# Opinion of the Scientific Panel on Biological Hazards on the revision of the Geographical BSE risk assessment (GBR) methodology[1]

**Question EFSA Q-2004-150**

## Adopted on 7 March 2007

### PANEL MEMBERS

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## SUMMARY

The Geographical BSE-Risk assessment (GBR) is an indicator of the likelihood of the presence of one or more bovines being infected with Bovine Spongiform Encephalopathy (BSE), pre-clinically as well as clinically, at a given point in time, in a country.

The methodology (SSC GBR), developed by the previous Scientific Steering Committee (SSC) of the European Commission between 1998 and 2002, categorizes the assessed countries into four different risk levels.

The European Food Safety Authority (EFSA) requested its Panel on Biological Hazards (BIOHAZ) to review and update the SSC GBR method, taking into account the World Organisation for Animal Health (OIE) Terrestrial Animal Health Code (Chapter 2.3.13 and appendix 3.8.5 to that chapter) and quantitative surveillance data and models. The Panel was requested to publish a draft document for public consultation, and to consider the comments received when finalising the method.

The Working Group (WG) under the EFSA BIOHAZ Panel proceeded by evaluating the SSC GBR method and, based on this evaluation, suggested possible amendments and improvements. In interpreting and addressing the terms of reference, the BIOHAZ Panel considered experience gained from previous assessments, new data and information, developments in EU policies, and the development of the OIE Terrestrial Animal Health Code.

The BIOHAZ Panel and its WG produced a stand-alone document describing the EFSA GBR methodology. The main purpose of this document is to describe the basic methodology to carry out the risk assessment. Where necessary, the document provides the rationale and scientific basis for specific parts of the methodology. This stand-alone document serves as the set of instructions that can be used by the members of any international independent expert group responsible for assessing a country, as well as by the contact points in the countries being assessed.

The BIOHAZ Panel agreed to refer to SSC GBR as the previous method and EFSA GBR as the revised method.

The main changes of the EFSA GBR with respect to the SSC GBR can be summarized in three main categories: changes in the external challenge assessment, changes in the stability assessment and changes in the categories of assessment. Furthermore the EFSA GBR considers the possibility of assessing zones such as defined in the OIE Terrestrial Animal Health Code.

The revised challenge assessment in the EFSA GBR methodology introduces an adjustment for the size of the challenged cattle population; defines in more detail the steps for the assessment (*i.e.* acquisition of import data, determination of whether the imports entered the BSE/Cattle system, estimation of the infectivity level in the imported material); clarifies the rules for the inclusion or exclusion of the imported material or animals; and introduces a weighting factor for the scaling of these imports.

The changes in the stability assessment consist of the utilization of a semi-quantitative approach, instead of the previous mostly qualitative approach to assess the impact of practices related to the BSE infection (Specified Risk Materials utilization, Rendering system and Feeding system).

The EFSA GBR no longer categorizes the countries. It assesses the overall challenge and the number of expected BSE cases and infections over time in a country, and includes an estimation of the future course of the infection.

**KEY WORDS**: BSE, Geographical Risk Assessment, GBR, Methodology

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## 1. INTRODUCTION

The Geographical BSE-Risk assessment (GBR) is an indicator of the likelihood of the presence of one or more bovines being infected with Bovine Spongiform Encephalopathy (BSE), pre-clinically as well as clinically, at a given point in time, in a country/region. It is based on a semi-quantitative analysis of:

(1) the likelihood that the BSE agent was introduced into a country/region and if so, when and to what extent

and

(2) the potential of it being recycled and potentially amplified or eliminated.

For ease of reference, the methodology as described hereunder and as developed and used by the previous Scientific Steering Committee (SSC) of the European Commission between 1998 and 2003 is referred to as **SSC GBR** and outcome of these assessments can be found on the former SSC website[2]. As from 2003 the European Food Safety Authority (EFSA) took over this task and assessed a number of countries using this SSC GBR method. Further details on the countries assessed follow below. The revised methodology, described in this opinion, will be referred to as **EFSA GBR**.

The GBR methodology was first developed by the Scientific Steering Committee (SSC) of the European Commission (EC) in 1998 (SSC, 1998 a and b with revisions in 1999, 2000 a and b and 2002 a and b). The aim was to develop a transparent methodology to assess the BSE risk in the domestic cattle population of any given country at a given point in time. The Risk Assessment is based on data and information provided by the country. This methodology is limited to bovine and feed based transmission of BSE (*i.e.* it does not take into account any other initial sources of BSE than the import of potentially infected cattle or potentially contaminated feed). An important characteristic of the GBR methodology is that it did/does not depend on the confirmed incidence of clinical BSE, which is sometimes difficult to assess due to serious intrinsic limitations of the detection component of surveillance systems.

On the basis of the outcome of these SSC GBR assessments, all EU Member states were classified in GBR classes[3] I through IV, class I being the lowest, meaning that it is considered highly unlikely that one or more cattle are clinically or pre-clinically infected. However, a number of EU countries did not detect any case of BSE before 1 January 2001 despite their rather high GBR level. The EC imposed the application of rapid BSE tests on all cattle when slaughtered for human consumption above 30 months of age, and on risk populations above 24 months such as emergency slaughtered animals and animals found dead on the farm ("active" surveillance).

By showing that many of the countries previously classified as Category III, did indeed have BSE present in their cattle populations, the results of the BSE testing confirmed the validity of the SSC GBR methodology. Germany, Italy, Spain, Poland, the Czech Republic and the

[2] Relevant opinions of the Scientific Steering Committee (SSC) of the European Commission on Web Address:http://europa.eu.int/comm/food/fs/sc/ssc/outcome_en.html

[3] **SSC GBR levels: GBR I** : Highly unlikely; **GBR II** :Unlikely but not excluded; **GBR III**: Likely but not confirmed or confirmed, at a lower level; **GBR IV**: Confirmed, at a higher level

Slovak Republic were all classified as GBR III before they detected their first case. The SSC GBR for Denmark was already at an advanced stage, pointing to GBR III, when the first case was confirmed. In addition, Japan and Greece have now confirmed the first domestic BSE cases. Also Austria, Finland and Slovenia, all three initially in GBR II, detected their first domestic case(s) of BSE and were therefore also classified in GBR III. In addition, Sweden which was classified as a GBR II country had a case during March 2006. In all cases, active surveillance detected BSE cases that could have remained undetected by the already existing passive surveillance, which was targeted at animals with neurological symptoms.

In 2003 responsibility for carrying out the GBR assessments was transferred from the SSC to EFSA. Two mandates were received (D (2003)/KVD/ip/420722 and D (2004)/KVD/ip/ 420863) in order to re-assess a total of 18 countries[4] and EFSA added one GBR assessment under a self-tasking mandate. EFSA used the SSC GBR to assess the given list of countries. The outcome of these assessments can be found on the EFSA website.[5]

The SSC GBR methodology was used up to now to assess the BSE risk in a given country. The model and its basic assumptions remained unchanged throughout the assessments carried out to date both by the SSC and the EFSA. Consistency of the past and future assessments was therefore ensured. However, over time the assessment of the external challenge was refined and the process was streamlined since the first assessments were completed in 2000.

Experience obtained by the EFSA experts while carrying out the most recent assessments of 19 countries, indicated that the SSC GBR methodology needed to be reconsidered taking account of the newly obtained scientific knowledge on BSE and the availability of new data on the assessed countries. The SSC GBR method was geared to identify or predict a potential first case in a certain country but the EFSA GBR methodology should also allow the assessment of "an expected future development of the risk over time" *i.e.* be able to allow the expert group to declare a decrease of the risk in a certain country and when the risk has reached a negligible level.

The issues necessitating change include the following:

- The SSC GBR methodology works well for assessing the risk from cattle and MBM exports from Category III European countries. However, the risk from exports from countries with a large cattle population was overstated and needs to be corrected.
- The assessment of the stability needs to be more flexible allowing partial improvements in stability to be taken into account. For example, under the SSC GBR methodology, a rendering system could only be considered to be "OK" if it was operating at 133 ° Celsius and 3 bar for 20 minutes. While these are the recommended operating conditions, the assessment of the stability in the GBR methodology should allow the recognition that sub-optimal conditions such as a temperature of 120 ° Celsius degrees are not "optimally OK" but would also lead to an improvement in stability.
- The SSC GBR method generally did not take account of surveillance data, since it was not part of the method and full sets of data were not yet available. The results of the

[4] Argentina, Australia, Botswana, Brazil, Canada, Chile, Costa Rica, El Salvador, Namibia, Nicaragua, Norway, Mexico, Panama, Paraguay, South Africa (EFSA self task), Swaziland, Sweden, United States of America, and Uruguay.

[5] http://www.efsa.europa.eu/en/science/tse_assessments/gbr_assessments.html

epidemiological surveillance of BSE in cattle since 2001 are now available and the EFSA GBR should take account of these data which could enable confirmation of the outcome of the assessment.

- The BSE status of countries will change over time depending on their external challenge based on their imports of cattle and MBM and their internal stability. Therefore there is a need for an ongoing reassessment of the BSE status of individual countries.
- While the situation for the foreseeable future indicates that the BSE epidemic is declining within the EU and most other third countries, the challenge is now how to assess any continuing risk allowing a proportionate management of that risk.
- Moreover, the CVO/EU Parliament dialogue of September 2005 concluded that the BSE classification should be based on the World Organisation for Animal Health (OIE) guidelines wherever possible.

Given the above reasons, the Scientific Panel on Biological Hazards (BIOHAZ) was requested by EFSA to update the SSC GBR methodology under a self-task.

This methodology for risk assessment is not an alternative to the determination of the OIE BSE risk status of the cattle population of a country but a risk assessment that can be utilized in the framework of article 2.3.13.2 of the OIE Terrestrial Animal Health Code.

## 2. Terms of Reference

The Scientific Panel on Biological Hazards is requested:

1. To review the SSC GBR methodology as currently described in the SSC opinions (SSC, February 1999; refined with SSC, 2000 and 2002) and to update the current method. In particular:
   a. To identify parameters and assessment rules in the current methodology, that needs to be updated and analyse new information, which could allow their update.
   b. To assess the various factors contributing to the assessment of BSE risk in a certain country and to attribute a more appropriate weight factor to these taking account of information now available.
   c. To consider a change of the current “GBR” to another acronym to determine the BSE risk in a certain country.
   d. The method should allow assessing an expected future development of the risk over time *i.e.* be able to allow declaring a decrease of the risk in a certain country.
   e. Prepare a detailed questionnaire to go alongside the new method
2. To take account of Chapter 2.3.13 of the OIE terrestrial animal health code (the general and new BSE Surveillance Chapter of the OIE (May 2005)) and the appendix 3.8.5 to this chapter (Factors to consider in conducting the BSE RA recommended in chapter 2.3.13.).
3. To consider an updated risk assessment method (*e.g.* GBR) taking into account quantitative surveillance data and models (*e.g.* BSurvE).
4. To finalize a draft update after which the document can be opened for a public consultation.

5. To produce a final document taking account of the comments made during the consultation period.

## 3. APPROACH TO THE MANDATE

The Working Group (WG) under the EFSA BIOHAZ Panel proceeded by evaluating the SSC GBR method and based on this evaluation suggesting possible amendments and/or improvements. In interpreting and addressing the terms of reference (see also Annex I for more details), the BIOHAZ Panel considered experiences gained from previous assessments, new data and information, developments in EU policies as well as development in the OIE methodology.

The BIOHAZ Panel and its WG decided to produce a stand-alone document describing the EFSA GBR methodology. The main purpose of this document is to describe the basic methodology to carry out the risk assessment. Where necessary, the document provides the rationale and the scientific basis for specific parts of the methodology. This stand-alone document serves as the set of instructions that can be used by either the members of any international independent expert group responsible assessing a country as well as by the contact points in the countries being assessed.

As part of the terms of reference, the BIOHAZ Panel agreed to refer to the SSC GBR as the previous method and EFSA GBR as the revised method. In this way continuity is retained in referring to the well known acronym of GBR but differentiating between the previous and updated version (see also Annex II outlining changes from the SSC GBR).

A preliminary report was put on the EFSA web for public consultation on 17 November 2006. The methodology was revised following consideration of the comments and the results of test runs of the new method of a few country dossiers (see Annex V outlining the comments received and the modification done after the public consultation).

## 4. THE EFSA GBR METHODOLOGY

### 4.1 Definition of the Geographical BSE-risk in cattle

The SSC GBR is an indicator of the likelihood of the presence of one or more bovines being infected with BSE, pre-clinically as well as clinically, at a given point in time, in a country.

In addition to this the EFSA GBR methodology indicates the likely evolution over time of the disease in the country.

Essentially, any GBR exercise attempts to answer two questions:

- Is it likely that the BSE-agent was imported into the country under consideration (**external challenge**)?
- If the BSE-agent was introduced into a country, is it likely that it would have been recycled and amplified or was the BSE/cattle system of that country able to eliminate the agent (*i.e.* internal **stability**)?

In addressing these issues a number of factors are taken into account including:

- Structure and dynamics of the cattle population
- Trade of cattle and meat and bone meal (MBM)
- Use of MBM and bans
- Use of specified risk materials (SRM) and bans
- Surveillance of BSE
- Rendering and feed processing and use of feed

Under the SSC GBR method the country was assigned a GBR category between I to IV (see footnote[3] for SSC GBR levels).

In the EFSA GBR method categories are not assigned to the country/region, rather an assessment is made of the likely risk of BSE in the native cattle population and its evolution over time.

### 4.2 Assumptions on transmission of BSE and origin of the BSE epidemic

The methodology for the assessment of the GBR is based on the assumption that BSE arose in the United Kingdom (UK) from a still unknown initial source and was propagated through the recycling of contaminated bovine tissues into animal feed. Later, the export of infected animals and infected feed provided the means for the spread of the BSE-agent to other countries where it was again recycled and propagated via the feed chain. A simplified model of the assumed BSE/cattle system is described in Figure 1.

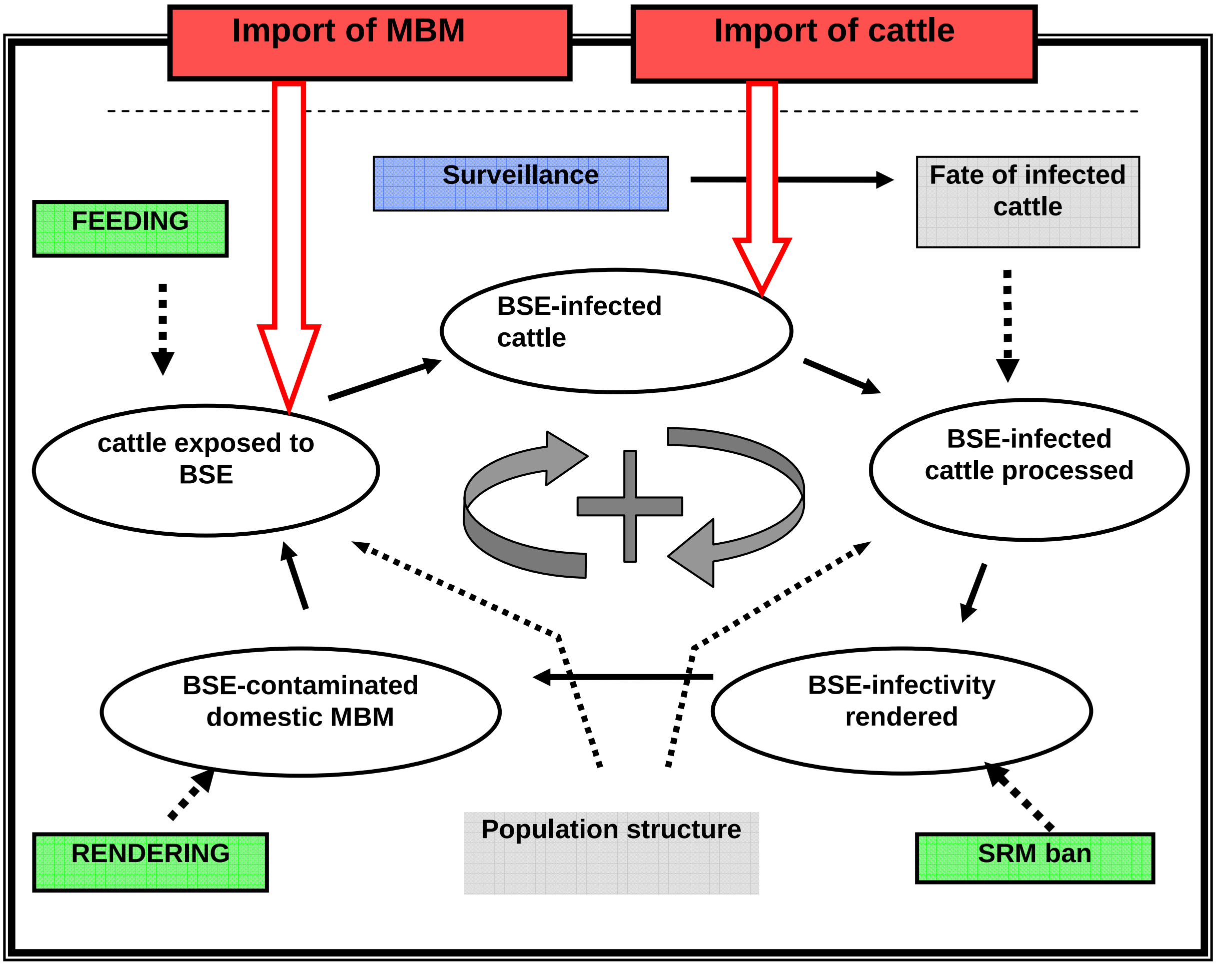



Figure 1: **The model of the BSE/cattle system**

For all countries other than the UK, import of contaminated feed or infected animals was the only possible initial source of BSE that was taken into account. Other sources such as potential spontaneous occurrence of BSE at very low frequency, or the transformation into BSE of another (animal) TSE (Transmissible Spongiform Encephalopathy) (scrapie, CWD or Chronic Wasting Disease, TME or Transmissible Mink Encephalopathy and FSE or Feline Spongiform Encephalopathy) being present in, or imported into a country were not considered, as these putative sources were not scientifically confirmed. Vertical transmission, although initially assumed to occur at maximum level of 10% of the offspring of dam within 12 months of the onset of BSE (Wilesmith et al., 1988; Donnely, 1998), was later considered to occur at a considerable lower level at maximum 2% (Saegerman *et al.*, 2005). In addition, in two documents with regard to Born after the Real Ban (BARB) cases in UK no evidence of maternal transmission was found in those cases (SSC, 2003a; SEAC, 2003). Therefore this risk is not taken into account in the EFSA GBR because even a 10% rate of vertical transmission would have a negligible impact on the EFSA GBR assessment.

The only transmission vehicle considered in any GBR exercise was and continues to be feed containing animal protein such as MBM. Blood (if not cross contaminated during the slaughter process), semen and embryos/ova are not seen as effective transmission vectors and accordingly, blood-meal or embryos/ova and semen were not taken into account. The results of large scale BSE-testing in combination with reports on feed controls have further substantiated the opinion of the SSC that any cross-contamination of cattle feed with bovine MBM, even below 0.5% (SSC 1998c), represents a risk of transmitting the disease. However, the influence of potential cross-contamination on the GBR had to be seen in the light of the risk that the animal protein under consideration could carry BSE-infectivity.

Other transmission routes can be considered if the scientific evidence becomes available to support, however, to-date no such evidence has been forthcoming that necessitates changes of the GBR assumptions.

### 4.3 Geographical limitations, Compartments and Zones

So far, the SSC GBR risk assessments have only addressed entire countries. This was due to the limited availability of detailed, regionalized data. However the issue of regional differences, for example in the types of animal husbandry, *e.g.* dairy or beef, or with regard to feeding or to slaughtering ages are not discounted. If complete data sets are provided on a regional scale, *i.e.* clearly relating to a defined geographical area smaller than a country, these can be assessed in the same way as data referring to entire countries. The OIE Terrestrial Animal Health Code opens the possibility of defining health status for compartments[6] of animals – *i.e.*, a defined production system. This could be an important development to enable a production system to achieve recognition of its health status within its compartment in a situation where a separate definition of disease status may not be possible in the geographical area enveloping the compartment. Moreover, the GBR assessment of a country does not exclude the possibility that a GBR assessment of different compartments or zones within a country might give varying results. This possibility should be explored as a separate exercise.

An example of compartmentalisation within the EU is the provision specific to the UK (EFSA, 2004a) that bovine animals born in the UK after 1 August 1996 (the date that the animal protein feed ban entered into force) are considered to be at no higher risk of developing BSE than animals in other EU countries, thus these bovine animals, beef and products thereof, can be traded having regard to the same rules as for the rest of EU. Hence the UK is set on equal footing in terms of trade with the rest of EU for these animals. On the other hand, all bovine animals born before 1 August 1996 are permanently excluded from the food and feed chain. This means that at the end of their productive life (*e.g.* producing milk and calves), these animals must be destroyed.

### 4.4 External challenge

The external challenge (ec) is defined as both the likelihood and the amount of the BSE agent entering into a defined geographical area in a given time period through infected cattle and MBM.

[6] ***Compartment*** (OIE Terrestrial Animal Health Code 2006, Chapter 1.1.1., General Definitions, Article 1.1.1.1.) means one or more *establishments* under a common biosecurity management system containing an animal *subpopulation* with a distinct health status with respect to a specific *disease* or specific *diseases* for which required surveillance, control and biosecurity measures have been applied for the purpose of *international trade*.

The assumed external challenge resulting from imports from the UK during the peak of the BSE epidemic in the UK is taken as the point of reference. The challenge resulting from imports during other periods and from other BSE-risk countries is assessed in relation to this baseline. If the Overall Challenge, as defined in section 4.7.2, in an exporting country in a particular time period is above negligible this country is considered as a BSE risk country in that period of time with respect to MBM and live cattle exports.

Imports from countries that have not been assessed before but which might pose a risk due to imports from BSE risk countries can be taken into account as external challenge on the basis of best estimates.

The only two possible routes of introduction of the BSE agent into a BSE/cattle system of a specific country are the imports of BSE-infected cattle or of BSE-contaminated processed proteins. In this document, all forms of processed animal proteins are referred to as "MBM". This includes Meat and Bone Meal as such, Meat Meal, Bone Meal and Greaves made from meat and offal. It is synonymous to "flours, meal, pellets made from meat or offal; greaves" (*i.e.* custom code 2301.10 of the Harmonized System Nomenclature of the World Customs Organization which excludes fishmeal) in the import/export context. Available import/export statistics do not, in fact, allow differentiation of the various forms of processed animal proteins referred to; they also do not differentiate between the type of product or by species from which it is produced.

A number of points need to be considered in relation to the external challenge:

- If BSE infected cattle are imported, they still need to be processed[7] before the agent can enter the domestic BSE/cattle system.
- Moreover, their BSE-load is regarded being significant, only if they are approaching the end of the incubation period when they are processed.
- Given that the incubation period is around 5 years and the import-age of breeding cows is normally around 2 years, the highest risk of introducing the BSE-agent due to cattle imports is about 3 years after the year of import of breeding stock. If the produced contaminated MBM is then fed to cattle, it will take a full incubation period, around 5 years, before any clinical BSE case could appear as a result of this initial importation of infected cattle. It is therefore unrealistic to expect clinical BSE-cases resulting from cattle imports, before 8 years after the import, even if the importing system is very unstable.
- If cattle are imported for immediate slaughter, the challenge will depend on their age at import which is close to their age at slaughter. If they are young, the likelihood of them approaching the end of the incubation period and representing an external challenge is very low. If, however, older cows are imported and slaughtered, the risk that they introduce the BSE agent into the importing BSE/cattle system is at least as high as in the exporting country.
- If contaminated MBM is imported it is used for feed in the year of import. If it is fed to domestic cattle, some of these can become infected. After approximately 5 years (average

[7] Processed: meaning fallen stock and cattle slaughtered and rendered for meat and bone meal so this can be fed to cattle.

incubation period) a certain number of them, which have survived until that age, could become clinical BSE cases.

The external challenge is assessed in three steps:

*Step 1* Acquisition of import data concerning live cattle and MBM from BSE-risk countries

*Step 2* Determination of whether the imports entered the BSE/cattle system

*Step 3* Estimation of the level of infectivity in the imported material using imports from the UK during the peak of the epidemic as the point of reference

The data for assessing the external challenge is compiled by the Competent Authority (CA) of the country being assessed using a specially designed questionnaire (see annex III) and the Excel spreadsheets ("Geographical BSE Risk Calculator").

### *4.4.1 Acquisition of import data from BSE-risk countries*

In the light of scientific knowledge and data, it is necessary when assessing the external challenge to take account of imports from all countries found to have a BSE risk. The information is gathered for each BSE-risk country for each year in which imports from that country are considered to present a risk. This is determined when those countries are themselves being assessed under the EFSA GBR methodology.

In some cases, import data from a particular country may be available from a number of different sources. For example, the country being assessed will have its own import data, but such data may also be made available by EUROSTAT and/or other sources (*e.g.* export data from the exporting country). In case of discrepancies the higher figure will be taken into account as the worst case scenario. If the assessed country wishes to make the case that this figure is incorrect, this can be done in Step 2.

### *4.4.2 Determination of whether the imports entered the BSE/cattle system*

In order to assess the external challenge that has entered the BSE/cattle system in a country through imported cattle or MBM, the fate of the animals and MBM following importation should be considered. The key question is whether the BSE-infectivity that could have been carried by these imports did enter the country's BSE/cattle system or not. Based on the analysis of the information provided, the revised figures for the number of cattle and amount of MBM that enters the BSE/cattle system are placed in "Cattle FINAL" and "MBM FINAL" worksheets of the "Geographical BSE Risk Calculator".

Only well-substantiated reasons are acceptable for excluding live animals or MBM imported from BSE risk countries, from the external challenge. Documentary evidence relating to the specific animals or MBM under consideration should be provided by the country being assessed to support the exclusions, if applicable. Other types of information such as common practices adopted in the country being assessed or recording systems may also be used to support the proposal. In cases where the available information indicates but does not conclusively show that the animals/MBM did not enter the feed chain, only a proportion of the imports may be deducted depending on the quality of the provided data. Therefore, this deduction will be done on a case by case basis. In the interest of transparency the rationale for including or deducting imports will be documented.

## A. Reasons accepted as basis to exclude certain live animals from the external challenge

The basic assumption is that all animals imported have potentially been rendered and thus entered the feed chain and could have been fed to cattle. However, if evidence is provided, these animals can be excluded from the external challenge.

- ***Animals that are recorded as imports in error.***

To have these animals excluded, the importing country needs to provide an acceptable explanation as to why the animals were erroneously recorded in the export figures of the country of origin. To this end, the exporting country can be asked to check the data and provide documentary evidence of the exact figures through an official letter signed by the importing country's Competent Authority (CA).

Importation can be excluded if it is not consistent with legislative requirements of the importing country; this could be the case if a license has to be issued based on a risk analysis before importation may take place and no such a license is available.

Where the export of cattle have been prohibited from certain countries during a certain period, in case such a consignment appears in the export statistics from the exporting country or in the EUROSTAT statistics, it could be assumed to be an error, after checking the original documentation.

- ***Age of animals at slaughter.***

Imported animals slaughtered young (*i.e.* below 30 months of age) can only carry a very small fraction of the infectivity found in a clinical case, even if infected prior to export. Imported calves that are immediately slaughtered or fattened and slaughtered before 2.5 years of age can, therefore, be assumed to represent, as long as this can be assessed with a reasonable certainty, no external challenge.

- ***Dead animals which were disposed-of by burial or incineration.***

Infectivity imported via live cattle only enters the BSE/Cattle system of the importing country if these animals die or are slaughtered and rendered into MBM that could reach cattle via the feed-chain. If rendering of imported cattle is avoided through burial or incineration of the dead animals, there is no risk that domestic infections could result from imported infected cattle. To have these animals excluded, the following information must be provided:

  - Evidence to show that a system was in place in the country at the time of importation that allowed imported animals to be traced;
  - Evidence to show that the particular animals were traced;
  - Evidence to show, either directly or indirectly, that the animals were buried or incinerated.

The critical issue in such a case is the quality and effectiveness of the cattle tracing-back system that should be described and confirmed. Specific data concerning the identification of all the traced-back animals and the disposal of those animals by burial or incineration must be available.

- ***Animals that are still alive and are prohibited from entering the feed chain.***

Live animals do not obviously constitute a risk since these cannot have reached cattle via the feed-chain. To have these animals excluded, the following information must be provided:

  - Evidence to show that a system is in place in the importing country that allows imported animals to be traced;
  - Evidence to show that the particular animals have been traced;
  - Evidence to show that a system is in place to ensure that the imported animals are excluded from the feed chain when they die or are slaughtered.

The critical issue in such a case is the quality and effectiveness of the cattle tracing-back system that should be described and confirmed.

- ***Animals imported into a country that only has rendering plants that process animal by-products from export abattoirs and where the imported animals were excluded from going to slaughter at such abattoirs.***

To have these animals excluded, evidence must be provided of systems in place to ensure that imported animals are excluded from the slaughter at export plant.

- ***Cattle which are re-exported.***

Live cattle imported into a country from a BSE-risk country and exported to another country obviously do not constitute a challenge for the importing country. In order to apply this criterion import/ export certificates or equivalent documentary evidence should be available with a clear identification of the involved animals.

**B. Reasons not accepted as basis to exclude certain live animals from the external challenge:**

- animals were older than 10 years of age at slaughter;
- animals were slaughtered after a feed ban was put in place in the country of destination;
- animals were born after a feed ban was put in place in the country of origin, however the impact of a feed ban is taken into account in the assessment;
- animals originated from herds that had no case of BSE.

## C. Reasons accepted as basis to exclude certain MBM from the external challenge listed in the export data from BSE-risk countries under the code 2301.10[8] of the Harmonized System Nomenclature[9]:

The basic assumption is that all MBM imported has potentially entered the feed chain and could thus have reached cattle. However, if evidence is provided, the MBM can be excluded from the external challenge.

- ***MBM recorded as imports in error.***

To have the MBM excluded, the importing country will need to provide documental evidence or an acceptable explanation as to why it was erroneously recorded in the export figures of the country of origin. The following would include some of the acceptable explanations:

  - A selling price significantly lower than the average market price for MBM at the time of the import provides a strong indication that the import was not MBM but rather another less valuable material recorded under a wrong tariff number. Documentation must be available indicating the selling price of the import and on market average price of MBM at the relevant time.
  - No protocol is in existence for MBM exports between the exporting and importing countries and an official letter to the effect that no MBM was exported will be required from the country of origin.
  - Where the export of MBM has been prohibited from certain countries during a certain period, in case such a consignment appears in the export statistics from the exporting country or in the EUROSTAT statistics, it should be assumed to be an error after checking the original documentation.
  - Importation is not consistent with legislative requirements of the importing country; this could be the case if a permit has to be issued based on a risk analysis before importation may take place and no such a permit is available.

- ***Imported MBM was only used as a feed for non-ruminant animals and was handled in a manner that would have prevented cross-contamination of ruminant feed.***

Infectivity imported via MBM enters the BSE/cattle system when it is integrated into feed that could reach cattle, be it deliberately or via cross-contamination during transport, in feed mills and on farms.

  - If imported MBM is reliably only used for non-ruminants, *e.g.* poultry, pet food, fish or pigs, it would not represent an external challenge. In such a case, it would be necessary to trace back the importer for each MBM batch and acquire the documents confirming the specific end use of each batch.

[8] Code 2301.10: “Flours, meals and pellets, of meat or meat offal; greaves”

[9] Harmonized System Nomenclature of the World Customs Organization http://www.wcoomd.org/ie/En/Topics_Issues/topics_issues.html

- o To have the material excluded from the external challenge, it would be necessary to provide documentary evidence to show that the MBM was only incorporated in non-ruminant feed and could not have given rise to cross-contamination.
- o In cases where the available information indicates but does not conclusively show that MBM did not enter the feed chain, only a proportion of MBM imports may be deducted.

- ***Imported MBM is of non-bovine origin.***

If evidence can be provided that the MBM was obtained from animals other than bovine (*e.g.* dehydrated pork meal or poultry meal), obviously no challenge can be attributed to the MBM. In such a case, to have the material excluded from the external challenge it would be necessary to identify not only the importer, but also the manufacturer in the exporting country and documentation should be available to confirm the nature of the materials used to produce the MBM.

- ***Imported MBM is of bovine origin but from materials very unlikely to be contaminated by BSE.***

If evidence can be provided that the MBM was obtained from bovine material very unlikely to be contaminated, it can be excluded from external challenge.

- ***MBM that is re-exported.***

MBM imported from a BSE-risk country and exported to another country without further handling that would allow cross-contamination obviously does not constitute a challenge for the importing country. In order to apply this criterion import/export certificates or equivalent documentary evidence should be available with a clear identification of the involved MBM.

**<u>Please note:</u>** The group responsible for carrying out the assessment may consider these and other reasons for the inclusion or exclusion of live cattle and MBM on a case-by-case basis.

#### *4.4.3 Estimation of the level of infectivity in the imported material, using imports from the UK during the peak of the epidemic as the point of reference*

In order to correctly assess the external challenge, it is important not only to take into account the number of live cattle and the amount of MBM imported from BSE-risk countries but also the type of intervention measures that are taken by the exporting countries to prevent the spread of the agent to live animals and subsequently to the animal products. These measures are included in the stability assessment of the exporting countries. In addition, the following factors may considerably reduce the associated challenge, in particular:

It is clear that all imports of live animals and MBM from BSE-risk countries do not pose the same risk. Consequently, it is necessary to have a system for relative weighting of the different imports. This system is implemented using the specially designed Excel spreadsheet “Geographical BSE Risk Calculator” and is based on the following assumptions:

- The external challenge is dependent on the size and characteristics of the challenged BSE/cattle system.
- The baseline of this assumed challenge results from imports from the UK during the peak of the BSE-epidemic in the UK.
- The challenge resulting from imports during other periods and from other BSE-affected countries is established in relation to this baseline.

The weighting is assigned when the exporting country is itself being assessed under the EFSA or SSC GBR methodology. The third refinement step deals with evaluating what proportion of the imported cattle and MBM, as estimated above, is likely to be infected by BSE.

The GBR has the task of combining the challenge from different countries, over different time periods, and different commodities (live cattle and MBM) into an overall measure of risk. To do so, it is assumed that 1 tonne (1000 kilos) of MBM is equivalent to 1 live animal (from the same year) and that the risk from animals are scaled relative to that posed by UK cattle from the reference period 1988 to 1993, *i.e.* the UK BSE prevalence was thought to be 5%.

In order to fully assess the relative BSE burden of 1 tonne of MBM and 1 live cattle export one would need information on the relative cattle birth cohort size, MBM production levels and then take into account the potential for the cattle BSE burden to increase over time while the MBM burden remains static. Based on UK data, the ratio of MBM production to birth cohort is 1 to 4. However, since infectivity in surviving exported cattle is expected to increase over time, we estimate that for risk assessment purposes, as an order of magnitude approximation, 1 tonne of MBM is equivalent to 1 live cattle.

In the **SSC GBR** methodology, the scaling of imports was achieved by the use of "*R*" values. These reflected the different magnitude and stage of a specific epidemic in relation to the UK highest risk period.

In the **EFSA GBR** methodology, although expanded here, exactly the same basic concept is applied. However, we have also taken this opportunity to clarify the method and the introduction of new terminology. Hence we use external challenge "*weighting factor*" ($w$) in place of the R1 and R2 values, which were previously found to be confusing.

**Determination of the weighting factors:**

- In the reference UK period, the prevalence of BSE was taken as 5%. For all the animals from this reference period we define $w = 1$, and one such animal (or tonne of MBM) is considered 1 "Risk Unit". If the prevalence in a country at the time of export is known (see below) to be, for example 0.5% then such exports are weighted by a factor $w = 0.1$. *i.e.*, $w$ is estimated by the prevalence in year of export /0.05. Ten such animals would therefore be equivalent to 1 Risk Unit (1 animal from the UK during the reference period).

- If weighting factors are identified and applied to each year of export from each BSE risk country, then the resulting risk units can be combined between different countries and between different years. These are then used to obtain a final estimate of the risk that BSE could have been imported. Table 1 indicates that ≥ 100 live cattle from the UK reference period are a "High" external challenge (reflecting the high probability that the imports included infected animals). The weighting factor ensures that imports from other years or countries can be combined and converted to this standard scale.
- As an example, (50 live cattle from the UK in the reference period having a weighting factor of 1) + (4000 live cattle having a weighting factor of 0.01) + (10000 tonnes of MBM having a weighting factor of 0.001) would also constitute a combined 100 Risk Units and a High challenge, in Table 1.

In practice, it is very difficult to estimate the yearly prevalence in the (exporting) BSE risk country and hence the weighting factor for a particular export of live animals or MBM. Here, three methods can be employed:

A) **Based on prevalence estimates** in the country using BSurvE (EFSA, 2004b) or another appropriate method. If yearly prevalence estimates are available for two or more years, *w* is obtained directly using the upper 95% percentile estimate of prevalence divided by 0.05 (which is the estimate used for the UK cattle BSE prevalence during the reference period 1988 to 1993).

B) **Based on *w* values.** For countries that have been assessed using the EFSA GBR the *w* values are obtained directly from the interaction between stability and challenge described in section 4.7.

C) **Based on a rules system**. When reliable prevalence estimates are unavailable, a rules based approach is used. First it must be established when the exporting BSE risk country itself received its high external challenge and also its stability levels over time. These are used to approximate the course of the epidemic: its prevalence increasing over time while unstable, and decreasing when stable. The exports from the risk country are then weighted as follows:

**When no changes in stability in the exporting country appear, this will have the following effect:**

- No risk until the year a cumulative high challenge occurred in the exporting country.
- The weighting factor (*w*) of the imports is 0.001 for the next 5 year period (very/extremely unstable) or 10 year (unstable), after which the *w* value increases to 0.01 unless there are changes in stability.

**When changes in stability in the exporting country appear, this will have the following effect:**

- If *w* = 0.01, a change to a stable system results in a reduction in *w* to 0.001 after a 5 year period. For every subsequent 5 year period there is a further 10 fold reduction in the *w* value.

**Note:**

- The **5-year period** is assumed to approximate the duration of BSE incubation time.
- The *w* values can be modified to reflect additional information of key importance. At present there are two examples in use. First, for MBM exports until 1996 from a number of countries (i.e. France, Netherlands, Belgium and Italy), it is assumed that 0.1 tonnes of MBM is equivalent to 1 live bovine animal within these countries. This was introduced because of the high risk of UK MBM being re-exported by other European countries. Second, for countries with large cattle populations an adjustment may have to be made to reflect the fact that if the challenge is not "very high", it will take longer for the epidemic to reach the same prevalence. As a guideline a cut off value of 10 million adult cattle is recommended. In these cases, no risk ($w$ = 0) is assumed until 5 years after the high challenge, and the progression from $w$ = 0.001 to 0.01 is extended by 5 years.

Table 1: **Level of external challenge in a given 5-year period resulting from import of live cattle or MBM from UK or other BSE-risk countries**

| **Level of external challenge** | **Risk units resulting from imported live cattle and MBM using weighting factors** |
|---|---|
| Extremely high | ≥10,000 |
| Very high | 1,000 - < 10,000 |
| High | 100 - < 1,000 |
| Moderate | 20 - < 100 |
| Low | 10 - < 20 |
| Very low | 5 - < 10 |
| Negligible | 0 - < 5 |

## 4.5 Stability Assessment

**Stability** is defined as: the ability of a BSE/cattle system (Figure 1) to prevent the introduction and to reduce the (amplification and) spread of the BSE agent within its borders. Stability relies on the avoidance of processing of infected cattle and the avoidance of recycling of the BSE agent via the feed chain. A "stable" system would eliminate BSE over time; an "unstable" system would amplify it if the BSE agent had entered the BSE/cattle system as determined by the external challenge assessment.

Stability is linked to the basic Reproduction Ratio[10] of the infection ($R_0$).

[10] Basic Reproduction Ratio: the expected number of secondary infections resulting from a typical primary infection in a susceptible population

- If $R_0$ is bigger than one, the epidemic will grow, and the system is "unstable".
- When this multiplication factor is close to 1, the infection level will remain constant and the system is called "neutrally stable".
- When the multiplication factor is below one, the epidemic will decrease and the system is "stable".

The most important stability factors are those to be able to prevent the building-up of BSE infectivity in the system and reduce the risk of recycling of the BSE agent within the cattle population, in particular SRM-removal, rendering and feeding.

### *4.5.1 SRM-removal*

The infectivity that could enter the feed chain can be reduced by excluding those tissues (SRM) known to carry the bulk of the infectivity that can be harboured by BSE infected cattle. Information on the distribution of BSE tissue infectivity is provided by the updated SSC Opinion on TSE Infectivity distribution in ruminant tissues (SSC, 2002c) and by Table 2 originating from the EFSA QRA Report (EFSA, 2004c).

Table 2: **Estimated tissue weights and infectivity levels from a clinical case of BSE**

| Tissue | Total mass (g) | Titre: $CoID_{50}/g$[11] | Total infectious Load (%) |
|---|---|---|---|
| Brain | 500 | 5 | 2500 (60.1) |
| Trigeminal Nerve Ganglia (TRG) | 20 | 5 | 100 (2.4) |
| Spinal cord | 200 | 5 | 1000 (24.0) |
| Dorsal Root Ganglia (DRG) | 30 | 5 | 150 (3.6) |
| Ileum | 800* | 0.5 | 400 (9.6) |
| Remaining tissues | 548450 | Below detection limit | (<0.5%) |
| Approximate Total | 550000** | | ~4160 $CoID_{50}$ |

* 800g may be excessive for the anatomical region strictly termed ileum (without content), which in an adult bovine represents about 1 meter of bowel.

** It should be noted that, in practice, these weights would vary between different animals, depending on age and breed. Area dependent there can also be large differences.

The removal involves SRM from all bovine animals that leave the population (healthy and casualty slaughtered animals, clinical suspect animals, fallen stock). For practical reasons the carcasses of fallen stock are most often entirely removed. Findings from the extensive active surveillance in Europe indicate that the frequency of infection in fallen stock and casualty

[11] $CoID_{50}/g$: Cattle Oral Infectious Dose 50% per gram of material

slaughter cattle is significantly higher than in normal slaughtered cattle. This effect is further increased by the fact that fallen stock will normally be more advanced in the stage of the disease with significantly higher level of infectivity in the SRM than can be assumed for apparently healthy cattle that pass ante-mortem inspection despite that they are incubating BSE. These should normally be less advanced in the BSE incubation period (SSC, 1998b; SSC, 2003b).

#### *4.5.2 Rendering*

In this document rendering is considered to be the treatment or processing of bovine material intended for non food purposes from fallen stock and slaughtered animals by commercial or non commercial methods.

According to the SSC opinion on the safety of MBM (SSC, 1998c), appropriate rendering methods reduce BSE-infectivity that enters the process via the raw material. The SSC assumes, for all practical purposes, a reduction factor of 1000 for a process known as “batch pressure cooking”, *i.e.* at 133°C during 20 minutes under a pressure of 3 bars and other conditions as listed in Regulation EC n° 1774/2002 (EU, 2002) . Rendering, however, can never be taken as a way to sterilize BSE contaminated material.

#### *4.5.3 Feeding*

The risk of new infections in the domestic cattle population would (under the basic assumptions made for the GBR) be nil if no feed that potentially carries the BSE-agent reaches bovines. However, experience from Europe has shown that traces of ruminant protein (other than milk) in feed are enough to infect cattle. These traces may result from cross-contamination of MBM-free cattle feed with MBM-contaminated pig or poultry feed, which may happen in feed mills that produce both types of feed in the same production lines. Apparently flushing batches, a method often used as a safeguard against such cross-contamination, is not sufficient. This conclusion from practical experience is supported by the oral exposure experiments in the UK that have shown that for 0.1g infective brain, 7 out of 15 animals became positive, for 0.01 gram of fresh infective brain, 1 out of 15 cattle became positive and for 0.001 gram infective brain, 1 out of 15 cattle became positive (Wells *et al.,* in press).

### 4.6 Methodology for assessing stability

The stability of the system is assessed for a particular period based on the set of stability factors existing at that time. The stability is assessed by estimating the level of propagation of the BSE agent for the set of factors using the reproduction ratio ($R_0$). The $R_0$ is initially set at a reference level based on minimum standards of stability. If the country being assessed has control measures in place to improve the stability, $R_0$ is adjusted downward accordingly. A final $R_0$ is obtained after the effect of all of the stability factors has been taken into account.

In setting the reference level, it is necessary to have information on the level of propagation of the BSE agent under minimum standards of stability. This is available for the UK during the pre-1986 period. During that time, it is estimated that the infection level multiplied by a factor of between 10 and 20 per generation (*i.e.* in about 5 years’ time, the number of infections increases approximately 14 times) (de Koeijer et al., 2004; Ferguson 2003). The stability conditions that existed during that period were that no SRM was excluded from the feed chain (some of it entered the food chain: approximately 30% was not rendered), rendering was mainly carried out under atmospheric conditions (this led to a estimated reduction of the infectious load of 0.1) and approximately twenty percent of MBM was used for cattle feed. Assuming a linear relationship between $R_0$ and the level of the risk factors, the upper value of $R_0$ (= $R_{max}$) would have been approximately 1000 (14/(0.1 x 0.2 x 0.7) = $R_{max}$ see calculation after Figure 2) if all of the MBM had been fed to cattle and if rendering had no effect whatsoever. This is taken as the reference level for $R_0$.

A schematic overview of the methodology for evaluating the stability is given in Figure 2.

This method assumes that the effect of control measures on the $R_0$ is linear (de Koeijer et al., 2004). Thus, by multiplying the reduction factor for each of the main control measures, we calculate the total effect of all the control measures together to give a final value for $R_0$.

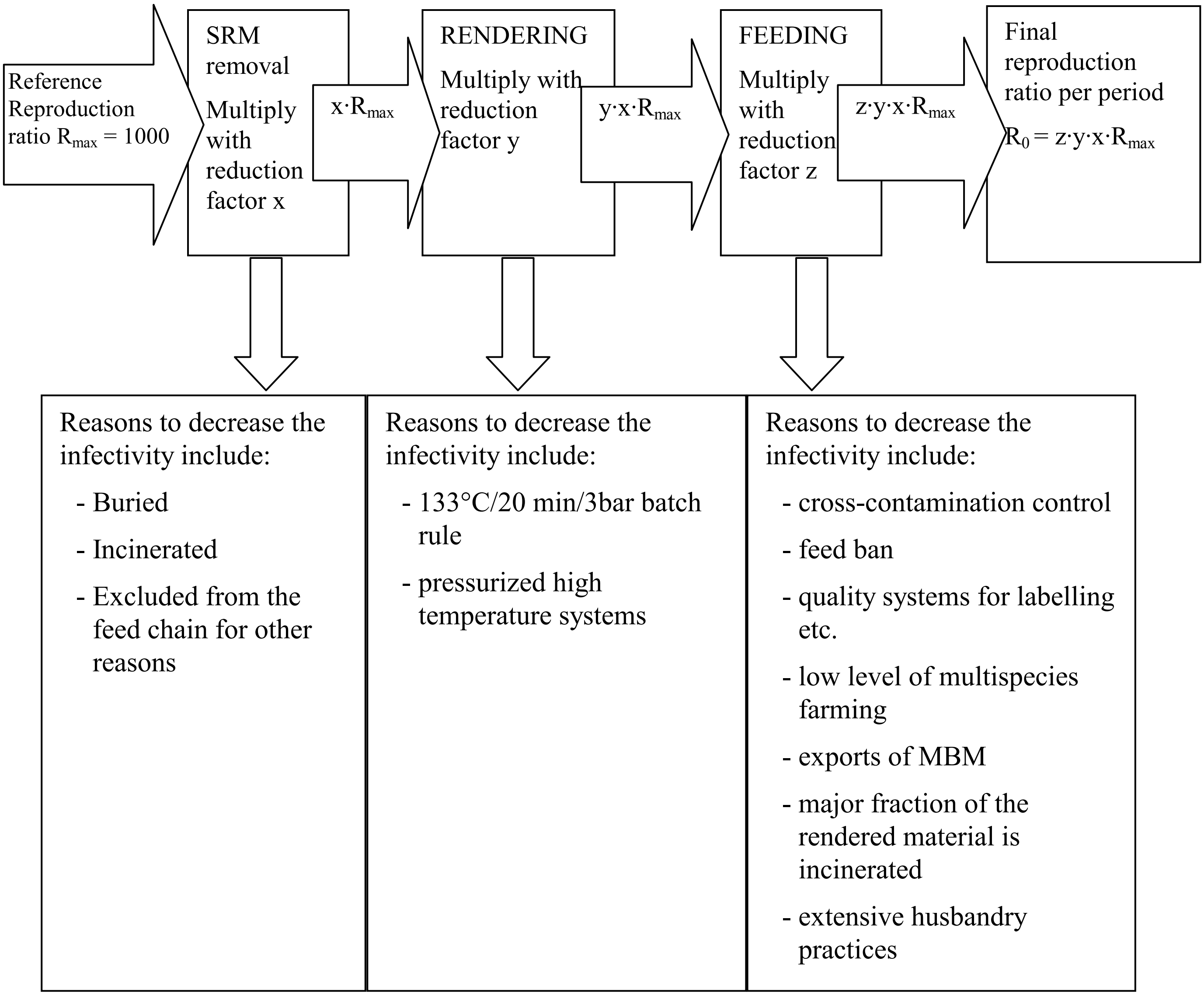



Figure 2. **Schematic overview of the method to analyse stability. This scheme can be worked out into a complete tree if required for more complicated systems.**

**Example UK 1986**, if we find:

- x = 0.7 (some SRMs are used in food, a large part is rendered)
- y = 0.1 (some reduction of infectious load in rendering)
- z = 0.2 (about 20% of all MBM is fed to cattle)
- setting $R_{max} = 1000$
- so we find that the final $R_0 = 1000*0.7*0.1*0.2 = 14$

Further details on the adjustments that should be made to $R_0$ to account for the various measures in place to improve stability are given in the next section.

In general the reduction factors can be modified on a case by case basis if justified by sufficient data. Guidelines are given in the following sections.

### *4.6.1 Assessing the impact of SRM removal*

In this block the removal and fate of all the SRMs of all cattle slaughtered, culled or died of other causes is assessed.

- The maximum reduction is proposed to be a factor of 0.001. Values between 1 and 0.001 should therefore be applied depending on the nature of the SRM removal from the feed chain and the assessed efficacy of the system.
- If **no SRMs** are removed from the rendering to feed chain, this is valued as a factor of 1.
- If **all SRMs** are incinerated, buried or used in the human food chain, *i.e.* cannot go to the feed chain, it is optimal.
- If SRM removal is applied in full compliance with at least the list of SRM of OIE, if fallen stock excluded, and implementation and control of measures guaranteed a maximum reduction factor of 0.001 can be theoretically achieved. However, this maximum indicated by the SSC document reflects an ideal situation that in practice hardly ever can be achieved, thus rather a maximum of 0.01 appears reasonable (SSC, 2002c).
- If only fallen stock is excluded a reduction factor of 0.4 can be applied (removal of 60 % of infectious load).
- If SRM is usually eaten: when it can be assumed that all brain is eaten a reduction factor of 0.4 (removal of 60 % of infectious load) can be applied (EFSA, 2004c).
- If an official SRM ban is in place, but evidence for full compliance can not be provided (no or only limited control data provided), the reduction factor may vary.

### *4.6.2 Assessing the impact of Rendering*

In this block the effect of rendering is assessed.

- When an atmospheric pressure is applied in rendering, a reduction factor of 0.1 is considered. Improved systems will get a better reduction value. Systems according to 133°C/20 min/3 bar are evaluated by a reduction factor of 0.001 if fully applied

(Schreuder *et al.*, 1998; Taylor and Woodgate, 2003). Other rendering systems or a combination of various systems can be evaluated between 1 and 0.001 depending on the evaluation of the information in the dossier provided by the country.

#### *4.6.3 Assessing the impact of Feeding*

In this block, the fraction of the MBM that may be fed to cattle is assessed.

- If all MBM of the national production is being fed to cattle this is valued by 1. In the UK prior to 1986 about 20% of the national MBM production (*i.e.* 20% of all rendered cattle protein) was used in cattle feed. This should be valued with a reduction factor of 0.2. An optimal feed ban supported by cross-contamination controls can be assessed with a reduction factor of 0.001.
- A well-implemented mammalian MBM feed ban to all farmed animals, evaluated by a credible audit, is considered the optimum (reduction factor of 0.001).
- For a well-implemented mammalian MBM feed ban to ruminants, evaluated by a credible audit, a reduction factor of 0.01 can be applied.
- For a well-implemented ruminant MBM feed ban to ruminants a reduction factor of at least 0.1 can be applied.
- If dedicated feed mills and/or rendering plants are used and data on the controls to exclude cross-contamination are provided a further reduction factor of 0.1 can be applied for the two later feed- bans.
- The occurrence of BSE in cattle born after a feed ban should be taken into account in the assessment of the efficacy of this feed ban.

#### *4.6.4 Evaluation of the overall stability of the system*

The different combinations of the three main stability factors accordingly result in different levels of stability, as shown in Table 3.

The overall stability is measured by the final value of $R_0$ and this works as follows

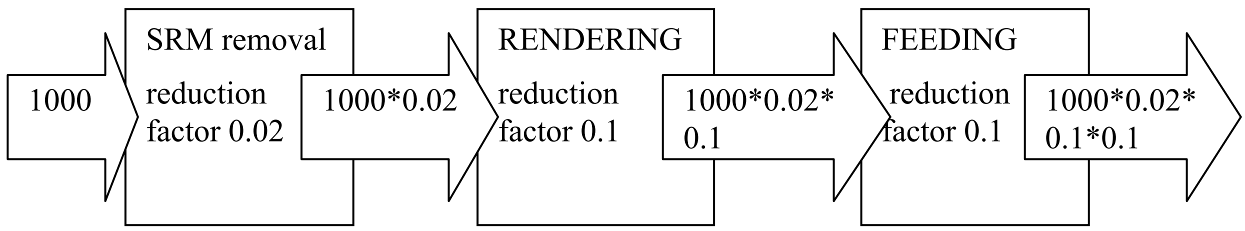
- As long as the basic reproduction ratio is bigger than one, the epidemic will grow, and the system is "unstable".
- When $R_0$ is close to 1, the infection level will remain constant, and the system is called "neutrally stable". In a neutrally stable system, the recycling rate of the BSE agent would just be high enough to maintain the total level of infectivity once introduced into the system. In other words, the number of new infections in the cattle population is more or less equal to the number of incubating cattle leaving the system.
- When $R_0$ is below one, the epidemic will decrease, which makes the system "stable".

It should also be understood that the table below is not intended to provide a semi-quantitative assessment of stability, but is rather designed as guidance for ensuring a consistent interpretation of comparable outputs. This should harmonize the assessment of different countries.

Table 3: **BSE stability levels and their interpretation with regard to Reproduction Ratio ($R_0$). Optimally stable should be understood as "as good as possible according to current knowledge".**

| STABILITY | Level | Effect on BSE prevalence | $R_0$ |
|---|---|---|---|
| **Stable:** The system will reduce BSE-infectivity | Optimally stable | Very fast | 0 to 0.05 |
| | Very stable | Fast | >0.05 to 0.2 |
| | Stable | Slow | >0.2 to 0.5 |
| **Neutrally stable** | | +- constant | >0.5 to 2 |
| **Unstable :** The system will amplify BSE-infectivity | Unstable | Slow | >2 to 5 |
| | Very unstable | Fast | >5 to 15 |
| | Extremely unstable | Very fast | > 15 |

**Examples of stability assessment**




**Example**, if we find:

- x = 0.02 (little SRMs are used in feed),
- y = 0.1 (atmospheric rendering)
- z = 0.1 (about 10% of all MBM is fed to cattle),
- using $R_{max}$ =1000 and we find that the final $R_0$ = 1000*0.02*0.1*0.1= 0.2

Further details on the adjustments that should be made to $R_0$ to account for the various measures in place to improve stability are given in the next section.

## 4.7 Interaction of stability and challenge

### *4.7.1 General overview*

The interaction between stability and challenge will determine how the GBR develops over time. Assuming that new challenges can be avoided, the current stability determines the slope of the GBR trend:

- A stable system will reduce the GBR level. In such a stable system, the rate of new infection is lower than the rate at which infected cattle leave the system. The risk is approaching zero once the last cattle born before achieving a stable system is slaughtered.
- An unstable system will amplify any BSE-infectivity that is already in the system and increase the GBR level.

As illustrated in Figure 3, four different basic combinations of stability and challenge can be foreseen during a particular period:

- o A **stable** system that is **negligibly challenged**: this is the best situation.
- o A **stable** system that is **highly challenged**: this situation is good since the system will be able to remove the BSE agent, over time.
- o An **unstable** system that is **negligibly challenged**: this situation is good. However, if the BSE agent enters the system it can be amplified.
- o An **unstable** system that is **highly challenged**: this is the worst situation, since the BSE-infectivity will be amplified over time and will lead to an epidemic.

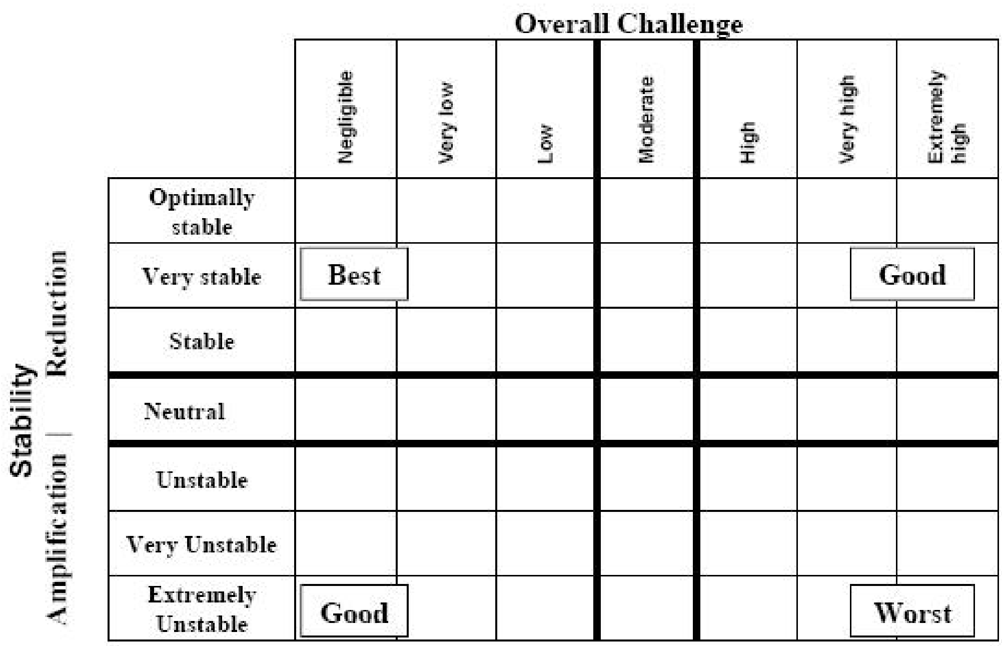



Figure 3: **Combinations of challenge and stability**

### *4.7.2 Definitions of internal and overall challenges*

The overall challenge is a combination of the external challenge, as defined in section 4.4, and internal challenges, defined below, present in a BSE/cattle system at a given point in time.

- The internal challenge (IC) is defined in the SSC opinion on the GBR (SSC, 2000b) as the likelihood and the amount of the BSE-agent being present in the native domestic cattle population and circulating in a specific geographical area in a given time period. If present, the agent could be in infected domestic animals, where it would be replicated, in particular in SRM, and in domestic MBM made from the infected domestic cattle. The internal challenge in a given time period is therefore a consequence of the interaction of the stability of the system and the past challenges (internal and external) to which it was exposed in a previous period (*i.e.* the overall challenge of the previous 5-year period).

**Interaction of Stability and Challenge**

The evolution of BSE level within a country is determined by the following interaction of challenge and stability.

- The initial level of BSE is given by the external challenge (ec) during the first 5-year time period ($ec_1$).
- In subsequent time periods *t* the overall BSE challenge ($oc_t$) is calculated as

$oc_t = ec_t + [R_{0t} \text{ x } oc_{t-1}]$

i.e. the overall BSE challenge ($oc_t$) is the sum of any new External Challenge ($ec_t$) plus the expected number of new domestic infections. This latter component is given by the multiplying the current $R_0$ value by the Overall Challenge in the previous time period ($oc_{t-1}$).

Since there will usually be considerable uncertainty surrounding the $R_0$ estimates in table 3, here we use simplified $R_0$ values that approximate the mid-point $R_0$ in the estimated stability level. Furthermore we do not distinguish here between “Extremely” and “Very” stable (or “optimally” and “very stable”). Again, this reflects the uncertainties in the stability analysis and generates smoothed predictions for the epidemic (avoiding wild fluctuations in the evolution of the BSE level). The following standardised $R_0$ values are therefore used, guided by the outcome of the stability analysis:

| | |
|---|---|
| Extremely / very unstable | $R_0 = 10$ |
| Unstable | $R_0 = \sqrt{10}$ |
| Neutrally stable | $R_0 = 1$ |
| Stable | $R_0 = \frac{1}{\sqrt{10}}$ |
| Very / Optimally stable | $R_0 = 0.1$ |

*4.7.3. Guidelines on the interaction between stability and challenge*

If the system has been assessed to have received only a negligible or very low challenge it is concluded that the infection didn't enter the country/region and therefore there is no further evolution of the BSE infection over time. For those that have received at least a moderate challenge the interaction chart (see Fig. 1 of the "challenge-stability interaction" worksheet of the "Geographical BSE Risk Calculator") should be used as an indication of the likely evolution of BSE level within the country. Given the many uncertainties usually present in the data, and the simplified calculations employed, the sensitivity of the chart to the assumptions behind the input values should be explored.

With these uncertainties kept in mind, the output of the interaction chart can be directly used to provide estimates of:

*Number of infected animals per million*

Given by $I_t = \frac{oc_t}{20P}$, where $P$ is the population size in millions (note the correction factor of 20 is used since challenge is measured in standard UK "risk units" where, for a challenge of 20 imported cattle, 1 BSE infected animal is expected which equals a prevalence of 5%).

*Number of cases per million*

Given by $C_t = \frac{I_{t-1}}{S}$ , ie assuming that of the infected animals in the *previous* 5-year time period ($I_{t-1}$) the fraction S will survive to display symptoms in the current time period. S is usually between 0.1 and 0.25.

*Weighting factors for exports in subsequent assessment*

The calculation of weighting factors for exports from BSE infected countries are described previously; based only on year of cumulative high challenge and stability indices. If a country has been assessed with the updated methodology, the weighting factors for this country can be updated, in each 5-year period, using the interaction chart and the formula:

$$w_t = \frac{I_t}{50000}$$

(since a weighting factor of 1 is equivalent to a prevalence of 1 in 20, or 50000 in a million).

We also note that if more complex methods for the estimation of weighting factors (such as modified BSurvE output) are available for certain countries these values can be used in the updated methodology.

## 4.8 Surveillance and its contribution

### *4.8.1 General comments*

Comprehensive surveillance system for BSE that includes monitoring the effectiveness of preventive measures is an essential element in controlling the spread of the disease. In general, the detection component of the surveillance system is aimed at demonstrating the absence of disease or infection or determining the occurrence or distribution of disease or infection. The type of applied system depends on the desired outputs needed to support decision-making.

Surveillance systems for BSE can have one or more goals, depending on the country's need and the BSE situation. These goals may include:

- to determine if BSE is present in the domestic cattle population;
- to support a claimed BSE status or to (re)gain a higher BSE status;
- and to monitor the level and evolution of the disease (when present), which will aid in assessing the effectiveness of control measures implemented.

In the SSC GBR method, surveillance data, specifically test results, were considered but the data did not contribute to the assessment outcome. These test results had limited impact on the final assessment of the SSC GBR in terms of preventing the introduction and spread of the BSE agent. In some cases it may enhance certain termination aspects concerning the stability of the country/region.

Surveillance data and their use in the EFSA GBR methodology:

- The lack of surveillance data will not be used to change the final outcome of countries with a negligible external challenge.
- Also, surveillance data will not be used to change the final outcome of countries with a high external challenge combined with a very or extremely unstable system.
- Evolution of the disease and its risk in a country, as estimated by the EFSA GBR, can be then used to determine the value of surveillance for the country/region.
- Test results obtained from a surveillance system can be used to support the assessment outcome, in particular for confirming an increasing or decreasing trend of the BSE risk.

### *4.8.2 Evaluation of surveillance systems capable of estimating the prevalence of BSE infection*

As indicated above, if yearly prevalence data are available from a reliable surveillance system then it is possible to estimate the weighting factor for a particular export of cattle from a country/region when exposure risks (external challenge) are being assessed.

An essential aspect of assessing the stability of a country or region is determining the effectiveness of the various controls instigated. One mean of achieving this is by including auditing as part of the surveillance system such as determining the removal and appropriate disposal of SRM from carcasses. The ultimate means of determining the effectiveness of controls is to estimate the prevalence of infection within birth cohorts before and after the introduction of the interventions. In the case of BSE, this is only possible to determine some years after the initiation of controls, and is a relatively expensive exercise. However, a number of countries, notably of the EU, have invested a great deal in extensive surveillance programmes with emphasis on testing. The BSurvE model does allow the synthesis of the testing results in the various surveillance streams in which cattle can be tested as they leave the population. One result of this synthesis is the provision of prevalence estimates in the birth cohorts for which sufficient test results are available. This therefore allows, if applicable, a more definitive assessment of the stability within a country or region.

In practice it is not possible to prove that a country is free of BSE, particularly by testing alone. To prove that a country is free of BSE infection all animals must be examined with a test that has perfect diagnostic sensitivity and yielding negative results. Furthermore, there should be no entry of animals or animal products of unknown status that could transmit the infection thereafter. In addition, the uncertainty introduced by testing only a sample from the population with tests with a known (or not known) ability to classify correctly the animals tested make it impossible to prove true BSE freedom of a population or a country. Therefore, only a negligible BSE risk can be defined as opposed to BSE freedom.

For some countries/regions the risk assessment may have revealed some uncertainty in the exposure status and the stability following potential exposure. If there has been targeted surveillance, then analytical methods such as those provided by the BSurvE model allows the estimation of the prevalence of infection in the cattle population and more importantly the upper 95% confidence interval. This is particularly important where the observed prevalence is zero.

### 4.9 Outcome of the assessment

Based on the assessment of the interaction between the overall challenge and stability a number of conclusions can be drawn:

- Likelihood of BSE being present.
- If likely:
  - due to which imports in which periods
  - Increasing/Decreasing
    - Period Increasing
    - Period Decreasing
- Evolution over time (including graph interaction stability-challenge and expected cases per million)

This assessment is not an alternative to the determination of the OIE BSE risk status of the cattle population of a country but a risk assessment that can be utilized in the framework of article 2.3.13.2 of the OIE Terrestrial Animal Health Code.

Some examples are given in Annex IV.

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