



September 7, 2016

Docket No. APHIS-2009-0095
Importation of Sheep, Goats and Certain Other Ruminants
Proposed Rule

We are commenting on this proposed rule on behalf of the American Sheep Industry Association (ASI). ASI is the national trade association for the U.S. sheep industry representing nearly 90,000 sheep producers and allied organizations through its affiliated state organizations.

ASI appreciates the publication of this proposed rule to amend the regulations and revise the conditions that govern the importation of sheep and goats and their products, especially with regard to bovine spongiform encephalopathy (BSE) and scrapie. The U.S. sheep industry, along with federal and state animal health regulatory partners, has invested heavily in the National Scrapie Eradication Program (NSEP), with over \$200 million invested thus far by the federal government alone in the past 15 years. While severely underfunded in recent years, this successful program includes a very robust surveillance and flock action program that has resulted in the reduction of the incidence of scrapie to a very low level. While targeted towards classical scrapie eradication, the NSEP surveillance effort has yielded useful data regarding the presence or absence of other TSEs in U.S. sheep flocks and goat herds. A relatively small number of atypical scrapie cases have been found and no BSE cases in sheep or goats have been found.

International trade in U.S., sheep, goats and their products has been severely limited since 2003 when a case of BSE was reported in the U.S. While the exports of beef has resumed gradually over the years, little progress has been made with lamb until very recently, even though there has never been a natural case of BSE reported in sheep globally. We believe that when a final rule that revises the importation requirements for sheep, goats and their products is published, trade opportunities will be enhanced.

ASI is generally supportive of the proposed rule and we believe that overall, the proposed changes are scientifically sound and appropriate. However, we find some areas that need further attention as described below:

- We note that the feeding of sheep and goat milk or milk products is not proposed to be prohibited due to the risk of scrapie transmission. We believe this is a mistake and that the importation of sheep and goat milk or milk products into the U.S. from scrapie infected countries for sheep and/or goat feeding should be prohibited as recommended by the OIE and supported by the literature. The U.S. sheep industry and the public sector have invested significantly in scrapie eradication and the U.S. measured incidence level is

now very low. Therefore, we believe that the risk of such a loophole as milk feeding is very high compared to economic gains.

We also believe that the importation and feeding of blood and blood products from sheep and goats to sheep and goats from countries not free of scrapie and not at least negligible-risk for BSE is a risk and should not be allowed. This is because blood and blood products are not covered under FDA's mammalian to ruminant feed rule and therefore not covered under the processed animal protein restrictions as discussed in this proposed rule.

- As mentioned above, we believe that the risk of scrapie transmission via semen or embryos is very low. We also believe that the genetic profile of rams for scrapie resistance may be even more important than "country status". Therefore, we urge APHIS to grant permit exemptions for semen collected from rams that have tested AA/RR and AA/QR. This should result in the sheep semen import requirements being generally equivalent to the embryo importation requirements.
- We agree that there is solid scientific evidence from the literature and both international and domestic surveillance on TSEs in sheep to conclude that the natural occurrence of BSE in sheep is extremely low or non-existent. However, we do not agree with APHIS that this is the case with live goats. As cited in the proposed rule, there have been two cases of BSE reported in goats and the cause/origin was not determined. Further, neither sufficient published literature nor large enough surveillance sampling exist to draw the conclusion that there is no BSE risk in goats. We note that APHIS does not cite quantitative BSE risk data on goats. We believe that there is little risk in importing semen, embryos and meat from goats. As mentioned above, USDA, states and industry have spent a large sum of money and are working hard to eradicate scrapie from the U.S. Surveillance continues to be an integral part of this effort. We believe that surveillance for goats needs to be expanded in the national scrapie eradication program and we urge APHIS to recommend that trading partners expand their TSE surveillance for goats so that good decisions can be made regarding safe trade for BSE. At such time as when APHIS is able to demonstrate and cite evidence that BSE restrictions on goats should be removed, we urge the agency to publish another proposed rule regarding goats specifically.
- We recommend that APHIS place additional requirements on "designated feedlots" that will receive imported animals from regions not free of classical scrapie for restricted feeding and eventual slaughter to include: That there be no fence-line contact with other sheep or goats. This could be accomplished by requiring at least a 30-foot fence separation or a solid-wall perimeter designed to prevent fluid transfer between animals in the designated feedlot and sheep or goats outside the feedlot. APHIS should also inspect and approve the designated feedlot's biosecurity provisions and practices to minimize the risk of TSE transmission between animals in and outside the designated feedlot.

- In this docket, APHIS has proposed regulatory changes with regards to TSEs/BSE and described as a broad category of “non-bovine ruminants other than sheep and goats” and specifically as “...Certain ruminants held in zoological facilities and certain wild ruminants”. APHIS clarifies their definition of these animals as “zoological ruminants”. APHIS appropriately cites literature and reports regarding TSE cases in some wild and zoological ruminant species, some of which as APHIS notes is limited. APHIS discusses several possibilities regarding the origin and potential transmission of TSEs in zoological and wild ruminants yet admits that the lack of evidence that TSEs exist in free-living zoological ruminants is based upon passive surveillance in southern African countries where “...wildlife have not encountered any clinical cases or histopathological lesions compatible with TSEs.” APHIS also states that “...Active surveillance has not been implemented in any region of the world for TSEs in antelope or free-living Caprinae.” APHIS goes on to state, appropriately in our opinion, that “The management of animal genetic resources must include a consideration of the potential risk of importing undetected prion diseases with rare breeding stock.” APHIS further states “Even in countries that have an enforced ban on the feeding of ruminant protein to domestic ruminants for an identifiable period of time, it can be difficult in some cases to determine when and if a country ceased feeding ruminant protein to zoo ruminants.” ASI believes that non-bovine ruminants other than domestic sheep and goats should be subject to import restrictions and agrees with APHIS that at least some animals in this category “...present enough of a potential risk of spreading TSEs that their importation should be prohibited unless certain risk mitigation measures are in place.”

Remarkably to us, APHIS continues by describing a permit system stating “In the case of zoological ruminants, the Administrator will consider the disease risk of each animal and the ability of the receiving zoo to manage the risks before deciding whether to issue an import permit” and states that “Although the precise measures APHIS considers necessary could vary on a case-by-case basis, such measures could include the following...” and a list is provided. APHIS seems to justify this section of the proposed rule by stating the following “Providing for the importation of specific animals in individual cases has great value for conservation efforts. In order to maintain genetic diversity in species with very small populations, animals must be moved between zoological collections, both domestically and internationally.”

We believe that it is inappropriate to propose TSE regulatory changes for zoological and wild ruminants in this docket and that APHIS should withdraw the sections dealing with these animals and propose separate rulemaking, if warranted, by better risk data and distinguishing between the suggested intentions of importing true zoo animals and wild animals.

Traditional zoos are by definition enclosures of animals where, if necessary, an effective quarantine could be enforced and records of feeding, matings, disease conditions, etc. could be made available. Tissue samples could also be collected and necropsies could be performed in zoos. We note that APHIS

does not define “zoos” in this docket nor do they reference a definition elsewhere in regulation or statute. Also, as described by APHIS, “...the Administrator could require that a zoo enter into a cooperative, compliance or other agreement that sets out specific requirements for releasing the progeny or contact animals based on postmortem testing of the imported animal with negative results.” Releasing wild ruminants into the wild or even on managed properties could pose a significantly higher TSE risk to domestic ruminants or other wildlife. We believe that the risk of introducing BSE or other TSE’s that are yet uncharacterized may not be mitigated by the proposed pre and post-entry quarantine measures listed. Therefore, should APHIS proceed with amending the regulations for the importation of true (traditional) zoo animals, we believe that the originally imported animals should stay in zoo confinement (essentially quarantined) for life and that only their progeny could move, provided there was the observed and/or tested absence of TSEs in the imported animals and the progeny. With regards to importing any zoological or wild animals into the U.S. other than to traditional zoos, we urge APHIS to consider this only after a whole country or region risk assessment has been done with a finding of negligible risk for TSEs and that a proposal for public notice and comment be published.

In conclusion, we commend USDA/APHIS for proposing to revise the conditions for the importation of sheep and goats including their products. With trade, especially in germ plasm and meat, being severely restricted since 2003, ASI is hopeful that when a final rule is published, market access for U.S. producers and industries will be enhanced. We also urge APHIS to consider carefully the scientific merits of: feeding sheep and goat milk and milk products to sheep and goats; the importation of blood and blood products from BSE-infected countries for sheep and goat feeding; recognizing the low scrapie-risk of sheep semen from genetically resistant rams; the unknown BSE risk of importing live goats; additional requirements for “designated feedlots” receiving imported feeder animals; and the BSE risk of importing non-bovine, non-sheep, non-goat animals into the wild without the process of conducting a risk assessment then publishing proposals for public notice and comment.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Burton Pfliger". The signature is written in a cursive, flowing style with a large, prominent initial "B".

Burton Pfliger, ASI President