systems

Advanced meat recovery (AMR) systems produce a product that can be called "meat" under current government regulations.[74] AMR systems strip any soft tissue from the bones that enter the equipment. According to the American Meat Institute, more than 50% of the meat

[74] 9 C.F.R. § 301.2(rr)(2).

derived from AMR equipment comes from hard-to-trim backbones and neckbones.[75]

A means by which low risk tissue could become contaminated with the BSE agent is through the use of advanced meat recovery systems, which can leave high risk tissues, such as the spinal cord or dorsal root ganglia, in the recovered meat. The use of the vertebral column of a bovine animal in the recovery of meat by mechanical means has been banned in the UK since 1995.[76]

An FSIS directive instructs inspectors to ensure that spinal cord be removed from the vertebral column before the backbones enter the AMR process if the product is to be labeled as meat.[77] If bits of spinal cord remain attached to the spinal column or neck bone that enters these machines, then that soft tissue may be incorporated into the product.[78] The USDA has estimated that 257 million pounds of beef were recovered using AMR systems in 2000.[79] The beef made by AMR systems enters a variety of products, including ground beef, meat-balls, taco fillings, jerky, and pizza toppings.[80] Machines are also used for making a product called "mechanically separated meat." The machinery forces bone and tissue through a high pressure system to

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[75] American Meat Institute, *Fact Sheet: Meat Derived by Advanced Meat Recovery* (July 2001).

[76] British Ministry of Agriculture, Fisheries and Food, *The Specified Bovine Offal (Amendment) Order*, 1995 No. 3246.

[77] FSIS Directive 7160.2 (Apr. 14, 1997).

[78] B.P. Demons 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.

[79] GAO, *Mad Cow Disease*, at p. 27. The American Meat Institute has estimated that 45 million pounds of beef are produced each year using AMR systems. *See* AMI, *Fact Sheet: Meat Derived by Advanced Meat Recovery* (July 2001).

[80] Sparks Companies, Inc., *Advanced Meat Recovery Systems - An Economic Analysis of Proposed USDA Regulations* (July 1999), p. 10. See also AMI, *Fact Sheet: Meat Derived by Advanced Meat Recovery* (July 2001).

separate bone from tissues and may grind, crush or pulverize bones.[81] This produces a slurry or puree that cannot be called "meat." However, as long as the product is labeled as containing "mechanically separated beef," it can be used in a wide variety of processed-meat products.[82] Hot dogs can contain up to 20% mechanically separated beef.[83]

A survey by the FSIS to assess the performance of advanced meat recovery systems found spinal cord and central nervous tissue in two samples from AMR systems compared to none in hand-deboned samples.[84] Further investigation of a subset of AMR systems samples were found to contain spinal cord. The survey also found that most of the AMR samples contained bone marrow tissue and bones exiting the AMR systems were not consistently intact.[85]

Although FSIS has implemented Directive 7160.2, which requires FSIS inspection personnel to determine whether an establishment is completely removing spinal cord from neck and/or back bones (if any) before bones enter AMR systems,[86] there are questions concerning the adequacy of FSIS's enforcement of this Directive. In its recent report on Mad Cow Disease, the GAO has noted the USDA's lack of rigorous enforcement against the presence of CNS tissue in meat recovered by AMR system technology.[87]

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[81] FSIS, Backgrounder, *FSIS Releases Survey of Advanced Meat Recovery Systems* (March 1997), available at *<http://www.fsis.usda.gov/oppde/rdad/frpubs/back_amr_sys_survey.htm>*, [hereafter FSIS, *Survey of Advanced Meat Recovery Systems*].

[82] FSIS, *Meat and Poultry Labeling Terms* (Slightly Revised, Jan. 2001), *<http://www.fsis.usda.gov/OA/pubs/lablterm.htm>*.

[83] FSIS, *Focus on Hot Dogs*.

[84] FSIS, *Survey of Advanced Meat Recovery Systems*, at p. 3.

[85] FSIS, *Survey of Advanced Meat Recovery Systems*, at p. 3.

[86] FSIS Directive 7160.2, *"Meat" Prepared Using Advanced Mechanical Meat/Bone Separation Machinery and Meat Recovery Systems* (Apr. 14, 1997).

[87] GAO, *Mad Cow Disease*, at p. 28.

Since 1997, the USDA has tested a total of only 63 beef samples from 18 plants using AMR systems. Of those, 12 tested positive for CNS tissue.[88] USDA inspector reports also have provided evidence that spinal cords attached to spinal columns are in fact entering AMR machines. Through the Freedom of Information Act, the Government Accountability Project obtained at least six inspection reports from 1997 that noted that inspectors saw bovine spinal cord material entering the AMR systems.[89]

Because it is still uncertain what amount of BSE-contaminated tissue must be ingested in the transmission of BSE to humans in the form of vCJD, **no** amount of spinal cord should be allowed in AMR systems or any system mechanically separating meat from the bone. Mechanically-recovered meat affords the most potential to be infected if spinal cord is attached to the vertebral column that enters these machines. This is **not** a food quality issue – it is a food **safety** issue. The only truly effective approach to prevent potentially BSE-infective material from entering food consumed by humans is to ban the use of vertebral columns in AMR and other mechanical systems that separate meat from the bone.

FSIS also has indicated that it is considering the potential risk associated with the use of the vertebral column as source material in rendering systems that do not use pressure. According to FSIS, the "potential for dislodging CNS materials into beef stocks, beef flavorings, and beef

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[88] GAO, *Mad Cow Disease*, at p. 28.

[89] USDA response to Government Accountability Project FOIA Request #97-501, 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 Port, 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 6/2/97, Internal Lab No. A39706, Serial No. 900755; Pathology Specimen Submission for sample taken on 8/8/97, Internal Lab No. A40580, Serial No. 108900.

extracts is unknown."[90] It is precisely because the impact is unknown that FSIS should ban the use of this material. There should be a presumption that such a potential exists until proven otherwise.

Option 3 - Cheek Meat

Under FSIS's current thinking, slaughterhouses would be required to remove cheek meat before the skull is split. Because the brain is one of the most infective parts of an animal with clinical BSE, its removal creates a high potential for contamination. Although the risk assessment assumes that harvesting some fraction of the trigeminal ganglia along with the cheek meat would have little impact on human exposure to the BSE agent,[91] the potential for contamination emphasizes the need for it to be removed prior to splitting the head. This is particularly important since cheek meat has been gaining popularity as a gourmet item.[92] Accordingly, FSIS should require cheek meat to be removed before the head is boned.

II. Economic Impacts

A. Further Government Action to Regulate The Potential Risk of BSE Cannot Await An Economic Analysis

FSIS has stated that it will conduct a formal economic analysis for each policy option before it implements any measures to minimize human exposure to materials that potentially could contain the BSE agent. This statement suggests that if FSIS determines that implementation of new protective measures is too costly to industry, it will not adopt them. Such an approach is unconscionable.

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[90] *Current Thinking Paper*, at p. 9.

[91] *Risk Analysis*, Section 4.2.3, at p. 89.

[92] Jerry Shriver, *Pomme frite with your beef cheek?*, USA Today (Jan. 21, 2000), available at <*http://www.usatoday.com/life/travel/dining/2000/ltd002.htm*>.

In the late 1960's and early 1970's, Ford Motor Company took a similar position, deciding that the costs of correcting a flaw in the fuel tank of the Pinto at a cost of $11 per car outweighed the value of a human life, which it estimated to be $200,000.[93] FSIS should flatly reject the application of a financial calculation to determine the necessity for additional regulation against the threat of BSE in this country. The focus must be on protection of public health – not delay in order to determine the ultimate costs and benefits of new regulation.

B. <u>The Benefits Of Regulation Far Outweigh Costs to Industry</u>

Even under a cost/benefit analysis, the benefits of additional regulation to protect against BSE would far outweigh any costs to industry. Although FSIS has identified industry costs of implementing new measures, it has stated that it cannot provide an accurate, quantitative, estimate of the extent of the human health benefits that would result from implementing the measures discussed.[94]

In fact, FSIS can monetize the public health benefits of avoiding BSE in this country. For years USDA and many other federal agencies have monetized the benefits of health and food-safety regulations, including most notably, in promulgating FSIS's HACCP rule. Accordingly, FSIS should use these other efforts as a model to predict the benefits of measures to protect the public health against BSE.

FSIS also should add to the benefits side of the economic equation the substantial economic costs avoided by adopting and implementing the various proposals to prevent and minimize the spread of BSE. If BSE were discovered in this country, it is highly probable that

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[93] Sajjad Haroon, *Engineering Disaster, The Ford Pinto Case*, "A Study in Applied Ethics, Business, and Technology, available at *<http://www.uoguelph.ca/~sharoon/a1/a1disate.htm>*.

[94] *Current Thinking Paper*, at p. 10.

beef consumption would drop precipitously, with a corresponding drop in prices, because of a loss of consumer confidence in the safety of the beef supply.

The recent GAO report determined that if BSE were to be found in U.S. cattle, "the economic impact on the $56 billion beef industry and related industries could be devastating"– costing as much as $15 billion in lost sales revenue.[95] After the first case of Mad Cow disease was confirmed in Japan in September 2001, it was reported that Japan's beef market with in "turmoil," with one poll showing 63% of Japanese saying that they would not eat beef again.[96] The same news report indicated that the Japanese government had estimated it would cost more than $1 billion to restore consumer confidence, even though the disease had only been found in two cows.[97] This loss of consumer confidence was recently demonstrated when McDonald's of Japan announced that its second-half profit fell 67 percent as customers "shunned" beef products because of mad cow disease.[98] In January 2001, sales of beef inside the European Union were down 27% and, in Germany, it was reported that beef sales dropped by half amid new fears over mad-cow disease.[99]

Other costs to the industry would be incurred as the result of mandatory herd depopulation and selective culls of cattle most at risk requiring cattle to be destroyed, recalls and investigating the source of the BSE contamination, cleaning up the contamination, and possible

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[95] GAO, *Mad Cow Disease*, at pp. 31-32.

[96] Yumiko Ono and Steve Stecklow, *Mad-Cow Disease Finds Japan Unprepared as Tokyo Fumbles in Bid to Resassure Public*, Wall Street Journal (Nov. 30, 2001), at A13 [hereinafter *Mad-Cow Disease Finds Japan Unprepared*].

[97] *Mad-Cow Disease Finds Japan Unprepared*, at p. A13.

[98] *Japan: McDonald's Profit Falls*, The New York Times (Feb. 16, 2002), B2.

[99] BBC News, *EU facing BSE cost explosion* (Jan. 30, 2001) [hereinafter BBC, *EU facing BSE cost explosion*], <*http://news.bbc.co.uk/hi/english/world/europe/newsid_1143000/1143597.stn*>.

plant closings. In addition, the costs of avoided litigation should be calculated. While there is limited information concerning the costs of litigation over foodborne illnesses, USDA's Economic Research Service has documented that the mean compensation for a premature death case between 1988 and1997 was $274,580 in 1998 dollars and the mean compensation for a foodborne-illness-related hospitalization was $141,199 in 1998 dollars.[100] These awards do not include the fees paid to attorneys, experts, and other costs associated with litigation. Nor do they include the costs of foodborne illness cases that have settled, since those awards are not public.

These avoided costs represent a substantial benefit from implementation of more protective measures.

III. *FSIS Collaboration With Other Agencies*

A. Only A Single Food Safety Agency Can Adequately Address Risks To The Food Supply

FSIS has indicated its intent to coordinate more closely with other federal agencies with responsibility for controlling the spread of BSE in this country should it exist. The potential threat of BSE disease in the United States underscores the need for Congress to establish an independent agency exercising responsibility for farm-to-table food safety. Under the current regulatory regime, numerous agencies have responsibility for administering dozens of laws and regulations concerning food safety, each with a different approach to its regulatory mission, different priorities, and different enforcement authorities.

A National Academy of Sciences (NAS) committee report completed in 1998 determined that the "current fragmented regulatory structure is not well equipped to meet the current

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[100] Jean C. Buzby, et al., U.S. Department of Agriculture, Economic Research Service, Ag. Econ. Report No. 799, *Product Liability and Microbial Foodborne Illness* 16 (April 2001).

challenges."[101] If BSE were discovered in the United States, extensive coordination would be necessary to minimize duplication of effort, prevent gaps in regulatory coverage and avoid conflicting actions. Consolidation of food safety functions into one agency is necessary, not only to ensure farm-to-table food safety, but to allow a quick and coordinated, rather than piecemeal, response. Therefore, USDA should support legislation creating an independent food safety agency.

B. Until Congress Adopts A Single Food-Safety Agency, Interim Collaboration Efforts Are Necessary

While a single food-safety agency is the only way to assure adequate protection of the food supply, we support any interim efforts by FSIS to coordinate and collaborate with other federal agencies in preventing BSE in this country. Only by assessing those coordination efforts now and adopting additional measures to close loopholes can the public be assured that the potential risk is being adequately addressed.

- **FSIS should adopt new measures to assist FDA in achieving 100% compliance with and enforcement of the mammalian feed ban.**

The spread of BSE in cattle in the United Kingdom was the result of the use of meat-and-bone meal in cattle feed that was infective because it was made by rendering offal from cattle infected with BSE. According to a Working Group of the European Union's Scientific Steering Committee, as little "as a gram of [infected MBM] material could cause death if ingested by other cattle." The Risk Analysis has concluded that "new cases of BSE would come primarily from lack of compliance with the regulations enacted to protect animal feed."[102]

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[101] The National Academy of Sciences, Institute of Medicine, National Research Council. *Ensuring Safe Food From Production to Consumption* (Washington, DC: National Academy Press, 1998), p. 12.

[102] *Risk Analysis*, Executive Summary, at p. i. Of course, a total ban on feeding MBM to any farm animal would eliminate the possibility of mis-feeding animals.

Although USDA has recognized that "[t]he compliance of rendering plants is particularly important because they are the source of most domestic meat-and-bone meal,"[103] the most recent FDA update on enforcement of the feed ban demonstrates that there is not full compliance by renderers.[104] Of the 174 renderers who handled prohibited material, 5% still did not properly label their products and 3% did not have adequate systems to prevent co-mingling. Compliance among feed mills, ruminant feeders, on-farm mixers, and protein blenders and distributors also is incomplete.

To assist FDA in assuring compliance, FSIS should adopt a mandatory program requiring that all cattle offered for slaughter are accompanied by a written certification from the supplier that the cattle have not knowingly been fed prohibited materials. While the cattle industry has implemented a voluntary certification program, which has been adopted by some of the major cattle and beef purchasers,[105] a mandatory certification program will help assure compliance by all suppliers of cattle and those who provide feed to cattlemen.

- **FSIS Should Work More Closely with APHIS To Increase Oversight of Imports**

USDA uses a dual scheme for assuring the safety of imported meat products. APHIS has primary responsibility for ensuring that meat products entering the United States from countries with animal disease restrictions are not contaminated with diseases. If the product can enter the United States, FSIS then re-inspects it to assure that only wholesome, unadulterated, and properly labeled products enter U.S. commerce.

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[103] USDA, Backgrounder, *Government Actions to Prevent Bovine Spongiform Encephalopathy in the United States* (Nov. 2001), p. 3.

[104] FDA, *CVM October 2001 Update.*

[105] Sam Groce, *New Certification Requirements for Selling Livestock*, NC State University Cooperative Extension (posted 3/26/01), available at <*http://chatham.ces.state.nc.us/ag/livestock/certifcation.html*>.

An audit by the USDA's Office of Inspector General (OIG) has documented significant gaps in this system, noting the absence of centralized communication and coordination by APHIS and FSIS with their field units relating to changes in country status and inspection procedures.[106] Among other things, the OIG concluded that FSIS and APHIS need to develop joint procedures that specifically identify the roles and responsibilities of each agency at U.S. ports and to better coordinate their communications to field units so that inspectors are up-to-date on all new instructions or restrictions.[107] In particular, the OIG found that all methods of communication – fax, e-mail and Internet – were not always available at all ports of entry.[108] The inadequacies in the current import inspection regime also have been highlighted by the GAO's recent report, which notes that at-risk beef or beef-derived products may still be entering this country.[109]

The OIG Audit also identified the lack of accountability and control by APHIS and FSIS over imported meat products from countries with foot and mouth disease (FMD) restrictions as a significant problem. For example, in one case, 32,000 pounds of imported sheep, beef and hog casings from Finland, a country with FMD, were shipped to a commercial warehouse rather than to a FSIS inspection facility. It was only after the product was discovered by a broker – not the government – that the shipment was inspected and partially destroyed.[110]

While the OIG Audit focuses on APHIS and FSIS inspection activities to prevent the

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[106] USDA, Office of Inspector General Audit Report, *Assessment of APHIS and FSIS Inspection Activities to Prevent the Entry of Foot and Mouth Disease Into the United States*, Report No. 50601-0003-CH (July 2001) [hereinafter *OIG Audit*].

[107] *OIG Audit* at 5.

[108] *OIG Audit* at 5.

[109] GAO, *Mad Cow Disease*, at p. 18.

[110] *OIG Audit* at 7.

entry of FMD at a time when the United States was on "high alert" to avoid an outbreak, the same failures documented in the report are likely to affect the entry of BSE into the United States. FSIS and APHIS must alter their existing procedures to increase their surveillance and tracking activities and assure they are exercising adequate controls over products that arrive at U.S. ports of entry from countries with BSE.

Conclusion

We commend FSIS on its ongoing efforts to address the risk of BSE in U.S. cattle. While BSE has never been found in U.S. cattle herds, it is clear that the risk is greater than estimated and that stronger precautionary measures are needed to prevent U.S. cattle from being infected and to prevent meat products potentially contaminated with infective tissue from ever posing a serious public health threat. FSIS should not wait until BSE is discovered to implement measures that are protective of the U.S. cattle populations and ultimately the public health. Only action now will assure that the risk is effectively minimized if an outbreak does occur.

Respectfully submitted,

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Joining in comments:

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CONSUMER FEDERATION OF AMERICA
NATIONAL CONSUMERS LEAGUE