Consumers Union's Comments to US Department of Agriculture Animal and Plant Health Inspection Service (USDA/APHIS), Docket No. APHIS-2006-0041, Bovine; Minimal Risk Regions; Importation of Live Bovines and Products Derived from Bovines March 9, 2007

Summary

Consumers Union¹ (CU), publisher of Consumer Reports, urges the US Department of Agriculture's Animal and Plant Health Inspection Service (USDA/APHIS) not further amend its regulations regarding the importation of animals and animal products so as to allow the importation into the US from Canada of live bovines born after March 1999, blood and blood products derived from bovines, and casings and parts of the small intestine derived from bovines. CU believes that such changes will increase the potential risk of spreading BSE in the US and so should be denied for the reasons listed below. CU is especially concerned that Canada has already identified four cases of BSE among cows born after March 1999. Under this new proposed rule, any or all of these cows could have been shipped to the United States (US), their carcasses turned into steaks and ground beef for US consumers, and their remains turned into feed for poultry and swine. Since the US does not routinely test cows at slaughter for BSE, it would be unlikely to catch any Canadian BSE cases among Canadian live cows shipped to the US. By contrast, no cases of BSE have been identified in Canadian cows under the age of 30 months, the current age limit for exports to the US.

Detailed comments:

Live Bovines

APHIS proposes to allow importation of live cattle from BSE "minimal-risk" regions "if the animals were born on or after a date determined by APHIS to be the date on and after which the ruminant-to-ruminant feed ban in the region has been effectively enforced." In the case of Canada, which is the only "minimal-risk" region, APHIS has determined that Canada's ruminant-to-ruminant feed ban became effective on March 1, 1999. APHIS' reasoning for this date is as follows. The original Canada ruminant-to-

¹ Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finances; and to initiate and cooperate with individual and group efforts to maintain and enhance the quality of life for consumers. Consumers Union's income is derived solely from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports*, with approximately 4.5 million paid subscribers to print and 2.5 million paid subscribers to the internet addition, regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions which affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

ruminant feed ban came into force in August 1997; 6 months was added to this date because the Canadian Food Inspection Agency (CFIA) determined that six months was needed "for practical implementation of the feed ban." APHIS then added another 12 months to the original 6 month extension, arguing that there is a 12-month calving cycle in Canada and that the calving occurs at basically the same time of year so that this 12month period is "sufficient to allow purchased feed products that may contain MBM [meat and bone meal] to be completely used." Thus, 18 months after August 1997 is March, 1999.

CU strongly disagrees that Canada's feed ban became "effectively enforced" in March 1999. First, we note that Canada discovered five cases of BSE in 2006, with three of these cases in animals born after March 1999². APHIS recognizes these three Canadian BSE cases were born after March 1, 1999 but argues that this is not important as "Experience worldwide has demonstrated that, even in countries with an effective feed ban in place, BSE has occurred in cattle born after a feed ban was implemented . . . [but] such isolated incidents are not epidemiologically significant and do not contribute to further spread of BSE."

First, the Canadian cases of BSE born after March 1999 do not represent "isolated cases." Since the Federal Register Notice was posted on January 9, 2007, there was a ninth Canadian BSE case that was confirmed on February 7, 2007. CFIA has confirmed that this cow was born in 2000³, making it the fourth Canadian BSE case born after March 1999. Thus, some 44% of all Canadian BSE cases (four of nine not including the cow that was slaughtered in the U.S. in December, 2003) were born after March 1999. Some 44% of a country's BSE cases do not represent "isolated cases."

In addition, APHIS argues that "Experience in the United Kingdom [UK] demonstrates that the implementation of a ruminant-to-ruminant feed ban causes BSE prevalence to decrease." This is the type of feed ban currently in place in Canada. However, this is a truthful but misleading comment. A ruminant-to-ruminant feed ban in the UK reduced confirmed BSE cases by half in just over two years. In the two year period after the feed ban began (e.g. August 1988 to August 1990), some 28,000 confirmed BSE cases would be born, compared to some 56,000 confirmed BSE cases being born in the two year period before the feed ban went into effect (e.g. July 1986 – July 1988). Serious declines in confirmed BSE cases did not happen until the UK took stronger measures, ultimately banning the feeding of all mammalian protein to food animals.

APHIS ignores the experience of implementation of ruminant-to-ruminant feed bans in the UK and France. Specifically, the UK's experience clearly shows that ruminant-to-ruminant feed bans do not drastically curtail the number of confirmed BSE cases and that much stronger measures are needed to eradicate the disease. The UK instituted a ruminant-to-ruminant feed ban in July 1988. In just a two year period (e.g. from August 1988 through August, 1990) some 28,000 cattle were born that would later

² At http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/comenqe.shtml

³ At http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/situatione.shtml

be confirmed BSE cases. In September, 1990, the UK took further steps to improve feed safety by banning the use of specified bovine offals (SBOs— defined as brain, spinal cord, spleen, thymus, tonsils and intestines from animals older than six months—similar to the tissues/materials defined as specified risk materials (SRMs) by USDA and CFIA) in all animal feed⁴ based on emerging science on BSE.

In March, 1996, the UK strengthened the feed regulations further by banning all mammalian meat and bone meal (MMBM) from feed for all food animals, including fish and horses⁵. However, between the dates of the SBO ban and the MMBM ban (e.g. from September, 1990 and March 1996), roughly 16,000 future confirmed BSE cases were born. Sixteen thousands animals are not "epidemiologically insignificant" numbers nor do they represent "isolated cases." However, even after the MMBM ban (also called the "reinforced ban"), cattle have continued to be born that later become confirmed BSE cases. Indeed, some 150 BSE cases have been born in the UK after the MMBM ban. In May 2001, the EU passed Regulation 999/2001 which, among other things, banned the feeding of all mammalian protein, including blood and blood products (but exempting milk protein), to all farmed animals, including fish and horses. Since this complete mammalian protein feed ban, less than five confirmed cases BSE have been born, finally controlling the disease.

In addition, Scientific studies in France⁶ and Britain⁷ have found that, after a ruminant-to-ruminant feed ban was put into place, 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 new Canadian BSE feed rule, to be implemented in July 2007 is similar to but weaker than the September 1990 UK SBO ban. By not following the lead of the UK, the proposed CFIA SRM ban may reduce but will not eliminate the risk of BSE in Canada, so that the disease may continue to spread and amplify.

At this time, the BSE situation in Canada does not appear to be getting better. Since January of 2006, some six BSE cases have been confirmed in Canadian cattle. This is a relatively large number, given the relatively small size of the Canadian herd compared to the US. According to the US National Agricultural Statistics Service, the size of the Canadian cattle herd in 2006 was roughly 14.8 million head, compared to 96.7 million head of US cattle⁸. If US were finding BSE cases at the same rate as in Canada, this would translate into roughly forty BSE cases since January 2006. This would be regarded as a large number.

⁴ At http://news.bbc.co.uk/1/hi/uk/218676.stm

⁵ At http://www.defra.gov.uk/animalh/bse/statistics/graphs/dtebirth1.pdf

⁶ 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.

⁷ Stevenson, M.A., Morris, R.S., Lawson, A.B., Wilesmith, J.W., Ryan, J.B., and R. Jackson. 2005. Arealevel 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.

⁸ At http://www.nass.usda.gov/Publications/Todays_Reports/reports/uscc0207.pdf

Thus, given that 44% of Canada's confirmed BSE cases were born after March 1, 1999, and given the experience of UK and France with ruminant-to-ruminant feed bans, CU believes that APHIS should not allow Canadian live cattle born after March 1999 to enter the US. It is unclear whether the feed ban was not effectively enforced, or whether it was effectively enforced but the ruminant-to-ruminant ban is not sufficient to eliminate Canada's BSE problem. In any event, new cases are continuing to appear in Canadian cattle born after March 1999. Thus, CU believes that APHIS should not remove the requirement in § 93.436(a)(1) that live bovines imported from BSE minimal-risk regions be less than 30 months of age when imported into the US when slaughtered. In fact, CU believes that until Canada bans all feeding of animals to food animals and both US and Canada test all cattle at slaughter, APHIS should not allow any cattle to be imported from Canada.

Another problem raised by APHIS' proposal to allow cattle born after March 1999 to be imported into the US is the contradiction it raises vis-à-vis Specified Risk Materials (SRMs). Under present regulations, meat from Canadian cattle over 30 months of age can be imported into the US, but all SRMs must be removed prior to importation. So, no SRMs from Canadian cattle over 30 months of age would come into the US. Under the present proposal, live cattle over 30 months of age would be allowed into the US and would not have to be kept segregated from other cattle. Since FSIS (Food Safety Inspection Service) regulations outlaw sales of SRMs from animals over 30 months of age, the argument goes that ante mortem inspection would prevent SRMs from these cattle entering the human food chain. However, there is evidence that ante mortem inspection doesn't guarantee that SRMs are always removed from cattle over 30 months of age. 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 age⁹. 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) 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's 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, USDA should not relax the present regulation that forbids live Canadian cattle older than 30 months of age being imported into the US.

⁹ http://www.citizen.org/pressroom/release.cfm?ID=2024

Since CU believes that APHIS should not remove the requirement in § 93.436(a)(1) that live bovines imported from BSE minimal-risk regions be less than 30 months of age when imported into the US, we also feel that the following requirements in § 93.436 that APHIS is proposing to remove, SHOULD NOT BE **REMOVED:** § 93.436(b)(6) which requires that cattle from a BSE "minimal-risk" region be moved directly to a feedlot, be handled as an easily identifiable group, and be slaughtered as a group; § 93.436(b)(8) which requires that such cattle sent to a feedlot be accompanied by APHIS Form VS 17 - 130 which must identify the physical location of the feedlot, the individual responsible for the movement of the cattle, and the individual identification of the animal; § 93.436(b)(9) which requires such cattle must remain at a feedlot until transported from the feedlot to a recognized slaughtering establishment for slaughter; § 93.436(b)(10) which requires that such cattle be moved directly from the feedlot to a recognized slaughtering establishment in conveyances sealed at the feedlot with seals of the US Government; § 93.436(b)(11) that cattle be accompanied from the feedlot to a recognized slaughtering establishment by APHIS Form VS 1-27 that identifies the physical location of the slaughtering establishment, the individual responsible for the movement of the cattle, and the individual identification of the animal.

Bovine Blood and Blood Products

APHIS is proposing to amend the regulations in § 95.5 to allow the resumption of imports of bovine blood and blood products from BSE "minimal-risk" regions, that is, of Canadian origin. Some of these bovine blood and blood products can be fed to cattle, in the form of bovine plasma or red blood cells, which 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 transfusion¹⁰. Studies have shown that either mice¹¹ or sheep¹² infected with BSE can transmit the disease to other mice or sheep via blood transfusion. In the sheep study, the disease could be transmitted via blood transfusion from sheep incubating BSE (e.g. not showing symptoms of disease). Thus, blood clearly contains the infectious agent. Although APHIS references a 2002 European Commission Scientific Steering Committee report on TSE (transmissible spongiform encephalopathy) infectivity in ruminant tissue that found that in infected cattle, infectivity has not been detected in cattle blood, we note that this reference, from 2002, is almost five years old. In addition, because of the data from humans, sheep and mice exposed to BSE show that the blood can transmit the disease,

¹⁰ 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.

¹¹ 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.

¹² 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.

APHIS should take a more precautionary approach and assume that it is possible for bovine blood to transmit BSE. Since the appropriate cattle feeding studies haven't been done with blood from infected cows, APHIS should work on the assumption that what is true for sheep, humans and mice could be true for cows.

Since the bovine plasma and red blood cells used in calf milk replacer are spraydried, 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 and will have more years to incubate it and become detectable, only increases the concern about potential BSE infection.

Thus, CU believes that APHIS should maintain the present prohibition on the importation of blood and blood products from BSE "minimal-risk" regions, i.e. blood and blood products from Canadian cattle.

However, if APHIS does allow the import of blood and blood products from Canadian cattle, it is essential that a number of conditions should be placed on how the blood is collected so as to minimize risk of contamination with known SRMs. Thus, **CU supports the proposed requirements in § 95.4(e)(1)(ii) and (e)(2)(ii) that the slaughtered animal not be subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or subjected to a pithing process**, because either of these processes could result in central nervous system material being introduced into a cow's circulatory system.

CU also supports the proposed requirement in § 95.4(e)(2)(iii) that the uterus be removed from a slaughtered dam's abdominal cavity intact and removed to a separate area to ensure that fetal blood is not contaminated with SRMs. Calves fetal blood would be used to produce fetal calf serum, which is used in production of vaccines and medicines.

Finally, if APHIS does allow importation of bovine blood and blood products from Canada, then **CU believes that APHIS should not allow blood and blood products that could be fed to cattle—such as spray-dried bovine plasma and bovine serum, for calf milk replacer and colostrum supplement, respectively—into the US.**

Bovine Small Intestines

APHIS proposes to remove the requirement in § 94.19(a)(2), (b)(2), and (f) that cattle meat, meat byproducts, meat food products, and carcasses must have the entire small intestines removed at slaughter before these products can be imported into the US. In addition, APHIS proposes to remove the requirement in § 95.4(g)(1)(i) that offal from BSE minimal-risk regions (e.g. Canada) must come from animals from which the small intestines have been removed. APHIS argues that since it is possible to separate the distal ileum (which has been shown to transmit BSE) from the rest of the small intestines, only the distal ileum (which is considered a SRM) should be banned.

CU believes that APHIS should continue to ban the import of bovine small intestines from Canada. Since Canada has BSE and appears to have a continuing problem, given that 44% of Canada's confirmed BSE cases were born after their feed ban was supposedly declared "effectively enforced," we feel that APHIS should follow the recommendation of the International Expert Committee that issued a report in February 2004 to the US Secretary of Agriculture that called for the banning from the human and animal feed of the intestines—from anus to pylorus—from cattle of any age¹³.

¹³ At http://www.aphis.usda.gov/lpa/issues/bse/US_BSE_Report.pdf