

# *Flimsy Firewalls: The Continuing Triumph of Efficiency over Safety in Regulating Mad Cow Disease Risks*

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*This publication is an executive summary of a larger and more comprehensive analysis of the Bush Administration's response to concerns about Mad Cow disease in the American beef supply. Visit CPR on the web at [www.progressiveregulation.org](http://www.progressiveregulation.org) for the complete report.*

## ***Introduction***

On December 23, 2003, Secretary of Agriculture Ann Veneman announced that the United States Department of Agriculture (USDA) had received word that a Holstein cow slaughtered on December 9 in Washington State had suffered from Bovine Spongiform Encephalopathy (BSE), or mad cow disease. Although this was a first for U.S. agriculture, Secretary Veneman offered the American public strong assurances that any risk to public health in the United States was “extremely low.”<sup>1</sup> Citing a recently completed study by the Harvard Center for Risk Analysis (HCRA), USDA officials predicted that mad cow disease would not spread to other animals in the United States because of feed restrictions that the U.S. Food and Drug Administration (FDA) had put in place in 1997. In fact, Veneman said she planned to have beef with her Christmas dinner.

The discovery of the Washington State mad cow should have been a much-needed wake-up call to a sleeping federal regulatory establishment. Instead, the Bush Administration treated it as a trivial annoyance that demanded a symbolic, but unobtrusive regulatory response and a carefully crafted public relations initiative. After USDA determined that the Washington State Holstein had been imported into the United States from Canada, it subtly suggested that the incident was a quirk of the international trading regime and at most a transitional problem stemming from the fact that animal feeding restrictions were not in effect in Canada when the aging cow was growing up.

Within a week after announcing the discovery of the Washington State Holstein, USDA attempted to send a comforting message to worried consumers and skittish importers by promulgating a set of interim final rules purporting to expand its regulatory presence.<sup>2</sup> Secretary Veneman characterized the new rules as “additional safeguards to protect the public health and maintain the confidence of consumers, industry, and our trading partners in our already strong food safety and protection systems.”<sup>3</sup> Soon thereafter, FDA announced that it would be promulgating a set of regulations aimed at enhancing the effectiveness of its pre-existing ban on feeding risky materials to cattle.<sup>4</sup>

An investigation by the Center for Progressive Regulation has found that the actions that the federal government has taken in recent months to address the very real risk that mad cow disease poses to the health of U.S. citizens do not match the Administration's confident rhetoric. Prior to the discovery of the Mabton, Washington mad cow, the federal government had confidently assured the public that three effective “firewalls” were in place to protect the public health from the risk of mad cow disease. First, USDA had established import controls prohibiting U.S. companies from purchasing cattle and feed from countries experiencing BSE outbreaks. Second, USDA had initiated a surveillance program under which suspect cattle were identified at the slaughterhouse and some were tested for BSE. Third, FDA had enacted restrictions on the kinds of protein that could be included in feed to cattle. After the discovery of the Washington State mad cow, the federal government announced that it was enhancing two of the three existing firewalls and adding two additional firewalls – a ban on the use of “downer” cattle in human food and a regulatory program to ensure that especially risky materials from animal carcasses did not enter the food supply – to protect human health and ensure against a

wholesale outbreak of mad cow disease in the U.S. cattle population.

CPR's investigation has discovered that these much ballyhooed "firewalls" have been so poorly conceived and implemented that they are providing very little protection at all to the American consumer. Although there are many reasons why these flimsy firewalls are not working, the primary underlying flaw with the current system is that it is built upon the dangerous assumption that mad cow disease in the United States is primarily an animal health problem and not a human health concern. Consequently, the firewalls have been designed more to protect the meat industry from economic loss than to protect the health of the American public from mad cow disease. As a result, American consumers, who in 2001 ate an average of 63 pounds of beef per person, are at much greater risk of consuming beef from mad cows and contracting a debilitating disease called Creutzfeldt-Jacob Disease (CJD), a slowly degenerative affliction of the central nervous system. The disease is characterized by the rapid degeneration of the brain, which eventually takes on a spongy quality, as patients are progressively robbed of their brain functions. The disease is always fatal.

The risk of a Mad Cow outbreak in the United States is very real. Several years ago, USDA contracted with the Harvard Center for Risk Analysis to evaluate its Mad Cow regulatory regime. Government agencies have repeatedly relied upon the resulting study to reassure the public that the risks of Mad Cow are minimal, and therefore as justification for eschewing more rigorous controls on the beef supply. But in fact, while the text of the Harvard study offers similar assurances, a careful reading of the underlying data reveals that the Center's analysis of one worst-case scenario, conducted at the behest of peer reviewers, identified circumstances under which there was a 25 percent probability of more than a

million cases of BSE occurring in the United States over a 20-year period.

One need not search far for evidence of how serious a Mad Cow outbreak could be in the United States. The

Mad Cow epidemic in Great Britain has so far claimed well over 100 human lives, forcing the destruction of millions of cattle and wreaking havoc on the British beef industry. Indeed, the implications of the single confirmed case of BSE in the United States have already been noteworthy from an economic perspective: Mexico and Japan, among others, moved to bar importation of U.S. beef,

and Japan has still not lifted the prohibition half a year later. By whichever measure -- human health or economic strength of the beef industry -- preventing Mad Cow is vital to the United States. This Center for Progressive Regulation study demonstrates that the government's protective measures so far are wholly inadequate.

### ***Background on BSE***

Bovine Spongiform Encephalopathy (BSE), or mad cow disease, is a member of a larger family of chronic, degenerative diseases called transmissible spongiform encephalopathies (TSEs). After a prolonged incubation period of months or even years, TSEs cause a progressive debilitating neurological illness that is always fatal. Scientists studying the mad cow outbreak in Great Britain in the 1990s discovered that the cause of the disease was cattle feed containing protein from infected cattle. Grain rations supplemented by additives derived from "rendering" tissues from animals of every conceivable size and species into raw protein can fatten animals more quickly and get them to market faster. At the same time, feeding rendered protein to cattle solves a serious disposal problem by converting useless material from slaughtered animals, and even other sources such as table scraps, into animal feed. The downside of this highly efficient process is the risk of spreading mad cow disease throughout the cattle population.

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Most scientists believe that TSEs are caused by an abnormally configured protein called a “prion.” Although much remains to be learned about prions, we do know that they are highly resistant to heat, ultraviolet light, ionizing radiation, and common disinfectants that normally inactivate viruses or bacteria. As a result, the TSE-inducing prions can survive severe environmental conditions and resist destruction by standard cooking practices, sterilization procedures, and the typical processes used to render cattle tissue into protein for feed supplements.

BSE can be communicated through consumption of brain, tonsils, spinal cord, trigeminal ganglia (clusters of nerve tissue near the brain), dorsal root ganglia (DRG) (clusters of nerve tissue near the spinal cord), and the distal ileum of the small intestine of cattle. USDA has concluded that BSE cannot be spread through consumption of muscle tissue of cattle. Although cattle younger than 30 months of age have rarely demonstrated clinical signs of BSE, some younger cattle not displaying clinical symptoms have tested positive for BSE. In addition, BSE has been shown experimentally to infect much younger animals.

Clinical manifestations of TSE infection in cattle include a wobbling gait or an inability to rise from a down position (the identifying characteristic of a “downer” cow). Since the incubation period in cows is 2 to 8 years from exposure to the clinical manifestation of the disease, it is possible for an infected cow to show no clinical signs of the disease. It is also possible that an animal that manifests clinical symptoms is not in fact suffering from the disease. The only way to be sure that a suspect animal is suffering from mad cow disease is to slaughter it and analyze its brain tissue in a laboratory. Currently, there are no tests for mad cow prions in feed or food.

In human beings, TSE manifests itself as a disease called Creutzfeld-Jacob Disease (CJD), a slowly degenerative affliction of the central nervous system. In March 1996, a high-level U.K. advisory committee concluded that ten cases of a new variant of CJD (called variant Creutzfeld-Jacob Disease or vCJD) had apparently been caused by human consumption of meat from cows suffering from BSE. Following this disturbing revelation, mad cow disease was no longer merely a threat to the agricultural economy; it was also

recognized as a vehicle for transmitting a devastating, crippling, and ultimately fatal human disease.

### *Mad Cow Protections Prior to December 2003*

Between the late 1980s, when it became clear that mad cow disease was a serious animal health problem in the U.K., until the discovery of the Mabton mad cow in December, 2003, the federal government erected what it described as three firewalls to protect the domestic cattle population from mad cow disease. First, USDA banned the import of cattle, meat from ruminants (mammals, like cattle, that chew cud and have multi-chambered stomachs), and most byproducts of ruminant origin from countries known to have BSE. Second, USDA in 1990 launched a BSE surveillance program aimed at annually sampling the brains of several hundred downer cattle and cattle exhibiting signs of central nervous system disorder for signs of BSE. The Department expanded this program in 2001 and 2003, and by 2004, it had tested almost 50,000 of more than 350,000,000 cattle slaughtered during the program.<sup>5</sup> Finally, FDA in 1997 promulgated regulations banning protein derived from all mammalian tissues in cattle feed – although the ban did not cover blood and blood products, gelatin, plate waste, milk products, and any product whose only mammalian protein consisted entirely of pig or horse protein. In addition, ruminant protein could still be used in feed for chickens, pigs and pets, and protein from those sources could still be rendered into cattle feed.<sup>6</sup>

### *The Harvard Center for Risk Analysis Study*

In 1998, USDA contracted with the Harvard Center for Risk Analysis (HCRA), a center associated with the Harvard School of Public Health, to “evaluate the robustness of U.S. measures” to prevent the spread of BSE to animals and humans “if it were to arise in this country.” Over the next three years HCRA developed and applied a “quantitative simulation model” to characterize how the introduction of BSE would affect animal health over time and to predict the extent to which it “could result in human exposure to contaminated food products.” The results of the HCRA simulation were published in November 2001 and updated in October 2003.<sup>7</sup>

The HCRA risk analysis was not a typical risk assessment in which data from epidemiological or animal studies are extrapolated to human populations to estimate the incidence of disease at human exposure levels. Instead, it was an exercise in scenario-building that used computer simulations to carry assumptions about hypothetical possibilities through to logical conclusions. Therefore, the conclusions that HCRA drew from this exercise were based upon assumptions, rather than on empirical analysis. Furthermore, the HCRA modeling exercise did not purport to be a human health risk assessment, because “the available information [was] inadequate” to “estimate how many people will contract variant Creutzfeldt-Jakob Disease.”<sup>8</sup>

The HCRA authors concluded that “the U.S. is highly resistant to any introduction of BSE or a similar disease” and that it was “extremely unlikely to become established in the U.S.”<sup>9</sup> Despite this confident assessment, there is no way to know whether the HCRA’s predictions are accurate for the simple reason that the model that it employed was “not amenable to formal validation.”<sup>10</sup> Moreover, the authors admitted a “lack of data on other factors that could have a greater effect on risk.”<sup>11</sup>

Of especially great concern is the report’s incomplete treatment of the uncertainties in its analysis. The report adequately addresses only one simple form of uncertainty about the model’s results. Many much harder questions go unanswered, and internal evidence suggests that the report could have seriously understated the risks of a BSE outbreak in the United States. In particular, the report’s worst case analysis suffers from numerous defects. The worst case values for each of the 17 parameters analyzed in the report reflect the authors’ judgments, not the worst logical possibilities. Worse, the computer modeling analysis almost completely ignores the possibility of synergies among worst case scenarios. The limited analysis of worst case synergy that the report did undertake (at the behest of peer reviewers) identified a scenario in which there was a 25 percent probability of more than a million cases of BSE occurring in the United States over a 20-year period. Rather than expand its worst case analysis in response to this startling finding, the authors buried it in one of the tables in an Appendix and barely mentioned it at all in the text of the report.

The HCRA is funded primarily by companies and trade associations that have an interest in belittling the health and environmental risks posed by their products and activities, and the center has a long history of producing analytically soft, but reassuring assessments of such hazards.<sup>12</sup> The Director of HCRA during the time that the mad cow report was being written once told a group of political strategists that “environmental regulation should be depicted as an incredible intervention in the operation of society.”<sup>13</sup> Although USDA funds paid for all of the HCRA mad cow risk assessment, some scientists have questioned USDA’s selection of HCRA, which has also received funding from the meat and beef industries, to conduct the study.<sup>14</sup>

Despite the many analytical shortcomings of the HCRA risk assessment, USDA and FDA have relied upon the “Harvard study” time and again to reassure the public that mad cow disease does not pose a serious risk to public health in the United States and to justify less stringent controls on the practices that pose the greatest risk of stimulating and perpetuating a mad cow outbreak in this country.

### *Governmental Actions in the Wake of the Discovery of the Washington State Mad Cow*

With the discovery of the first U.S. case of mad cow disease, USDA immediately implemented its BSE Response Plan, which required, among other things, an intensive investigation of the origin of the mad cow and its herd mates.<sup>15</sup> USDA also attempted to persuade the slaughterhouse, renderers and marketers of beef that might have come from the cow to undertake a voluntary recall of what was expected to be about 10,000 pounds of potentially contaminated beef from the suspect cow and 19 others that were processed at the same time.<sup>16</sup> Although neither effort was altogether successful, the Department implemented its BSE Emergency Response Plan carefully and effectively.

To calm public fears, muffle expected criticism from Democratic presidential candidates, and reduce the opposition of foreign countries to U.S. beef, the Administration had to appear to take forceful action to prevent an outbreak of mad cow disease. But because the Administration views the cattle industry as an important constituency, it also had ample incentive to do as little as



possible to burden, damage, or otherwise alienate it. It navigated this difficult terrain adroitly by: (1) taking to the airwaves with frequent and repeated assurances that the public health was not at risk; (2) promulgating a group of stringent-looking, but mostly toothless regulations to prevent risky materials from getting into human food; (3) promising, but not delivering much more costly regulations that could cause economic pain to the beef industry; (4) pressuring importers to drop any import restrictions; and (5) doing as little as possible to find another mad cow.

## ***The January 8, 2004 USDA Regulations***

On December 30, 2003, USDA Secretary Veneman announced that USDA would be implementing “additional safeguards to bolster the U.S. protection systems” against BSE and “further protect public health.” In addition to promulgating a series of “interim final rules” to bolster the old firewalls and add two new firewalls aimed directly at human health risks, Secretary Veneman promised that USDA would “begin immediate implementation of a verifiable system of national animal identification.”<sup>17</sup> USDA’s Food Safety and Inspection Service (FSIS) followed up on January 8, 2004 with a notice requiring slaughterhouses to hold meat from BSE-tested cattle off the market until the agency received the testing reports (the “product holding guideline”)<sup>18</sup> and with three “interim final” rules for specified risk material, Advanced Meat Recovery processes, and the air-injection stunning of cattle. The rules for specified risk material included a ban on the use of mechanically separated meat and a requirement that all downer cattle be “condemned.”<sup>19</sup>

### ***1. The Specified Risk Material Interim Final Rule***

USDA’s new regulations governing “specified risk material” (SRM) were intended to be a “fourth firewall” aimed particularly at preventing human beings from contracting vCJD from BSE-infected cattle. The regulations prohibited the use in human food of SRM, a term that was defined to include brain, skull, eyes, trigeminal ganglia, spinal cord of cattle more than 30 months old and the tonsils and distal ileum (part of the small intestine) of all cattle. All SRM had to be properly disposed of in a manner specified in USDA regulations. Establishments that slaughtered cattle and establishments

that processed meat from cattle were required to “develop, implement, and maintain written procedures for the removal, segregation, and disposition” of SRMs. Covered establishments had to incorporate such procedures into their formal Hazard Analysis at Critical Control Points (HACCP) plans (which generally require scientific testing for food contaminants and must be approved by FSIS) or, if appropriate, into much less formal “prerequisite programs” (which do not require scientific testing and need not be approved). When either the establishment or FSIS determined that an establishment’s procedures or the implementation of those procedures, “failed to ensure” that SRMs were removed from edible materials, the establishment had to take “appropriate corrective action.” Finally, the rules required establishments to maintain daily records sufficient to document the implementation and monitoring of the required SRM removal procedures and any corrective action.

### ***2. The Advanced Meat Recovery Rule***

The Advanced Meat Recovery (AMR) rule applied to 30 or so facilities in the United States that use a technology that employs hydraulic pressure to emulate the physical action of high-speed knives for the purpose of removing skeletal muscle tissue from bone. The AMR rule amplified the prohibition of SRM in edible meat by barring the use of the word “meat” to describe the output of any AMR process that contained “any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG)” without regard to the age of the animal from which the meat was derived. It furthermore applied the same restriction to skulls and vertebral column bones from cattle 30 months of age or older. Like the SRM rule, the AMR rule required establishments operating AMR systems to come up with procedures in their HACCP plans or prerequisite programs to ensure that their production process complied with the zero-tolerance restrictions for SRM. All plans had to describe the establishment’s “on-going verification activities,” including “the testing of the product exiting the AMR system” for prohibited materials.” As with the SRM rule, establishments had to keep accurate records and make them available to USDA inspectors. Any product not meeting the requirements of the rule could not be labeled “meat,” and any violative material labeled “meat” would be subject to seizure.

### ***3. The Ban on Mechanically Separated Meat Technologies.***

Because USDA's existing rules did not prohibit the incorporation of SRM into mechanically separated meat and because the separation processes involved in producing mechanically separated meat could result in such contamination, FSIS decided to ban mechanically separated meat technologies altogether. This did not represent a significant regulatory action, however, because few, if any, U.S. companies had employed mechanically separated meat technologies since the mid-1990s.

### ***4. Limited 'Condemnation' of Downer Cattle.***

In addition to addressing SRMs directly, the SRM regulations required that all "seriously crippled" and non-ambulatory disabled livestock be identified as "suspect." Furthermore, all non-ambulatory disabled cattle had to be condemned and properly disposed of in accordance with USDA's condemnation regulations. Disabled cattle that were not non-ambulatory could still be slaughtered for human consumption.

### ***5. The Air Injection Stunning Rule***

Another interim final rule prohibited the use of a previously approved technique called "air-injection captive bolt stunning." Recent studies had demonstrated that this technique, in which a metal bolt and compressed air are driven into the cranium of cattle to render them unconscious, could force pieces of brain and other central nervous system tissue into the circulatory system, where it could be transferred to otherwise edible tissues. Moreover, malfunctioning captive bolt stunners could transfer much higher amounts of such tissue into edible meat. Like the ban on mechanically separated meat, this action had no

impact on the relevant industries, because the industries had already abandoned the technique years ago.

### ***6. Expanded Governmental Testing, but Zero Nongovernmental Testing***

After the discovery of the Mabton mad cow, USDA gently expanded its testing program from 20,000 tests per year to 40,000.<sup>20</sup> The USDA's Animal and Plant Health Inspection Service (APHIS) continued to limit the program to downer cattle or adult cattle displaying signs of central nervous system disorders, and it continued to be wholly voluntary. In March 2004, USDA responded to public pressure and two advisory committee reports by initiating a one-time, greatly enhanced testing program in

which less accurate rapid testing techniques would be used to test as many animals as possible in the high-risk population of downer cattle and cattle showing signs of central nervous system disorders over a one-and-a-half year period. In addition, the program would for the first time include approximately 20,000 healthy looking animals of more than 30 months in age.<sup>21</sup> Early predictions were that this would increase the total number of animals tested

to between 200,000 and 268,000 animals over a one-and-a-half year period.<sup>22</sup>

At the same time that USDA was dramatically expanding its own testing program, it refused to allow individual producers and slaughterhouses to test their cattle voluntarily for mad cow disease. In late February 2004, Creekstone Farms, a small company specializing in gourmet meats for export, announced that it had received assurances from its Asian customers that their governments would accept its beef products if the company voluntarily tested all of the animals that it slaughtered for BSE. After investing \$500,000 in a state-of-the-art mad cow testing laboratory, Creekstone petitioned USDA for permission to use rapid response BSE testing kits to test all of its animals for BSE.<sup>23</sup>

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***Instead of the promised ban on mammalian blood, chicken litter and plate waste, FDA and USDA issued a joint Advance Notice of Proposed Rulemaking that did not take or even propose any particular action but offered some additional "considerations for further action" sometime in the future.***

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USDA rejected Creekstone's petition in early April 2004, and even threatened to file a criminal action against Creekstone if it conducted any testing at all.<sup>24</sup>

### ***The January 26, 2004 FDA Announcement***

On January 26, 2004, Health and Human Services Secretary Tommy G. Thompson announced that FDA would be implementing several new "public health measures . . . to strengthen significantly the multiple existing firewalls that protect Americans from exposure to the agent thought to cause" BSE. First, FDA would ban from human food a wide range of bovine-derived material to match USDA's recently promulgated restrictions on downer cattle and SRMs in meat. Second, FDA would amend the feed ban rule to eliminate the exemptions for mammalian blood, poultry litter, and plate waste and to require any feed manufacturing facilities using prohibited protein to be dedicated to non-ruminant feed. Finally, FDA promised to increase inspections of feed mills and renderers to ensure compliance with the revised feed rule.<sup>25</sup>

### ***The July 9, 2004 FDA Rule and Considerations for Further Action***

FDA curiously failed to take any action to implement these promises until July 8, 2004, when it announced that it was fulfilling one of the promises that Secretary Thompson made in January and renegeing on another.<sup>26</sup> FDA promulgated not two interim final rules as promised, but a single interim final rule limited to the promised ban on putting SRMs and meat from downer cattle in any food, cosmetics or dietary supplements.<sup>27</sup> Instead of the promised ban on mammalian blood, chicken litter, and plate waste, FDA and USDA issued a joint Advance Notice of Proposed Rulemaking that did not take or even propose any particular action but offered some additional "considerations for further action"<sup>28</sup> sometime in the future.

### ***The International Advisory Committee Report***

On January 6, 2004, Secretary Veneman appointed an international team of experts, headed by Dr. Ulrich Kihm, the former chief veterinary officer of

Switzerland, to review USDA's programs related to mad cow disease, including the recently promulgated interim final regulations and make recommendations for improvement. The International Panel Report, published on February 2, 2004, had some good news and some bad news for USDA. The good news was that the Department had done a good job in reacting to the discovery of the Mabton mad cow. The bad news was that there were probably more mad cows in the United States, and existing regulatory protections, even as supplemented by USDA's recent promulgated interim final rules, were insufficient to protect public health and the agricultural economy. The panel urged USDA to expand its definition of materials banned from human food, eliminate AMR techniques, greatly increase the number of cattle tested for BSE, test all downer cattle for BSE, and adopt rapid BSE screening tests. It urged FDA to extend the existing feeding restrictions to ban the use of risky material from cattle in all animal feed and to ban the use of all rendered animal protein from cattle feed.<sup>29</sup>

### ***Flimsy Firewalls***

The American public has apparently taken comfort in the Administration's assurances that the regulatory "firewalls" that USDA and FDA have created will prevent mad cow disease from becoming a serious public health problem in the United States. It may pose a significant economic issue for the beef industry because of the apparent unwillingness of our trading partners to accept U.S. beef, but so far it has not resulted in reduced demand for beef and beef products in the United States. Relying heavily upon the HCRA modeling exercise, government officials have actively encouraged this benign assessment. Industry-friendly think tanks blame the flurry of media attention that mad cow disease has thus far received on "attempts by activists and special interest groups of all kinds to scare consumers into making irrational choices."<sup>30</sup>

As the International Panel Report suggests, however, the reality of the current regulatory regime, even as supplemented by the Administration's January 2004 announcements, belies these bold assurances. Although the Administration's initial response to the Mabton mad cow reflected solid advance planning and a sensible approach to ensuring that meat from future cows identified for BSE testing did not enter the food

supply too soon, it undertook very little in the way of genuine substantive reform to a regulatory regime that is badly broken. Unfortunately, none of the frequently alluded to “firewalls” provide the precautionary protections that are implied in the “firewall” metaphor and demanded by the meat safety laws. If they are firewalls at all, they are flimsy firewalls, easily breached, and much in need of repair or replacement.

### ***1. Sound Advance Planning and a Precautionary Product Holding Guideline***

USDA deserves credit for engaging in a thoughtful planning exercise prior to the outbreak of mad cow disease in the United States. It had in place a rapid response plan setting out in detail how it would respond to the discovery of mad cow disease. Indeed, the USDA’s actual response to the discovery in Washington State closely adhered to the highly technical BSE Response Plan, and was reasonably successful in bringing about a recall of potentially contaminated meat and investigating the source of the infected animal.

The Bush Administration also deserves credit for issuing the Product Holding Notice to FSIS and state inspectors. If adequately enforced, the Notice will prevent meat from mad cows that are detected during future ante-mortem inspections from entering the human food supply. It will not, of course, protect the food supply from tissue from mad cows that are not identified during ante mortem inspection prior to slaughter.

After these initial steps, however, the Administration’s efforts soon veered away from the precautionary action suggested in its planning documents, and began to focus instead on an intense public relations campaign designed to put the public’s mind at ease and thereby ensure the continued economic well-being of the beef industry.

### ***2. The Import Restriction Firewall***

Although the import restriction firewall has worked reasonably well to ensure that infected cows do not enter the United States from countries where BSE has been detected, it was significantly jeopardized on April 19, 2004 when USDA quietly informed import brokers that it would immediately lift the ban on imports of all edible

beef products from Canadian cattle under 30 months of age, including processed meat that contained bones and offal.<sup>31</sup> Within a week, however, a court issued a preliminary injunction against the action, finding it “troubling” that USDA would quietly rescind important aspects of its previous order when it was at the time engaged in a public rulemaking to determine whether to do just that.<sup>32</sup>

Even worse, APHIS covertly allowed U.S. meatpackers to import 33 million pounds of beef from Canada between September 2003 and May 2004 despite Secretary Veneman’s August 2003 announcement that she was extending the May 2003 ban on such meat. Although the border was “officially” closed to beef imports from Canada, APHIS officials had quietly granted individual “exemptions” to the ban for meat processors that agreed to certain “mitigations.” The Department has refused to disclose which meat processors had received the special exemptions.<sup>33</sup>

### ***3. The Feed Restriction Firewall***

Probably the most critical of the three original “firewalls” is FDA’s Ruminant Feed Rule. That rule prohibited feeding protein derived from all mammalian tissues to ruminants, but it provided gaping exceptions for blood and blood products, gelatin, plate waste, milk products, and any product whose only mammalian protein consisted entirely of pig or horse protein. Cattle protein could be fed to pigs and chickens, which can in turn be rendered into cattle feed. Litter from poultry farms could be fed to cattle, even though it could easily contain significant amounts of uneaten poultry feed made from protein derived from ruminants.<sup>34</sup> In sharp contrast, the European Union (EU) prohibits the use of any processed animal protein in feed intended for ruminants and all farm animals that are kept, fattened, and bred for production of food in all EU Member States.<sup>35</sup>

Unfortunately, FDA has a very spotty record of enforcing even these limited feed restrictions. This is especially disturbing because poor enforcement of animal feed regulations very similar to those currently in place in the United States greatly exacerbated the mad cow disease outbreak in the U.K. Although indications are that FDA’s enforcement record has improved, it is not at all clear that the regulations have attained the degree of compliance



necessary to ensure that mad cow disease will not spread in the United States.

On January 26, 2004, then-FDA Commissioner Mark McClellan announced: “Today we are bolstering our BSE firewalls to protect the public.” To accomplish this, FDA would “publish two interim final rules that will take effect immediately upon publication.” FDA would ban from human food “a wide range of bovine-derived material so that the same safeguards that protect Americans from exposure to the agent of BSE through meat products regulated by USDA also apply to food products that FDA regulates.” It would also “prohibit certain currently allowed feeding and manufacturing practices involving feed for cattle and other ruminant animals.”<sup>36</sup>

The press understandably reported these actions as if they had in fact been taken. In reality, however, FDA did not take any action at all on these measures during the next five months.

FDA finally did promulgate the human food restrictions on July 9, 2004, but it did not promulgate the promised amendments to the feed rule. Instead, it issued an Advance Notice of Proposed Rulemaking (ANPR) in which it provided “considerations for further action” that included a wide variety of possible amendments. A decision to issue an ANPR is in reality a decision not to decide. Rather than “bolstering our BSE firewalls to protect the public” by beefing up its animal feed rules, as Secretary Thompson promised, FDA elected to put off to another day, long after the upcoming November 2004 elections, additional animal feed-related protections. The delay appears calculated to ensure as little disruption in the animal feed and poultry industries as possible.

#### 4. The Surveillance Firewall

USDA has been looking for mad cow disease for a number of years, but the unavoidable truth is that it has not been looking very hard. The Department has historically taken the position that its testing program is merely an animal health surveillance program designed to detect a one-in-a-million incidence of mad cow in the cattle population, not a food safety program designed to

protect the public health.

Public pressure and strong advice from scientists outside of USDA forced the Department to initiate a one-time testing program of as many animals as possible, estimated to be about 200,000 to 268,000, over a one-and-a-half year period. Although the new program is supposed to include approximately 20,000 healthy looking animals more than 30 months old,<sup>37</sup> it will continue to depend upon the voluntary participation of the slaughterhouses. The program

will not be random, but will instead concentrate on the 40 slaughterhouses that have historically slaughtered 86 percent of the total slaughtered cattle at federally inspected plants. APHIS will, however, make some attempt to assure geographical diversity.<sup>38</sup>

Even the greatly expanded program, however, suffers from several critical weaknesses that will greatly limit its potential for determining the true incidence of mad cow disease in the U.S. cattle population. First, the expanded surveillance program will include only 20,000 normal animals, and that limited population will consist only of older animals. Second, the cattle that are selected will be drawn from a population that is not representative of the entire universe of cattle being raised in the United States. Third, the program will not be “scientific” in any rigorous sense because it is incapable of taking a random selection of the incomplete universe of cattle from which it is able to draw. Fourth, there are several disturbing indications that APHIS has adopted a “see-no-evil” approach to administering its surveillance program in the past, and there is little indication that the agency plans to abandon

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that approach in the future. Finally, USDA has adamantly rejected any sort of universal approach for testing all cattle or all cattle above a prescribed age, despite the adoption of universal approaches in several other countries that have experienced mad cow outbreaks. For example, France tests more cows in one week than the United States has tested in a decade.<sup>39</sup>

The clearest indication that USDA is pursuing a “see-no-evil” policy with respect to mad cow disease is its flat rejection of a petition by Creekstone Farms to conduct universal testing of its own cattle on the ground that universal testing is not based on “sound science.” USDA may in its wisdom have decided that universal testing would be a grossly inefficient use of its limited resources. It is, however, paternalistic in the extreme for USDA to be so confident in its assessment that it is unwilling to abide the possibility that Japanese consumers (or American consumers for that matter) might rationally decide that they would prefer to pay a little extra for the additional assurance that testing brings to their dinner tables.

In the final analysis, it seems clear that the real reason that USDA is willing to threaten executives of companies that voluntarily test for mad cow disease with jail time has much more to do with the economic well-being of the five huge companies that control 84 percent of the meatpacking market than with the efficiency with which USDA or consumers allocate their resources. The larger companies, which primarily serve domestic markets, did not see any drop in demand for their products after the discovery of the Mabton mad cow and could therefore keep prices higher while at the same time paying lower prices to producers for cattle in a market depressed by reduced exports. They no doubt understood that as soon as smaller competitors were able to reestablish export markets, the windfall profits they were deriving from lower cattle prices would dry up. In addition, the large companies feared that universal testing by any company would give rise to consumer demands that all meat be tested, and this would cause larger companies to go to the added expense of universal testing as well. As Creekstone farms lays off employees and careens toward bankruptcy as a result of USDA’s inexplicable refusal to allow universal testing, Australian beef producers are rapidly establishing themselves, perhaps inextricably, in Japanese meat markets.

## ***5. The Downer Cattle Firewall***

The new Specified Risk Material (SRM) Rule requires that all non-ambulatory cattle presented to a slaughterhouse must be condemned. Assuming that this prohibition is adequately enforced, it represents a reasonable and long overdue precautionary requirement. Since several states had already banned the sale for human consumption of meat from downer cattle and many of the large restaurant chains had likewise eliminated meat from downer cattle from their product lines, this additional precaution was a “no-brainer.”<sup>40</sup>

The ban on downer cattle does not, however, ensure that human beings will not consume proteins from mad cows. First, mad cow disease is not limited to nonambulatory cattle or even to cattle displaying signs of central nervous system disorders. Second, it is not always easy to identify a downer animal. Third, a strict ban, without more, does not solve the problem of what to do with the downer cattle once they are condemned. The ban may have the perverse effect of encouraging producers to slaughter downer cattle for their own use, dispose of them on the premises, or leave them by the side of an isolated stretch of road. Fourth, in requiring that nonambulatory animals be condemned and kept out of human food, USDA failed to require that brains from all such animals be tested for mad cow disease. Finally, the ban still allows downer cattle to be sold to renderers for processing into feed for nonruminants that may in turn be rendered into cattle feed.

## ***6. The SRM Restrictions Firewall***

The SRM firewall was a direct attempt to protect the human food supply from especially risky tissues that might be infected by mad cow disease. Keeping risky material out of the food supply is a commendable ideal if the universe of risky material is properly defined and if the restrictions are effective in practice. Unfortunately, the requirements that FSIS enacted in January 2004 meet neither of these conditions. They define “specified risk material” much more narrowly than most other countries that have experienced mad cow disease outbreaks, and they are written as highly flexible “performance standards” that give the operators of slaughterhouses and meat processing establishments far too much leeway in deciding how to comply.

The definition of “specified risk material” contains two significant loopholes that appear to reflect cost-benefit balancing considerations that are not permitted by the relevant statutes. The loophole for cattle less than 30 months old is not well supported in the existing literature, and in fact BSE has been detected in many animals under 30 months of age.<sup>41</sup> Since the same tissues can be infective when they come from cattle less than 30 months of age, there is no good reason why they should not also be considered unfit for human food. The bone marrow loophole is also not well justified. The agency recognized that bone marrow had demonstrated infectivity 38 months after exposure in one experiment, but it concluded that the findings of that study were “not conclusive.”<sup>42</sup> USDA should not, however, await a “conclusive” study before exposing the U.S. population to a risk of contracting vCJD.

Far more important than the loopholes, however, is the way that the industry has gone about implementing the new SRM rule. The regulations require establishments to “develop, implement, and maintain written procedures for the removal, segregation, and disposition of specified risk materials” and to incorporate such procedures into their HACCP plans or other prerequisite programs.<sup>43</sup> The HACCP concept has been well received among industry groups, consumer groups and the scientific community as a “science-based” alternative to outmoded organoleptic inspection techniques – those reliant on inspectors smelling, touching, and visually examining meat. At the core of the HACCP program is a company-prepared plan for ensuring that proper sanitation measures are undertaken and that critical control values are not exceeded at critical control points. Although the operator bears the initial responsibility for drafting the HACCP plan, the plan and major revisions to the plan must ultimately be approved by FSIS. Prerequisite programs, by contrast, do not require FSIS approval.

The HACCP regulations require each establishment to conduct a hazard analysis to determine the “food safety hazards reasonably likely to occur in the production process.”<sup>44</sup> HACCP plans must specify control measures to be undertaken at critical control points for every food safety hazard that the hazard analysis determines is “reasonably likely to occur.”<sup>45</sup> The HACCP regulations express a strong preference for quantitative monitoring to determine whether indicators

of food safety hazards exceed critical safety levels at the critical control points (e.g., monitoring for the presence of SRMs in finished carcasses and finished meat product).

It now appears that virtually all of the establishments subject to the January 2004 regulations are addressing SRMs in their prerequisite programs, rather than by amending their HACCP plans. The companies have reassessed their HACCP hazard analyses, determined that a food safety hazard from the presence of BSE is not “reasonably likely to occur” with prerequisite programs in place, and concluded that it is therefore unnecessary to establish critical control points and quantitative critical control limits for SRMs in their operations. This, in turn, appears to reflect a general view on the industry’s part that mad cow disease is primarily an animal safety problem and not a food safety threat.

This largely unobserved move by the industry to prerequisite programs has enormous consequences for the integrity of the SRM prohibition for the following reasons:

- *USDA Approval.* Whereas FSIS inspectors must approve HACCP programs under USDA’s HACCP regulations, they do not approve prerequisite programs.
- *Informality.* Prerequisite programs consist primarily of various background procedures, practices, and aspirational statements. They typically do not contain quantitative limits, like the critical limits that the HACCP regulations require at critical control points. Rather than the scientific tests for SRMs that HACCP programs would surely require, prerequisite programs allow company employees to perform visual inspections for SRMs on meat as it moves down the line.
- *Triviality.* Prerequisite programs are probably so ill-defined because they are generally used to address issues that “are not of high importance from the standpoint of food safety.” In the words of an author of model HACCP programs and Sanitation Standard Operating Procedures (SOPs) for the industry, “[p]rerequisite programs and SOPs are usually for things that you don’t have to worry about very much.”<sup>46</sup>

- *Consequences of Failure.* An exceedence of a critical limit at a critical control point in a HACCP plan requires corrective action and a reassessment of the plan, and it may precipitate an enforcement action on the part of FSIS. Prerequisite programs rarely specify performance criteria, and when they do, a failure to meet the criteria is merely an indication that greater sanitation efforts are necessary and not a violation of law.
- *Documentation.* An establishment must document all the monitoring it conducts and any corrective action undertaken in response to exceedences of critical levels at critical control points. Prerequisite programs do not require extensive documentation of deviations from prescribed sanitary procedures and resulting corrective actions.

Although FSIS has for years touted the virtues of quantitative tests at critical control points in HACCP programs, the move by the industry to prerequisite programs means that companies have opted for a less scientific approach in which the monitoring device is the human eye and the primary corrective action tool is a sharp knife.

The industry's legal rationale for electing prerequisite programs is at best questionable. The industry has apparently concluded that the relevant "food safety hazard" is the presence of the mad cow prion, and not the presence of SRM. Given the various "firewalls" in place, the companies have concluded that mad cow prions are not reasonably likely to occur in finished product even if critical control points (e.g., tests for SRM at one or more stages in the process) are not established. Although FSIS publications take the opposite view, USDA has tolerated the wholesale adoption of this dubious rationale.

Whether or not companies elect to implement the SRM rule through prerequisite programs, it is not at all clear that USDA's HACCP regulations, as currently implemented, are up to the task of preventing human beings from contracting vCJD by eating meat from mad cows. Problems with the HACCP regulations include:

- *High Tolerance for Contamination.* Because the primary culprits addressed by the regulations are well-understood microorganisms that can be eliminated by properly cooking the product, the regulations have a high tolerance for imperfection that is exceedingly

troublesome in the context of prions that are not destroyed by ordinary cooking.

- *Verification Vacuum.* By failing to prescribe the performance and measurement criteria that are essential to a functional performance-based regime, the SRM rule has created a verification vacuum that may effectively render it unenforceable.
- *Technological Torpidity.* HACCP programs, and especially prerequisite programs, leave the regulated establishments with far too much discretion to draft and implement their own procedures without putting any pressure on them to adopt easily available technologies and techniques to reduce the levels of SRMs in finished product.
- *Sticky Enforcement Triggers.* The consequences of repeated failure to remove SRMs from meat products are so minimal and the likelihood of getting caught so low that SRM-contaminated meat is virtually certain to enter the food supply in substantial amounts under the HACCP regulations. For example, FSIS employs a "three-strike rule" under which no enforcement action is undertaken until the third violation.
- *Shirking Responsibility.* The SRM rule apparently allows a slaughterhouse to shift responsibility for removing SRMs from its meat to downstream meat processors when its product will undergo further processing prior to sale.
- *Legal Impotence.* In light of a Fifth Circuit Court of Appeals holding in an earlier challenge to the HACCP regulations, uncertainty lingers over the agency's legal authority to adapt a flexible performance-based approach to the mad cow problem.

## ***7. Faux Firewalls: Supporting Protective Rhetoric with Regulations that Don't Matter***

Two of the announced actions were apparently included solely for their public relations value. Both the ban on air injection stunning and the ban on mechanically separated meat imposed no burden whatsoever on the cattle industry and provide little if any additional protection for consumers, because neither technology had been used in the United States since soon after the outbreak of mad cow disease in England in 1996.



## ***Faulty Responses to Firewall Failure***

### ***1. A Perverse Recall Policy***

One perennially mentioned impediment to effective protection from food-borne disease is USDA's lack of authority to order manufacturers to recall contaminated beef and beef products. Companies are generally sufficiently concerned about the public relations impact of a failure to recall potentially adulterated meat that they have been willing to engage in recalls voluntarily. But a firm is completely free to decline a request if it decides not to go to the expense and effort of a recall. USDA's unwillingness to defray the costs of a recall may dissuade small companies in the future from participating voluntarily. More importantly, forcing slaughterhouses to assume financial responsibility for recalls provides a strong economic incentive to avoid the risk of recalls by stiffening their procedures for handling suspicious animals.

### ***2. Lack of a Universal Animal Identification Program***

When Secretary Veneman promised on December 30, 2003 to "begin immediate implementation of a verifiable system of national animal identification,"<sup>47</sup> the Department was not prepared to put such a system into place in the immediate or even fairly distant future. Working with state agencies and industry groups, USDA had been struggling since 2002 to come up with an acceptable universal Animal Identification Plan, and it had recently predicted that livestock would not receive identification numbers until at least July 2005. Many countries have had operational animal identification systems in place for many years. Despite the easy availability of animal tracking technologies, USDA will probably not have a system in place until it is willing to pay for it and can overcome industry fears that it will be used in lawsuits by consumers who have contracted foodborne illnesses.

## ***Why the Firewalls Are Failing — Underlying Causes of Inadequate Regulation***

In addition to reasons specific to individual firewalls, the overall firewall regime is also failing for general reasons common to each of the firewalls. Both USDA

and FDA have engaged in a sustained and ultimately deceptive campaign to characterize their lax regulatory choices as required by considerations of "sound science," when in fact they have clearly been dominated by economic and political considerations. Although robust public debates might have helped to avoid many of the problems that plague the current firewalls, USDA has vigorously shielded the industry and its own deliberations from public scrutiny and criticism. Both FDA and USDA face numerous legal and resource constraints that hamper effective enforcement of the regulatory requirements that underlie the firewalls. The capacity of FSIS inspectors to uncover instances of adulteration and cases of fraud is far too limited, the pressures on those inspectors to ignore potentially serious violations of USDA regulations are far too pervasive, and the options available to FSIS inspectors to require companies to address serious problems are far too limited.

Finally, several institutional and structural deficiencies in the current regulatory regime, such as institutional conflicts-of-interest, the revolving door, and the great influence that the industry has over USDA and its oversight committees in Congress, greatly hamper the government's efforts to maintain adequate firewalls against the spread of mad cow disease.

## ***Additional Actions that USDA Should Take***

The analysis contained in this report strongly suggests that changes are in order. The agencies themselves have the authority to implement some of the necessary changes, and they should do so as quickly as possible. The following actions are within USDA's power under its current statutory authorities. USDA should:

- *Ensure that Imported Beef Complies with U.S. Requirements.* USDA should promulgate regulations providing for an open process for granting import exemptions in which the public is provided notice of exemption requests and is given an opportunity to comment on those requests. USDA should also take steps to ensure that beef and beef products imported into this country comply with the January 2004 regulations.

- *Increase Surveillance.* USDA should follow the example of the EU and test all cattle of more than 30 months in age for BSE prior to slaughter for human consumption. Failing that, USDA should test all downer and otherwise suspect cattle, no matter how old. USDA should also continue its expanded surveillance program beyond the one-and-a-half years that it is currently anticipated to operate and convert it into a permanent surveillance program of all suspect and downer animals and a random selection of healthy animals.

- *Decentralize surveillance.* Until recently, a single USDA laboratory has historically done all of the BSE testing for the entire country. The Department has recently authorized several state agencies to begin BSE testing, and it should continue to decentralize testing for BSE.

- *Permit Voluntary Testing.* USDA should grant any petitions from companies that express a desire to engage in universal testing and can demonstrate the ability to do so. Any concerns about the efficacy of the testing can be addressed through frequent inspections of company testing laboratories.

- *Deal with the Disposal of Downer Cattle.* USDA should establish a program under which it will pay up to \$300 plus travel costs for downer cows that are taken to a designated location for BSE testing. If the determination that the cow was suffering from a neurological disease was a reasonable one (e.g., based upon a veterinarian's assessment), then the government should ensure proper disposal and guarantee reimbursement of any disposal costs.

- *Establish An Effective Animal Identification And Tracking Program.* USDA should as expeditiously as possible implement an effective mandatory animal identification system for all animals born or imported into the United States.

- *Eliminate the Specified Risk Material Loopholes.* USDA should follow the lead of the European Union and the advice of its own International Panel and broaden the definition of "specified risk material" to the relevant tissues from all animals over 12 months of age. In addition, USDA should immediately fund studies to determine whether and to what extent bone marrow from BSE-positive cattle is infective. If the previous study indicating that it can be infective is confirmed, USDA should promulgate an interim final rule expanding the definition of SRM to include bone marrow.

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***USDA should follow the example of the EU and test all cattle of more than 30 months in age for BSE prior to slaughter for human consumption. Failing that, USDA should test all downer and otherwise suspect cattle, no matter how old.***

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- *Remove the Option of Relying upon Prerequisite Programs.* FSIS should amend its SRM rule to eliminate the option of relying upon prerequisite programs as a means to implement the rule's zero-tolerance for SRMs standard.

- *Require Quantitative Testing for SRMs in Implementing any Performance-Based Requirements.* Whether or

not it continues to allow establishments to rely upon prerequisite programs, USDA should prevent establishments from relying upon ad hoc visual inspection to monitor for SRMs in meat and meat products. Instead, USDA should amend the SRM Rule to require testing for SRMs at the time that the product exits the facility. USDA should also establish a testing program of its own under which FSIS inspectors periodically test several samples of final product for the presence of SRMs.

- *Write Protective Standards for SRM Removal.* FSIS should undertake a comprehensive survey of existing technologies and techniques that are currently on the drawing board, identify feasible techniques and technologies for reducing mad cow risks, and promulgate regulations requiring the installation and use of those technologies and techniques.

- *Less Tolerance for Repeated Violations.* If the agency is serious about its zero tolerance goal for SRMs in edible meat, it should require its inspectors to stop a production line any time SRM contaminated meat is observed on

otherwise edible meat and ensure that the contaminated meat is either destroyed or fully reconditioned and that the cause of the contamination is identified and corrected before allowing the line to resume. If SRM is detected in final product, a Noncompliance Record should be issued automatically, and a recall should be implemented if it appears that the deficiency caused additional meat to become similarly contaminated.

- *Prevent Shifting of Responsibility to Downstream Establishments.* FSIS should either amend the SRM Rule or issue a revised notice to its inspectors informing them that SRM-contaminated meat may not leave the slaughterhouse, whether or not downstream processors are capable of identifying such meat and removing it from the food supply.

- *Consider Banning Advanced Meat Recovery Technologies.* FSIS should initiate a rulemaking to solicit public comment on whether it should implement a complete or partial ban of AMR technologies. If FSIS decides not to ban AMR techniques, it should require that labels of meat containing AMR product bear the statement that: “This meat product contains tissue from Advanced Meat Recovery processes and may include small amounts of materials from the central nervous systems of cattle.”

- *Increase Regulatory Transparency.* USDA should amend its HACCP regulations to require that all written HACCP plans and prerequisite programs be submitted to FSIS for its files where they will be available for public inspection. If USDA has a serious concern about whether such plans are legitimate trade secrets, it should seek legislation specifying that such plans are not trade secret and are fully disclosable to the public.

- *Increase Transparency in Imports.* USDA should promulgate procedural regulations ensuring that future requests for “exemptions” from health-related import restrictions are published in the *Federal Register* and that the public has an opportunity to comment on such requests before USDA grants them. Both the substance of the request and the identity of the requesting entity should be available for public scrutiny and comment, and the Department should not grant or deny such requests until it has reviewed and prepared a response to relevant public comments.

- *More Effective Enforcement.* USDA should seek additional resources from Congress for enforcing its January, 2004 regulations and future mad cow-related regulatory requirements. More importantly, upper-level USDA officials should not put pressure on on-line inspectors to keep production lines running even when they have doubts about whether the ultimate product has become contaminated with SRMs or other unsafe material. To the contrary, upper-level supervisors should support their inspectors in the field and thereby send a message to the regulated establishments that the FSIS takes its public health responsibilities seriously.

### *Additional Actions FDA Should Take*

The following actions are within FDA’s power under its current statutory authorities. FDA should:

- *Expand the Feed Ban.* On January 26, 2004, FDA announced that it would amend the feed ban rule to eliminate the exemptions for mammalian blood, poultry litter, and plate waste and to require any feed manufacturing facilities using prohibited protein to be dedicated to non-ruminant feed. For reasons known only to its leaders, the agency decided instead to solicit more information and thereby effectively postpone any additional regulation until after the 2004 elections. FDA should proceed ahead with the publication of a Notice of Proposed Rulemaking (NPRM) requesting public comment on its January promise and on an even more protective proposal to prohibit the addition of any animal protein to any feed consumed by animals that may be eaten by humans or rendered into cattle feed.

- *Better Enforcement of the Feed Ban.* FDA should adopt a feed ban enforcement strategy providing for a sophisticated inspection program that includes sampling and testing of the actual feed produced and used at the inspected facilities. The inspection program could be modeled on the OSHA inspection program, which has two components – a complaint-inspection element to deal with specific complaints of unlawful conditions and a random element in which facilities are randomly selected for inspection.

## ***Additional Actions Congress Should Take***

Although many of the reforms advocated here can easily be implemented by USDA and FDA, some do not clearly come within the aging authorizing legislation under which those agencies regulate meat and feed. These reforms will require congressional attention. In light of the failure of existing firewalls to keep mad cow disease out of this country, Congress should consider the following reforms:

- *Require Testing of all Downer Cattle.* Congress should provide “facilitated pathways” for testing downer cattle by providing appropriate economic incentives for farmers to present downer cattle for inspection and testing before destroying them.

- *Require Additional BSE Testing.* If USDA persists in restricting its BSE testing program to downer cattle and a few nonrandomly selected healthy cattle, Congress should require the Department to follow the example of the EU and test all cattle of greater than 30 months in age for BSE prior to slaughter for human consumption. To eliminate any doubt, Congress should clearly grant USDA explicit authority to make such testing mandatory.

- *Allow voluntary BSE Testing.* Congress should amend the aging Virus-Serum-Toxin Act to provide that any company may use USDA-approved tests to test some or all of its meat for food-borne diseases. If deemed necessary, Congress could further provide legal authority to USDA or (preferably) the Federal Trade Commission to prevent companies from relying upon such tests to provide a misleading characterization of the safety of its meat and meat products.

- *Set Deadlines for Creating an Effective Animal Identification Program.* Congress should enact legislation establishing enforceable deadlines for writing proposed and final regulations establishing a national cattle identification program. Congress should also allocate sufficient funds

for USDA to manage the program. Congress could kill two birds with one stone by requiring the cattle identification program to be financed from monies collected under the beef check-off program.

- *Clarify USDA Authority to Enforce HACCP Programs for SRMs.* To eliminate any doubt about USDA’s ability to promulgate and enforce HACCP regulations, Congress should amend the Federal Meat Inspection Act to authorize USDA to mandate and enforce HACCP programs under which scientific testing for SRMs must be

undertaken at critical control points and at the point at which product exits the plant.

- *Recall Legislation.* Congress should provide FSIS with the legal authority to order recalls of contaminated meat and poultry products. Mandatory recalls should be conducted at the

expense of the companies ordered to participate in the recalls, but USDA should have a fund available for hardship cases. The terms and conditions of all recalls should be a matter of public record and easily available to the print media, local television, and local radio.

- *Country of Origin Legislation.* Congress has enacted legislation requiring retailers of certain imported foods to feature the country of origin on the label of the food so that consumers will know where the food came from in deciding whether to purchase it. Unfortunately, Congress enacted a rider in January 2004 that made the program voluntary until 2006. It is now time to eliminate the rider and allow previously enacted mandatory country of origin labeling to go into effect.

- *Civil Penalty Power.* Congress should enact legislation granting USDA the authority to collect penalties in civil proceedings subject to judicial review. Such legislation should require mandatory penalties for uncorrected violations of HACCP plans or prerequisite programs addressing SRMs in beef and processed meats. In addition, Congress should mandate civil penalties for

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***Congress should provide “facilitated pathways” for testing downer cattle by providing appropriate economic incentives for farmers to present downer cattle for inspection and testing before destroying them.***

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repeated violations of HACCP plans, even if corrective action is undertaken for individual violations.

- *User Fees.* Congress should enact legislation enabling USDA to charge user fees to FSIS-inspected establishments of sufficient magnitude to cover the costs of inspections and oversight of HACCP programs.
- *Greater transparency.* If USDA does not act on its own to increase the transparency of the HACCP process, Congress should amend the FMIA to make it crystal clear that HACCP plans, Sanitation SOPs, prerequisite programs, and FSIS inspection reports and associated files are fully accessible to the public. Subject to reasonable exceptions for commercially valuable information, Congress should require that the records generated by any universal animal identification program be a matter of public record.
- *Whistleblower Protections.* Congress should enact strong protections for those employees who have the integrity and courage to blow the whistle on companies that falsify documents or otherwise fail to comply with their regulatory obligations.
- *Citizen enforcement.* Congress should enact legislation providing for citizen enforcement of FSIS safety requirements.

## Conclusions

USDA told the American public that an outbreak of mad cow disease would never happen in the United

States, but it did. After the outbreak, USDA told the American public that it will never happen again, but it will. USDA expanded its BSE testing program to persuade Japan and other countries to re-open their markets to U.S. beef, but they didn't. To calm consumer fears, USDA promulgated a set of regulations built on the assumption that mad cow disease is primarily an animal health problem, but it isn't.

It should be painfully apparent that forceful governmental action is absolutely necessary to protect the American public from the tragedy that befell the United Kingdom. The same “pernicious, pervasive and deeply corrupt antigovernment fanaticism that ha[d] taken hold in Britain” in the mid-1990s has now taken hold in the United States, and the results could be equally devastating. As in England, the deeply embedded problem in the United States is that “the meat industry and its allies in government assess the risk differently from the scientists and physicians who know most about the transmissible spongiform encephalophies.”<sup>48</sup>

It is time for USDA and FDA to stop using “science-based” excuses for failing to take strong regulatory action to protect the public from mad cow disease and to start following the protective policies of the existing statutes. If those agencies do not soon demonstrate a new commitment to protective regulatory action, Congress should intervene with sufficient vigor and precision to send a clear message that public health must trump production efficiency.

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## End Notes

- <sup>1</sup> Aaron Zitner, *Bovine Disease Surfaces in U.S.*, Los Angeles Times, December 24, 2003.
- <sup>2</sup> USDA, *Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter*, 69 Fed. Reg. 1885 (2004) [hereinafter cited as *USDA Stunning Device Interim Final Rule*]; USDA, *Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems*, 69 Fed. Reg. 1874 (2004) [hereinafter cited as *USDA AMR Interim Final Rule*]; USDA, *Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle*, 69 Fed. Reg. 1862 (2004) [hereinafter cited as *USDA SRM Interim Final Rule*]; Food Safety and Inspection Service, *Bovine Spongiform Encephalopathy Surveillance Program*, Notice, Docket No. 03-048N, undated.
- <sup>3</sup> USDA Transcript of Agriculture Secretary Ann M. Veneman Announcing Additional Protection Measures to Guard Against BSE, Washington, D.C., December 30, 2003.
- <sup>4</sup> Food and Drug Administration, *Expanded “Mad Cow” Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission*, Press Release, January 26, 2004.
- <sup>5</sup> Marian Burros And Donald G. McNeil Jr., *Inspections for Mad Cow Lag Those Done Abroad*, New York Times, December 24, 2003.
- <sup>6</sup> 21 C.F.R. § 589.2000(a)(1).
- <sup>7</sup> Joshua T. Cohen, et al., *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States (2003)* [hereinafter cited as *Harvard Center for Risk Analysis BSE Report*]
- <sup>8</sup> Harvard Center for Risk Analysis BSE Report, *supra* note 7, at 2.
- <sup>9</sup> Harvard Center for Risk Analysis BSE Report, *supra* note 7, at vii.
- <sup>10</sup> Harvard Center for Risk Analysis BSE Report, *supra* note 7, at ix.
- <sup>11</sup> *Review of the Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States*, Final Report, Prepared for USDA by RTI, Research Triangle Park, N.C., Oct. 2002, available at [http://www.fsis.usda.gov/oa/topics/BSE\\_Peer\\_Review.pdf](http://www.fsis.usda.gov/oa/topics/BSE_Peer_Review.pdf) [hereinafter cited as *RTI HCRA Risk Assessment Review*], at 2-2.
- <sup>12</sup> See Public Citizen, *John Graham and Corporate America’s Back Door to the White House* (March, 2001) [hereinafter cited as *Public Citizen Graham Report*], at 11-12.
- <sup>13</sup> Public Citizen Graham Report, *supra* note 12, at 4.
- <sup>14</sup> Michael Kilian, *Mad Cow Risk Low in U.S.*, Report Says, New York Times, December 1, 2001, at 12.
- <sup>15</sup> United States Department of Agriculture, *Bovine Spongiform Encephalopathy (BSE) Response Plan Summary*, undated, available at [http://www.aphis.usda.gov/lpa/issues/bse/bse\\_geninfo.html](http://www.aphis.usda.gov/lpa/issues/bse/bse_geninfo.html). See Mike Allen, *Mad Cow Case Clouds Bush’s Political Outlook*, Washington Post, December 28, 2003, at A9.
- <sup>16</sup> Matthew L. Wald, *U.S. Scours Files to Trace Source of Mad Cow Case*, New York Times, December 25, 2003.
- <sup>17</sup> Veneman Announces Additional Protection Measures To Guard Against Bse, USDA Press Release No. 0449.03, December 30, 2003.
- <sup>18</sup> USDA, *FSIS, Bovine Spongiform Surveillance Program*, 69 Fed. Reg. 1892 (2004).
- <sup>19</sup> 9 C.F.R. §§ 309.3, 319.5.
- <sup>20</sup> Donald G. McNeil Jr., *Doubling Tests for Mad Cow Doesn’t Quiet Program Critics*, New York Times, February 9, 2004; Sandi Doughton, *Groups Urge Expanded Mad-Cow Protections*, Seattle Times, January 16, 2004.
- <sup>21</sup> Veneman Announces Expanded BSE Surveillance Program, USDA Press Release No. 0105.04, March 15, 2004.
- <sup>22</sup> Marc Kaufman, *Testing for Mad Cow Disease To Expand*, Washington Post, March 16, 2004, at A1 (268,000 estimate); Steve Mitchell, *Consumer Groups: New Mad Cow Plan Lacking*, United Press International, March 16, 2004 (200,000 estimate).
- <sup>23</sup> Marc Kaufman, *Company’s Mad Cow Tests Blocked*, Washington Post, April 16, 2004 at A1; Sandra Blakeslee, *One Producer of U.S. Beef Wants to Test All Its Cattle*, New York Times, February 27, 2004. In May, 2004, another small establishment, Gateway Beef, filed a similar petition. Stephanie Simon, *U.S., Some Ranchers Clash Over Mad Cow Tests*, Los Angeles Times, May 24, 2004.
- <sup>24</sup> Donald G. McNeil Jr., *U.S. Won’t Let Company Test All Its Cattle for Mad Cow*, New York Times, April 10, 2004; Libby Quaid, *USDA Rejects Meatpacker’s Mad Cow Plan*, Seattle Post-Intelligencer, April 9, 2004; Bette Hileman, *Mad Cow Disease*, 82 Chemical & Engineering News 21 (2004) [hereinafter cited as *Hileman, Mad Cow Disease*], at 24.
- <sup>25</sup> Food and Drug Administration, *Expanded “Mad Cow” Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission*, Press Release, January 26, 2004.
- <sup>26</sup> Letter to Colleague from Melinda K. Plaisier, dated July 9,

2004, available at <http://www.fda.gov/oc/bsc/ltr-InterimReg.html>.

<sup>27</sup> Food and Drug Administration, Use of Materials Derived from Cattle in Human Food and Cosmetics, Interim Final Rule, 69 Fed. Reg. 42256 (2004) [hereinafter cited as FDA Food and Cosmetics Rule].

<sup>28</sup> Department of Agriculture and Department of Health and Human Services, Federal Measures to Mitigate BSE Risks: Considerations for Further Actions, 69 Fed. Reg. 42288 (2004) [hereinafter cited as USDA/HHS BSE ANPR].

<sup>29</sup> Subcommittee on the United States' Response to the Detection of a Case of Bovine Spongiform Encephalopathy of the Secretary's Foreign Animal and Poultry Disease Advisory Committee, Report on Measures Relating to Bovine Spongiform Encephalopathy (BSE) in the United States (February 2, 2004) [hereinafter cited as International Panel Report].

<sup>30</sup> Gregory Conko, Creating Cow Concerns Should Make Mad Consumers, Competitive Enterprise Institute Press Release, February 27, 2004.

<sup>31</sup> Veneman Announces that Import Permit Applications for Certain Ruminant Products from Canada Will Be Accepted, August 8, 2003. Available at [www.usda.gov/news/releases/2003/08/0281.htm](http://www.usda.gov/news/releases/2003/08/0281.htm).

<sup>32</sup> Marc Kaufman and Cindy Skrzycki, USDA Rescinds Policy Allowing Sale of Canadian Beef, Washington Post, May 6, 2004, at A2.

<sup>33</sup> Marc Kaufman, USDA Allowed Canadian Beef In Despite Ban, Washington Post, May 20, 2004, at A1.

<sup>34</sup> 21 C.F.R. § 589.2000(a)(1).

<sup>35</sup> Regulation (EC) No 1234/2003, amending Regulation (EC) No 999/2001, available at <http://europa.eu/int/comm/food/food/biosafety/bse/ban> and [www.defra.gov.uk/animalh/bse/animal-health/feed-ban.html](http://www.defra.gov.uk/animalh/bse/animal-health/feed-ban.html) [last visited June 3, 2004].

<sup>36</sup> Food and Drug Administration, Expanded "Mad Cow" Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission, Press Release, January 26, 2004 [hereinafter cited as FDA Statement 1/26/04]

<sup>37</sup> Veneman Announces Expanded BSE Surveillance Program, USDA Press Release No. 0105.04, March 15, 2004.

<sup>38</sup> Overview of Bovine Spongiform Encephalopathy (BSE) Surveillance Plan, March 15, 2004, available at [www.aphis.usda.gov/lpa/issues/bse/BSE\\_Surveil\\_Plan03-15-04.pdf](http://www.aphis.usda.gov/lpa/issues/bse/BSE_Surveil_Plan03-15-04.pdf); Transcript of Technical Briefing, May 21, 2004, [www.usda.gov/Newsroom/0204.04.html](http://www.usda.gov/Newsroom/0204.04.html).

<sup>39</sup> Sandra Blakeslee, Jumble of Tests May Slow Mad Cow Solution, New York Times, January 4, 2004.

<sup>40</sup> Johanna Neuman & Edwin Chen, Hunt on to Trace Diseased Animal, Los Angeles Times, December 27, 2003 (restaurant bans); Judy Pasternak, Disease Heightens Beef Debate, Los Angeles Times, December 26, 2003 (state bans, USDA ban).

<sup>41</sup> Center for Science in the Public Interest, CSPI Reacts to New BSE Safeguards, Press Release, December 31, 2003.

<sup>42</sup> USDA SRM Interim Final Rule, *supra* note 2, at 1864.

<sup>43</sup> 9 C.F.R. § 310.22(d)(1).

<sup>44</sup> 9 C.F.R. § 417.2(a)(1).

<sup>45</sup> 9 C.F.R. § 417.2(b), (c).

<sup>46</sup> Thomas O. McGarity, Telephone Interview with Dennis Burson, Meat Science Extension, University of Nebraska-Lincoln, May 4, 2004 [hereinafter cited as Burson Interview 5/4/04].

<sup>47</sup> Veneman Announces Additional Protection Measures To Guard Against Bse, USDA Press Release No. 0449.03, December 30, 2003.

<sup>48</sup> Richard Rhodes, *Deadly Feasts: The Prion Controversy and the Public's Health* (1997), at 232.

## *About the Center for Progressive Regulation*

*Founded in 2002, the Center for Progressive Regulation is a nonprofit research and educational organization of university-affiliated academics with expertise in the legal, economic, and scientific issues related to regulation of health, safety, and the environment. CPR supports regulatory action to protect health, safety, and the environment, and rejects the conservative view that government's only function is to increase the economic efficiency of private markets. Through research and commentary, CPR seeks to inform policy debates, critique anti-regulatory research, enhance public understanding of the issues, and open the regulatory process to public scrutiny. For general information, email [info@progressiveregulation.org](mailto:info@progressiveregulation.org). Direct media inquiries to Matthew Freeman at [mfreeman@progressiveregulation.org](mailto:mfreeman@progressiveregulation.org). Visit CPR's website at [www.progressiveregulation.org](http://www.progressiveregulation.org).*

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