Opinion

of the Scientific Steering Committee

on a method for assessing the

Geographical BSE-Risk (GBR)

of a country or region

Up-date, January 2000

Background

In January 1998 the SSC established a list of factors on which it would require information for assessing the Geographical BSE-Risk (GBR)[1].
In July 1998 the Commission recommended to Member States and interested third countries that they provide information on these factors.[2]
In February 1999 the SSC adopted an opinion on a method for assessing the Geographical BSE-Risk of a country or region[3]. Following the experience gained with a first round of assessments carried out in March 1999, the SSC issued a first update of their risk assessment on 23 April 1999. Since then two more assessment exercises have been carried out with about 35 independent experts participating and 26 countries being analysed at least once, and the majority twice.

In the context of the exercises intensive methodological discussion took place and a number of clarifications/modifications were found to be needed for a clear, consistent and practicable output.

This update takes account of the evolution of the applied method.

In addition to this development the OIE has made progress with its BSE-chapter (3.2.13) in the Animal Health Code. The European Commission has tabled a proposal to exclude Specified Risk Materials from processing in relation to the BSE-situation of a country (but this proposal was rejected by the Member States). The Commission proposal contained a provisional classification of countries on the basis of the reported BSE incidence.
At the last December 1999 meeting of the SSC, the Commission, however, underlined the provisional nature of the proposed categorisation and its intention to take the outcome of the SSC's assessment of the GBR into account. At the same time it is also felt necessary to take account of international standards, such as that set by OIE.

This update therefore shows the further development of SSC-method for assessing the GBR and serves as the basis for the final review of the assessments carried out so far. The compatibility of this method with the OIE-approach is also addressed.

It is intended to finalise the assessment exercise as soon as possible.

Introduction

Currently BSE-related import restrictions and BSE risk management measures are often based on the incidence of clinical BSE. But as already noted on several occasions by the SSC the BSE incidence is not the best indicator because it depends heavily on the quality of the surveillance system, which is difficult to judge. In the view of the SSC it cannot be taken as the only criterion for deciding on import restrictions or on other necessary risk management

[1] Opinion of the SSC on defining the BSE-risk for specified geographical areas. 22/23 January 1998
[2] Commission recommendation of 22 July 1998 concerning information necessary to support applications for the evaluation of the epidemiological status of countries with respect to transmissible spongiforme encephalopathies. (C(1998) 2268); 98/477/EC)
[3] Opinion of the SSC on a method to assess the Geographical BSE)Risk of countries or regions. 18/19 February 1999

measures. The SSC is of the opinion that a risk assessment should underpin the reliability of the reported number of clinical BSE-cases and improve the basis for decision making.

1. The OIE approach

The OIE has adopted a BSE-classification of countries using four categories:

- BSE-free,
- provisionally free of BSE,
- low incidence of BSE, and
- high incidence of BSE.

(It should be noted that the proposed revision of the code foresees[4] that countries with and without an incidence of BSE could be placed in "provisionally free" or "low incidence", depending, inter alia, on the outcome of the risk assessment required by the OIE).

Although it is understandable that the names of the categories suggest that these are based on incidence, one of the criteria always taken into account is a risk analysis. This risk analysis is based on a list of factors that could have lead to a risk of introducing or propagating the BSE agent in the country/region under consideration.

According to the OIE, such a risk analysis has to evaluate whether potentially infected material was imported and, in such a case, whether the conditions in the country were/are sufficient to cope with potentially affected material, i.e. to prevent the disease being propagated by:

- importation of meat-and-bone meal (MBM) or greaves potentially contaminated with a transmissible spongiform encephalopathy (TSE) or feedstuffs containing either MBM or greaves;
- importation of animals, embryos or ova potentially infected with a TSE;
- consumption by cattle of MBM or greaves of ruminant origin;
- the origin of animal waste, the parameters of the rendering processes and the methods of animal feed production;
- the epidemiological situation concerning all animal TSE in the country or zone; and
- the extent of knowledge of the population structure of cattle, sheep and goats in the country or zone.

Moreover, the OIE requests the following measures, and their date of effective implementation ("relevant period of time"), to be considered when determining the BSE-category:

- compulsory notification and investigation of all cattle showing clinical signs compatible with BSE;
- a BSE surveillance and monitoring system with an emphasis on the risks identified;
- an on-going education programme for veterinarians, farmers, and workers involved in the transportation, marketing and slaughter of cattle, so as to encourage the reporting of all cases of neurological disease in adult cattle;
- examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system;
- treatment of at-risk animals linked to confirmed cases (culling).

[4] International Animal Health Code, BSE, Chapter 3.2.13 (proposal under consideration in January 2000)

The items listed by the OIE give a framework for an appropriate risk analysis. However, the OIE is neither explicit on the method that should be applied when carrying out the risk assessment, nor on the resulting risk levels and the measures to be in place to manage iteffectively.

2. The SSC-approach

2.1 General description of the SSC-approach

The Scientific Steering Committee's method for a qualitative assessment of the Geographical BSE-Risk (GBR) aims to assess in qualitative terms the probability that an animal present in a country or region is infected (clinically and sub-clinically) with BSE. This probability depends on the country's past and present exposure to BSE cases and BSE contamination ("challenge") and its ability to cope with this exposure (its "stability").

Given the qualitative nature of its method, the SSC specifies "GBR" as an indicator of the probability of a cattle being infected with the BSE-agent (clinical and sub-clinical), at a given point in time, in a geographical region/country.

The SSC uses four levels of GBR. At a later time it will adapt its previous opinions, that used three levels of risk, to this new classification:

GBR class	Probability for a cattle to be infected (clinical or pre-clinical) with the BSE agent
I	highly unlikely
II	unlikely but not excluded
III	likely but not confirmed
	confirmed, at a lower level
IV	confirmed, at a higher level

Table 1: GBR-classes

The GBR is assessed on the basis of information on 8 factors that are very similar to those applied by the OIE (see table 2 and figure 1 for the numerical listing of the SSC-factors).

Some of these factors are "stability" factors, covering the countries past and present policy regarding (6) surveillance, (6) education, (8) culling, (3, 4) feeding, (7) rendering, (5) SRM, and (1) information on population dynamics. Other factors describe "challenges" the system had and has to cope with. They refer to potential imports of the BSE-agent via live cattle (2) or contaminated feed (3) or domestic circulation of the BSE-agent.

OIE factors	SSC-factors (Opinion of Jan/Feb 98)
Import of potential contaminated meat-and-bone meal (MBM) or greaves or feedstuffs containing either.	**3)** Import of infected MBM *(greaves and feed stuffs containing MBM or greaves not explicitly mentioned).*
Import of animals, embryos or ova potentially infected with a TSE.	**2)** Animal trade *(Embryos or ova not seen as an effective transmission route).*
Consumption by cattle of MBM or greaves of ruminant origin.	**3)** Animal feed, **4)** MBM-bans (*greaves and feed stuffs containing MBM or greaves not explicitly mentioned).*
The origin of animal waste, the parameter of the rendering processes and the methods of animal feed production.	**5)** SRM-ban(s), **7)** Rendering and feed processing.
The epidemiological situation concerning all animal TSE in the country or zone.	**6)** Surveillance of TSE, with particular reference to BSE and scrapie.
The extent of knowledge of the population structure of cattle, sheep and goats in the country or zone.	**1)** Structure and dynamics of the bovine, ovine and caprine animal population.
Compulsory notification and investigation of all cattle showing clinical signs compatible with BSE	**6)** Surveillance of TSE, with particular reference to BSE and scrapie.
A BSE surveillance and monitoring system with emphasis on factors identified above.	**6)** Surveillance of TSE, with particular reference to BSE and scrapie.
An on-going education programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle, so as to encourage reporting of all cases of neurological disease in adult cattle	**6)** Surveillance of TSE, with particular reference to BSE and scrapie.
Examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system	**6)** Surveillance of TSE, with particular reference to BSE and scrapie.
Culling of cattle related to confirmed cases.	**8)** BSE-or scrapie related culling.

Table 2: Comparison of factors required for the risk assessment by OIE and by the SSC, numbers as in the SSC's opinion of February 1998.

In addition to OIE, and in order to clarify the (often-delayed) interaction between these factors, and between challenge and stability, the SSC uses a simple model of the BSE/cattle system (Figure 1).

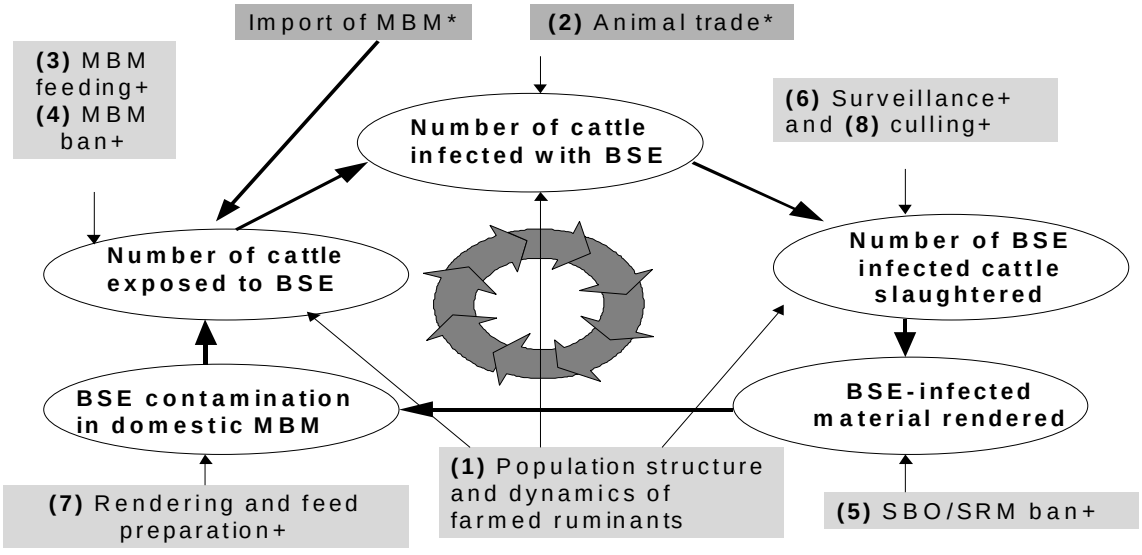


Figure 1: The SSC model of the BSE/Cattle system
*** external challenge,+stability- factors, numbers as in SSC, February 1998**

This model regards BSE imports (via infected feed (MBM) or live cattle) as the only initial source of BSE. Without this "external challenge" the feed-back, that ultimately could lead to an epidemic, will not be started. The only transmission vector considered in the model is feed. The single feed-back loop, which according to this model drives the BSE-epidemic, is controlled by the stability factors, identified above.

The stability of the system, i.e. its ability to reduce BSE-infectivity, depends on its ability to identify BSE-infected cattle and exclude them from processing and its ability to avoid recycling of the BSE-agent via feed. A stable system would eliminate BSE over time; an unstable system would amplify it.

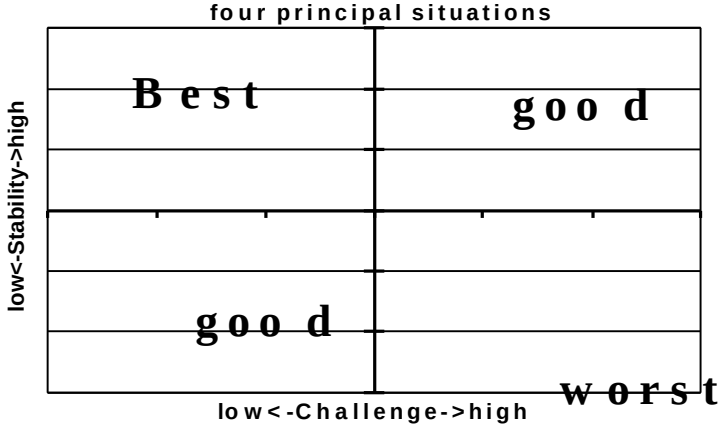
The stability of a system can be challenged by incoming and/or circulating BSE infectivity. The more BSE-infectivity comes-into/circulates in a system, the bigger the challenge.

Four different basic combinations of stability and challenge can be seen:

- A stable system is not or only slightly challenged: this is obviously the best situation.
- A stable system is significantly challenged: This is still rather good because the system will be able to cope with the challenge, even if this might need some time.
- An unstable system is not or only slightly challenged: as long as BSE is not entering the system, the situation is good. However, even a small challenge could spark the amplification of the BSE problem.
- An unstable system is challenged: Obviously this is an unfortunate situation. The BSE-infectivity will be amplified and an epidemic can develop.

Stability and **challenge** are illustrated by the two-dimensional diagram given in figure 2, where both axes spread between the respective lowest and highest feasible level.

Figure 2: Stability/challenge combination, four principal situations



The cross-point of the axes being zero, the following qualitative description of stability and challenge is valid:

Stability < 0: The system would amplify BSE-infectivity.
Stability > 0: The system would reduce BSE-infectivity.
Challenge < 0: Lower challenge.
Challenge > 0: Higher challenge.

Having taken account of the draft country reports the SSC charges the independent experts invited for the final review of these reports, to agree on criteria for determining the respective degrees of stability and challenge, and to apply these consistently to all assessments. Equally they should apply a consistent approach to estimating the current and future risk derived from the past and current interaction of stability and challenge.

2.2 The assessment process

The thrust of the SSC's method is to answer two questions

- **How stable was the BSE/cattle system over the reference period (the last 10-20 years)?**
- **Over the reference period (the last 10-20 years), was the BSE/cattle system challenged and if so, when, how, and to what extent?**

From the interaction of stability and challenge over time the assessment concludes on the resulting risks. At the end of the process the current GBR, and its development over the coming 4-6 years (one incubation period) is estimated.

An assessment of the GBR typically follows five-steps:

1. **Appraisal of the quality of the available data (completeness and reliability)**

2. **Assessment of the Stability of the BSE/cattle system (over time)**
   Note: Stability is independent of the presence of BSE.
   2.1 Ability to identify BSE-cases and to eliminate animals at risk of being infected before they are processed (factors 1, 6 & 8; the quality of the surveillance (6) is of critical importance for this aspect of stability.)
   2.2 Ability to avoid recycling BSE-infectivity, should it enter processing (factors 3, 4, 5, & 7).
   2.3 Overall assessment of the stability (over time)
3. **Assessment of the challenges to the system (over time)**
   3.1 External challenge resulting from importing BSE (factor 2 & 3)
   3.2 Internal challenge resulting from domestic infected animals.
   3.3 Overall assessment of the challenges (over time)
4. **Conclusion on the resulting risks (over time)**
   4.1 Interaction of stability and challenge (over time)
   4.2 Risk that BSE-infectivity enters processing (over time)
   4.3 Risk that BSE-infectivity is recycled and the disease propagated (over time)
5. **Conclusion on the Geographical BSE-Risk**
   5.1 The current GBR as function of the past stability and challenge
   5.2 The expected development of the GBR as a function of the past and present stability and challenge

2.3 Comments

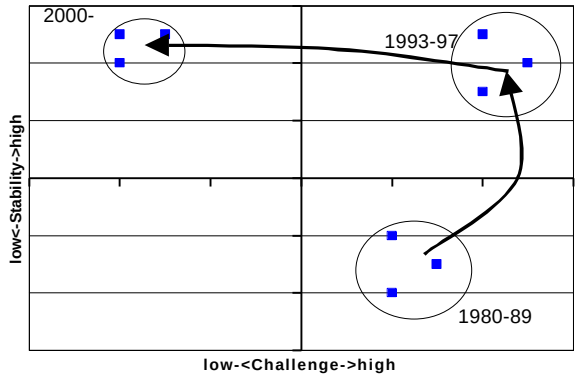
- The SSC-method is qualitative in nature, and after having seen the quality of the information provided by the countries, it is difficult to imagine carrying out a quantitative risk assessment without incurring effort of far greater magnitude. In many cases the necessary information seems simply not to be available.

- Because estimations and judgements are often needed to compensate for the shortcomings in the data, the SSC method requires that the GBR of each country be assessed by at least three individual and independent expert assessors. By this requirement the inevitable differences in judgement of the available information are expected to be minimised. In addition the countries are always invited to send "country experts" who should ensure that the available data are interpreted correctly and that gaps are bridged by sensible assumptions.

- When carrying out the risk assessment exercise for a country, each expert assessor should individually assess the challenge and stability over time and use the two-dimensional diagram to illustrate the changes.

- The three assessments should be recorded in the report under the heading "interaction of stability and challenge" and illustrated by a diagram as given in figure 3.

Figure 3: Developmen of stability and challenge over two decades, assessed by 3 experts



- Since the 8 factors change over time it is necessary to assess the challenge and stability for different periods of time. These might, for example, be determined as a function of significant changes in stability (e.g. by an MBM-ban) and/or challenge (e.g. import stop). An example of a chart showing this development over time, as assessed by three experts, is given in figure 3. In the nineteen eighties, the situation was rather bad and characterised by a low stability and a high challenge. The amplification lead to increasing (internal) challenge but fortunately the stability started to improve. Once the system became stable enough to reduce the BSE infectivity, the challenge started to decrease, while the stability increased further. Between 1993 and 1997 the impact of the high stability became visible and lead to a significant decrease to the challenge and hence to a rather good situation in 2000.

Understanding that the interaction of challenge and stability in the past determines the current risks, the diagram should be helpful for assessing and understanding

- the risk that infected cattle could enter processing (processing risk, over time),
- the risk that the disease could be propagated (propagation risk, over time) and,
- the current and expected Geographic BSE-risk, as defined above.

Furthermore, the SSC wants to make clear that

- the risk assessment is based on a simplified concept of the origin of BSE. Possible, but not confirmed initial sources of BSE such as sporadic cases, other TSEs, exotic diseases, etc. are for the time being ignored. However, should any of these sources be confirmed, the risk assessment will need to be revised as appropriate;
- the main initial sources of BSE are therefore imports from BSE-affected countries. In this context it is to be understood that the imports are evaluated on the current appraisal of the BSE situation in exporting countries. Should it become apparent that this appraisal needs to be changed, the assessment of the geographical BSE-risk of the importing country would have to be reviewed;
- while imports of live animals and MBM or MBM-containing feed stuffs are regarded as effective vectors for the introduction of the BSE-agent, semen and embryos are not, assuming that they are appropriately collected and treated[5].

3. Testing and qualitative risk assessment

As a final point the SSC wants to express its opinion that the currently available rapid post-mortem tests and the qualitative assessment of the GBR are complementary.

The currently available rapid post-mortem tests are able to prove the presence of PRP^{res} in the CNS of cattle that are close to the end of the incubation period for BSE or are already clinically ill. It is not clear, how far these tests are able to identify pre-clinical cases at earlier stages of the incubation process.

The SSC therefore regards these tests as useful for complementing existing surveillance efforts based on the notification of BSE-suspects and the detection of infected cattle with heavy loads of infectivity. They should not, however, be used as a guarantee of the absence of the BSE-agent from an individual animal tested and found to be negative.

In order to make optimal use of the available tools, the SSC therefore suggests a combination of the qualitative assessment of the GBR, as described above, with the results of conventional surveillance efforts and targeted application of any suitable emerging rapid post mortem tests. Whenever it is not highly unlikely that infected cattle are present, testing for infected cattle approaching the end of the incubation period could confirm the assumption that the GBR is low. Any assessment should regularly be repeated in order to verify the expected trends in the GBR and, where appropriate, the incidence figures.

As a general point the SSC wants to underline its support for the development of improved rapid BSE-diagnostic tests which ultimately aim at obtaining reliable ante-mortem tests which are able to detect pre-clinical BSE.

[5] See opinion of the SSC on "Vertical transmission", October 1998