EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C1 - Follow-up and dissemination of scientific opinions

PROVISIONAL STATEMENT ON THE SAFETY OF CALF-DERIVED RENNET FOR THE MANUFACTURE OF PHARMACEUTICAL LACTOSE.

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING OF 4-5 APRIL 2002.

Introduction:

As rennet may be sourced from certain animal species (besides using biotechnological processes or certain plant sources), the SSC was invited to prepare a general opinion on the safety of rennet obtained from calves, adult cattle, small ruminants and pigs with regard to animal TSE risks and particularly BSE risks, including those resulting from the method of harvesting, risks from the epithelium, contamination with lymphoid tissues, contamination with feed, feed bans, risk from cross-contaminated feed, and geographical sourcing.

The SSC asked the TSE/BSE *ad hoc* Group to prepare a scientific report on the subject, which could serve as input into the discussions when preparing its opinion. The report is currently being prepared, but may not be finalised in the immediate future because it requires the inputs from several other opinions which are still pending. These include the opinions on *Safe sourcing of small ruminant materials* (addressing, amongst others, the safety of the small ruminant stomachs) and the *Quantitative risk assessment of tallow and fats* (assessing, amongst others, the possible residual risk in milk replacers fed to calves).

However, pending the finalisation of the above comprehensive report on animal rennet, an opinion on the safety of calf rennet used in the production of whey, then used for lactose in medicinal products is urgently required. Rennet is used in animal and human foodstuffs (including food supplements) and in medicinal products and for the manufacture of lactose. In fact, approx. 80% of all pharmaceutical drugs may contain lactose. The SSC adopts the statement hereafter, which is based on the already exploitable parts of the above draft TSE/BSE *ad hoc* Group report and on Report on the risk and regulatory assessment of lactose prepared using calf rennet adopted by EMEA's[1] Biotechnology Working party.

[1] **EMEA (European Agency for the Evaluation of Medicinal Products), 2002.** Risk and regulatory assessment of lactose prepared using calf rennet. Report from Biotechnology Working Party of the EMEA, London, 12 February 2002. Doc. Ref: EMEA/CPMP/BWP/337/02/Final.

Statement:

The SSC shares the conclusion of 27 February 2002 of EMEA's Committee for Proprietary Medicinal Products (CPMP) and its Biotechnology Working Party that the BSE risk in pharmaceutical grade lactose is negligible when rennet is sourced from the abomasum of bovine calves that are fit for human consumption and produced according to the steps as referred to in the above EMEA report of 11-13 February 2002.