Consumers Union's comments on FDA Docket No. 2002N-0273: Substances prohibited from use in animal food and feed
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Prepared by Michael Hansen Ph.D., Senior Scientist

Summary

FDA's decision to only ban a limited subset of specified risk materials (SRMs)—the brain and spinal cord—from cattle over 30 months from all animal feed, leaves the safety of beef at risk. Although this is a small step forward, this ban will not close the loopholes in the present feed ban and fully protect the US from the spread of bovine spongiform encephalopathy (BSE). The proposed feed ban appears to put the economic interests of the rendering and feed industry above public health concerns.

FDA proposes to ban a number of materials of cattle origin in the food and feed of all animals, including:

1. brains and spinal cords from cattle 30 months of age or older;
2. brain and spinal cords from cattle of any age not inspected and passed for human consumption;
3. the entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed
4. tallow that is derived from materials prohibited by this proposed rule that contains more than 0.15 percent insoluble impurities; and
5. mechanically separated beef that is derived from the materials prohibited by this proposed rule

These steps are not sufficient. If a cow is infected with BSE, infectious material can be found in many other parts beside brains and spinal cord. Cases of BSE have also been found in Europe and Japan in animals that are under 30 months of age. It is particularly worrisome that FDA will continue to allow plate wastes, chicken coop floor wastes (aka poultry litter) and cattle blood to be fed to cattle. For the reasons we explain below, FDA should ban all feeding of mammalian protein to food animals, as both the European Union and Japan have done.

Infectivity Not Limited to Brain and Spinal Cord

One major problem with the FDA's proposed rule is it limits prohibited materials to brains and spinal cords, when other materials are known to carry the infectious prions that can transmit BSE. The tissues that have been shown to contain infectivity at some point during the incubation period and so are considered to represent the greatest risk for BSE exposure are known as specified risk materials (SRMs). For human food, FDA and USDA have defined SRMs to include: brain, skull, eyes, trigeminal ganglia, spinal cord,

vertebral column and dorsal root ganglia from cattle 30 months or older; and tonsils and distal ileum from all cattle. These SRMs have been prohibited in human food. The reason USDA gave for this action is that "Science indicates that in animals with BSE, these materials harbor the infectious agent before the animal shows any clinical signs of disease. Canada took similar actions when a single case of BSE was discovered there in May 2003"[1]. FDA took complementary action and banned these SRMs from the foods (e.g. processed meat, etc.) under its jurisdiction.

In light of the actions taken by USDA and FDA to protect the human health by banning use of SRMs in human food, the FDA's proposed feed rule does not make scientific sense. If cattle SRMs could transmit BSE to humans, then surely they can transmit BSE to other cows. Scientific studies of transmissible spongiform encephalopathies (TSEs) have clearly shown that animals are far more susceptible to infectious materials from members of the same species with the disease, compared to infectious materials that come from other species. This phenomenon is known as a species barrier. Yet FDA is proposing to put fewer restrictions on cattle material in animal feed than on cattle material in human food. Since cattle are more sensitive to BSE, compared to humans, how can something that is considered unsafe for humans to consume—eyes, dorsal root ganglia, and trigeminal ganglia from cattle older than 30 months, and distal ileum from all cattle—be allowed to be fed to cattle?

The FDA's answer to this question is that brain and spinal cord from animals older than 30 months represents 90% of the infectivity found in cattle, yet make of only a small percentage of total SRMs, when looked at on a weight basis. According to FDA, the weight of head, spinal column and small intestines (more expansive definition of SRM) from cows over 30 months of age averages 88.5 pounds per animal, while the weight of the brain and spinal cord averages only 1.3 pounds per animal. Given the supposedly large costs for disposal of SRM material, the FDA argues that it can reduce 90% of the potential infectivity by banning only brains and spinal cords from cattle over 30 months. Effectively, FDA is saying that it will cost renderers and the feed industry too much to dispose of all SRMs. All SRMs couldn't just be deposited in a land fill, because the potential infectivity of these tissues can survive in the soil; a study demonstrated that scrapie-infected hamster brain buried for three years still contained detectable infectivity[2]. So, cattle SRMs could too hazardous to be put in simple land fills. But rather than burden the industry with disposal costs, FDA will allow them to dispose of this material in animal feed.

This FDA view is clearly bending to the economic concerns of the feed industry at the expense of public health. FDA should in fact, at a minimum, prohibit all the potentially infectious material, as it does in human food. As an infectious disease, FDA should be careful not even to allow BSE to get a toe hold in US cattle. For the reasons laid out below, we feel that FDA should in fact ban the feeding of all mammalian protein to food animals.

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[1] http://www.fsis.usda.gov/Fact_Sheets/FSIS_Further_Strengthens_Protections_Against_BSE/index.asp

[2] Brown, P. and D.C. Gajdusek. 1991. Survival of scrapie virus after 3 years' interment. *Lancet* 337(8736): 269-270

Even USDA's definition of SRMs is too narrow, as tissues other than those in the present USDA definition have been shown to contain the infections agent (PrPres). Bone marrow is not included, even though it contains the supposed infectious agent (deformed prions or PrPres) and has shown some infectivity in mouse inoculation studies[3]. Studies with scrapie, the sheep version of the disease, have clearly shown that the peripheral nerves themselves (e.g. when teased out of those muscles), contain the deformed prions[4] and are clearly infectious in mouse inoculation studies[5]. A new study on a case of natural BSE in Japan[6] has extended these findings to cattle, e.g. using sensitive technology (Western blot with the sodium phosphotungstate precipitation step) deformed prions (e.g. PrPSc) have been found in peripheral nerves (sciatic nerve, tibial nerve, vagus nerve). This Japanese study also found the deformed prions in the sublingual ganglion (associated with the tongue) causing the authors to conclude, "Our results suggest that the currently accepted definitions of SRM in BSE cattle may need to be reexamined"[7]. This study clearly shows that the deformed prions can be found in non-SRM tissues in cattle with BSE. Recent studies have also found the deformed prions in the muscles of rodents exposed to scrapie[8], humans with CJD[9] and sheep with natural scrapie[10]. Finally, another recent mouse study found that inflammation can cause deformed prions to invade organs—such as pancreas, liver or kidney—that normally resist infection[11]. If this new research holds true for cattle, it could mean that some organs previously thought safe to eat are not. This means that the definition of SRMs may need to be expanded.

BSE Not Limited to Cattle More than 30 Months Old

Not only is the list of tissues excluded from feed too narrow, but even the age distribution is too restricted. FDA is only banning brain and spinal cord from cattle 30

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[3] Wells, G.A.H., Hawkins, S.A.C., Green, R.B., Spencer, Y.I., Dexter, I., and M. Dawson. 1999. Limited detection of sternal bone marrow infectivity in the clinical phase of experimental bovine spongiform encephalopathy (BSE). *Veterinary Record*, 144: 292-294.

[4] Heggebø, R., González, L., Press, C.M., Gunnes, G., Espenes, A. and M. Jeffrey. 2003. *J. Gen. Virology*, 84: 1327-1338.

[5] Groschup, M.H., Weiland, F., Sraub, O.C. and E. Pfaff. 1996. Detection of scrapie agent in the peripheral nervous system of a diseased sheep. *Neruobiology of Disease*, 3: 191-195.

[6] Iwamaru, Y., Okubo, Y., Ikeda, T., Hayashi, H., Imamura, M., Yokoyama, T. and M. Shinagawa. 2005. PrPSc distribution of a natural case of bovine spongiform encephalopathy. Pg. 179 in T. Kitamota (Ed.). *Prions*. Springer Verlag, Tokoyo, Japan.

[7] Ibid, pg. 179.

[8] Thomzig, A., Schulz-Schaeffer, W., Kratzel, C., Mai, J. and M. Beekes. 2004. Preclinical deposition of pathological prion protein PrPsc in muscles of hamsters orally exposed to scrapie. *The Jouirnal of Clinical Investigation*, 113(10): 1465-1472.

[9] Glatzel, M., Abela, E., Maissen, M. and A. Aguzzi. 2003. Extraneural pathologic prion protein in sporadic Creudzfeldt-Jakob disease. *New England Journal of Medicine*, 349: 1812-1820.

[10] Andreoletti, O., Simon, S., Lacroux, C., Morel, N., Tabouret, G., Chabert, A., Lugan, S., Corbiere, F., Ferre, P., Foucras, G., Laude, H., Eychenne, F., Grassi, J. and F. Schelcher, F. 2004. PrPSc accumulation in myocytes from sheep incubating natural scrapie. *Nature Medicine*, 10(6): 591-593.

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

months and older. Thus, brain and spinal cord, as well as eyes and other central nervous system tissue from cows younger that are over 30 months can still be put into poultry and pig feed. Although FDA argues that the level of the potentially infectious agent is too low in brain and spinal cord from animals younger than 30 months to cause disease, this too seems contrary to the scientific literature. BSE has been detected in animals less than 30 months old. For example, two of the 20 BSE cases in Japan were in animals younger than 30 months (a 21 month and 23[12] month case). In the United Kingdom, there have been at least 19 cases of BSE in cattle under 30 months of age, with the youngest case occurring in a 20 month old cow[13]. As part of their sampling program, the European Union has identified more than 20 cases of BSE in animals younger than 30 months. So, contrary to FDA assertions, BSE has been found in animals less than 30 months of age.

A bigger problem with younger cattle is that cattle may be infected with BSE at a very young age, and may be infectious while in the pre-clinical stage e.g. while incubating the disease. In a sheep study, sheep infected with BSE via the oral route but that were not showing symptoms of disease were shown to transmit BSE to other sheep via blood transfusion[14]. If the same thing holds true for cattle, then tissues—including SRMs—from cattle less than 30 months of age could also transmit the disease.

The U.S. surveillance program, which tests roughly 1% of cattle at slaughter and says it tests only older animals, will not identify any younger BSE cases that might exist in the U.S. The international expert committee that advised the US Secretary of Agriculture after the first case of mad cow disease was found in the U.S. December, 2003, strongly urged FDA to consider banning all SRMs from cattle above 12 months as well as the entire intestines from all animals[15]. In addition, the World Health Organization, the Food and Agriculture Organization and the World Animal Health Organization (OIE) have jointly recommended that "if a country has identified BSE . . . then MBM for use in non-ruminant should be prepared from non-SRM material" (e.g. SRMs should be banned from all animal feed for countries that have BSE)[16]. Consumers Union urges FDA, at a minimum, to ban all cattle SRMs in animal feed.

FDA's Proposed Approach Did Not End Epidemic in UK

The experience of the United Kingdom (UK) with BSE suggests that FDA should take far more stringent action to stop the spread of BSE. In September, 1990 the UK banned the use of specified bovine offals (SBOs—cow brains, spinal cords, eyes, etc.—what are now called SRMs) in all animal feed[17]. The tissues/materials defined as

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[12] Yamakawa, Y. et al. for the Expert Committee for BSE Diagnosis, Ministry of Health, Labour and Welfare of Japan. 2003. Atypical proteinase K-resistant prion protein(PrPres) observed in an apparently healthy 23-month old Holstein steer. *Japan Journal of Infectious Disease* 56:221-222.
[13] http://www.defra.gov.uk/animalh/bse/statistics/bse/yng-old.html
[14] Hunter, N., Forster, J., Chong, A., McCutcheon, Parnham, D., Eaton, S., MacKenzie, C. and F. Houston. 2002. Transmission of prion diseases by blood transfusion. *Journal of General Virology*, 83: 2897-2905.
[15] At http://www.aphis.usda.gov/lpa/issues/bse/bse_sec_adv_comm.pdf
[16] At http://www.oie.int/esp/publicat/rapports/en_bse%20who-fao-oie.htm
[17] At http://news.bbc.co.uk/1/hi/uk/218676.stm

SBOs—brain, spinal cord, spleen, thymus, tonsils and intestines from animals older than 6 months—are similar to the tissues/materials defined as SRMs by USDA. However, the UK definition of SBOs refers to material from animals older than 6 months of age. This SBO ban was thus actually far more stringent than the FDA's current proposal to ban only brain and spinal cord from cattle over 30 months of age from all animal feed. Yet, more than 16,000 confirmed BSE cases were found in cattle born between September 1990—when SBOs (were banned in all animal feed—and March 1996[18]. The UK subsequently concluded that just banning brains and other SRMs from all animal feed was ineffective in preventing transmission of the disease. The UK therefore banned all feeding of mammalian meat and bone meal to food animals in March, 1996. Thus, the UK clearly recognized that even a stringent SBO/SRM ban in all animal feed was insufficient is halting BSE and so they took the stronger step of banning all mammalian protein in all animal feed. If the FDA does not follow suit, the proposed FDA SRM ban may reduce but will not eliminate the risk of BSE in the U.S., so that the disease may continue to spread and amplify. Only by taking more stringent measures can the US hope to eliminate the risk of BSE in the US cattle herd.

Recent scientific studies in France[19] and Britain[20] have found that, after a ruminant-to-ruminant feed ban was put into place (like the present FDA feed rule), the subsequent incidence of BSE was correlated to pig and, potentially to pig and poultry density, e.g. BSE incidence was higher in regions with lots of pigs compared to regions with few or no pigs. The studies concluded that there was either cross-contamination at the feed mills or on the farms. There is also the possibility that farmers were illegally feeding pig and poultry feed to cattle, due to its cheap price. In addition, in the UK, a ruminant-to-ruminant feed ban was implemented in July 1988. Between July 1988 and September 1990, when all SBOs (now known as SRMs) were banned from all animal feed, more than 27,000 cows were born that later developed BSE, showing the real weakness of a ruminant-to-ruminant feed ban. Ironically, the FDA has called their ruminant-to-ruminant feed ban a "firewall." Clearly, such a "firewall" in the UK still allowed large numbers of BSE cases to still occur.

Partial Feed Ban Makes Enforcement Difficult

In the U.S., ruminant materials can still be in animal feed, it just must be labeled "Do not feed to cattle and other ruminants." Each farmer must make sure that pig and poultry feed is not given to cattle.

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[18] At http://www.defra.gov.uk/animalh/bse/statistics/graphs/dtebirth1.pdf

[19] Abrial, D., Calavas, D., Jarrige, N. and C. Ducrot. 2005. Poultry, pig and the risk of BSE following the feed ban in France - A spatial analysis. *Veterinary Research*, 36(4): 615-628.

[20] Stevenson, M.A., Morris, R.S., Lawson, A.B., Wilesmith, J.W., Ryan, J.B., and R. Jackson. 2005. Area-level risks for BSE in British cattle before and after the July 1988 meat and bone meal feed ban. *Preventative Veterinary Medicine*, 69(1-2): 129-44.

But a series of reports by the General Accounting Office over the last five years has painted a troubled picture of FDA enforcement of their feed rule. In a report[21] issued in September, 2000, GAO pointed out that of FDA inspection of the 2,481 firms identified as handling prohibited material—material not permitted to be fed to ruminants—699, or 28 percent, did not label their product with the warning "Do not feed to cattle and other ruminants." Since most animal feed is not labeled as to which species the feed is derived from, even farmers that want to follow the feed ban regulations could inadvertently feed their cattle prohibited material. A 28 percent failure rate at the facilities known to handle prohibited material should be unacceptable.

In a report[22] issued in January, 2002, GAO noted that problems continued with FDA enforcement of the BSE feed rule and concluded, "FDA has not acted promptly to compel firms to keep prohibited proteins out of cattle feed and to label animal feed that cannot be fed to cattle. We identified some noncompliant firms that had not been reinspected for 2 or more years and instances when no enforcement action had occurred even though the firms had been found noncompliant on multiple inspections. Moreover, FDA's data on inspection are severely flawed and, as a result, FDA dose not know the full extent of industry compliance."

In a report[23] issued in February 2005, GAO found that while the FDA had made improvements in their management and oversight of the feed-ban rule, problems still remained, including the facts that FDA has not been able to identify exactly how many firms that manufacture, transport or mix feed on-farm might be subject to the feed-ban rule; that feed intended for export does not have to contain the caution label "Do not feed to cattle and other ruminants" (meaning that feed containing prohibited material could be inadvertently or intentionally diverted back to U.S. cattle or could be fed to cattle in other countries, such as Mexico, that are then imported to the U.S.); and that FDA inspections did not include instruction to routinely sample cattle feed to test for potentially prohibited material.

It is clear from these GAO reports that there are still problems with FDA's enforcement of the feed rules. Consequently, FDA should make their feed-ban rule more stringent to take into account the problems with enforcement of the feed rules.

The issue of cross-contamination is a serious one. We now know tiny amounts of infected brain material can transmit BSE. A new study conducted by some of Europe's leading experts of BSE found that the oral dose of infected brain necessary to induce BSE in a cow is very, very small. The study found that 7% (1 of 15) of the cattle fed 1 mg of

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[21] GAO. 2000. FOOD SAFETY: Controls Can be Strengthened to Reduce the Risk of Disease Linked to Unsafe Animal Feed. GAO/RCED-00-255. (at http://www.gao.gov/new.items/rc00255.pdf)

[22] see pg. 3 in GAO. 2002. MAD COW DISEASE: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts. GAO-02-183. (at http://www.gao.gov/new.items/d02183.pdf)

[23] GAO. 2005. MAD COW DISEASE: FDA's Management of the Feed Ban has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness .GAO-05-101. (at http://www.gao.gov/new.items/d05101.pdf)

BSE brain developed BSE[24]. So, the lowest infectious oral dose is smaller than 1 mg. This exceedingly small dose—0.000035 ounces (3.5 hundred-thousandths of an ounce), or 0.00021 teaspoons (2.1 ten-thousandths of a teaspoon)—could scarcely be detected in animal feed, meaning that cross-contamination could be occurring without detection on production lines that produced both ruminant and non-ruminant feeds. Even on dedicated production lines only used for producing ruminant feeds from pig and bird (e.g. poultry) remains, there is the possibility of inclusion of ruminant-derived protein contained in the porcine or avian intestines (since ruminant protein can be fed to pigs and poultry), as pointed out by an international expert committee that advised the Secretary of Agriculture in 2004[25].

Given the new studies from France and Britain, we feel that, to close all the loopholes in the FDA's feed ban and to prevent spread of BSE via infected feed, we urge FDA to ban the feeding of all mammalian protein to food animals, as is done in the European Union and Japan. The US should learn from the experience of Europe and not repeat its mistakes. With a confirmed US BSE case announced this past June, we feel that only this strong action will stop the potential spread of BSE via infected feed.

Three Loopholes Create Unacceptable Risks

In January, 2004, FDA Commissioner Mark McClellan announced that FDA would close the loopholes in the 1997 feed rule and would ban the use of mammalian blood products in all animal feed, as well as the feeding of poultry litter to cattle[26]. The present FDA feed proposal would still allow these materials to be used.

Both cattle blood and poultry litter pose a risk of potential transmission of BSE. The FDA proposal would still allow bovine blood products to be fed back to cattle. Much of this, in the form of bovine plasma or red blood cells, may be used as calf milk replacer; there is also the use of bovine serum in colostrum supplements. We now know that blood can contain the infectious agent. Two people in the United Kingdom are believed to have contracted a human form of the disease, vCJD, from blood transfusion[27]. Studies have shown that either mice[28] or sheep[29] infected with BSE can transmit the disease to other mice or sheep via blood transfusion. In the sheep study, the disease

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[24] Lasmézas, C.I., Comoy, E., Hawkins, S., Herzog, C., Mouthon, F., Konold, T., Auvré, F., Correia, E., Lescoutra-Etchegaray, N., Salès, N., Wells, G., Brown, P. and J.-P. Deslys. 2005. Risk of oral infection with bovine spongiform encephalopathy agent in primates. *Lancet*, 365(9461): 730-731.

[25] At http://www.aphis.usda.gov/lpa/issues/bse/US_BSE_Report.pdf

[26] Grady, D. and D.G. McNeil. 2004. Rules Issued on Animal Feed and Use of Disabled Cattle. *New York Times*, January 27, 2004.

[27] Llewelyn, C.A., Hewitt, P.E., Knight, R.S. et al. 2004. Possible transmission of variant Creutzfeldt-Jakob disease by blood transfusion. *Lancet*, 363: 417-421. and Peden, A.H., Head, M.W., Ritchie, D.L., Bell, J.E. and J.W. Ironside. 2004. Preclinical vCJD after blood transfusion in a *PRNP* codon 129 heterozygous. *Lancet*, 364: 527-528.

[28] Taylor, D.M., Fernie, K., Reichl, H.E. and R.A. Somerville. 2000. Infectivity in blood of mice with a BSE-derived agent. Letter to the Editor. *Journal of Hospital Infection*, 46: 78-79.

[29] Hunter, N., Forster, J., Chong, A., McCutcheon, Parnham, D., Eaton, S., MacKenzie, C. and F. Houston. 2002. Transmission of prion diseases by blood transfusion. *Journal of General Virology*, 83: 2897-2905.

could be transmitted via blood transfusion from sheep incubating BSE (e.g. not showing symptoms of disease). Thus, blood clearly contains the infectious agent. Since the bovine plasma and red blood cells used in calf milk replacer are spray-dried, this form of processing would not reduce the infectivity titer of the bovine plasma and/or red blood cells. This combined with the fact that milk replacer is fed to weaning animals, which appear to be more susceptible to BSE than older animals, only increases the concern about potential BSE infection.

Poultry litter—chicken coop floor wastes that include feces, feathers and uneaten chicken feed—can still be fed to cattle and are very risky material. An estimated 2 billion pounds of poultry litter is fed to cattle every year[30]. As FDA Commissioner Dr. Lester Crawford stated in an 2003, "There is a possibility that chickens waste so much feed that the litter can contain up to 30% meat and bone meal"[31]. This translates to 600 million pounds of meat and bone meal—which can come from cattle—that may be fed to cattle every year. This is potentially a huge amount of material, some portion of which could be highly infectious. Under FDA's new proposed rule, brain and spinal cord from cattle less than 30 months old, and eyes, trigeminal ganglia, dorsal root ganglia and intestines (including distal ileum) from animals of any age still will legally be permitted in poultry feed and so can be fed back to cattle as part of poultry litter. Given that the minimum infectious dose is still not known[32], this is a serious concern.

In the BSE feeding study published this year, the authors note that the brain of a cow weighs 500 grams and the spinal cord 200 grams[33]. If one milligram is an infectious dose, and even assuming that only one in every 15 (or 6.3 percent) cows that consumes a milligram comes down with BSE (as happened in this study), then one infected brain and spinal cord could contain enough infective agent to transmit BSE orally to 45,100 cows (6.3% of 700 grams if 1 milligram is needed). In the view of Consumers Union, this is why we have to be so careful to make sure that not even one BSE-infected cow gets into animal feed.

In fact, the extremely low level of infectivity of material argues for taking a more expansive definition of SRMs than FDA does at present. According to the FDA, the brain and spinal cord of a cow weighs 1.3 pounds. FDA cites studies that argue that 90% of the total BSE infectivity occurs in the brain and spinal cord, with 10% of the infectivity in the other SRMs (e.g. dorsal root ganglia, trigeminal ganglia, distal ileum, tonsils, and eyes). Since the brain and spinal cord of a cow with BSE contain enough infective agent to transmit the disease orally to 45,100 cattle, the other SRMs would collectively contain enough infective agent to transmit the disease orally to an additional

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[30] Hileman, B. 2003. Guarding against mad cow disease. *Chemical and Engineering News*, 81(31): 32-34.

[31] Ibid, pg. 34.

[32] Lasmézas, C.I., Comoy, E., Hawkins, S., Herzog, C., Mouthon, F., Konold, T., Auvré, F., Correia, E., Lescoutra-Etchegaray, N., Salès, N., Wells, G., Brown, P. and J.-P. Deslys. 2005. Risk of oral infection with bovine spongiform encephalopathy agent in primates. *Lancet*, 365(9461): 730-731.

[33] Lasmézas, C.I., Comoy, E., Hawkins, S., Herzog, C., Mouthon, F., Konold, T., Auvré, F., Correia, E., Lescoutra-Etchegaray, N., Salès, N., Wells, G., Brown, P. and J.-P. Deslys. 2005. Risk of oral infection with bovine spongiform encephalopathy agent in primates. *Lancet*, 365(9461): 730-731.

5,000 cattle. Thus, the infectious material from all SRMs (e.g. the definition used by USDA and FDA for human food) contains enough infective agent to transmit the disease orally to approximately 50,000 cattle (45,100 plus 5,000). This calculation assumes that the infectious material would be uniformly distributed in the animal feed, while it is more likely to have a far more clumped distribution. The FDA appears willing to accept a 90% reduction in potential BSE exposure while only removing just brain and spinal cord from cattle older than 30 months just to save on the disposal costs of getting rid of all SRMs. But FDA's proposal would still potentially permit 5,000 oral infectious doses from the excluded SRMs in animal feed from each BSE positive cow. This figure 5,000 oral infectious doses is of serious concern. Since we believe that FDA should be taking all actions to reduce exposure to BSE as much as possible, to leave a loophole permitting 5,000 oral infectious doses from each (undetected) BSE positive cow that enters the animal feed chain should is unacceptable.

The current FDA proposal would still allow poultry and pigs to be ground up and fed back to cattle. Prion diseases have not been seen in the field in these animals although BSE was induced in pigs in the laboratory[34]. Research done at the National Institutes of Health has found one species of animal may not get a TSE but can still act as a "silent carrier" of the disease and spread that disease to a second animal species that is susceptible to the disease[35]. The NIH experiment found that mice injected with material (brain or spleen) from scrapie-infected hamsters did not get sick. However, material from these mice, when injected into hamsters, caused some of those hamsters to get sick (e.g. develop hamster scrapie). The potential implications of the work were pointed out in an accompanying commentary on the paper in *Nature*: "Pigs and chickens that have been fed with cattle-derived bone and meat meal are thought to be safe to eat with respect to BSE, because these animals do not develop disease after oral exposure to bovine prions. But, to the best of our knowledge, bovine prions from BSE-exposed pigs and poultry have never been assayed using calves as 'indicator' animals"[36].

Absence of Animal ID Makes Age Determination Unreliable

FDA will find the feed rule difficult to implement, in large part due to the difficulty in accurately aging animals, in large part due to the absence of a mandatory animal ID system. The proposed FDA feed rule depends on slaughterhouses (under USDA's jurisdiction) to accurately age animals and accurate identify and remove all SRMs. The consumer group Public Citizen issued a report in August, 2005 that demonstrated there were 829 violations, from January 2004 through March 2005, of USDA's rules on ensuring removal of SRMs from animals over 30 months of age[37]. Of the 829 violations (referred to as "noncompliance records" or NRs), over half of them involved having an inadequate HACCP (Hazard Analysis and Critical Control Point)

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[34] Dawson, M., Wells, G.A.H., Parker, B.N.J. and A.C. Scott. 1990. Primary parental transmission of bovine spongiform encephalopathy to the pig. *Veterinary Record*, pg. 338.
[35] Race, R. and B. Chesebro. 1998. Scrapie infectivity found in resistant species. *Nature,* 392: 770
[36] Aguzzi, A. and C. Weissmann. 1998. The prion's perplexing persistence. *Nature,* 392: 763-764
[37] http://www.citizen.org/pressroom/release.cfm?ID=2024

Plan. Of the NRs involving inadequate HACCP plans, some 60 percent (or 275 NRs) were due to the failure to even mention BSE or SRMs as part of the company HACCP Plan while another 22 percent (or 100 NRs) involved the plant not having documentation from suppliers that the beef they are processing came from cattle under 30 months or that SRMs were removed. If a plant can't be bothered to recognize the risk of BSE in their HACCP plan, how much of a priority would it be in daily operations and training of staff? About one third of the violation (or 276 NRs) involved improper removal or handling of SRMs, with a common situation being that over-30 month and under-30 month cattle were processed simultaneously, without adequate rinsing or sanitation of equipment, so that cross contamination could occur. Finally about 10 percent of the violations (or 86 NRs) involved improper age determination of the cattle. Given the problems that USDA clearly has in accurately aging animals and accurately identifying and removing all SRMs, it would be prudent for FDA to simply require that all mammalian protein not be allowed to be used in any animal feed. This would obviate the need for USDA personnel to accurately age animals and accurate identify and remove all SRMs.

Comments on Specific Sections of Proposed Feed Rule

II. Proposed Measures to Strengthen Animal Feed Safeguards

II.A. FDA response to comments to the 2004 ANPRM

"FDA seeks comments on whether a full SRM ban is warranted"
See discussion above. CU believes that not only is a fully SRM ban warranted, but that the definition of SRMs should be expanded to include material from animals over 12 months of age, not 30 months. In addition, for the reasons argued above, CU feels that FDA should ban all mammalian protein from all animal feed.

II.C. Basis for Proposing to Apply Additional Measures to All Animal Food and Feed

FDA has requested comment on the new study on the minimum infectious dose for: "Further increasing FDA's concerns about cross-contamination are preliminary data from an unpublished showing that the minimum infectious dose for BSE may be lower than previously thought. Interim results at approximately 5 years post exposure of an oral challenge experiment have demonstrated transmission of BSE to 1 out of 15 animals that received 0.01 gram of brain tissue from a BSE-infected animal (Ref. 13). The lowest dose previously tested was 1.0 gram of brain tissue which showed transmission in 7 out of 10 animals in the trial group. This finding of a lower minimum infectious dose for BSE would suggest that the risk from cross-contamination is greater than previously thought. We seek comment on this interpretation of theses [sic] interim results."

CU agrees with FDA about the concerns of cross-contamination, but we believe that the situation is even more serious than FDA believes. The reference to the "unpublished study" FDA refers to—which demonstrates that the minimum infectious dose is 100 times lower than previously thought (0.01 gram vs. 1.0 gram)—is to a European Commission Scientific Steering Committee report on BSE risk assessment. However, this assessment was published more than two and a half years ago—on June 5, 2003. FDA seems to be unaware a new paper on this issue that was published earlier this year in the *Lancet*[38] that demonstrated that the minimum infectious dose is ten times lower than the 0.01 gram figure from the "unpublished study." As pointed out in the *Lancet* article, 1 of 15 cows fed 1 milligram (e.g. 0.001 gram) came down with BSE. This infection rate of 6.7% (1 of 15 cows) is the same regardless of whether the cows were fed 0.01 gram or 0.001 grams of BSE brain. Since a ten-fold reduction in exposure level—from 0.01 grams to 0.001 grams—did not result in a reduction in the rate of infectivity, this raises the question as to whether a further reduction in exposure—such as to 100 micrograms (e.g. 0.0001 gram) of BSE brain—would also result in the same infection rate. But this new published study clearly shows that the minimum infectious dose is at least ten times smaller than the lowest dose from the previous unpublished study. Thus, the concern over cross-contamination is even more severe than FDA realizes.

As noted in the discussion in previous sections above, the implications of this new feeding study are serious indeed. That is why we argue that FDA must take the most stringent steps and ban the feeding of all mammalian protein to food animals as that is about the only way to prevent cross contamination from happening.

II. D. Cattle Materials Proposed to be Prohibited From Use in All Animal Food and Feed

II.D.4 Tallow

As noted above, the minimum infectious dose for BSE from oral exposure is ten times smaller than FDA now recognizes. Based on this, we feel that no tallow with any protein contamination should be permitted in animal feed. FDA has proposed exempting tallow if it contains less than 0.15 percent insoluble impurities and has asked for comments on this proposal. Given that 1 milligram of CNS tissue from a BSE case can infect over 6 percent of all the cattle that ingest this dose, the proposed exemption could allow infectious material to be present in the tallow. Since the FDA's goal should be to minimize exposure to the BSE agent as much as possible, we feel that tallow should not be exempted from the BSE animal feed rule.

[38] Lasmézas, C.I., Comoy, E., Hawkins, S., Herzog, C., Mouthon, F., Konold, T., Auvré, F., Correia, E., Lescoutra-Etchegaray, N., Salès, N., Wells, G., Brown, P. and J.-P. Deslys. 2005. Risk of oral infection with bovine spongiform encephalopathy agent in primates. *Lancet*, 365(9461): 730-731.

III. Description of Proposed Rule and Legal Authority
III.C. Proposed Recordkeeping and Access Requirements

FDA asks for comment on who in the feed chain should retain records and argues that only the renderers should be required to keep records: "FDA believes that requiring the maintenance of such records at all manufacturing and processing points downstream would be redundant and provide little additional information of value. FDA seeks comments on the need to require that records be maintained by persons other than the renderer." CU believes that records should be kept at all levels—from the renderer to the feed processor/mixer to the seller to the farmer—to facilitate trace back of the feed. We note that FDA tried to do a feed traceback for both US BSE cases—the one discovered in Washington State in December 2003 and the 12 year old Texas cow discovered in November 2004 (but only confirmed as a BSE case in June, 2005). In the case of the 2003 BSE case, the FDA determined that the feed had probably come from a certain rendering plant in Alberta, Canada (in fact, three of the first four North American cases of BSE were traced to the this same plant). The fact that FDA attempted feed traceback on both US BSE cases demonstrates that feed traceback is important. Requiring all steps in the feed chain to keep the records would greatly facility feed traceback.

A case of BSE will most likely be found when the animal is brought to slaughter. Once a BSE case is found, FDA searches records to figure where the farm or birth is and where the animal spent the first couple years of life (when the animal is probably far more susceptible to BSE). The FDA then goes to those farmers and tries to look at their feed records to determine where the feed that was fed to the BSE case within the first year or two of its life was purchased. Then the FDA would go to the feed seller to determine where other batches of that feed went so that any exposed animals could be tested for BSE. So, having all steps in the feed chain—from renderer to farmer—would greatly facilitate feed traceback. Thus, FDA should require that all steps in the feed chain—from renderer to farmer—keep feed records.

As for the amount of time that feed records should be kept, FDA's new rule states "that the records required by this proposed rule be maintained for a minimum of 1 year. . . . We believe that for the purposes of recordkeeping requirements, 1 year is appropriate in light of the time that the products will be in the animal feed production and distribution systems. *Extending the record retention period would have little practical value in determining the source of BSE in an animal" italics added.* CU vigorously disagrees with FDA on this issue. We believe that feed records are very important in tracing potential exposure to infected feed. We note that FDA tried to do feed traceback for both US BSE cases—the one discovered in Washington Dtate in December 2003 and the one discovered in November 2004 and confirmed in June, 2005. Given that the first U.S. born BSE case was a 12 year old cow born in Texas, we feel that feed records should be kept for at least 12 years. If complete feed records—throughout the whole feed chain—had been available for the Texas-born BSE case, FDA would easily have been able to track exactly where the feed fed to that cow in the first couple years of life had come from and could also have determined which cows on other farms may have been exposed

to other lots of feed from the same sources. Thus, we believe that a minimum time period for keeping records should be 12 years.