

Summary: Revised Preventive Measures to Reduce the Possible Risk of Transmission of CJD and Variant CJD by Blood and Blood Products

Rationale: To increase stringency of donor deferrals for risk of exposure to variant CJD (vCJD). Transmission of vCJD by human blood products has not been demonstrated. However, in sheep a single transfusion transmission of BSE has been described, the BSE epidemic is increasing in some European countries, and vCJD cases are increasing in the United Kingdom. To ameliorate impact of new deferrals upon supply, FDA has recommended a phased implementation, that pilot studies be undertaken by industry members who choose more stringent deferral criteria, and makes an exception for Source Plasma collected from donors who have been to Europe.

New Donor Deferrals for risk of exposure to BSE:

Phase I, implementation by May 31, 2002

- ≥ 3 months residence in United Kingdom (U.K.) 1980- 1996¹
- ≥ 5 years residence in France, 1980- present²
- ≥ 6 months residence in U.S. military bases North of the Alps 1980- 1990, or South of the Alps 1980- 1996 (risk from consumption of British beef purchased by the military)

Phase II implementation, by October 31, 2002

- ≥ 5 years residence in Europe 1980- present

Previous Deferrals for vCJD and CJD which remain unchanged:

- Diagnosis of CJD or vCJD
- Donors with risk factors for CJD (dura mater transplant, family history, injection of human pituitary-derived growth hormone)
- Donors who have injected bovine insulin since the 1980's³

Source Plasma: All of the above deferrals are recommended, except for 5 years residence in Europe. This exception is based upon experimental evidence that TSE agents are removed by manufacturing processes, the expected low incidence of vCJD in Europe (except for France), and concerns about serious disruption of plasma derivative supplies if a European deferral were undertaken.

Plans: 1) Comment period until October 28, 2001

2) Rapid issuance of final guidance, in conjunction with blood supply monitoring

¹ After 1996, British controls were instituted and enforced, to keep infected beef out of the human food supply

² In the case of blood components, this question is superceded by the Phase II question for Europe. French donors are deferred earlier due to higher exposure to British beef compared to the rest of Europe, and the occurrence of vCJD in France.

³ Some bovine insulin was legally sourced from the U.K. before 1996. Since then, some individuals have obtained insulin from the U.K. for personal use.