Recommendations on Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products

Products with risk of transmitting agents of animal spongiform encephalopathies are those derived from tissues or secretions of animals susceptible to transmissible spongiform encephalopathies other than by experimental challenge. This definition applies to all substances or preparations obtained from such animals and to all substances or preparations where products obtained from such animals are included as active substances or excipients or have been used during production, e.g. as raw or source materials, starting materials or reagents.

Materials of animal origin should be avoided whenever possible. However, if used, manufacturers should be aware of the risk and have a system in place to minimize it, especially since international trading patterns often include the processing and re-export of products, so that their origin may not be traceable. In order to minimize the risk of transmitting animal spongiform encephalopathy agents via medicinal products, manufacturers should follow the current WHO Guidelines on Transmissible Spongiform Encephalopathies in Relation to Biological and Pharmaceutical Products[1] and the recommendations of the Joint Technical Consultation on Bovine Spongiform Encephalopathy, public health, animal health and trade, convened by the WHO, the Food and Agriculture Organization of the United Nations and the Office International des Epizooties 11-14 June 2001 in Paris.[2]

[1] Note: the current guidelines are published on the WHO web site [http://www.who.int/bloodproducts/tse]. These guidelines are kept under review and are regularly updated.

[2] Proceedings - Joint WHO/FAO/OIE Technical Consultation on BSE: public health, animal health and trade. Paris: Office International des Epizooties, World Health Organization, Food and Agriculture Organization, World Organisation for Animal Health, 2002.