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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 2002N-0273 (RIN No. 0910-AF46)

Submitted electronically to www.fda.gov/dockets/ecomments and by regular mail to the above address.

To Whom It May Concern:

The Center for Food Safety (CFS) submits these comments pursuant to the Food and Drug Administration, Department of Health and Human Services, proposed rule entitled "Substances Prohibited From Use in Animal Food or Feed," contained at Federal Register volume 70, number 7, pages 58570-58601 (October 6, 2005).

The proposed regulations on animal feed are not sufficient to prevent the spread of BSE within the US cattle population, nor are they adequate for protecting human health from the human form of BSE. By failing to propose a rule that sufficiently limits the spread of BSE within cattle, the agency has failed to fulfill their mandate to protect "the public health by assuring the safety, efficacy, and security of … our nation's food supply…."[1]

FDA should have addressed inadequacies in its feed regulations long ago. For over six years, FDA has been on notice of the need for more stringent animal feed protections against BSE.[2] Yet, the proposed rule is more lax than those previously proposed by the

[1] Food and Drug Administration. FDA's Mission Statement. <http://www.fda.gov/opacom/morechoices/mission.html> Accessed November 14, 2005.

[2] CFS has been notifying the FDA of the inadequacies in its feed regulations for over 6 years, with little response from the agency. This began with a legal petition that CFS submitted in January 1999, seeking immediate action to combat the spread of transmissible spongiform encephalopathy (TSE) (Docket number 99P-0033/CP1). CFS submitted subsequent comments in response to FDA's advanced notices for proposed rulemaking (ANPRMs) in 2002 and 2004 (Docket numbers 02N-0273 and 2004N-0264 respectively). Throughout this period the FDA has repeatedly delayed taking action, and has failed to implement any additional BSE regulations. Despite the recommendations from CFS and other organizations the agency still has not eliminated the dangerous loopholes in the current regulations.

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FDA, including plans released as recently as January 26, 2004.[3] In 2004, the FDA announced their intention to prohibit the use of blood, plate waste, and poultry litter from cattle feed. However, the current proposed rule includes none of those prohibitions, despite the recent discovery of BSE within US cattle, a finding which should have initiated an increased level of concern.

BSE is the bovine form of a class of diseases known as transmissible spongiform encephalopathies (TSEs). TSEs are degenerative diseases of the central nervous system that create holes in the brain, turning it sponge-like after a number of years. There is currently no cure, treatment, or vaccine for TSEs and they are invariably fatal. The disease agent is thought to be an abnormal prion protein, which does not elicit an immune response and is very difficult to detect or eliminate. Creutzfeldt Jakob Disease (CJD) is the human form of TSE. Recently a new form of CJD, called new variant CJD (nvCJD), has appeared and been attributed to the consumption of beef products from cattle infected with BSE. To date, over 150 cases of nvCJD have occurred in the UK. It is well known that BSE spreads quickly within cattle populations by the practice of feeding infected cattle material to cows. Feeding bovine protein back to cattle has been implicated as the main cause of the BSE and nvCJD epidemic in the UK.

BSE is present in North America. Two cows in the US have tested positive for BSE in the last two years, one in Washington State and one in Texas. In addition, three cows in Canada have been found to have BSE. While most of these cases are thought to have been caused before any feed bans went into effect, they show that BSE is a problem that must be immediately addressed. Other infected cows are likely to exist in this country and current feed regulations would allow for the continued spread of the disease.

If we continue to feed mammalian protein to any livestock, the risk of transmitting BSE will continue. The UK example is instructive. The number of BSE cases in the UK did not decrease until they stopped feeding mammalian meat and bone meal to all livestock. The original UK feed ban, implemented in 1988, included the same exemptions for blood, plate waste, and poultry litter as the current and proposed US feed rules. Another 44,000 cases of BSE occurred among cattle born in Great Britain between 1988 and 1996 while this limited ban was in place.[4] It wasn't until 1996, when the UK implemented a more substantial ban on feeding mammalian material to livestock, that the number of BSE cases significantly dropped. There have only been 110 BSE cases among cattle born in Great Britain between 1996 and 2005 (as of August 2005).[5] Similar to the initial UK feed ban, the new proposed rule will permit the continued feeding of protein to cattle that can cause BSE.

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[3] US Department of Health and Human Services. January 26, 2004. Expanded mad cow safeguards announced to strengthen existing firewalls against BSE transmission. <http://www.hhs.gov/news/press/2004pres/20040126.html> Accessed November 18, 2005.

[4] Department for Environment, Food and Rural Affairs (UK). November 14, 2005. BSE: Disease control & eradication-The feed ban-Born after the July 1888 feed ban cases. <http://www.defra.gov.uk/animalh/bse/controls-eradication/feedban-bornafterban.html> Accessed November 17, 2005.

[5] Id.

The new rules proposed by the FDA leave too many pathways for BSE to spread within the cattle population and have not taken into consideration a number of recent studies that suggest that BSE may be more infectious than previously thought. This indicates that under current circumstances, BSE may proliferate within the cattle population and continue to threaten the emergence of human cases of nvCJD in the US. The United States must take strong action to prevent these outcomes. The FDA must make every effort to eliminate any risk of transmitting BSE by banning the use of all mammalian protein in the feed of animals that will enter the human food supply.

**I. The proposed rule leaves too many loopholes for the spread of BSE, including the continued feeding of some bovine parts back to other cows.** Recent scientific evidence and past events in Europe suggest that all known and possible pathways for transmission of the disease must be eliminated. The FDA should not knowingly allow any loopholes to persist whereby the spread of BSE could occur. Specifically, the proposed rule allows the continued feeding of some cow parts back to other cows through the exemptions for blood, plate waste, poultry litter, and tallow. In addition, it only prohibits the brain and spinal cord, allowing other risk materials to remain in the animal food supply. It does not address the risk from cattle younger than 30 months old and allows the continued feeding of some non-ruminant protein to cattle. These are all potential pathways for the transmission of BSE and should not be ignored.

***a. Blood:***

Under the proposed ruling, products containing bovine blood could still be fed to cattle. Blood products are commonly fed to calves as milk replacements as well as being used as feed additives. As blood has been shown to transmit TSEs, it should not be fed to cattle, nor should cattle be exposed to the blood of other cows. Evidence from several species shows that blood can contain the infective agent of TSE diseases, and the disease can be transmitted through blood even before symptoms are visible. So far, two of the cases of nvCJD in the UK are thought to have been caused by blood transfusions from infected individuals. BSE has also been transmitted between sheep by blood transfusion, before the infected sheep began to show symptoms of the disease.[6] Infectivity has been detected in the blood of mice infected with a strain of nvCJD.[7] The blood of these mice was infective both before and after symptoms of the disease became visible. Therefore, it is likely that cow blood can also contain the BSE infection and its continued use in cattle feed and as a milk replacement creates an unnecessary risk for the transmission of BSE between cattle. Cattle should not be exposed to or allowed to consume any material from other cattle, let alone a tissue that is known to harbor BSE infectivity.

***b. Poultry Litter:***

The proposed rule would continue to allow cows to be fed poultry litter, which includes spilled feed, excrement, dirt, and feathers from the floors of poultry cages. An estimated

[6] Houston F, Foster JD, Chong A, Hunter N, Bostock CJ. 2000. Transmission of BSE by blood transfusion in sheep. The Lancet 356 (9234): 999-1000.

[7] Cervenakova L, Yakovleva O, McKenzie C, Kolchinsky S, McShane L, Drohan WN, Brown P. 2003. Similar levels of infectivity in the blood of mice infected with human-derived vCJD and GSS strains of transmissible spongiform encephalopathy. Transfusion 43(12): 1687.

1 million tons of poultry litter is fed to cattle every year.[8] This is another means by which cattle will continue to consume high risk bovine materials. Meat and bone meal from rendered cattle are often added to poultry feed; up to 30 percent of the poultry litter fed to cattle can be mammalian meat and bone meal. While poultry food would no longer contain the brains and spinal cords of cattle over 30 months old under the new rule, it could still contain these materials from younger cattle, as well as other high risk cattle parts (eyes, tonsils, intestines, nerves, vertebrae) from cows of all ages. Therefore cows that are fed poultry litter would still be consuming high-risk materials from other cows. Scientists believe that BSE-infective prions are not destroyed by digestion, and therefore could be contained in the droppings, as well as the spilled food, contained in poultry litter if the poultry food contained material from an infected cow. Feeding poultry litter and rendered poultry to cattle thus provides a pathway whereby BSE proteins can be fed to cattle.

***c. Plate Waste:***

This proposed rule maintains the exemption for restaurant plate waste, which can contain high-risk animal parts that can then be fed back to cattle. This exemption allows the continued feeding of some cattle protein back to cattle, including cuts of meat that may have been contaminated with spinal tissue, bone marrow, or other potentially infectious tissues. The heat treatment applied to plate waste processed for cattle feed will not necessarily kill the disease agent, as prions have been found to remain infectious after exposure to temperatures over 1000° F.[9] Plate waste will also include meat from other ruminants, such as sheep, deer, and goats, which are banned from feed for cattle through other routes. In previous statements the FDA has planned to eliminate the exemption for plate waste and the Department of Health and Human Services has stated that, "The use of 'plate waste' confounds FDA's ability to analyze ruminant feeds for the presence of prohibited proteins, compromising the Agency's ability to fully enforce the animal feed rule."[10] Therefore, the continued allowance of this substance in cattle feed is arbitrary and contradicts prevailing scientific knowledge on the spread of BSE. In addition, the use of plate waste increases the risk of spreading BSE from imported beef, as it allows imported beef from BSE affected countries to enter the food supply for US cattle.

***d. Tallow:***

The proposed rule provides that tallow can still be fed to cattle and other animals if it contains less than 0.15% impurities, including protein, and is derived from cattle materials not prohibited from animal feed. These small amounts of protein may be sufficient to transmit BSE between cattle, particularly in light of recent data which suggest that the infectious dose may be much smaller than previously thought (see section on infectious dose, below). This potential risk must be addressed. No amount of bovine protein, however small, should continue to be fed back to cattle.

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[8] Fontenot, JP. November 5, 2001. Utilization of Poultry Litter as Feed for Beef Cattle. <www.fda.gov/ohrms/dockets/dailys/01/Nov01/110501/ts00014.doc> Accessed November 16, 2005.

[9] Brown P, Rau EH, Johnson BK, Bacote AE, Gibbs CJ, Gajdusek DC. 2000. New studies on the heat resistance of hamster-adapted scrapie agent: Threshold survival after ashing at 600°C suggests an inorganic template of replication. Proceedings of the National Academy of Sciences 97(7): 3418-3421.

[10] See 3.

***e. Risk materials other than brain and spinal cord remain in animal food supply:***

Of all the materials known to harbor BSE infectivity, the proposed rule only prohibits cattle brains and spinal cords from animal feed. Other bovine materials which have previously been identified as Specified Risk Materials (SRMs), and are known to carry the infection could still be fed to animals. These include the eyes, tonsils, intestines, nerves, and vertebrae from cattle of all ages. While these materials are already prohibited from cattle feed, they will remain in the animal food supply, and may be fed back to cattle through the mixing of foods, incorrect feeding, contamination at rendering plants, etc. There also may be a risk from feeding these high risk materials to animals other than cattle. TSE diseases are known to sometimes move between species, therefore we cannot continue feeding materials potentially infected with BSE to any animals. As one researcher stated, "'I think we have to be so careful that by constant exposure we do not force infectivity into another species just because we think they have a resistance…The resistance may, in some cases, be able to be overpowered or the TSE agent might adapt.'"[11]

The proposed rule also leaves a loophole whereby the carcasses of cattle not approved for human consumption can be used in animal feed as long as the brain and spinal cords have been removed. Cattle not passed for human consumption include cattle that could not walk due to a disability or injury, cattle found dead or killed on the farm, and cattle subject to emergency slaughter due to health problems. These cattle have been shown to be more likely to have BSE than healthy cattle that are slaughtered under normal circumstances. Since a number of tissues have been shown to contain BSE infectivity, removing only the brain and spinal cord will not be sufficient to prevent the presence of infected material from these cattle in the animal food supply. The continued use of materials such as the eyes, tonsils, vertebrae, intestines and nerves from cattle not passed for human consumption could spread a BSE infection through the use of poultry litter, accidental feeding back to cattle, or through transfer of the infection to other species. Even if brains and spinal cords are removed, cattle not passed for human consumption should not be allowed in animal feed.

***e. Non-ruminant mammalian protein can still be fed to cattle:***

Pigs and chickens could still be fed to cattle under the new rule and could possibly infect cattle with BSE. Cattle matter that is fed to pigs and chickens can find its way back to cattle, because cattle are legally fed rendered pigs and chickens. Although the chickens and pigs may never manifest BSE symptoms, they may be "silent carriers" of the protein. When the chickens or pigs are slaughtered and ground up and fed to other ruminant animals, the protein can complete the cycle. Several studies have shown that BSE can cross species barriers by creating a sub-clinical, or "silent," infection in another species. Animals with sub-clinical infections do not display symptoms of the disease, but yet still

[11] Bren, L. May-June 2004. Agencies work to corral mad cow disease. FDA Consumer Magazine. <http://www.fda.gov/fdac/features/2004/304_cow.html> Accessed November 10, 2005.

carry the infection and can pass it on when their infected tissues are consumed.[12] One study has shown that mice can develop a sub-clinical infection from consuming hamster prions which were previously thought to be non-pathogenic to mice.[13] Therefore just because pigs and chickens do not normally manifest TSE diseases does not mean that they won't still harbor the BSE agent at a sub-clinical level, and possibly pass it on to cattle that consume them. There are no restrictions on which tissues can be fed to cattle from non-ruminant animals. In order to prevent the spread of BSE through silent carriers, no animal protein should be fed to cattle.

***f. 30 month age cut-off is too old:***

The proposed rule focuses on cattle aged 30 months and older, and therefore continues to allow the presence of materials from younger cattle in the animal food supply. Although BSE infectivity is more common in older cattle, the 30 month age cutoff is too old to adequately prevent the spread of BSE, as the disease is found in younger cattle and may be infective during the incubation period. In Japan, two cases of BSE were identified in cows under 30 months old; these were in cows that were 21 and 23 months old. In the UK a number of BSE cases have been found in cattle under 30 months old, including one as young as 20 months old.[14] BSE can also be infectious in younger cattle during the incubation period, or pre-clinical phase, before any symptoms are visible and before the disease would be detected.[15] Therefore the brain, spinal cord, and other tissues of younger cattle could spread the disease, as these materials can still be fed to pigs and chickens, and to cows through the consumption of poultry litter, plate waste, contaminated food, and silent carriers. It is not known at what stage in the incubation period BSE can become infectious and we are still unable to detect the disease in younger animals, before the infection has reached the brain. An age limit of much less than 30 months is necessary in order to effectively limit the spread of BSE.

**II. Recent scientific information on BSE supports the need to ban the feeding of mammalian protein to any food animals.** New science in general indicates that TSE diseases are more infectious than previously thought, this should be a cause for increased concern, and lead to much stricter animal feed regulations than those recently proposed. It has recently been shown that BSE can be infective with smaller doses, there may be a cumulative effect of very small doses, additional organs can be infective, and the species barrier may be much lower than previously thought.

***a. Cumulative effect of small doses:***

Very low level doses of infected material, which wouldn't cause an infection after one dose, can have a cumulative effect and cause a BSE infection after repeated doses. A

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[12] Hill AF, Collinge J. 2003. Subclinical prion infection in humans and animals. British Medical Bulletin 66: 161-170.

[13] Hill AF, Joiner S, Linehan J, Desbruslais M, Lantos PL, Collinge J. 2000. Species-barrier-independent prion replication in apparently resistant species. Proceedings of the National Academy of Science 97(18): 10248-10253.

[14] Department for Environment, Food and Rural Affairs (UK). October 1, 2005. BSE Statistics: Youngest and oldest cases by year of onset - GB (Passive surveillance only). <http://www.defra.gov.uk/animalh/bse/statistics/bse/yng-old.html> Accessed November 10, 2005.

[15] See 12.

study released in 2005 showed that, in mice, repeated injections of low prion doses caused scrapie infections over time, even when a single injection of the same size did not cause an infection.[16] Another study has shown similar results in hamsters, but is more applicable to the current feed rule because oral doses of the infectious agent were used. In this experiment the incidence of scrapie infections was much higher among hamsters that were fed repeated doses of the infectious material when compared with those fed a single dose.[17] In addition, low doses of infected feed that did not cause an infection after a single dose, did lead to infections in a significant number of individuals when given repeatedly. These studies suggest a much higher risk of infection to both cows and humans from repeatedly consuming small amounts of BSE infected material, or material with a very low level of infectivity. FDA's proposed rule would leave loopholes for this type of exposure, because it assumes that these low doses will not cause infection, however the cumulative effects of consuming low doses over time have not been assessed.

***b. Additional organs may be infectious:***

Several recent studies have shown that more organs may play host to BSE infectivity than previously thought, particularly in animals that also have inflammatory diseases or viral infections. A study released this year (2005) showed that in mice with inflammatory diseases, prions were found to accumulate in a number of organs not normally associated with prion infection, including the pancreas, liver, and kidney.[18] This suggests that in all species TSE infections may be present in a wider range of tissues than originally believed, if the animals have some form of inflammatory disease. Therefore the focus on only the brain and spinal cord in the current feed rule will be an inadequate protection. As one of the researchers stated, "The study suggests that the current prion risk-classification of farm animal organs may need to be reassessed in animals suffering from inflammation due to microbial infection or autoimmune disease."[19]

In addition, prions have recently been detected in the urine of mice infected with scrapie that were also suffering from kidney inflammation.[20] As recently as November 2005, a study was released which found prions in the mammary glands of sheep infected with scrapie when they also had inflamed mammary glands.[21] Prions are expected to be found

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[16] Jacquemot C, Cuche C, Dormont D, Lazarini F. 2005. High incidence of scrapie induced by repeated injection of subinfectious prion doses. Journal of Virology 79(14): 8904-8908.

[17] Diringer H, Roehmel J, Beekes M. 1998. Effect of repeated oral infection of hamsters with scrapie. Journal of General Virology 79: 609-612.

[18] Heikenwalder M, Zeller N, Seeger H, Prinz M, Klohn PC, Schwarz P, Ruddle NH, Weissmann C, Aguzzi A. 2005. Chronic lymphocytic inflammation specifies the organ tropism of prions. Science 307(5712): 1107-1110.

[19] Medical News Today. February 5, 2005. Infectious agent linked to mad cow disease found in organs other than the brain. <http://www.medicalnewstoday.com/medicalnews.php?newsid=19660> Accessed November 10, 2005.

[20] Seeger H, Heikenwalder M, Zeller N, Kranich J, Schwarz P, Gaspert A, Seifert B, Miele G, Aguzzi A. 2005. Coincident scrapie infection and nephritis lead to urinary prion excretion. Science 310 (5746): 324-326.

[21] Ligios C, Sigurdson CJ, Santucciu C, Carcassola G, Manco G, Basagni M, Maestrale C, Cancedda MG, Madau L, Aguzzi A. 2005. $PrP^{Sc}$ in mammary glands of sheep affected by scrapie and mastitis. Nature Medicine 11(11): 1137-1138.

in the milk of these sheep as well. While prions have not been detected in cows' milk, milk from cows with mammary gland infections has not yet been tested and may also contain prions. Mastitis, or mammary gland inflammation, is the most common disease amongst dairy cows around the world.

These studies reveal additional possible pathways for the spread of BSE between cattle, showing that the disease may be much more infective than previously thought and may be transmitted by substances and organs that were previously considered safe. These results also demonstrate a possible influence of viruses and other infections on the infectivity of BSE. This topic has not yet been adequately addressed for its impact on the spread of BSE and it is clear that we do not yet know everything about which organs and tissues can harbor BSE infectivity. This new information therefore indicates an increased need for stringent measures to prevent the spread of BSE. Tissues which are known to contain BSE infectivity should not be allowed in any animal feed. As new information continues to be revealed on organs that can be infective, in order to adequately prevent the spread of BSE no mammalian protein should be fed to any animals in the human food supply.

***b. Barrier to transmission between species may be smaller than previously thought:***

In some studies, TSE diseases have been found to spread between species that were previously thought to be protected by a strong species barrier. A substantial species barrier was thought to limit the transmission of TSEs between hamsters and mice. However, a hamster prion strain thought to be nonpathogenic to mice has created a sub-clinical infection in mice.[22] This suggests that TSE infections may spread between species by creating sub-clinical infections, which do not show symptoms, but are still infectious. The researchers of this study concluded, "Importantly, these data seriously question our current understanding of species barriers."[23] Previously, the measurement of species barriers has depended upon detecting a clinical infection in the inoculated species, and sub-clinical infections have not been tested for.[24] If TSE diseases can cross species barriers by creating a sub-clinical infection in another species, then the barrier to transmission of these diseases between different species may be significantly lower than previously thought. The fact that BSE has crossed the species barrier to humans in the form of nvCJD as a result of the consumption of infected material also indicates that this disease can spread to other species. The feeding of mammalian proteins to any food animals must be ceased in order to prevent the spread of BSE from cattle to other species or from other species back to cattle.

***c. Infectious dose is smaller than originally thought:***

The FDA's proposal notes recent data which suggest that the smallest oral infective dose for the transmission of BSE may be smaller than previously believed and requests comments on this matter. The FDA's rationale (page 58577) mentions a study which has demonstrated transmission of BSE with an oral dose of 0.01g of infected brain tissue.

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[22] See 13.
[23] See 13 (at page 10252).
[24] See 12.

However, cows have actually been shown to contract BSE with an even smaller oral dose, of 0.001g (a ten-fold smaller dose than is mentioned by FDA). The UK's continuing attack rate study has found that BSE was transmitted to 1 out of 15 cows that were fed 0.001g of infected brain tissue.[25] This result indicates that an incredibly small amount of bovine material could transmit a BSE infection, if intentionally or accidentally fed back to cattle. As a result, all the current loopholes which allow the continued presence of potentially infective bovine material in animal feed should be considered significant risks for the transmission of BSE. Cross-contamination and misfeeding in particular are thought to have been the main causes for the continued cases of BSE after the initial ruminant feed ban in the UK. The discovery of such a small infectious dose indicates that under the current feed rules in the US, there will continue to be an extremely high risk of spreading BSE through cross-contamination between the ruminant and non-ruminant food supply, during food manufacture or misfeeding. This data also demonstrates a high risk from continuing to feed any potentially infectious bovine material back to cattle; substances such as poultry litter, tallow, blood, and other materials could still be present in bovine and animal feed and this recent study indicates that extremely low levels of infectious material in these substances could transmit the disease. This level of infectivity is much higher than previously thought and indicates that the proposed rule, with its many loopholes, will not be sufficient to prevent the spread of BSE within the US cattle population. A feed rule that does not adequately address ALL risk materials in all animal feed will not be sufficient; the continued feeding of any mammalian protein to food animals poses a serious risk of spreading BSE.

**III. Improved record keeping requirements are necessary.** Based on the long incubation period of BSE and the time it has taken to confirm cases, a 1-year record keeping requirement is not adequate to detect the source of an infection and record keeping requirements should be increased to 10 years. Animals generally do not show signs of a TSE within one year of infection and have been known to incubate the disease for periods between 2 and 8 years.[26] In the recent case of BSE in Texas, it took close to 8 months for the cow to be confirmed as BSE positive. The cow was found and first tested in November 2004, however it was not confirmed as having BSE until June 2005.[27] The FDA should require detailed records be kept throughout the feed chain for a minimum of 10 years. An adequate paper trail is necessary for agencies to trace the source of any contaminated and infectious material. When an infected animal is found, records are needed to trace what the animal has been fed, where the food came from, and where its meat has been sold. Extensive records are also very useful in epidemiological studies. One year of records in insufficient for these purposes, therefore the timeframe should be

[25] UK attack rate study conducted by Danny Matthews, described on page 11 of: Hueston WD. January 27, 2005. The science of bovine spongiform encephalopathy: What we know today. University of Minnesota, Center for Animal Health and Food Safety. <http://www.meatami.com/BSE/Hueston1.pdf> Accessed November 14, 2005.

[26] American Veterinary Medicine Association. January 2005. Facts About BSE. <http://www.avma.org/communications/brochures/bse/bse_faq.asp> Accessed November 17, 2005.

[27] United States Department of Agriculture. June 24, 2005. News Release Number 0232.05: USDA Announces BSE Test Results and New BSE Confirmatory Testing Protocol. <http://www.aphis.usda.gov/lpa/issues/bse/bse.html> Accessed November 17, 2005.

increased to 10 years. A 10 year record keeping period would assure the agency is reasonably prepared to prevent BSE outbreaks.

**IV. FDA's environmental review of the proposed rule was inadequate.** NEPA requires environmental review for all major federal actions significantly effecting the human environment.[28] An environmental assessment (EA) must include a discussion of the environmental effects of the proposed action.[29] Environmental effects are broadly defined under NEPA to include: ecological, aesthetic, historic, cultural, economic, social, or health, whether direct, indirect, or cumulative.[30] NEPA regulations require an agency to discuss the need for the proposal, a reasonable range of alternatives to the proposal, the environmental impacts of the proposed actions and alternatives, and a listing of agencies and persons consulted.[31] Ultimately, the EA must "provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact."[32]

Given the evidence in the record of the significant environmental and public health effects of BSE, the FDA improperly made a finding of no significant impact. FDA should have a prepared an Environmental Impact Statement ("EIS") that examined the environmental and public health effects of the proposed rule and that considered the more stringent alternative described in these comments. Compliance with NEPA would provide the agency and the public with greater resources for informed decision making. Although FDA prepared an EA for its proposed rule, the EA was inadequate for several reasons:

FDA's conclusion that the SRM prohibition would have greater environmental effects than the proposed rule lacked basis. The EA failed to assess the environmental, health, and economic effects of a BSE epidemic among US cattle or contamination of the food supply with BSE. Both of these possibilities are more likely to occur under the proposed rule than under a full SRM ban. FDA should analyze the likelihood of a BSE outbreak for each alternative and its associated effects on the human environment. Such information bears upon the effectiveness of the animal feed rule and the significance of its environmental effects. Specifically, BSE contamination would generate a large amount of animal waste material requiring disposal and subsequent environmental effects. The industry would experience effects such as costs for disposal of animals and beef, loss of sales, and processing changes. Most importantly, there would be impacts on human and animal health due to the disease and disposal methods. The EA acknowledges the negative environmental consequences of BSE spreading in the US,[33] but fails to acknowledge that this outcome will be much more likely under the proposed rule than under a full SRM ban. This is a significant environmental impact that is not adequately discussed. Additionally, the assessment of an SRM prohibition failed to consider

[28] 42 U.S.C. § 4332.
[29] 40 C.F.R. § 1508.9(b).
[30] 40 C.F.R. § 1508.8.
[31] *Id.* § 1508.9(b).
[32] 40 C.F.R. 1508.9(a).
[33] FDA. Sept. 22, 2005. Environmental Assessment for Amendments to 21 CFR 589 Substances Prohibited from Use in Animal Food or Feed, page 24 [hereinafter "EA"].

alternative methods for disposal of the increased waste, other than rendering and landfills, and might therefore incorrectly assume that the increased waste would create a major environmental problem.

The EA also lacked an adequate discussion of alternatives. The only alternatives assessed in the EA are "no action" and an SRM prohibition. It should have included assessments and comparisons between more alternatives, particularly ones that FDA has previously considered and requested information on, such as a prohibition on the use of all mammalian and poultry protein in ruminant feed.[34]

Finally, FDA inadequately assessed the risk of wildlife being exposed to BSE through the carcasses of dead infected cattle. This would be more likely under the proposed rule than under a full SRM ban because loopholes in the proposed rule risk spread of BSE. Recent studies show that BSE has a low species barrier and could cause an environmental problem for wildlife.[35]

**V. Conclusion**

FDA's proposed rules leave the United States vulnerable to the spread of BSE and continue to put the public at risk from nvCJD. While we agree that the existing feed rules are in need of strengthening, we find the current proposal inadequate. Despite the knowledge that mad cow is spread through contaminated feed, a number of potentially infective mammalian materials are still included in feed for cattle and other animals. Based on the experiences in the UK and scientific information on BSE, the knowledge is available to determine which measures work best to prevent the spread of this dangerous disease. The United States should not wait until a major outbreak occurs before taking the only step known to stop the spread of mad cow disease-a complete ban on feeding mammalian materials to food animals.

Therefore, in order to protect U.S. consumers from exposure to BSE it is necessary and scientifically supported that FDA enact a much stricter feed regulation that proposed. In particular, FDA should eliminate the dangerous loopholes in the proposed rule by doing the following:

- Ban the use of blood, poultry litter, plate waste, and tallow in feed for all animals.
- Ban the use of cattle not approved for human consumption in the animal feed supply.
- Ban the use of all SRMs, not just the brain and spinal cord.
- Apply restrictions to cattle of all ages, not only those older than 30 months.
- Extend all record keeping requirements to 10 years.
- Rectify errors and omissions in the FDA's EA on the proposed rule.

In sum, it is time for the FDA to amend the feed rule so that it provides maximum protection against the amplification of BSE in the US food supply. A failure by the agency to enact the type of regulation described by CFS runs counter to the prevailing

[34] *See* EA page 3-4.
[35] See 13.

science, the international record of addressing BSE issues in feed, and would be arbitrary, capricious and an abuse of discretion.

Respectfully submitted,

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