

**Joint Meeting  
of the  
Blood Products Advisory Committee (BPAC)  
and the  
Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC)  
January 17, 2002**

**Topic 1.**

**Effectiveness of measures taken to protect humans from food-borne exposure to the agent of bovine spongiform encephalopathy (BSE): Implications for risk of variant Creutzfeldt-Jakob disease (vCJD) and blood safety**

**Issue**

FDA seeks to be advised on whether food chain controls for preventing human exposure to BSE as implemented in the UK since 1996 provide a sufficient basis to obviate the need to defer blood and plasma donors based on subsequent travel or residence in a BSE risk country.

**Overview**

In August 1999 we, the FDA, recommended that, as a preventive measure, manufacturers of FDA-regulated blood and blood products should defer some donors based on their potential exposure to the BSE agent in the UK between 1980 and the end of 1996. That time period encompasses the peak years of the BSE epidemic in the UK and related human exposures, prior to implementation of several control measures designed to prevent contamination of food with the BSE agent. By deciding not to consider donors who were in the UK only after 1996 as being at risk for vCJD, we recognized that measures taken in the UK to reduce opportunities for food-borne exposures of humans to the BSE agent have probably been effective. In our recently published document **Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products** (1-3), we recommended instituting new precautionary deferrals of donors potentially exposed to the BSE agent outside the UK and reducing the time that suitable donors may have spent in the UK during the 17 years of concern from six months to three months. We continue to accept that measures implemented in the UK by the end of 1996 (4) have sufficiently mitigated the risk of contracting vCJD to renew our earlier recommendation that time spent there after 1996 need not be considered when determining the suitability of blood donors. This position was taken despite the fact that the reported incidence of BSE in the UK remains higher than in any other country (at least 688 cases recognized in 2001 [5]).

Since other European BSE countries (countries identified by the USDA as having BSE or being at substantial risk of having BSE in native cattle) instituted measures to protect human food much later than did the UK, we concluded that time spent in those countries must be considered to pose an unknown but significant risk that was not mitigated after 1996 and that time spent there from 1980 until the present should be considered in determining the suitability of blood donors. We intend to reconsider frequently our recommendations for deferral of donors who spent time in various BSE countries as more information becomes available about the estimated numbers of people who might have been infected with the BSE agent and about the potential of their blood to transmit infection (which remains a theoretical possibility). We also expect to consider the effectiveness of measures taken by various countries to keep the BSE agent out of their food supplies in deciding when risk of human exposure has been sufficiently mitigated to warrant a change in blood donor deferral policy.

Our current policy acknowledges that, by the end of 1996, efforts of the UK were sufficient to reduce the risk of further human exposures to a negligible level—presumably less than the risk in other BSE countries that, while recognizing smaller numbers of cattle with BSE, have not yet successfully or consistently implemented similar effective measures to protect the food supply. That FDA policy has not been universally endorsed. Some blood programs recently elected to defer donors who spent three months or more in the UK from 1980 through the present time. We continue to believe that current UK measures to protect human food from contamination with the BSE agent have markedly reduced opportunities for human exposure and that the small additional reduction in theoretical risk afforded by deferring donors who spent time in the UK after 1996 does not justify the probable substantial loss of otherwise suitable donors. However, we appreciate ongoing concern about the effectiveness of UK measures to protect human food and believe it to be in the public interest for BPAC and TSEAC to review those measures.

A variety of measures are generally accepted as reducing the risk of human food-borne exposure to the BSE agent. We believe that, by adopting and implementing a system simultaneously incorporating those protective measures, the UK has greatly increased the assurance that—in spite of inevitable failure to achieve perfect implementation of every measure at all times—humans have been protected from food-borne exposures to the BSE agent. In acknowledging the probable effectiveness of measures implemented in the UK to protect the human food chain, we hope to encourage authorities in other BSE countries to adopt similar measures as quickly as possible.

The following measures, taken together, are believed to offer substantial protection of the human food chain against contamination with the BSE agent:

- Effective BSE control in cattle and small ruminants (sheep and goats) including OIE-compliant national surveillance programs (with extensive testing of brain tissues from animals at increased risk of BSE), prohibitions on the feeding of most mammalian proteins to ruminants (“feed bans”), immediate condemnation and prompt destruction of animals showing signs of BSE, and preventive culling of animals at increased risk
- Age-based slaughter schemes (reducing risk by prohibiting consumption of meat products from ruminants slaughtered after an age when substantial amounts of BSE agent are likely to be present in tissues, generally taken to be 30 months for cattle)
- Removal of “specified risk materials (SRM)” (CNS, lymphoid, intestinal tissues, ? other) from ruminant carcasses at the time of slaughter and effective segregation of SRM from edible materials
- Prohibition of sale for human consumption of meat products recovered by methods likely to contaminate the products with high-risk materials (“advanced” or mechanical meat recovery systems)
- Application of measures to protect the human food chain as consistently to imported food as to domestically produced food

### **Charge**

We ask the committees to evaluate the probable effectiveness of those measures taken by the UK to protect humans from food-borne exposure to the BSE agent and their value in mitigating risk otherwise addressed through donor deferral.

### **Questions**

1. Do members of the committee agree that the combination of measures implemented in the UK by the end of 1996 to protect the human food chain from BSE contamination are sufficient to obviate the need for donor deferrals based on subsequent travel or residence in the UK?
2. If the answer to Question 1 is “yes,” which measures should the FDA consider to be of greatest importance when it considers future revisions in recommendations for determining the suitability of donors who spent time in other BSE countries?
3. If the answer to Question 1 is “no,” what other measures, if any, would committee members consider sufficient to obviate the need for donor deferrals based on subsequent travel or residence in a BSE-endemic country?

## References

1. Final Guidance for Industry. Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products. January 2002.  
<http://www.fda.gov/cber/guidelines.htm>
2. FDA Questions and Answers on BSE. 2001.  
<http://www.fda.gov/cber/bse/bseqa.htm>
3. FDA Questions and Answers on Variant CJD (vCJD) 2002.  
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4. Review of BSE Controls. [UK] Food Standards Agency. Dec 2000.  
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