



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate C - Scientific Opinions

Scientific Steering Committee

OPINION ON

**SOURCING OF FROM GBR I COUNTRIES
(SOURCING OF RUMINANT MATERIALS FROM GBR I
COUNTRIES FOR MEDICAL DEVICES)**

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE

AT ITS MEETING OF 6-7 SEPTEMBER 2001

I. MANDATE

Commission Services invited the Scientific Steering Committee (SSC) to address the following question in an opinion:

"Under which conditions can (ruminant) substances sourced from Geographical BSE Risk (GBR) category I countries be safely used for the production of medical devices?"

The question was discussed by the TSE/BSE *ad hoc* Group at its meeting of 26 July 2001. On the basis of its discussions, the SSC adopted the opinion hereafter.

Keywords: Medical devices, geographical risk, GBR, specified risk materials, sourcing, TSE, BSE

II. BACKGROUND

The present opinion was adopted in the context of the preparation by Commission Services of a Proposal for a Commission Decision on Medical devices incorporating tissues or derivatives originating from animals.

III. OPINION

1. Materials sourced from countries or regions where the presence of one or more cattle clinically or pre-clinically infected with the BSE agent is highly unlikely (GBR I countries or regions), are considered safe for the manufacture of medical devices.

The wide range of criteria and the methodology used by the SSC for the assessment of the geographical BSE risk takes into account both the risk of a country's cattle population to have been challenged with BSE infectivity and the way it is and has been dealing with such risk should it have occurred. The SSC therefore concludes that a "GBR I" country or region poses negligible risk with regard to sourcing of cattle materials for medical devices, provided a number of basic precautions are respected. These include, as far as BSE is concerned, exclusive sourcing from animals fit for human consumption following *ante-* and *post mortem* inspection (no sourcing from fallen stock, sick or emergency slaughter - See also the SSC opinion of 24-25 June 1999 on "Fallen stock"¹) and compliance with existing measures related to animal identification and back-tracing.

2. The SSC considers that sourcing from "Closed herds" as defined in its opinion of 22-23 July 1999 can be considered equally safe as sourcing from GBR I countries or regions, provided all requirements are fully implemented and all controls are in place.

3. What precedes does not imply that other countries or regions are excluded from sourcing of materials for medical devices, provided all TSE-relevant risk criteria and procedures laid down in the various SSC opinions on the safety of products, are appropriately dealt with on a case-by-case basis.

¹ Complete title: *The risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials.*