



**EUROPEAN COMMISSION**  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

## **TSEs IN SMALL RUMINANTS**

**OPINION ON THE SAFETY OF SMALL RUMINANT PRODUCTS SHOULD BSE  
IN SMALL RUMINANTS BECOME PROBABLE / CONFIRMED.**

**ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE AT ITS MEETING OF  
18-19 OCTOBER 2001**

## I. MANDATE

In September 2001, the Scientific Steering Committee was invited to address in an opinion the following questions:

*"In view of the statement in August 2001 by the UK Food Standards Agency, in the event that new research confirms or cannot exclude that BSE was present in the UK sheep population in the early 1990's, the SSC is invited to deliver an opinion on the following questions:*

1. *What criteria can be used for (a) sheep and (b) goats as a tool in the context of routine slaughter to ensure that meat is safe for the consumer in terms of:*
  - *source of the individual animal;*
  - *age of animal, bearing in mind that it is difficult to determine the age of sheep less than one year old using physical characteristics;*
  - *Use of rapid testing;*
  - *Genotyping;*
  - *Removal of SRM;*

*Can the quantitative risk reduction be evaluated in relation to the production of meat resulting from the removal of each SRM linked to the age of animal, to the use of rapid testing and genotyping, to the status of the source flock and to the GBR?*

2. *Is the consumption of milk and milk products derived from (a) sheep and (b) goats safe? What criteria if any can be used to ensure or maximise safety in terms of:*
  - *Age of animal;*
  - *Use of rapid testing;*
  - *Genotyping;*
  - *TSE free flocks;*

*Can the quantitative risk reduction be evaluated in relation to the production of milk, linked to the age of animal, to the use of genotyping, to the status of the source flock, and to the GBR?*

3. *Is it possible to define a TSE-free sheep flock/goat herd? If so, what criteria can be used to establish such a group?*
4. *What are the criteria which should be used in a widespread genotyping and breeding programme for resistance to TSEs in small ruminants?*
5. *Is it possible to actualise the existing geographical BSE risk analysis to small ruminants, by taking into account factors that may be unique to sheep?"*

On 18 October 2001 it appeared that the sheep brain samples collected in the early 90s and referred to in the UK Food Standards Agency's statement, did probably not provide the appropriate starting material for research aiming at the verification of the possible presence of BSE or a BSE-like agent in the UK sheep population. The SSC nevertheless did address the various questions in the mandate because sheep have been exposed to potentially contaminated feed and the risk that BSE is present in small ruminant populations cannot be excluded on theoretical grounds. There is nevertheless at present no evidence that BSE is present in small ruminants under field conditions.

To prepare the scientific bases for the opinion, the mandate was first discussed on 4 October 2001 by the TSE/BSE *ad hoc* Group and on 9 October by the Working Group on "TSEs in small ruminants". The draft report of these meetings was made available to the SSC at its meeting of 18-19 October 2001.

## II. PREAMBLE:

Since 1998, the SSC has addressed the issue of TSEs in small ruminant populations in several opinions:

- Opinion on the Risk of Infection of Sheep and Goats with BSE Agent. Adopted on 24-25 September 1998 .
- The policy of breeding and genotyping of sheep, i.e. the issue of whether sheep should be bred to be resistant to scrapie. Adopted on 22-23 July 1999.
- Opinion on specified risk materials of small ruminants. (Follow-up to the SSC opinion of 24-25 September 1998 on the Risk of Infection of Sheep and Goats with the BSE Agent). Adopted on 13-14 April 2000.
- Report and Opinion on the criteria for diagnosis of clinical and pre-clinical TSE disease in sheep and for differential biochemical diagnosis of TSE agent strains. Adopted on 13-14 April 2000.
- Opinion on the Implications of the Houston *et al* paper in The Lancet of 16 September 2000 on the Transmission of BSE by blood transfusion in sheep (The Lancet, Vol. 356, pp 999-1000; 955-956; 1013). Adopted on 26-27 October 2000.
- Pre-emptive risk assessment should BSE in small ruminants be found under domestic conditions. Adopted on 8-9 February 2001.
- Statement on the Safety of milk with regard to TSE: State of affairs. Adopted on 29-30 March 2001.

These opinions already address most of the issues of the mandate of September 2001 and the SSC considers that the conclusions and recommendations made in these opinions are still valid. The present opinion is therefore to be considered as a conversion and further exploitation of the above list of documents into a set of scientific bases to support risk reduction strategies should the presence of BSE in small ruminant populations become probable.

## III. OPINION

### A. Background

The SSC concludes as follows with regard to various aspects linked to the issue of BSE in small ruminants:

1. **Sheep as a model for goats.** Ideally separate risk assessments should be carried out for sheep and goats. However, very limited data are available for goats. Therefore the conclusions for sheep are currently considered to be a reasonable and best possible approximation for goats.
2. **Current incidence of TSEs in small ruminants.** There seem to be no clear indications of increased TSE incidence in small ruminants. However, due to weaknesses of reporting, there are no data that are precise enough to detect small variations in incidence.
3. **If BSE was introduced in small ruminants,** it is most likely still present in today's population of small ruminants because, given that BSE in sheep is assumed to be likely to behave in a manner similar to scrapie, transmission from generation to generation would have occurred through horizontal (including environmental) and vertical routes.

4. **Possible current incidence of BSE as fraction of total TSE incidence, should BSE be present in small ruminants.** Considering the absence of an observed increase in scrapie, and the assumed smaller exposure to contaminated feed as compared to cattle (both in terms of number of sheep exposed as of MBM content of the feed), it may for the time being be expected on reasonable grounds that the fraction of BSE in the real TSE incidence is likely to be small. However, taking into account the limitations in available data, the possible current incidence of BSE as a fraction of the total TSE incidence, should BSE be present in small ruminants, is at this moment unknown.
5. Whereas for **genotype** in relation to scrapie substantial data are available, the research results on the link between BSE in small ruminants and genotype are rather limited. The SSC considers that it currently has not enough data at its disposal to comprehensively judge on genotyping as a possible tool as part of consumer protection strategy, e.g., in combination with rapid tests or removal of specified risk materials (see below). It considers that for the time being, genotyping alone can not be considered to offer full protection, as could, for example, be expected from excluding susceptible genotypes from consumption and/or from accepting only animals with a resistant or semi-resistant genotype for human consumption.
6. The SSC considers that, should BSE in small ruminants become probable, 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 needs to be developed combining several strategies for example of testing and genotyping (see also further).
7. For the time being and pending the outcome of currently ongoing research projects, there are no reasons to revise the current opinions of the SSC with regard to the **safety of ruminant milk**. The conclusions of the Scientific Veterinary Committee (E.C., 1996), the Multidisciplinary Scientific Committee (E.C., 1997) and the SSC (E.C., 1999, 2001), remain valid also in so far as and that the evidence available does not point at milk or colostrum representing a possible risk. For precautionary reasons the milk, colostrum or milk products from suspect cases or from the animals involved in the corresponding culling/eradication measures should not be offered for consumption. (See also further: research recommendation).

## **B. Risk identification.**

1. **Validation of tests for survey purposes.** The currently **available rapid tests** have been validated only on cattle and therefore need to have been validated for use on small ruminants before they can be used for large scale surveys or surveillance. New tests should whenever possible be validated for cattle, sheep and goats in parallel.

Currently no rapid scrapie/BSE **differential diagnosis** tests are available. The detection of a TSE in an animal with one of the currently available rapid tests would therefore not be indicative of the presence of BSE, but only of a TSE. The development of differential BSE/scrapie tests needs to be accelerated and applied as soon as available.

2. The establishment of a firm **quantitative knowledge base** on the current incidence of TSEs in small ruminants is a first priority. It will provide essential information for the

assessment of the level of the possible risk, if any, consumers in a given country may be exposed to. A survey should urgently be carried out with the available rapid tests (once validated for use on small ruminants) using a statistically sound sample design and size<sup>1</sup>. It would at the same time provide more exhaustive information on the age-distribution of TSEs in small ruminants.

The survey should be combined with a survey of the TSE-resistance genotype distribution in sheep population by genotyping TSE positive cases and some controls per case.

The possible application of immunological tests allowing early detection of PrP<sup>Sc</sup> in peripheral tissues would offer a more accurate picture of the prevalence of infected animals.

3. **Geographical BSE Risk in small ruminants.** The SSC considers that assessing the risk that BSE could be present in domestic flocks of small ruminants (sheep and goats) would require developing a new methodology. This methodology has to include, in addition to those included in the GBR for cattle, other issues than feed born transmission within small ruminant populations, on which established scientific assessment are still lacking.

It has also to be taken into account that the BSE agent introduced into the small ruminant population via contaminated feed is likely to be recycled and amplified via horizontal, vertical and “diagonal” (via environmental vectors) routes. Little is known about the latter for scrapie, however all these routes seem possible, and virtually nothing is known for BSE in small ruminants.

## C. **Recommendations for urgent preparatory actions.**

1. In terms of consumer protection, the use of **rapid TSE tests** on individual small ruminants will only result in a higher risk reduction if they can be applied on tissues that show infectivity in the early stages of incubation, for example the lymphoid tissues.

Currently, 3 “rapid TSE tests” are considered to be reliable detectors of BSE PrP<sup>Sc</sup> in cattle brain material in the final stages of disease incubation. Initial validation results show that these tests are capable of detecting PrP<sup>Sc</sup> in sheep brains. Applying them to sheep brain, however, will not offer direct consumer protection because of the TSE pathogenesis pattern in small ruminants that causes infectivity to be present in peripheral tissues early in the incubation period. Indirectly even their application to CNS will, however, significantly increase the level of consumer protection, because they will contribute to improved culling policies and eradication programmes and to a better knowledge of the geographical and within-flock distribution of TSE in small ruminants.

The applicability of these tests on other tissue material, e.g., lymph nodes or spleen, can be accepted on theoretical grounds and preliminary validation results are promising. Further validation, particularly for tissues that show infectivity at early stage, is most urgently needed. Such validation could for example be carried out rapidly on samples of lymph nodes or other tissues collected at slaughterhouses from animals of various ages and breeds.

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<sup>1</sup> The SSC is currently preparing an opinion on the Requirements for conclusive statistical TSE surveys in ruminants.

2. **Improved surveillance, movement restrictions and culling** In its “Pre-emptive risk assessment should BSE in small ruminants be found under domestic conditions”, adopted on 8-9 February 2001, the SSC makes a number of detailed recommendations regarding surveillance, movement restrictions and culling. These remain valid.
3. **Information.** Information campaigns on TSEs in small ruminants are needed for all involved people, to reduce the risk that animals with TSE symptoms would be offered for consumption.
4. As the available research on **milk and TSEs** is limited, the SSC recommends that more research on the safety of milk of ruminants is urgently carried out, including testing of milk from BSE incubating sheep/goats in the most sensitive testing system, i.e. i/c inoculation in fully susceptible animals VRQ/VRQ.
5. The concept of **genotyping as a tool for consumer protection** should urgently be verified. It is recommended to early investigate or verify whether “scrapie-resistant strains” possibly could be silent carriers and in addition do accumulate infectivity.

In any case, it is recommended that any rapid testing programme be linked with a genotyping programme to confirm that none of the possible positive test results corresponds with a resistant genotype.

#### D. Recommendations for long-term safety

1. The SSC regards the implementation of a policy of **certification of flocks** as essential to guarantee safe sourcing at the long term. The SSC considers that its opinion of 22-23 July 1999 on the conditions related to “BSE Negligible risk (closed) bovine herds” is also, *mutatis mutandis*, adaptable in the context of small ruminants and provides a frame and the basic elements for the definition of the TSE status of a flock of small ruminants. It will permit the development of criteria for the determination of scrapie- and TSE-free status of small ruminant flocks and definition and introduction of an accreditation scheme for scrapie and TSE-free status. The SSC will prepare an opinion that takes into account its opinion on closed herds of 1999 and the specific context of small ruminants. It will make provision for the application of expected future developments in the field of rapid tests and genotyping.

The SSC wants to underline that flock certification programmes need to go along with the implementation of better **identification and tracing** of individual small ruminants, using for example special earmarks or other methods such as electronic identification.

3. **Breeding of resistant sheep.** It is recommended that the general and EU-wide introduction of breeding programmes as an overall long term strategy for the reduction / elimination of TSE prevalence in populations of small ruminant should be evaluated in detail in the light of the existing uncertainties which have also be listed in the SSC's opinion of 22-23 July 1999 on the policy of breeding and genotyping of sheep.

Meanwhile, the SSC will prepare an opinion on the criteria which should be used in a widespread breeding programme for resistance to TSEs in small ruminants, should such programme be decided upon.