

1/17/01

Transmissible Spongiform Encephalopathies
Advisory Committee Meeting

18-19 January 2001

Issue 4.

Potential Exposure of Blood, Plasma and Tissue Donors
to Various TSE Agents of Animals

The FDA has received inquiries expressing concern about the potential transmissibility of various TSEs of animals. Except for vCJD, no human TSE has been attributed to infection with an animal TSE agent. (BSE agent, the presumed cause of vCJD, has not been found in US cattle.)

Nonetheless, as part of its commitment to ensure the safest possible supply of blood, blood components, plasma derivatives and tissue products, the FDA asks the TSEAC to consider whether exposure to any of the TSE agents known to infect animals in the USA or to the BSE agent that might accidentally be introduced into the USA in an imported product, might pose sufficient risk as to compromise the suitability of blood, plasma or tissue donors.

The following sources of potential exposure of donors to animal TSE agents within the USA will be discussed:

- Products derived from sheep and goats from BSE countries including imported sheep and their progeny with an undifferentiated TSE ("Vermont" sheep)
- Products derived from deer and elk with chronic wasting disease
- Ruminant-derived materials as components in dietary supplements

Reference

Norton SA. Raw animal tissues and dietary supplements. New Engl J Med 2000;343:304-305

Charge

The TSEAC should consider whether the agent of any of the animal TSEs that occur in the USA is likely to infect humans exposed to the animals or to their products and whether the probability that blood, plasma or tissue donors have been infected is sufficient to warrant the FDA recommending their deferral. The Committee should also consider whether the BSE agent is likely to be accidentally introduced into the USA in imported products or as components of products and whether—in the absence of evidence that accidental importation has actually occurred—exposure of donors to some products poses a sufficient risk to warrant the FDA recommending deferral.

Questions

1. Should the FDA be sufficiently concerned about the suitability of any blood, plasma and tissue donors potentially exposed to TSE agents of animals, both agents known to infect animals in the USA and agents that might be accidentally imported, to consider recommending deferral?
2. If so, which animal TSE agents present in the USA or accidentally imported into the USA, what types of product and what intensity of exposure should be of concern?