

Opinion of the SSC on
defining the BSE risk for specified geographical areas
23 January 1998

Preamble

In the context of the assessment of the risk of humans being exposed to the BSE agent¹, three interlinked risks appear to be of major importance:

- Incident risk: probability that an infectious animal (or materials thereof) enters the food and/or feed chains.
- Propagation risk: probability that an initial infection is propagated within the system of a given region and within a given time period.
- Human exposure risk: probability that a human being is exposed to an infective dose of the BSE agent, within a given time period.

Only the first two risks, which together constitute the geographical risk, are considered in this opinion. The human exposure risk within a geographical area will not be directly addressed at this stage. Although this risk is strongly influenced by the incidence and propagation risks in that area, other factors which are not confined to the limits of that specific geographical area are also important. It is critical in the context of the risk of human exposure to BSE in a given region, to understand that this risk is not always exclusively related to the known number of BSE cases per unit time in that region. For example in a country with an ineffective surveillance system it may fail to detect cases of BSE and the risk of human exposure to the agent may be higher than would be perceived on the basis of the reported incident.

The SSC was asked to define the BSE risk for specified geographical areas. To that end, it asked the TSE/BSE ad-hoc group to look into it by applying a stepwise approach:

- first to establish a methodology which would allow a quantitative risk assessment and could be consistently applied to any geographical region, and
- second to apply this methodology to the dossiers which have already been provided by certain countries which claim to be BSE-free.

This opinion is only referring to the first step.

Introduction

For this first step the mandate was defined as follows:

How can the risk be estimated that an animal from a given geographical area is infected with BSE but is not yet showing clinical signs of BSE and enters the human food and/or the animal feed chain at a moment where certain tissues of that animal are already infective ?

¹ The approach developed in this opinion is especially developed for the BSE issue. It is not intended to be transferred to other fields.

The SSC noted that the nature of the question is such that it may be difficult to be answered fully on the basis of the available information and within the limited time frame. In evaluating the risk of the BSE agent entering the feed and food chains, the SSC has evaluated the information presently available on this subject, including the working document "Risk factors and surveillance with regard to BSE in the community" (VI/2001/97 MT/aif) and the information provided by individual countries (currently: Finland, Denmark, Sweden, Germany, Canada, New Zealand, Australia and the USA)².

The SSC also noted that the OIE has developed criteria for the assessment of the BSE status of countries and that a list of criteria has been established in the past for the assessment of the BSE status of New Zealand, Australia and the USA by the Veterinary Scientific Committee of the Commission. It was decided to use this work as a starting point for establishing the list of factors determining the incident and propagation risks (see below) in a given geographical area. It was, however, noted that the goal of the OIE criteria was to come to a definition of areas with a BSE-free status whereas the SSC risk assessment would rather aim at a quantification of the incident and propagation risks (*see below*) in those areas.

As regards the risk posed by BSE the SSC has distinguished three levels of risks of which the first two together constitutes the geographical risk:

- | | |
|----------------------|---|
| Incident risk: | probability that an infectious animal (or materials thereof) enters the food and/or feed chains. |
| Propagation risk: | probability that an initial infection is propagated within the system of a given region and within a given time period. |
| Human exposure risk: | probability that a human being is exposed to an infective dose of the BSE agent, within a given time period. |

The SSC decided to identify the factors which influence or determine the incident and propagation risks and for which information should be obtained to allow the assessment of the BSE status of a given area. A list of these factors is given below. It could be used by present and future applicants to establish the documentation needed to determine the BSE status of the specified geographical area.

The SSC stressed that it will only be possible to determine the incident and propagation risks of BSE in a certain geographical area if the submitted data are sufficiently complete and of adequate quality. Concerning the data quality the opinion of the inspection services of the Commission shall be requested.

The approach chosen was to identify an exhaustive set of data which would allow the best possible analysis of the incident and propagation risks. However, the SSC is aware that such a complete set of data will not be available from any country but wants to underline that the more comprehensive the data set, the better the risk assessment. The relative importance of each of the factors listed, as well as their interrelationship, has yet to be established.

² No in-depth analysis of the dossiers was carried out but it became clear that currently no dossier provides all the information as listed by the SSC.

To assess these risks, mathematical modeling systems should preferably be developed. They should permit to introduce the appropriate values for the factors which describe the situation in a specific geographical region, and should, by taking into account their relative weights and mutual dependencies, provide a scientifically sound relative risk assessment per geographical area. It is important to understand that this risk evaluation will not be static but will largely depend on the dynamics of the factors considered.

A small group of mathematical modelers has been constituted to evaluate the possibilities of developing and using the appropriate modeling or system analysis methods for this purpose. The group initiated its work in January. The work of the SSC shall not, however, await the outcome of the modeling work.

At its first meeting the modeling group expressed the opinion that the highest priority should be given to the propagation risk, so they prepared a preliminary paper on the issue. They considered it possible to develop within a relatively short time a preliminary mathematical model which would allow an approximation of the propagation risk, the focus being on robustness against an infection spreading. Hence the model would allow an assessment of the propagation risk rather than of the incident risk. The model, as it develops, will be validated against historical data sets to the satisfaction of the SSC which will closely monitor the modeling work.

The SSC asked the modeling group to continue this approach and to present a more comprehensive analysis. This would also be important for the implementation of the Community's TSE action plan for research (DG XII). The aim of such a modeling effort should be to allow simultaneous assessment of the incident and propagation risks in a specific geographical area.

In the knowledge that such a comprehensive modeling effort is unlikely to provide results within a year, the SSC proposed to develop an interim view on geographical risk on the basis of a list of factors (see below). The SSC will apply expert judgment to preliminarily classify geographical areas in terms of their combined incident and propagation risks. As far as possible they will make use of the results generated by the modeling group.

List of factors contributing to the incident and propagation risks in a geographical area.

The SSC wishes to stress that the following is an ideal set of information and accordingly does not expect that any country or area will be in a position to provide all such data. However, the more information available, the more precise the risk assessment. An effort will be made to interpolate missing data, but in certain cases worst case assumptions will have to be used to replace not available data.

1. Structure and dynamics of the cattle, sheep and goat populations

The picture of the cattle, sheep and goat populations in the geographical area under consideration needs to be as complete as possible. Population data should therefore include information on the:

- absolute numbers of animals per species, alive and at time of slaughter. Although absolute numbers do not affect the propagation risk (R(t)) they are necessary in the case of an outbreak to determine the time required for the infection to disappear;
- age distributions of animals per species and age distributions at time of slaughter;
- geographical distribution of the animals by species and breeds. This is only considered important if the infection rate from sheep to cattle is significant;
- geographical distribution of the animals by husbandry systems, herd sizes and production purposes. This information is useful to provide cross checks on MBM³ usage and age distribution of animals.
- system of identification, and capacities for tracing of animals: the identification of the movement of animals between farms, herds and geographical areas.

These data should be provided on an annual basis and ideally for the period from 1980 onwards in order to understand their dynamics.

2. Animal trade

As the import of infected animals is a major source of risk for an infected animal entering the food and feed chain, a comprehensive picture of the relevant trade flows was felt to be essential and data, ideally from 1980 onwards (annual basis), are requested. These should include information on:

- import and export of cattle, sheep and goats with special emphasis on population data on these animals as mentioned under 1 and a clear definition of the geographical origin of the animals;
- trade within the geographical area, with special emphasis on population data on these animals as mentioned under section 1 and with a clear definition of the geographical origin of the animals;
- imports of embryos of cattle, sheep and goats into the geographical area and a clear definition of the geographical origin of the embryos;
- imports of semen of cattle, sheep and goats into the geographical area and a clear definition of the geographical origin of the semen;
- use made of imported animals (fattening, breeding, milk production, ...);
- use made of imported embryos or semen;
- mechanisms used by slaughterhouses to identify animals and their origins, as well as data from these procedures.

3. Animal feed

The consumption of infectious MBM must be seen as (one of) the major source(es) of BSE. It is therefore essential to have a good understanding of the consumption and source of MBM in a given geographical area for assessing the probability that BSE might occur in its animal populations (incident risk).

With regard to the quantity of MBM used, the information should include a full profile on data ideally from 1980 onwards (on an annual basis) relating to:

- the production of domestically produced MBM and its usage per species and husbandry system;
- imported and exported MBM and its usage per species and husbandry system.

³ Meat and bone meal, assumed to be the major route of transmission for BSE.

With regard to the quality (infectivity) of the consumed MBM is concerned, data are needed on the production and constitution of the consumed MBM. These data should include figures about rendering, processing (see below) and about the relative and absolute contributions of specified bovine offals and specified risk materials, as well as their origins with regard to geography, species and the tissues involved.

4. Meat and bone meal (MBM) bans

The existence or not of a MBM-ban and its effective implementation will strongly influence the risk that BSE is transmitted by this route. Data on the MBM-ban should therefore include data about the:

- nature of the bans (full description of details, including species involved);
- dates of introduction;
- actual implementation, policing and compliance/breaches figures;
- possibilities of cross-contamination with other feed.

5. Specified bovine offals (SBO) and specified risk materials (SRM) bans

The suppression of SBOs and SRMs from entering the food and feed chains will reduce the risk of BSE infection further. Data are therefore requested on this issue. These should include data about the:

- nature of the bans (full description of details, such as species, tissues and ages of materials used);
- dates of introduction, actual implementation, policing and compliance/breaches figures.

6. Surveillance of TSE, with particular reference to BSE and scrapie

The quality of these data is very important for the estimation of the basic risk that an infective animal could enter the food and feed chain (incident risk). The SSC therefore requests information on the surveillance system for BSE and scrapie (the latter because of the possible link between scrapie and BSE and vice versa). This information should include data preferably from 1985⁴, on the following:

- incidence of laboratory confirmed cases of BSE and scrapie;
- kinetics of age distribution, geographical distribution, and countries of origin of cases;
- incidence of neurological disorders in which TSE could not be excluded on clinical grounds in different animal species;
- methodologies and programs of surveillance and recording of clinical cases of BSE and scrapie, including training for awareness of farmers, veterinarians, control services and authorities;
- incentives for reporting cases, e.g. compensation and rewarding schemes;
- methodologies of laboratory confirmation and recording of suspect cases of BSE and scrapie;
- strains of BSE and scrapie agents possibly involved;
- existing systems or current plans for targeted active surveillance.

⁴ First case of BSE was recognised in 1985

7. Rendering and feed processing

As the quality of the MBM in terms of its infectivity is influenced by the process of conditions under which it is produced, information on the rendering and feed-processing systems in the given geographical region is requested. This is relevant because most of the MBM is normally consumed close to the place of production⁵.

This information should include data, ideally from 1980 onwards, about the:

- description of all rendering and feed processing systems used and description of the nature of the records of all the rendering and processing plants (e.g. feed mills) involved;
- quantitative and qualitative parameters of MBM and tallow production by each of the processing systems and by each plant, the geographical areas from which the rendered materials originate and the type of material used;
- parameters on separate processing lines for materials from healthy and suspected animals
- transport and storage systems for MBM or MBM containing feed which ensure the prevention of cross contamination of MBM-free feed.

8. BSE and scrapie related culling

The culling of BSE and scrapie cases and of related animals will strongly influence the dynamics of the disease.

Data should include data, ideally from 1985⁶, onwards about:

- targets of culling with detailed specification of criteria;
- time of introduction;
- animals involved (as specified under 1, including imported animals);
- sizes of herds involved.

Conclusion

The SSC is of the opinion that, on the basis of appropriate data, a preliminary assessment can be made of the incident and propagation risks of defined geographical areas (countries), using expert judgment and, as far as possible, mathematical modeling techniques.

On the basis of such a strategy the SSC considers that it will be possible to categorize countries or geographical areas with regard to their incident and propagation risks, provided that sufficient data are made available.

The SSC proposes that the Commission invites the Member States to provide the relevant and readily available information within the shortest possible time in order to allow the SSC to embark on a preliminary assessment of the incident and propagation risks.

Third countries, requesting a certain BSE-status, should also be asked to provide all readily available data to allow for an appropriate risk assessment to be carried out.

⁵ MBM has a shelf life of about 3 weeks, composite feed made from it may last up to about 3 months.

⁶ First case of BSE was recognised in 1985