EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Scientific Steering Committee

COMPLEMENT TO THE SSC OPINION OF 4-5 APRIL 2002 ON SAFE SOURCING OF SMALL RUMINANT MATERIALS (WITH SPECIAL REFERENCE TO THE SAFETY WITH REGARD TO BSE RISKS OF SHEEP INTESTINES AND CASINGS.)

ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING OF 12-13 SEPTEMBER 2002

BACKGROUND

1. In its Opinion of 18-19 October 2001 on the safety of small ruminant products, the SSC considers that, should BSE in small ruminants become probable/confirmed, its previous opinions on Specified Risk Materials in small ruminants are no longer adequate. These opinions were developed under the scenario that BSE in small ruminants would be possible, but not probable. Therefore a new consumer protection approach would need to be developed combining several strategies for example of testing and genotyping .

   The scientific bases for this new approach were developed in the SSC Opinion of 4-5 April 2002 addressing the various aspects of safe sourcing of small ruminant materials should BSE in small ruminants become probable. This opinion did not address in detail the issue of the safety of sheep intestines and casings, because data and information to assess the risk possibly posed by casings, were at that time still being collected by a number of research bodies. The current opinion should thus be read in close connection with the SSC opinion of 4-5 April 2002.

2. Between May and August 2002, the following additional scientific data and information on the safety with regard to BSE risks of sheep intestines became gradually available to the Commission's Scientific Steering Committee and its TSE/BSE *ad hoc* Group:

   - FSA (UK Food Standards Agency), 2002. Report of May 2002 of the FSA core stakeholder group on BSE and sheep.
   - DNV Consulting , 2002. Assessment of the Risk of Exposure to the BSE Agent through the Use of natural Sausage Casings. Prepared for the European Natural Sausage Casings Association. London, June 2002.

- P.A.Koolmees, B.R.Berends, M.H.G.Tersteeg, 2002. Risk assessment of the use of sheep natural casings and legs of lamb Pilot Research for ENSCA, INSCA and NANCA. VVDO Report No. H0204. July, 20002, Utrecht.
- P. Comer (DNV Consulting), R.Bradley (private BSE Consultant), 2002. Note on weights of intestine in small ruminants and expected risk reduction. Prepared on behalf of the European Natural Sausage Casings Association.
- C. Lacroux, C. Grandjean, F. Corbière, O. Andréoletti, F. Schelcher, 2001. Search for PrPsc by immunohistochemistry in the wall of scaled and non-scaled intestines from ovine animals in the clinical phase of scrapie. AFSSA/DGAL/INRA-ENVT Protocol. Study N° UMR INRA-ENVT 959. (Translation into English of the report Version of 17.11.01.)

In addition, the SSC and its TSE/BSE *ad hoc* Group had access to some of the comments sent to the UK Food Standards Agency (FSA), following the release in May 2002 of the FSA core stakeholder group on BSE and sheep. These documents, as well as recent data and risk assessments already presented in the SSC's opinion of 4-5 April 2002, were discussed by the TSE/BSE *ad hoc* Group at its meeting of 5 September 2002 and reported on to the SSC at its meeting of 12-13 September.

OPINION

The Scientific Steering Committee concludes as follows:

a) The recent risk assessments and tissue analysis data presented or discussed in the above documents clearly illustrate the implications, in terms of potential human exposure risk to BSE infectivity, of the essential differences in TSE infectivity distribution between tissues in cattle and sheep. For cattle, BSE infectivity distribution is mainly confined to a limited number of tissues representing approx. 95% of the total infectivity present in a clinical BSE case. For TSE-susceptible sheep (scrapie or experimental BSE), tissue infectivity distribution is much more widespread. As a result, the sheep tissues that would pose a potential risk should BSE be present in sheep, cannot be listed by simple extrapolation from what is known about BSE infectivity distribution in cattle.

   For older sheep of a TSE-susceptible genotype in an advanced stage of incubation, the larger fraction of the total infectivity would be present at high concentrations in what are currently listed as the "sheep specified risk materials". The remaining part of the infectivity would be present in other tissues, particularly in intestine and lymph nodes, but also peripheral nerves and blood[1]. In younger animals, infected but not yet showing clinical signs, the intestine, lymph nodes, perepheral nerves and blood would probably contain most of the infectivity and would need to be considered as possible specified risk materials.

   What precedes should be taken into account for safe sourcing of small ruminant materials should BSE in sheep become probable or evident under field conditions[2]. At present there is no evidence that BSE is present in small ruminants under field conditions and no indications pointing at an increased likelihood of such being the case.

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1 See also the SSC Opinion of 12-13 September on The implications of the recent papers on transmission of BSE by blood transfusion in sheep (Houston *et al*, 2000; Hunter *et al*, 2002)

2 See also the SSC opinion of 4-5 April 2002, proposing a Strategy to investigate the possible presence of BSE in sheep

b) The estimates of how the intestine and other tissues contribute to an animal's total infective TSE load, vary greatly. In TSE-susceptible sheep, the intestine would contribute an important part of the possible TSE infectivity – the exact proportion depending upon the age and clinical status. This proportion might be sufficient for it to be considered as a possible SRM should BSE be present in the animal. As far as casings are concerned, the available data permit to conclude that the amount of infectivity that would be present in the intestine, would be reduced by a factor of at least 100, possibly more than 1000, during the casings production processes. Some residual infectivity may nevertheless remain present which may pose a risk should the presence of BSE in sheep become probable or proven.

   Nonetheless, the levels of possible residual infectivity in intestine and casings should be small if they are sourced on the basis of the scientific principles regarding genotype, age, rapid TSE testing, early TSE testing, flocks certification and geographical origin, presented in the SSC opinion of 4-5 April 2002.

Note: data and research results available on TSEs in goats are much less comprehensive than on TSEs in sheep. The SSC considers it reasonable that, for the time being, the above opinion is also valid for goats.