

North American Spray Dried Blood and Plasma Producers

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

Response to Docket No. 2002N-0273, Proposed Rule Substances Prohibited From Use in Animal Food or Feed

Executive Summary

The North American Spray Dried Blood and Plasma Producers Association agrees with the conclusion of the FDA that there is no scientific evidence to suggest that BSE infectivity is present in bovine blood. Banning the use of bovine blood or blood fractions in ruminant rations will not reduce the risk of exposure of humans or animals to BSE infectivity. Animal health will be compromised if the use of bovine blood or blood proteins in ruminant feeds is restricted.

The North American Spray Dried Blood and Plasma Producers Association (NASDBPP) (see **Appendix A**) is a group of companies located in North America involved in the production and development of spray dried blood and plasma products. These companies organized a working group within the American Feed Industry Association (AFIA) with the purpose of developing Manufacturing Standards to insure that the safety of blood derived proteins is preserved. In addition, it is the intention of NASDBPP to insure that data supporting the safe nature of these proteins is communicated to industry and government officials. The NASDBPP is committed to producing safe, high quality blood products for use as an ingredient in feeds for commercial livestock and companion animals.

BSE infectivity has never been detected in blood or any component of bovine blood. There is no epidemiological evidence that bovine blood or blood component carries BSE infectivity. Spray dried blood and plasma products are consumed orally, which is the least efficient method of transmission (100,000 times less efficient compared to intracranial injection). The NASDBPP developed Manufacturing Standards to insure that our blood products do not become contaminated with high-risk tissues. The Manufacturing Standards have been reviewed by internationally recognized BSE experts. Finally, the NASDBPP have agreed to and completed annual third party inspections to certify compliance to these Manufacturing Standards.

It is critically important that regulatory policy developed to prevent BSE from becoming established in the US cattle population is grounded on sound science. The NASDBPP support APHIS, FSIS and FDA in their efforts to develop policies to mitigate the risk of BSE. The NASDBPP appreciate the opportunity to comment on the questions and issues raised in the Proposed Rule, Docket No. 2002N-0273, Proposed Rule Substances Prohibited From Use in Animal Food or Feed. We will restrict our comments to the request for further comment and scientific information regarding the need to prohibit the use of blood and blood products in ruminant feed.

NASDBPP COMMENTS

There is no scientific evidence to show that the use of bovine blood or blood products in feed pose a risk of BSE transmission in cattle and other ruminants.

A. BSE infectivity has never been detected in bovine blood.

Bovine blood has never been implicated in bovine-to-bovine transmission of either natural or experimental BSE (European Commission Scientific Steering Committee (SSC), April 2000; SSC, October 2000). Despite intensive research trials and detailed epidemiological evidence, no BSE infectivity has been detected in bovine blood in either natural or experimental cases (Bradley, 1993, 1999, 2000; Fraser et al., 1992; Kimberlin and Wilesmith, 1994; Middleton and Barlow, 1993; Moon, 1996).

BSE infectivity has not been detected in the buffy coat, spleen or lymph nodes from naturally or experimentally infected cattle when bioassayed in susceptible mice or directly in calves (Wells, et al., 1994; 1998). In an experiment initiated in 1996, buffy coat from a BSE infected cow (the cow was experimentally infected and the blood cells were collected 32 months post exposure) was injected intracerebrally into recipient calves. To date (over 7 years post exposure) the recipient calves have not developed BSE (Dr. Ray Bradley, 2004, personal communication).

Following the discovery of BSE in the United States, the Secretary of Agriculture appointed an international panel of BSE experts to review the US BSE response and to make recommendations on the US national program. The panel defined Specified Risk Materials (SRM) as those that are considered to represent the greatest BSE exposure risk to humans and animals because they contain infectivity at some point during the disease incubation period. Blood was not identified as a SRM (Kihm et al., 2004). Numerous international organizations include blood and plasma products in Category IV; tissues with no detected infectivity (DEFRA, 2001; OIE, 1998; SSC, 1997; WHO, 1997).

These data indicate that BSE infectivity is not present in bovine blood of BSE infected cattle.

B. The Harvard-Tuskegee Risk Assessment demonstrates that feeding bovine blood will not spread BSE in the cattle population.

The Harvard Center for Risk Analysis and the Center for Computational Epidemiology at Tuskegee University released the findings of a major 3-year initiative (Harvard-Tuskegee Study) to develop a risk assessment model that allows evaluation of the impact of various risks for exposure of US cattle to BSE (Cohen et al., 2001). The initial report has since been reviewed and updated (Cohen et al., 2002; Cohen and Gray, 2003a; Cohen et al., 2003; Cohen and Gray, 2003b). These reports were extensive and evaluated numerous risk factors associated with the introduction and transmission of BSE.

In the report, the authors recognize that BSE infectivity has never been detected in bovine blood. However, in tissues where BSE infectivity has not been detected, the European Scientific Steering Committee recommends that it should be assumed a minimum BSE infectivity of 10

oral ID₅₀ / kg (in BSE infected cattle; SSC, 2000). The Harvard-Tuskegee model assumed this level of BSE infectivity was present in the blood of BSE infected cattle. The model also assumed that heifer calves consumed blood from birth while bull calves consumed blood from 7 months to market. Finally, it was assumed that BSE infected cattle existed in the U.S. cattle population. When these assumptions were included in the model, blood contributed on average 0.11 new cases over a 20-year period. The authors summarized:

“...recycling (feeding) this material (blood) poses little risk of exposing cattle to BSE.”

The outcome of the Harvard-Tuskegee model shows that when used as a feed ingredient, blood does not contribute to the spread and amplification of BSE in the cattle population.

C. The detection of TSE infectivity in the blood of other species does not mean BSE infectivity is present in bovine blood.

Pathology of TSE diseases differs significantly depending on the disease and on the animal model being studied, especially with respect to involvement of the lymphoreticular system (Barclay et al., 2002, Foster et al., 1996, 2001; Wells et al., 1998; Wells, 2003). For this reason, it is not appropriate to speculate that TSE infectivity found in the blood of humans, rodents or sheep proves that BSE infectivity is present in bovine blood. Differences in the distribution of TSE infectivity among tissues of different species of animals make extrapolation among species impossible (Dodd and Busch, 2002; Barclay et al., 2002; Šimák et al., 2002).

The work by UK researchers (Houston et al., 2000; Hunter and Houston, 2002; Hunter et al., 2002) indicated that one sheep of 21 transfused has developed BSE. The EU SSC (SSC, 2002) evaluated the data and concluded (p 6):

“The TSE ad hoc Group considered that the finding of infectivity in the blood of sheep could not be extrapolated to BSE in cattle. Indeed, the most recent research results do not support the hypothesis that bovine blood or lean meat constitutes a risk for humans.”

Based on these data it is not appropriate to conclude that detection of TSE infectivity in the blood of other species proves that BSE infectivity must also be present in the blood of BSE infected cattle.

D. By banning the use of air injection stunning the USDA has eliminated the risk of neural emboli being disseminated in the blood and other tissues.

Although bovine blood is not inherently infective with BSE, contamination with specific risk material (primarily neural tissue) is possible within the abattoir. Use of various stunning methods and the risk associated with neural contamination of blood and other tissues have been evaluated by several organizations, including the SSC (SSC, 2000, 2002). The SSC (2002) concluded *“Penetrative stunning without pithing appears to be the safest of the three methods of stunning [captive bolt without pithing, pithing, air injection stunning] in regard to the production of CNS emboli.”* USDA FSIS has since banned the use of air-injection pneumatic stunners in the

U.S. (<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/01-033IF.htm>). The USDA concluded (page 1887):

“In general, studies have not demonstrated that penetrative captive bolt stunning without air injection results in CNS tissue macro-emboli in the blood or other tissues of stunned cattle.”

By banning the use of air injection stunning the USDA has eliminated the risk of neural emboli being disseminated in the blood and other tissues.

E. Oral consumption is the least efficient method of transmission of BSE.

The route of exposure is a major factor determining the efficiency of transmission of BSE. The least efficient method of transmission that has been studied is oral exposure (Kimberlin et al, 1991). Intracerebral injection has been found the most efficient method of transmission. It has been estimated that oral exposure is up to 100,000 times less effective than intracerebral injection. It is important to point out that numerous attempts to detect BSE infectivity in bovine blood involved intracerebral injection. All these attempts have failed to detect BSE infectivity in blood of BSE infected cattle (European Commission Scientific Steering Committee (SSC), April 2000; SSC, October 2000; Bradley, 1993, 1999, 2000; Fraser et al., 1992; Kimberlin and Wilesmith, 1994; Middleton and Barlow, 1993; Moon, 1996).

Injected intracerebrally, BSE infectivity has never been detected in bovine blood. Oral exposure is a method 100,000 times less effective in transmitting BSE. Blood and blood products used in the feed industry are consumed orally.

F. Manufacturing Standards

As an Industry Group, the NASDBPP are committed to producing a safe, wholesome and effective product. Based on the published scientific data, we conclude that bovine blood does not contain infective levels of the BSE agent. In April 2001, the companies in the United States and Canada involved in the collection and processing of spray dried blood and plasma established a series of Manufacturing Standards. These Standards were established to insure that the blood based products we manufacture do not become contaminated with High Risk Tissues such as brain, spinal cord or distal ileum. These guidelines have been developed and reviewed by internationally recognized BSE experts. Finally, the NASDBPP have contracted with the Facilities Certification Institute (FCI), an independent auditing firm, to annually inspect company facilities to insure compliance with the Industry Guidelines.

These Guidelines have been published for public review (Russell, 2001). In addition they have been presented (formally and informally) to numerous government agencies in the United States and around the world. See **Appendix B** for a more complete description of the NASDBPP Manufacturing Standards.

G. Summary

BSE infectivity has never been detected in bovine blood. The International Review Team appointed by the Secretary of Agriculture did not include blood in the list of SRM. The Harvard-Tuskegee Risk Assessment demonstrates that feeding bovine blood will not spread BSE. The presence of TSE infectivity in the blood of other species does not prove that BSE infectivity is present in bovine blood. By banning the use of air injection stunning the USDA has eliminated the risk of neural emboli being disseminated in the blood and other tissues. Bovine blood products are fed orally and oral consumption is the least effective method of transmission of BSE. Manufacturing Standards have been developed to insure that spray dried blood and plasma products do not become contaminated with high risk tissues.

In summary, there is no scientific evidence to show that the use of bovine blood or blood products in feed pose a risk of BSE transmission in cattle and other ruminants.

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Appendix A. North American Spray Dried Blood and Plasma Producers

APC, Inc.
2425 SE Oak Tree Court
Ankeny, IA 50021

California Spray Dry
P.O. Box 5035
Stockton, CA 95205

DuCoa
7720 Buckwood Drive
Smithville, MO 64089

Harimex, Inc.
3010, 715 Fifth Ave. S.W.
Calgary, Alberta T2P 2X6

Hemotech
601 Carlson Pkwy., Suite 400
Minnetonka, MN 55305

Land O'Lakes
P.O. Box 64406
MS 7405
St. Paul, MN 55164

Merrick's
654 Bridge Street
P.O. Box 99
Union City, WI 53962

Proliant, Inc.
2425 SE Oak Tree Court
Ankeny, IA 50021

Sanimal, Inc.
9900 6e Rue
Montreal, Quebec H1C 1G2

Appendix B. Manufacturing Standards

Careful collection and processing methods are important to insure that an inherently safe product like blood does not become contaminated with prohibited tissues during collection and subsequent processing. The NASDBPP has developed Manufacturing Standards to insure a consistent, safe product is produced.

Blood is collected from registered abattoirs in the United States or Canada under Federal Inspection. All source animals have been passed ante-mortem inspection as fit for slaughter for human consumption prior to entry into the slaughter facility. Animals showing symptoms of neurological diseases are not allowed to enter the abattoir.

All source facilities process only single species: bovine, porcine or avian. Blood is not collected from abattoirs processing more than one species. This allows blood to be collected with strict species identification. Most importantly this eliminates the potential for accidental sourcing of blood from sheep, goats, deer or mink, species naturally susceptible to TSE diseases.

Some stunning methods have been shown to result in contamination of blood with central nervous tissue (Anil et al., 1999; Garland et al, 1996; Munro, 1997; Schmidt et al, 1999; Taylor, 1996). Neural contamination has not been shown associated with captive bolt stunning. The GMPs developed by the NASDBPP prohibit sourcing of bovine blood from animals stunned by methods shown to result in contamination with neural emboli.

Blood is collected from animals immediately after stunning while the carcass is whole (i.e. before decapitation) reducing the risk of contamination with tissues such as brain, spinal cord or cerebrospinal fluid. Blood is either collected from individual animals or on a stainless steel pan designed to eliminate contamination with other tissues or extraneous material. Immediately after collection the blood is removed from the collection area in a dedicated closed system to a processing and storage area. This area is dedicated to handling of blood only with no other tissues allowed in the area. At the abattoir, blood is stored in dedicated insulated storage tanks prior to transportation to the processing facility.

Blood or plasma is then shipped to off-site spray drying facilities in either dedicated tankers or in tankers certified not to have contained prohibited tissues. This eliminates the potential for contamination of blood with prohibited tissues.

The spray drying facilities are off-site from the abattoir and are dedicated to processing blood or other non-prohibited tissues. Prohibited tissues are not processed at these plants eliminating the possibility of any contamination.

Third Party Verification

The NASDBPP has contracted with Facility Certification Institute to verify member companies are compliant with Manufacturing Standards. On site audits are performed annually.

North American Spray Dried Blood and Plasma Producers

Guidelines for Blood Collection and Spray Dried Blood and Plasma Processing

1. Blood is collected only from bovine, porcine and avian species in facilities in the United States and Canada which are registered to ship interstate or inter-province and are continuously inspected by USDA/FSIS or Canadian Food Inspection Agency, or a state or provincial inspection authority that has been determined to be equivalent by USDA/FSIS or Canadian Food inspection Agency and slaughter animals for human consumption.
2. Blood is collected only from animals inspected ante-mortem by USDA/FSIS or Canadian Food Inspection Agency, or a state or provincial inspection authority that has been determined to be equivalent by USDA/FSIS or Canadian Food inspection Agency and passed as fit for slaughter for human consumption.
3. All collection facilities are dedicated to one species: bovine, porcine or avian.
4. Bovine blood is collected from facilities certified to stun animals using captive bolt. Bovine blood will not be collected from abattoirs stunning with captive bolt followed by injection of compressed air or captive bolt followed by pithing (see Definitions for complete description of this term).
5. Blood is collected while the animal is whole prior to decapitation and evisceration and in an area where cross contamination cannot occur from exposed internal organs or tissues including nervous tissue or other prohibited tissues (see Definitions for complete description of this term).
6. Blood is transferred immediately from the collection area to a dedicated area for processing.
7. At the abattoir, blood is stored in insulated dedicated storage tanks.
8. Spray drying facilities are isolated and remote from the slaughter facility or any facility that handles prohibited tissue.
9. All transfer lines, pumps and tankers used to transport liquid blood or plasma are dedicated only to blood products or are thoroughly washed (see Definitions for complete description of this term). All non-dedicated equipment is inspected and documented as being thoroughly cleaned (see Definitions for complete description of this term) prior to use with blood products.
10. Spray drying facilities do not co-process, store or utilize any prohibited tissues.
11. Packaging material will be new. If not new, packaging material will be certified to not have contained prohibited tissues or feed containing prohibited tissues. Bulk shipments will be made in dedicated containers or trailers. If the container or trailer is not dedicated, it will be thoroughly cleaned. If the container or trailer can not be thoroughly cleaned or the previous material can not be confirmed, then the product will be clearly labeled 'Do not feed to cattle or other ruminants'.
12. These guidelines are regularly re-evaluated in light of new scientific evidence with regard to natural or experimental BSE.

Definitions

Prohibited tissues. Prohibited tissues shall mean any protein containing portion of mammalian animals, excluding: Blood and blood products; gelatin; inspected meat products which have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings); milk products (milk and milk proteins); and any product whose only mammalian protein consists entirely of porcine or equine protein.

Thoroughly washed or thoroughly cleaned. To use clean-out procedures or other means adequate to prevent carry-over of products that contain or may contain protein derived from mammalian tissues (prohibited material as defined above) into animal protein or feeds that may be used for ruminants.

Also, to maintain written procedures specifying the clean-out procedures or other means and specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue (prohibited material as defined above) from all other protein products from the time of receipt until the time of shipment.

Pithing. Insertion of an elongated rod shaped instrument into the cranium through the stun wound.