

Secretary of Health and Human Services Tommy Thompson
The U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

April 12, 2001

Dear Secretary Thompson and Secretary Veneman,

We are writing to request that the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) immediately take action beyond what has already been done to address “mad cow disease.” In light of the continued discovery of cases of both bovine spongiform encephalopathy (BSE) and its fatal human form, variant Creutzfeldt-Jakob Disease (vCJD), in countries formerly considered to be free of these diseases, we are requesting specific actions by your agencies. These include an immediate end to human consumption of cattle tissues with high risk for transmitting BSE, an end to loopholes in the regulation of animal feed, significant increases in testing and surveillance, and the withdrawal of support for policies that promote trade regardless of impact on human and animal health.

We know that vCJD kills. We know that BSE has spread to animals in Europe and beyond from the recycling of BSE-infected cattle as ingredients in animal feed. We know, thanks to the United Nations Food and Agriculture Organization, that the export of contaminated feed and livestock has put millions of people at risk throughout the world.¹

Therefore, we recommend that the U.S. government take the following precautionary actions:

1. Prohibit the Production and Sale of High Risk Materials

Despite assertions to the contrary, USDA continues to permit human consumption of potentially dangerous materials through meat processing techniques such as mechanical deboning and advanced meat recovery. Reasonable precaution suggests that the high-risk materials produced by these processes should be removed from the human food supply.

¹ Food and Agriculture Organization of the United Nations, “Mad cow disease: FAO recommends precautions” February 8, 2001, www.fao.org/2001/010202-e.htm

Both mechanically deboned meat (MDM) and advanced meat recovery (AMR) use the muscle and connective tissue, nerve fibers, bone fragments and marrow that remain after steaks and roasts have been cut from a carcass. In mechanical deboning, these materials are forced through a sieve, creating a paste to be used in processed meat products. AMR is a similar process that uses hydraulic pressure to separate meat from bone.

Consumption of MDM and products derived from AMR may substantially increase the level of risk of exposure to BSE. Experts believe the likely pathway for BSE transmission is consumption of nervous system tissue such as brains, certain nerve fibers, and spinal cord. The failure to prevent these tissues from entering the human food chain through MDM and AMR is exposing millions of children and adults who regularly consume hot dogs, bologna, sausage and hamburger to greater risk of exposure to BSE. Both spinal cord and dorsal root ganglia (nerve tissue next to the vertebrae) can enter MDM. And information obtained by the Government Accountability Project through the Freedom of Information Act shows that in 1997, four out of 34 samples of AMR product tested because of suspicions that they contained central nervous system (spinal cord) tissue did contain this contaminant.

The concentration of metals in bones and the bacterial load of the tissues used in MDM and AMR mean that products derived from these processes are not wholesome. Additionally, misleading labeling that allows AMR products to be called “meat” denies consumers the information they need to avoid these products.

Because of the threat of BSE posed by the presence of spinal cord and nervous system material, we believe that the unwholesome meat products derived from mechanical deboning and advanced meat recovery should be banned.

Another high-risk material that should not be available for human consumption is brains. The sale of brains from ruminant animals should be prohibited, as should products that could be ingested and contain brain or spinal cord from ruminants.

Human consumption of meat from “downer” cows should also be prohibited. Downer cows are too sick to stand when they arrive at slaughterhouses, yet they are often slaughtered and enter the food chain. These sick cows are not a source of wholesome meat and may be more likely than normal cows to carry diseases including BSE. The USDA added a requirement to the 2000-2001 contracts for their school lunch program that prohibits the processing of downer cows into meat products.² This requirement should be extended to the industry as a whole, not just to plants producing school lunch meat, so that this unwholesome product is not in our food supply.

A 1998 petition by the advocacy group Farm Sanctuary requested that USDA and FDA end the practice of slaughtering downer cows for human food.³ USDA denied the petition and FDA has not responded. In light of the continued threat of BSE, we urge USDA to reconsider this issue and FDA to grant the petition.

² USDA Agricultural Marketing Service, “Notice to the Trade: Ground Beef Suppliers” June 2000

³ Farm Sanctuary, “Petition Requesting Immediate Action Regarding the Introduction of Downed Cattle Into the Food Supply” March 4, 1998, www.nodowners.org/petition.htm

2. Regulate Dietary Supplements

An issue of particular concern is that of dietary supplements. Currently, the FDA must demonstrate that a particular dietary supplement is unsafe before it can take action. The supplement industry is not required to prove the efficacy of its products and the FDA has failed to issue long-overdue Good Manufacturing Practice (GMP) regulations for the industry. Manufacturers are not required to register with the FDA and the agency inspects only one percent of imported items subject to its jurisdiction, a fraction that may be still lower for dietary supplements. The agency has issued an Import Alert for materials from countries with BSE cases, but compliance is voluntary. This means that an unscrupulous manufacturer could literally take a British cow brain, crush it, dry it out, formulate it into a dietary supplement and export it to the U.S. Indeed, a letter by Dr. Scott Norton in the *New England Journal of Medicine* mentions a product available in the U.S. that contains tissue from 17 cow organs including the brain, the pituitary, and the pineal gland.⁴

We are asking FDA to seek new authority in order to protect consumers from ingredients in supplements that carry a high risk for BSE. Specifically, we recommend a mandatory adverse event reporting requirement for all dietary supplement manufacturers, mandatory risk warnings for consumers, requirements for company and product registration, and identification of the raw ingredients and the source (by country) for every ingredient. Ultimately, the use of high risk bovine tissues such as brain, spinal cord, and dorsal root ganglia should be prohibited for use as ingredients in dietary supplements.

3. Strengthen Animal Feed Regulations

FDA banned the use of some animal protein in ruminant feed in 1997, but this ban is not sufficient. Although the agency's recent announcement that it is strengthening its feed inspection program to better enforce the 1997 ban⁵ is welcome, it is lamentably late and inadequate.

Currently, the FDA has only ten of its own inspectors⁶ and must rely on states to do the majority of their inspections of feed mills and rendering plants. As of March 23, inspections revealed that 14 percent of rendering facilities handling material prohibited for ruminant feed still did not have a system to prevent commingling of prohibited and non-prohibited material. Inspections also revealed that 33 percent of non-FDA licensed feed mills had not labeled their products with the required caution statement about not feeding prohibited materials to ruminants.⁷

Uncertainty over the effectiveness and enforcement of existing regulations has led meatpacking companies to require livestock producers to certify that their cattle have not been fed prohibited materials. This shifts the burden for ensuring compliance with feed regulations from feed manufacturers and the FDA to cattle producers, who in most cases cannot be expected to know if

⁴ S. Norton, "Raw animal tissues and dietary supplements" *New England Journal of Medicine* 343:304-5

⁵ "Keeping BSE Out of United States Top Priority for FDA, Acting Chief Says" *BNA Food Safety Report* March 14, 2001

⁶ Ibid.

⁷ FDA Center for Veterinary Medicine, "CVM Update: Ruminant Feed (BSE) Enforcement Activities" March 23, 2001

their feed manufacturer commingled feed. It also unfairly shifts liability for non-compliance from feed manufacturers to cattle producers. This shift in liability and the increased record-keeping burden on producers is a result of FDA's failure to adequately regulate feed.

Given the FDA's inability to enforce current feed regulations, the burden put on cattle producers, and the potential for commingling of prohibited and allowable proteins at rendering plants, feed mills, and farms, we believe that the feed ban should be strengthened. This could be done by prohibiting the feeding of mammalian protein to mammals. This is especially prudent in light of the fact that ruminants and many other food animals are vegetarians and are fed animal protein simply as a way to hasten weight gain, not because of any dietary requirement.

An end to the practice of feeding mammalian protein to mammals would close loopholes in current FDA ruminant feed regulations. These loopholes still allow cattle to eat cattle tissue such as blood and gelatin. And non-ruminants such as pigs can currently eat cattle protein (through feed containing bone meal or rendered cattle remains), and in turn be fed back to cattle. For BSE prevention and general wholesomeness reasons, the ban must be expanded to remove the following exemptions:

- blood and blood products
- gelatin
- pure porcine and pure equine protein
- "plate waste" (inspected meat products which have been cooked and offered for human consumption and then processed for animal feed.)

The practice of feeding poultry protein, including chicken litter, to ruminants is not only unnatural, but raises wholesomeness concerns. Additionally, the number of feed inspectors must be increased to ensure that the regulations are being enforced and penalties must be established for non-compliance. Another aspect of the feed regulations that must be strengthened is the record keeping requirement. Currently feed producers, suppliers, and users must maintain records for one year. This is not adequate for a disease with an incubation period that can last more than a decade. Records should be maintained for at least 10 years.

In 1999, the Humane Farming Association, the Center for Food Safety, the Center for Media and Democracy, and families of CJD victims made similar recommendations in a petition to the FDA.⁸ They have received no response. This is unacceptable and casts doubt on the FDA's commitment to protecting U.S. livestock from BSE.

4. Controls on Trade in Animal Feed and Livestock

The U.S. currently bans imports of meat and livestock from countries reporting cases of BSE. The FDA has banned the import of rendered cattle as a feed ingredient, but USDA continues to allow live cattle to be imported from countries which cannot certify that their herds are free of BSE. In fact, when determining if other countries' standards should be considered "equivalent"

⁸ Humane Farming Association et al, "Petition Seeking Immediate Action by the FDA to Combat the Spread of Transmissible Spongiform Encephalopathy (TSE) in the United States" January 7, 1999, www.centerforfoodsafety.org/li/BSEpetFDA.html

to those of the U.S. and therefore eligible for export, the Food Safety Inspection Service did not even inquire about the countries' BSE surveillance programs.⁹

Considering that more than two million cattle were imported into the U.S. in 2000,¹⁰ the threat of BSE to the people of the United States bears greater vigilance. We support a ban on the importation of meat, ruminants, and animal products to protect food safety, U.S. livestock, and family farmers and ranchers. The ban should apply to:

- Countries with identified cases of BSE.
- Countries that received potentially contaminated feed or livestock from the European Union, either directly or via trans-shipment through another country.
- Countries that do not have an adequate testing program for BSE.

The ability to enforce import restrictions is critical. Adequate resources and inspectors must be available to make sure that bans are actually implemented.

5. Significant Increases in Testing and Surveillance

The chief reason that the present BSE surveillance program has not confirmed cases in the U.S. could be because the surveillance program has been unjustifiably weak. According to data from the National Veterinary Services Laboratories, only 11,954 post-mortem inspections for BSE were done on the 350 million cattle slaughtered in the U.S. between 1990 and 2000.¹¹ The Animal and Plant Health Inspection Service (APHIS) goal of increasing its BSE testing to 5,000 cattle a year¹² is welcome, but inadequate.

A thorough BSE surveillance plan must include more testing of downer cows. A better definition of a "downer" cow is needed to ensure that all downers get counted and tested, not just those that are brought to slaughterhouses and caught by inspectors. In Switzerland, any cow that gets sick and dies cannot be destroyed without being tested for BSE. This resulted in a testing rate last year of 14,000 downer cows (out of approximately 800,000 slaughtered), in contrast to the U.S. testing rate of about 2000 downers tested (out of 36 million slaughtered.)¹³ A program for statistically significant testing of cows that arrive at slaughterhouses dead or die awaiting slaughter should also be established.

Any testing regime must be more transparent to the public. Current testing rates appear to vary widely from state to state, raising questions about sampling representativeness. Yet agency information on BSE testing is often presented as a national total, without any details of how the animals are selected and where they are located. A testing program that was more transparent would allow concerns like these to be raised and hopefully remedied. Additionally, any APHIS

⁹ Audit reports of international food safety systems for 1997-1999, obtained by Public Citizen through the Freedom of Information Act

¹⁰ USDA Economic Research Service, "U.S. Agricultural Trade Update" February 28, 2001, <http://www.ers.usda.gov/publications/so/view.asp?f=trade/fau-bb/text/>

¹¹ USDA Animal Plant Health Inspection Service, "BSE Surveillance" www.aphis.usda.gov/oa/bse/bseurvey.html

¹² Dr. Tom Gomez, USDA Animal Plant Health Inspection Service, personal communication, April 12, 2001

¹³ Jeffrey A. Nelson, "USDA Mad Cow Strategy: Don't Look, Don't Find" April 2, 2001, www.vegsource.com/articles/bse_usda.htm

testing protocol should include new tests developed in Europe to more rapidly detect the presence of BSE and other TSEs, if they meet FDA standards.

6. Increase vCJD and other TSE Surveillance

Surveillance for human CJD and vCJD is coordinated through the Centers for Disease Control and the National Prion Disease Pathology Surveillance Center at Case Western Reserve University. The Center has examined the brains of about 300 patients with CJD in the past four years. This represents an estimated 39% of patients with CJD in 2000, whereas in Germany and Britain the brains of almost all CJD patients are examined by pathologists. Canada has recently revamped its surveillance system and provides much more funding for such efforts than does the U.S.

The U.S. government also needs to do more to increase the overall hospital autopsy rate in this country, which has declined from over 40% after World War II to under 10% at present, as well as to increase the rate of examination of brain material specifically. Currently, hospitals and families bear the costs of autopsies, including transportation costs; they should be reimbursed for these costs. The government should also consider creating a network of regional pathology centers to do brain examinations for CJD and needs to do more to contact all neurologists to inform them of the current surveillance system.

Other measures that should be taken include exploring the possibility that CJD has been misdiagnosed and underreported. This could include widely examining brains from Alzheimer's patients, and better tracking of all types of CJD and diseases with similar symptoms. Absent this kind of aggressive and thorough monitoring system, public health officials will have no guidance on where to direct traceback operations to look for a source of BSE exposure.

Beyond BSE and vCJD, we believe that research and surveillance for other transmissible spongiform encephalopathies (TSEs) should be expanded. TSEs are a potential threat to human health and we must both learn more about all of their possible causes and become more vigilant in identifying them. This research should look at all TSEs, including chronic wasting disease in elk and deer and TSEs in pigs, mink, and other animals. Research into tools for earlier diagnosis and strain typing to determine the relationship between various forms of TSEs is also vital.

7. Proposed Codex "Equivalency" Guidelines Threaten To Undermine U.S. Protections

Also of concern in this global health crisis are the actions of the international standard setting bodies that impact food safety. In particular, we are concerned about recent developments at the Codex Alimentarius Commission in Rome (Codex). This United Nations body has been officially recognized by the World Trade Organization as setting the world's "trade-legal" international standards for food safety. International standards set in the Codex have the potential to impact domestic standards around the world.

We urge you to instruct the U.S. Delegate to the Codex Commission meeting to withdraw U.S. support for adoption of proposed "Draft Guidelines on the Judgement of Equivalence of Sanitary

Measures Associated with Food Inspection and Certification Systems".¹⁴ This document will be debated at the Codex Commission meeting July 2 through 7 in Geneva. Not only is the proposal deeply flawed, it has been "fast tracked" in the Codex eight step process in reckless disregard for consumer health and safety.

Under the WTO's notion of "equivalence", significantly different and possibly less protective regulatory systems and standards in other countries can be declared equivalent to domestic regulatory systems. Put simply, a system with strong BSE measures could be declared equivalent to a country with out such protections. Once a foreign system is declared equivalent, it must be treated as if it were a domestic system, even if it differs from the domestic system in significant ways. Equivalency determinations are designed to allow foreign goods produced under equivalent systems free passage into the U.S. market. If a nation rejects an equivalency agreement with another nation, they could be charged with violating WTO rules in the powerful dispute resolution system of the WTO and forced to change their mind or pay punitive tariffs. Just the threat of a WTO suit could result in unwise equivalency decisions between countries with very different regulatory systems and standards.

Equivalency decisions can and have served as a back door around strong domestic standards. In 1993, for example, a trade panel operating under the auspices of the Canada-U.S. Free Trade Agreement declared pasteurized milk and non-pasteurized milk to be "equivalent", requiring Puerto Rico to open its market to non-pasteurized milk products. The U.S. government's poor performance with regard to the bilateral equivalency agreements it has established was amply documented in U.S. Department of Agriculture Office of the Inspector General's June 20, 2000 review of Food Safety and Inspection Service (FSIS) equivalence determinations. The inspector general condemned FSIS for the sloppy job it had done in determining equivalency and concluded that FSIS had reduced its oversight to such a degree that it undermined consumer protection.

The proposed equivalency guidelines before the Codex Commission are grievously flawed and are an invitation to an increased deterioration of U.S. oversight in making bilateral equivalency agreements. The proposed guidelines do not even contain an agreement on the types of information to be judged in determining equivalence.¹⁵ Codex cannot fulfill its fundamental mandate of protecting the health of consumers with these U.S. supported guidelines, since the absence of agreement on types of information to be judged equivalent means that there is no common understanding between exporting and importing countries about the meaning of equivalence. If the arbitrary meaning of "equivalence" facilitated by these guidelines is adopted by the Codex Commission, U.S. precautionary measures, including the BSE measures suggested in this letter, could be inhibited under threat of WTO challenge.

We urge you ensure to that the U.S. Codex delegation withdraw its support for the fast-tracked adoption of these guidelines at the Commission meeting. The proposed guidelines should be returned to the Codex Committee on Food Import/Export Inspection and Certification Systems at Step Five for further elaboration by Codex member governments and their publics.

¹⁴ Codex Alimentarius ALINORM 01/30A, para. 89 and Appendix III, <ftp://ftp.fao.org/Codex/ALINORM01/al0130ae.pdf>

¹⁵ Codex Alimentarius ALINORM 01/30A para. 88, <ftp://ftp.fao.org/Codex/ALINORM01/al0130ae.pdf>

Conclusion

Clearly these reforms will take resources. The Bush Administration's proposed budget should substantially increase provisions for food safety. Increased testing will take money, yet the proposed USDA budget would be cut by nine percent.¹⁶ The administration needs to direct more resources specifically for inspectors, veterinarians, testing and other measures to ensure that an epidemic of BSE is prevented in the United States. If the Office of Management and Budget must conduct cost-benefit analyses on the impact of these recommendations on industry, these analyses should be made available for public comment immediately.

BSE is a potential global health crisis that demands immediate precautionary action. We urge FDA and USDA to adopt these recommendations on human consumption, animal feed, testing, and trade. We look forward to your response to our recommendations and to your prompt action to protect human and animal health from bovine spongiform encephalopathy and variant Creutzfeldt-Jakob Disease.

Sincerely,

Animal Welfare Institute
Cancer Prevention Coalition
Center for Food Safety
Community Nutrition Institute
Family Farm Defenders
Farm Sanctuary
Global Resource Action Center for the Environment
Government Accountability Project
Humane Farming Association
Institute for Agriculture and Trade Policy
National Joint Council of Food Inspection Locals
National Family Farm Coalition
National Catholic Rural Life Conference
Organic Consumers Association
Public Citizen
U.S. Public Interest Research Group

¹⁶ Elizabeth Becker, "Who Gets What Slice of the President's First Federal Budget Pie" *New York Times* April 10, 2001