Draft opinion of the Scientific Panel on Biological Hazards on the revision of the Geographical BSE risk assessment (GBR) methodology

Approved for public consultation

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SUMMARY OF OPINION:

Key Words

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1. INTRODUCTION

The Geographical BSE-Risk assessment (GBR) is a qualitative 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. It is based on a qualitative analysis of:

(1) the likelihood that the BSE agent was introduced into a country 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[1]. 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 updated 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 with revisions in 1999, 2000 and 2002). 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[2] 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. Therefore, and also to protect consumer health, 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 such as emergency slaughtered animals and animals found dead on the farm, sent to the rendering plants ("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

[1] 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

[2] **GBR level:** *Presence of one or more cattle clinically or pre- clinically infected with the BSE agent in a geographical region/country.* **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

the SSC GBR methodology. Germany, Italy, Spain, Poland, the Czech Republic and the 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 all cases, active surveillance detected BSE cases that would have remained undetected by the already existing passive surveillance, which was targeted at animals with neurological symptoms. In addition, Sweden which was classified as a GBR II country had a case during March 2006.

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)/KVDip/ 420863) in order to re-assess a total of 18 countries[3] 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.[4]

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 low BSE prevalence and 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.

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3 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.

4 http://www.efsa.europa.eu/en/science/tse_assessments/gbr_assessments.html

- The SSC GBR method could 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 epidemiological surveillance of BSE in cattle since 2001 are now available and the EFSA GBR should take account of these data which allow a better perspective of geographical risk.
- 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 OIE guidelines wherever possible.

Given the above reasons, the Scientific Panel on Biological Hazards (BIOHAZ) was requested by EFSA in March 2005 under a self-task to update the SSC GBR methodology.

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 CHOSEN BY THE BIOHAZ PANEL

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 (see also Annex II for comparison of the GBR method with OIE method).

The BIOHAZ Panel and its WG decided to produce a standalone 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 people in the countries being assessed.

As part of the terms of reference, the BIOHAZ Panel agreed on referring to SSC GBR as the old method and EFSA GBR as the updated 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 III 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. (*The comments of the public consultation as well as the experience of the test runs will be reflected in the final report and opinion).*

4. THE EFSA GBR METHODOLOGY

4.1 Definition of the Geographical BSE-risk in cattle

The Geographical BSE-Risk assessment (GBR) is a qualitative 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.

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, the following factors are taken into account:

- Structure and dynamics of the cattle population
- Animal trade
- Animal feed
- Meat and bone meal (MBM) bans
- Specified risk materials (SRM) bans
- Surveillance of BSE

- Rendering and feed processing

Following consideration of these issues, an assessment is made of the likelihood of one or more cattle in the native population being infected with BSE.

On the basis of this assessment, the country/region using the SSC GBR method was assigned a GBR category between I to IV (see footnote[2] for GBR levels).

Under the EFSA GBR these categories are changed to the following:

- **Unlikely** – cases of BSE are unlikely to be present in the evaluated cattle population
- **Likely - one or more cases of BSE are present in the evaluated cattle population.**

The category **likely** is split into two subcategories based on the assessment of the stability of the system:

- **Likely and decreasing**

or

- **Likely and increasing**

If the country assessed is categorised as likely and neutrally stable, it falls into the category of likely and increasing applying worst case assumptions.

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.

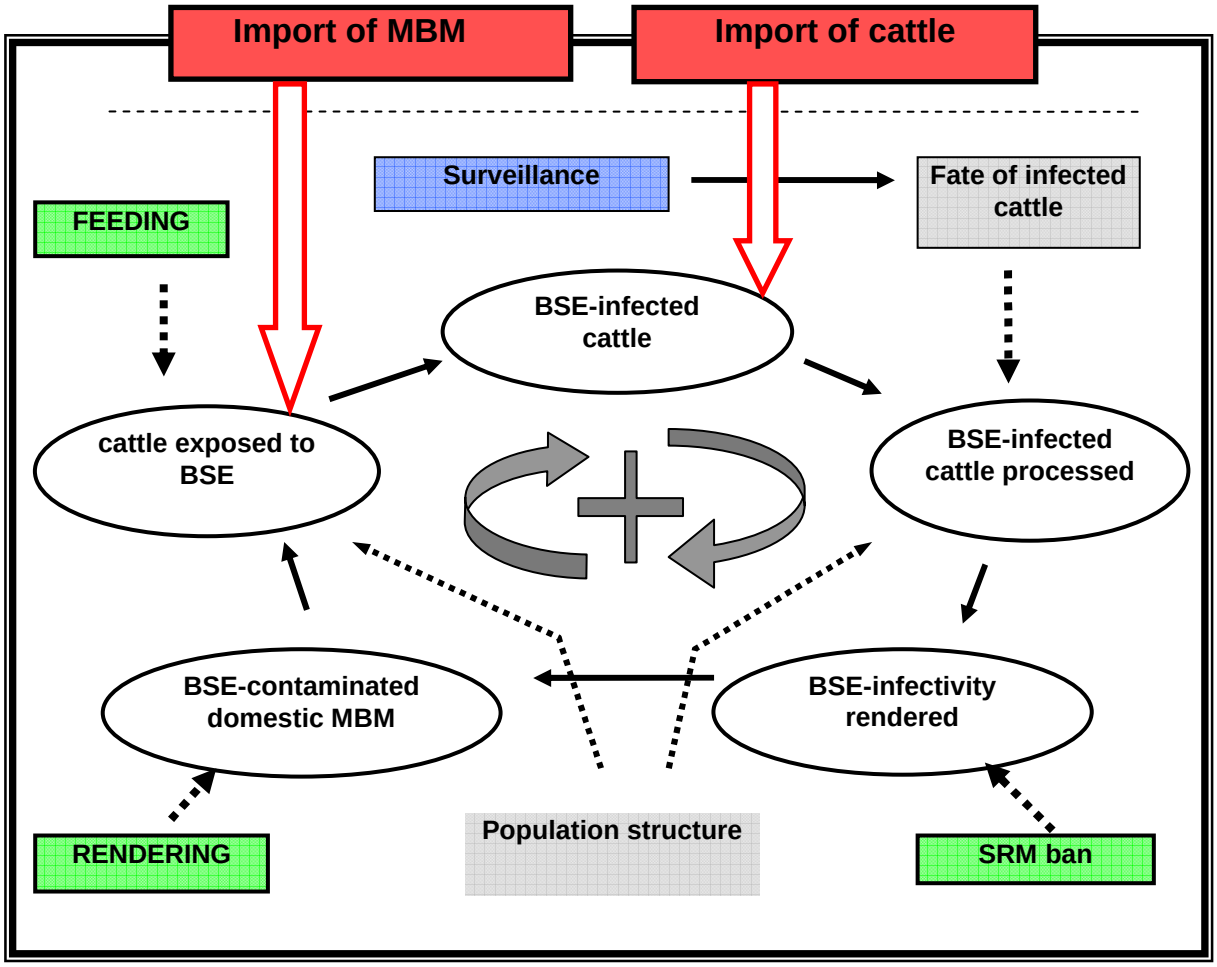


Figure 1: **The model of the BSE/cattle system**

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 vertical transmission, 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.

The only transmission vehicle considered in any GBR exercise is, was and continues to be feed containing animal protein such as MBM. Blood, 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 recent 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%, 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 and national herds. 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. This assessment applies to the BSE status of a country and does not necessarily apply to the trade of commodities as this is dealt with separately by EU legislation and the OIE terrestrial animal health code.

The OIE animal health code opens the possibility of defining health status for compartments[5] 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 term **external challenge** refers to both the likelihood and the amount of the BSE agent entering into a defined geographical area in a given time period through imported cattle or MBM. 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. A BSE-risk country is any country classified as "Likely" under the EFSA GBR methodology (under the SSC GBR this would relate to a GBR III or IV level).

Imports from countries that have not been assessed before but that might pose a risk due to imports from BSE risk countries can be taken into account as external challenge.

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

5 ***Compartment*** (OIE Terrestrial Animal Health Code, 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*.

proteins. In this document, all forms of processed protein 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.* EUROSTAT custom code 230110) 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.

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 IV) and Excel spreadsheets ("GBR Template import table_July06b").

4.4.1 Acquisition of import data from BSE-risk countries

In the light of new 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 and categorized under the 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 between the number of EUROSTAT and the number of the dossier, 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 Table 2 of the Excel spreadsheet.

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.

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 slaughtered, rendered and thus entered the feed chain and could have reached 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).

- ***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 will be 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;
- 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 custom code 230110:

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, these animals 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 that 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.

- As the export of MBM has been prohibited from the UK since 1996, in case such a consignment appears in the export statistics from the UK or in the EUROSTAT statistics, it should be assumed to be an error.
- Importation 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.

- ***Imported MBM was only used as a feed for non-ruminant animals and was processed 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.
- 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.
- 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 cattle (*e.g.* dehydrated pork meal or fishmeal), 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 (*e.g.* gristle meal), 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.

Please note: The international independent working 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 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 (see in annex 'import tables') and is based on the following assumptions:

- The external challenge is dependent on the size of the challenged BSE/cattle system and in particular the size and structure of the cattle population.
- 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 and categorised under the 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 Ton (1000 kilo) 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 the UK at the end of the 1980s, the size of a birth cohort is roughly 2 million cattle. The cohorts with the highest infection level showed cases in about 5% of the cohort (Schreuder *et al.*). Assuming that only 20% of the animals live long enough to become a case, this suggests that about 25% of the cohort had been infected, *i.e.* roughly 500 000 cattle in that year. Annual production of MBM in the UK is a bit less than 500 000 tonnes of MBM (including fish meal). Under "regular" feeding conditions, these 500 000 tonnes led to 500 000 infected cattle. Thus, we conclude that one live animal is comparable to one tonne of MBM. The numbers in this calculation are very rough, which suffices, since we are merely interested in the order of magnitude to compare live animals to MBM.

The comparison is valid for the UK in that period. We extrapolate this number to all other situations, using a worst case assumption for the risk level of MBM, assuming that in the observed case the feeding was similar to that applied in the UK during the 1980s.

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 these animals we define *w* = 1, and one such animal (or Ton 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 + 4000 live cattle having a weighting factor = 0.01 + 10000 Tons of MBM having a weighting factor 0.001 would also constitute 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. Here, two complementary methods are 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 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.

Note:

- The **5-year period** is chosen 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 non-UK EU (EU-15) MBM exports until 1996, it is assumed that 0.1 Tons of MBM is equivalent to 1 live cattle. This was introduced because of the high risk of UK MBM being re-exported by other European countries. Second, for countries with very 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 a long time for the epidemic to reach appreciable prevalence. 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 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
Extremely low	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.

Stability is linked to the basic Reproduction Ratio of the infection (R_0).

- 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 from rendering those tissues (SRM) known to carry the bulk of the infectivity that can be harboured by pre-clinical BSE case. Information on the distribution of BSE tissue infectivity is provided by the updated SSC Opinion on TSE Infectivity distribution in ruminant tissues (SSC, 2002) and by Table 2 originating from the EFSA QRA Report (EFSA, 2004c).

Table 2: **Estimated tissue weights and infectivity levels from adult beef cattle, for an infectivity titre of 5 $CoID_{50}$ per gram in brain of a clinical case**

Tissue	Total mass (g)	Titre: $CoID_{50}$/g	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)
Spleen*	800	0.0005	0.4 (0.01)
Rest of head, excl. skull and brain****	6,500		6.6 (0.16)
All bones, total:	58,000		
All bones, without skull	50,000		
Bones, excl. skull and vertebrae	37,000		
Bone marrow (10% ww)	2,900	0.0005	1.5 (0.04)
Bone adnexa (20% ww)	5,800	0.0005	2.9 (0.7)
Manure, gut content, …	80,000		
Hooves, hide, horns, …	50,000		
Other by-products / offals	129,450		
Consumed (excl. bones)	215,000		
Totals	550,000***		~4160 $CoID_{50}$

* No BSE infectivity has so far been found in the spleen of bovines. As a prudent view, bovine spleen is considered to be possibly infectious, but the infectivity level attributed corresponds to the current limit of detection.

** 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. In the Netherlands for instance the average weight might be considerably lower because of the very large proportion of calves that are slaughtered there.

**** The rest of head is assumed to include the eyes (100g) and the tonsil (50g) both with an infectivity assumed to be 4 logs less than brain from the result for tonsil (0.0005 $CoID_{50}$/g) plus 1.3g of CNS contamination from captive bolt slaughter (Cooper & Bird 2002).

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 pre-clinical infection in fallen stock and casualty 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, 1998).

4.5.2 Rendering

According to the SSC opinion on the safety of MBM (SSC, 1998), 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. 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 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 10 to 20 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, 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 1000 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 uses the fact that the effect of control measures on the R_0 is linear. 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.

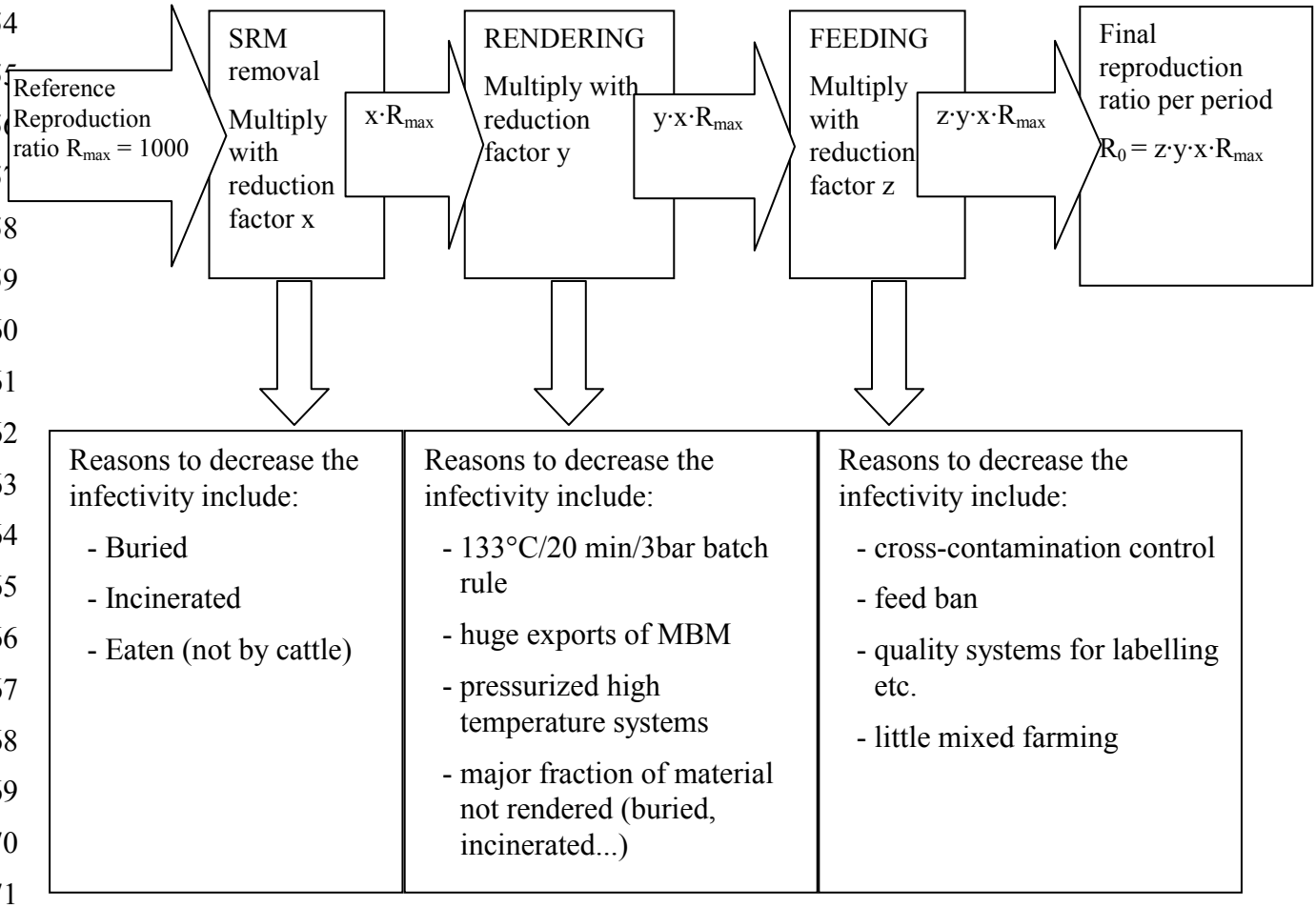


Figure 2. **Schematic overview of the method to analyse stability. This scheme can be worked out into a complete tree if required for more complicated systems.**

Example: 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.

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 the list of SRM of OIE or EU, if fallen stock excluded, and implementation and control of measures guaranteed a maximum reduction factor of 0.001 can be theoretically achieved (SSC, 2002). 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.
- 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 133/20/3 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 information provided by the country.
- If no rendering exists a maximum reduction factor of 0.001 can be applied as no MBM is then produced.

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 is considered the optimum (reduction factor of 0.001).
- For a well-implemented mammalian MBM feed ban to ruminants a reduction factor of 0.01 can be applied.
- For a well-implemented ruminant MBM feed ban to ruminants a reduction factor of 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.

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

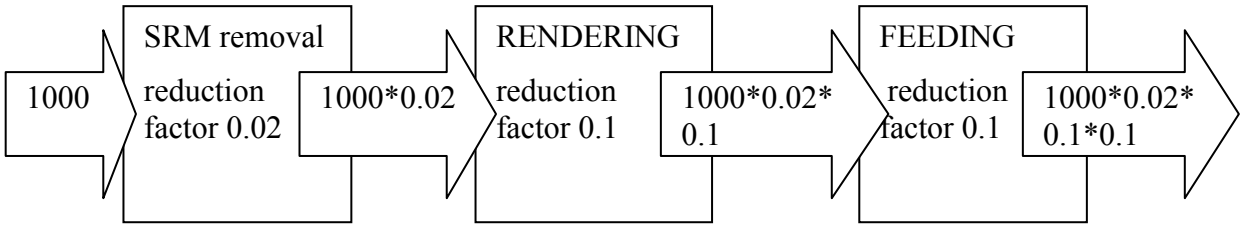
- As long as the basic reproduction ratio is bigger than one, the epidemic will grow, and the system is "unstable".
- When R_0 is close to 1, the infection level will remain constant, and the system is called "neutrally stable". In a neutrally stable system, the recycling rate of the BSE agent would 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	Ro
Stable:	Optimally stable	Very fast	0 to 0.05
The system will reduce BSE-infectivity	Very stable	Fast	0.05 to 0.2
	Stable	Slow	0.2 to 0.5
Neutrally stable		+- constant	0.5 to 2
Unstable :	Unstable	Slow	2 to 5
The system will amplify BSE-infectivity	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 very stable levels of stability 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:

  - A **stable** system that is not or only **slightly challenged**: this is the best situation.
  - A **stable** system that is **highly challenged**: this situation is rather good since the system will be able to remove the BSE agent, over time.
  - An **unstable** system that is not or only **slightly challenged**: as long as the BSE agent is not entering the system, the situation is good. However, the possibility of the BSE agent entering the system and being amplified can occur.
  - An **unstable** system is **challenged**: this is an adverse situation, since the BSE-infectivity will be amplified over time and will lead to an epidemic.

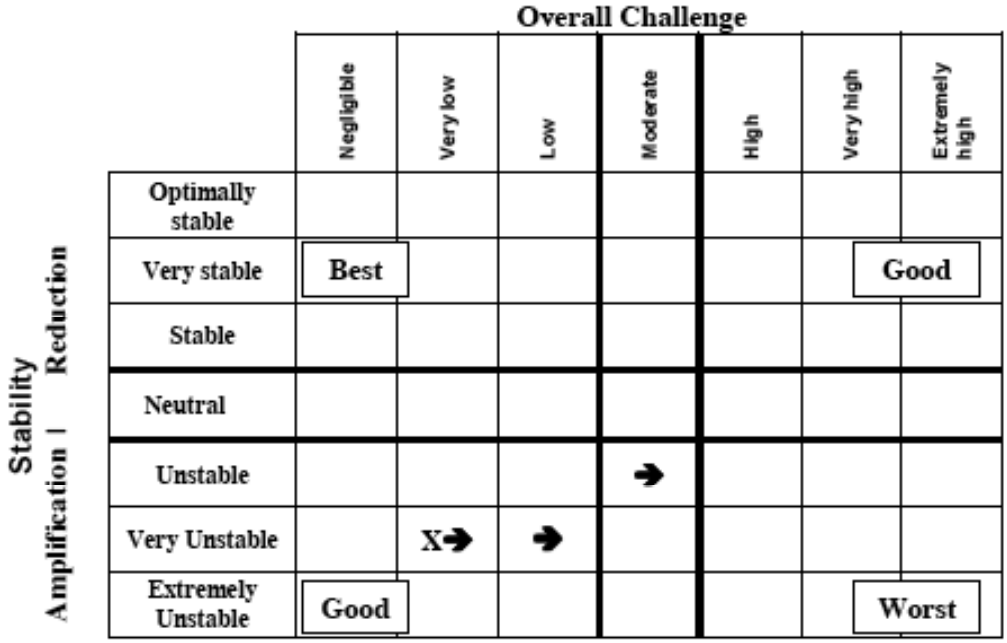


Figure 3: **Combinations of challenge and stability**

4.7.2 Definitions of challenge

The overall challenge is a combination of the external and internal challenges present in a BSE/cattle system at a given point in time.

The external and internal challenges are defined as follows:

- 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, as defined in chapter 4.4 of this document.

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

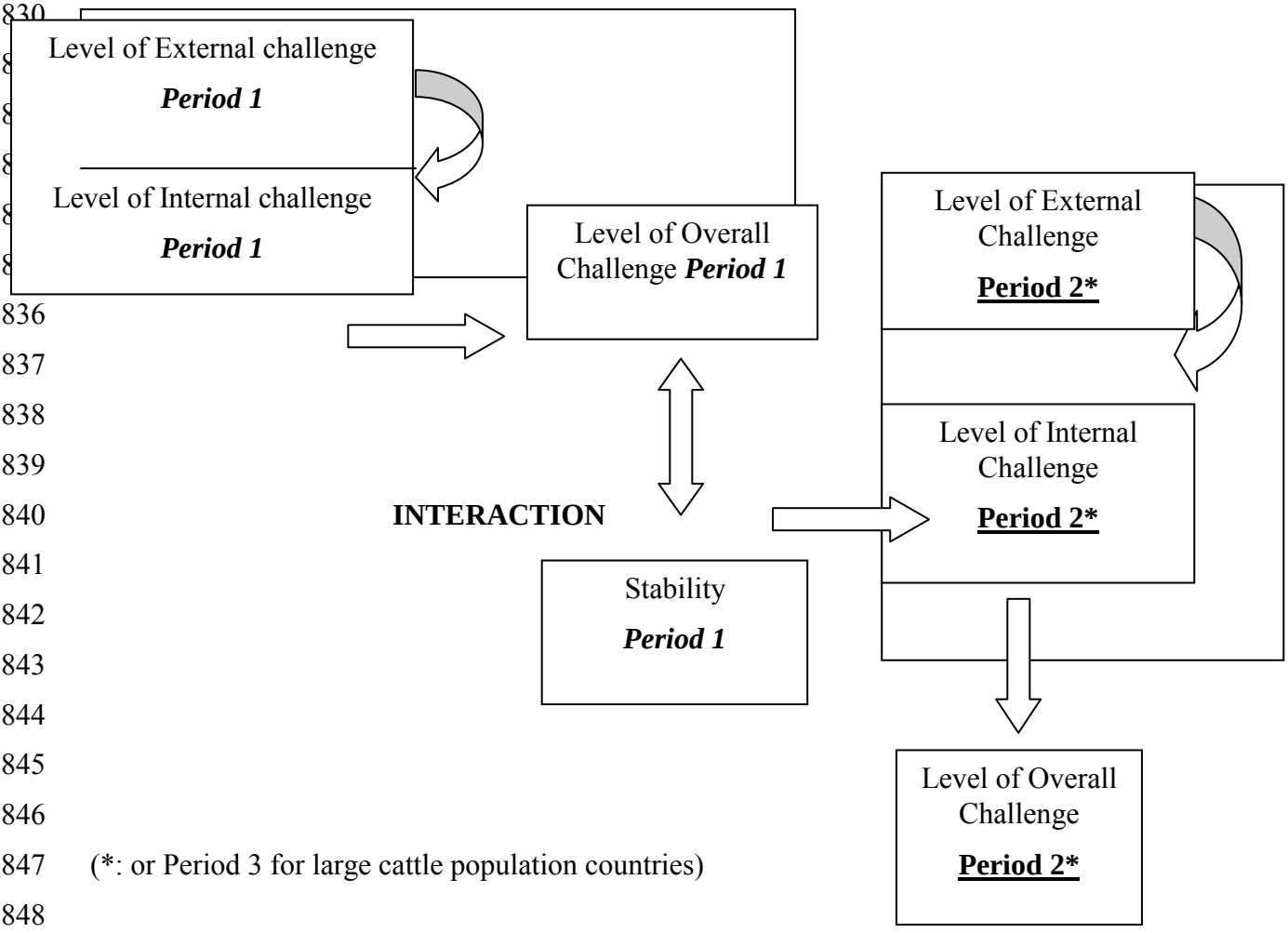
  - If BSE infected cattle are imported, they still need to be processed[6] before the agent can enter the domestic BSE/cattle system.
  - Moreover, their BSE-load is regarded being significant, only if they are approaching the end of the incubation period when they are processed.
  - Given that the average incubation period is 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, on average 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.

6 Processed: meaning cattle slaughtered and rendered for meat and bone meal so this can be fed to cattle.

- 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 the GBR 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, these are likely to become infected. After approximately 5 years (average incubation period) a certain number of them, which have survived until that age, could become clinical BSE cases.

- The internal challenge (IC) is defined in the SSC opinion on the GBR (SSC, 2000) 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 SRMs, 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). This concept is illustrated in Figure 4.

Figure 4: **Evolution of the overall challenge from one period to the next**



(*: or Period 3 for large cattle population countries)

4.7.3 Rules for assessing the interaction between challenge and stability

The interaction between stability and challenge is assessed by a rules based approach. The main goal is to compute any challenge occurring at a period n, and to be able to infer, while using the stability level at period n, the internal challenge that will occur at period n+1.

Then it will be possible, at the period n+1, according to the internal and the external challenges, to evaluate the level of overall challenge for this particular period.

Expressed differently, this approach is using as inputs the external challenge and the stability of the cattle system of one 5-year period, to infer both the resulting internal challenge and the overall challenge of the following 5-year period.

The rules for assessing the interaction between challenge and stability are as follows:

a. An extremely to very unstable system will lead to an upgrade of one level of overall challenge (Table 4). This will occur in the next 5-year period for small cattle population countries (< 20 million cattle) and in the second next 5-year period for large cattle population countries.

b. An unstable system, will lead to an upgrade by one level of the challenge. This will occur in the second next 5-year period for small cattle population countries (< 20 million cattle), and in the fourth next 5-year period for large cattle population countries.

c. In a neutrally stable country, the overall challenge will stay at the same level from one period to the next.

d. A stable system, will lead to a downgrade by one level of challenge. This will occur in the second next 5-year period that the system is stable.

e. An extremely to very stable system will lead to a downgrade of one level of challenge. This will occur in the next 5-year period.

f. When both challenges are on the same level, for an unstable country, their effects add up and the overall challenge may therefore be one step higher in the second next 5-year periods. For a stable country, the overall challenge goes one step lower in the second next 5-year periods.

g. It is assumed that the change in the overall challenge, over time, is on a logarithmic scale. Consequently, the highest level of one of the challenges (either external or internal) can be considered as equivalent to the level of the overall challenge at that particular time.

h. For the same reason, the level of the overall challenge will be equivalent to those of external and internal challenges, when they both share the same levels of challenge (*i.e.* their effect on the level of challenge is not additive).

The following table (Table 4) present the basic rules to use the interaction chart.

889

890 Table 4: **Diagrammatic representation of rules for assessing the interaction between**
891 **challenge and stability**

<table>
<tr><td>LEVEL OF CHALLENGES</td><td colspan="7"></td></tr>
<tr><td>Extremely high</td><td colspan="3">Stay at the same level</td><td rowspan="2">One downgrade of level on the second next 5-year period*</td><td colspan="2" rowspan="2">One downgrade of level on the next 5-year period</td></tr>
<tr><td>Very high</td><td colspan="2" rowspan="5">One level up on the next 5-year period*</td><td rowspan="5">One level up the second next 5-year period</td><td rowspan="4">Stay at the same level</td></tr>
<tr><td>High</td></tr>
<tr><td>Moderate</td></tr>
<tr><td>Low</td></tr>
<tr><td>Very low</td></tr>
<tr><td>Extremely low</td><td colspan="4">Stay at the same level</td></tr>
<tr><td>STABILITY LEVELS</td><td>Extremely unstable</td><td>Very unstable</td><td>Unstable</td><td>Neutrally stable</td><td>Stable</td><td>Very stable</td><td>Optimally stable</td></tr>
</table>

892 (*: for large cattle population countries, the level goes up or down on the second next 5-year period. The stability taken into account to
893 assess the overall challenge is the one for the second next-5 year period).

894 *4.7.4 Example*

895 An example is worked out and presented in Annex V.

4.8 Overall challenge and new EFSA GBR categorization

Table 5 below gives the equivalence between the overall challenge and the new different GBR categorization.

Table 5: **Equivalence between the overall challenge and the new different GBR categorization**

Level of Overall Challenge	Estimated number of risk units	EFSA GBR categorization
Extremely high	≥10,000	Likely
Very high	1,000 -<10,000	
High	100 -<1,000	
Moderate	20 -<100	
Low	10 -<20	Unlikely
Very low	5 -<10	
Very Low	0 -<5*	

* The risk unit as defined in this opinion is one cow with a 5 % probability of being infected.

The difference between likely and increasing, and likely and decreasing will be given according to the evolution of the stability of the country and the challenges occurring over time.

4.9 Surveillance and its contribution

4.9.1 General comments

In general, surveillance through its detection component is aimed at demonstrating the absence of disease or infection or determining the occurrence or distribution of disease or infection. The type of surveillance applied depends on the desired outputs needed to support decision-making.

Surveillance systems for BSE can have one or more goals, depending on the risk category of a country. 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
- 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 was taken into account, however, this factor had very little impact on the final assessment of the GBR in terms of preventing the introduction and spread of the BSE agent. In some cases it influenced, marginally, the assessment of the stability.

4.9.2 Some points concerning surveillance data and their use in the EFSA GBR methodology

- Relevant surveillance data can be taken into account for countries with overall challenge and stability resulting in an unclear outcome of the risk.
- The lack of surveillance data will not be used to change the final outcome of countries with a negligible external challenge and subsequently an unlikely BSE risk.
- Also surveillance data will not be used to change the final outcome of countries with a high external challenge combined with an (very/extremely) unstable system.

In general available surveillance data can be used to support the outcome of the assessment, in particular for confirming an increasing or decreasing trend of the BSE risk.

4.9.3 Evaluation of surveillance systems capable of estimating the prevalence of BSE infection

As indicated above, if yearly prevalence data are available 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 auditing, *e.g.* determining if SRM are removed from carcasses and disposed of appropriately. 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 this is a relatively expensive exercise. However, a number of countries notably of the EU have invested a great deal in extensive surveillance programmers. The BSurvE model does allow the synthesis of the results of the testing 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.

It is not possible to prove that a country is free of any disease by surveillance alone. To prove that a country is free of disease all animals must be tested with a test with perfect diagnostic sensitivity and yielding negative results, and 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 disease freedom of a population or a country.

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.

5. DOCUMENTS PROVIDED TO EFSA

EFSA, (2004). European Food Safety Authority, 25 October 2004, ref HK/sm(2004) 872. Letter with Terms of Reference for Self task EFSA on the update of the GBR methodology.

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ANNEX I

INTERPRETATION OF THE TERMS OF REFERENCE

In deliberating the terms of reference the working group/Biological Hazards Panel noted the following points:

A. Experience gained from previous GBR-assessments

1. The GBR methodology as developed by the Scientific Steering Committee (SSC) and used up to now by the SSC GBR Peer group and the EFSA GBR expert group was found to be a helpful and evidence based assessment tool for assessing the BSE risk in cattle of a country.

2. The SSC GBR methodology worked well for assessing the risk from cattle and MBM exports from Category 3 European countries. However, the risk from exports from countries with a low BSE prevalence and large cattle populations was overstated and this needed to be corrected.

3. The assessment of the stability needed to be more flexible to allow for partial improvements in stability to be taken into account. For example, under the SSC GBR methodology, a rendering system was only considered to be ok if it was operating at 133 degrees, 3 bar for 20 minutes. While these are the recommended operating conditions, it should be recognized in the assessment of the stability in the GBR methodology that conditions such as a temperature of 120 degrees at rendering will also lead to an improvement in stability.

4. The SSC GBR method was geared to identify or predict a potential first case in a certain country but the future GBR method should also allow the expert group to assess "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.

5. The SSC GBR method could benefit from an increased transparency, *i.e.* the tables in the report did not reflect the actual inputs as taken into account but were the *raw data*. The tables with the *final data* were not included in the report. However, an explanation was provided in the body of the report where an indication was given that certain animals or MBM imports were deducted from the risk factors. Adding a table with the final data of the imported commodities taken into account in the risk assessment may increase the transparency of the reports.

6. The GBR classification of countries will change over time depending on their imports of cattle and MBM and their stability. In turn, the risk posed by exports from those countries could have a domino effect on the GBR classification of their trading partners. The BSE-cases, confirmed in Austria, Finland, Sweden and Slovenia that were initially classified as GBR II, underlined the appropriateness of this statement. The explanation for these cases was that imports into these countries from GBR III countries were not regarded as external challenge when the GBR of these countries was assessed. Therefore there is a need for an ongoing reassessment of the GBR of individual countries.

It was concluded that for an update of the GBR methodology, the following points in particular would need to be clarified:

a. General:

- Type and quality of data that is needed from the country being assessed
- Assessment of the possible other transmission routes

b. External challenge assessment

- Indication of criteria for exclusion/inclusion of imports of animals and MBM
- Determination of the time when an internal challenge became possible (R1) or likely (R2) in the exporting country
- Determination of the time when the internal challenge decreased from R2 to R1, and the possible development of a newly defined risk period.
- The inclusion of a dilution factor for the more realistic evaluation of the risk due to introduction of BSE infectivity in a large cattle population by using an extended R1.
- Surveillance systems of the exporting countries.
- Stability of the exporting countries e.g., determination whether a challenge originating from a GBR category 3 country outside of Europe represents a similar challenge as the challenge from a GBR category 3 country within Europe.
- Estimation of the risk from exporting countries when they are not yet formally categorised

c. Stability in the country being assessed

- Overall appreciation of the ability to prevent recycling and entry, and overall assessment of the stability; especially the effect of different control measures e.g. MBM ban, SRM removal.

d. Surveillance in the country being assessed

- Assessment of the surveillance system of the country being assessed and its results

e. GBR categorisation

- Appropriateness to have 4 categories as defined in the current GBR methodology
- Criteria for improving the GBR classification over time
- Appropriateness to define BSE risk status for compartments of animals and its relationship to the classification of a geographical area.

B. New information and methods available – epidemiology and surveillance

1. Since 2001 BSE surveillance has been intensified in many countries which give a better perspective of geographical risk.
2. BSE surveillance software, BSurvE, has been developed to analyse the results from the TSE surveillance in the EU and to design the most cost effective surveillance. The generic idea is that all surveillance results are weighted in a points system and that the necessary points can be achieved by surveillance in healthy cattle, fallen stock, emergency slaughter and clinical suspects. This tool enables a better assessment of the surveillance and planning of the most cost effective surveillance given a certain design prevalence, and also to validate the results of the risk assessment, albeit retrospectively.

3. Consideration of developments in EU policy and the OIE methodology

1. The European Commission's TSE Roadmap published in July 2005 clarified the objectives of the EU for TSE control policies (EC, 2005). These include (a) a reduction in the number of tested bovines without sacrificing the epidemiological information to be gained, thus still continuing to measure the effectiveness of the measures in place and (b) better targeting of the surveillance activities. The Roadmap also includes the strategic goal for BSE Risk Assessment for different countries, namely, "Simplification of the categorisation criteria and conclusion of the categorisation of the countries before 1 July 2007". The Roadmap notes that the objective of a categorisation system according to the BSE risk is to define trade rules that afford the necessary guarantees to protect animal and public health for the importing countries. The Roadmap further states that the conditions for such trade are already laid down in the current recommendations of the Terrestrial Animal Health Code ("Code") of the World Organisation for Animal Health (OIE).

2. The CVO/ EU Parliament dialogue September 2005 concluded that the BSE classification should be based on OIE guidelines wherever possible. In line with this conclusion, the EFSA considered that an updated GBR assessment method should as much as possible match the outline of the OIE already presented with the intention to harmonize with the existing method. However, it was noted that OIE takes both risk assessment and risk management parameters into account. The EFSA Biological hazards panel greed that the EFSA GBR methodology would only deal with the risk assessment elements.

3. The approach of OIE is documented in Chapter 2.3.13 of the OIE terrestrial animal health code (the general and new BSE Surveillance Chapter of the OIE (OIE, 2005). At the OIE General Session in May 2006, an agreement was reached on the simplified categorisation procedure including the requirements on surveillance within the different categories. OIE Classifications will be based on a risk assessment, a functioning MBM ban to ruminants, the presence of indigenous cases and the quality of the surveillance. The categorisation procedure includes three categories:

   Category 1: Countries with a **negligible BSE risk** and surveillance programme detecting a design prevalence of 1 per 50,000. The country must have had a functioning ruminant meat and bone meal ban for at least 8 years and no indigenous case of BSE born within the last 11 years.

   Category 2: Countries with a **controlled BSE risk** and surveillance programme detecting a design prevalence of 1 per 100,000. The country must have a functioning ruminant meat and bone meal ban.

   Category 3: Countries with an **undetermined BSE risk**.

Based on this new OIE standard the current provisions under the TSE Regulation will be amended. Following adoption of the new categorisation criteria, the countries will be categorised starting with the major trading partners. EC indicated (as mentioned in the TSE road map) that it considers OIE should play a major role in these re-assessments. Following this self-tasking mandate, EFSA received further input and clarification from the EC in a letter from DG Sanco (D(2005)/KVD/cin/42 1007, 20-10-2005) clarifying the EC's intention to ask the OIE to take the lead in this work. However, the letter further states that in the event that OIE fails to assess all countries or these assessments are significantly delayed, EFSA would be the most appropriate body to carry out these risk assessments.

ANNEX II

COMPARISON OF GBR METHOD AND OIE METHOD ASSESSING GEOGRAPHICAL RISK FOR BSE IN A COUNTRY.

1. General Comments

OIE has not developed a new method, rather given guidelines as what parameters should be taken into account when carrying out a RA. Not included in the OIE is the surveillance data.

The OIE – Terrestrial Animal Health Code, section on Risk Analysis (section 1.3) outlines methods for the risk assessment as they are related to issues for the importation of animals or animal products. The OIE identifies the components of the risk analysis process as: hazard identification, risk assessment, risk management and risk communication. The risk assessment is the component of a risk analysis that estimates the risk associated with a hazard. Risk assessment methods should be chosen in relation to the specific situation. They may be qualitative or quantitative.

The method for the assessment of the (*European Commission initiated and taken over by the European Food Safety Authority*) Geographical BSE-Risk (GBR) is one of the possible qualitative methods that can be used for the risk assessment component of this process. It is an innovative approach, however, using terminology somewhat different to those applied in the risk assessment literature and the OIE-chapter on risk analysis. The method for the assessment of the GBR is comparable to the OIE-guidance on risk analysis and in particular the chapter on risk assessment.

2. Comparison of BSE-status according to OIE and GBR Categorisation

The OIE International Animal Health Code, Chapter 2.3.13 related to BSE, adopted May 2005, states that the status of a country or zone should be determined from the outcome of a risk assessment.

The release assessment required according to the OIE-guidance and described in Article 2.3.13.2., could be compared with the assessment of the external challenge and the internal challenge and their interaction as described in this opinion. The GBR assessment is still completed even if the risk of an external challenge has been identified as negligible. This is contrary to the OIE-guidance that conducts the exposure assessment only, if the release assessment identifies a risk factor. The GBR approach is justified by the high degree of uncertainty with the epidemiology and biology of the BSE-agent as well as with its monitoring and surveillance. The GBR method attempts to address the stability of the assessed BSE/cattle systems as a means to establish its capacity to resist future challenges that are currently unknown.

The assessment of the inherent stability of a given BSE/cattle system with regard to BSE might be compared, to a certain degree with an analysis of the pathways needed to allow the exposure of animals to BSE. In an unstable system the pathways are open and would lead to exposure whereas in a stable system the risk of exposure occurring is much lower because the pathways are closed. Typically, a pathway assessment would depend on the specific situation and could, according to the OIE, vary from country to country. The GBR-method applies systematically one model of the BSE/cattle system that describes the pathways in a fully

transparent and standardized manner. This provides a basis for obtaining comparable results in different countries.

The GBR-method derives a similar end-point as an exposure assessment described in the OIE-guidelines for risk assessment: it provides a qualitative estimation of the likelihood of the exposure to an identified hazard (the BSE-agent), at a given point in time. However, the SSC-method requires assessing the consequences of past exposures, in the GBR-terminology the internal challenges, which together with the external challenges again interact with the stability and create a new exposure situation.

The GBR method tries to cover the last twenty years in view of the long incubation period of the disease and its initially apparent slow progress. However, this long retrospective period leads to poor quality data especially from the early stages (1980s). Therefore a shorter period covering only approximately two incubation periods (i.e. 10 years) could be envisaged in the GBR to increase the quality of the data. This would be somewhat in line with the time frame of the OIE that a country has to be controlled (8 years for a functioning MBM ban and no indigenous case of BSE for the last 7 years) to become “negligible” status.

Because of the importance of the time dimension in this delayed process the GBR-terminology seems to be more adequate to describe the positive feed-back loop that is responsible for the BSE risk than the more static terms used in conventional Risk Analysis and Risk Assessment.

3. Methods and parameters

The GBR-risk assessment is well in keeping with the recommendation in the BSE-chapter of the OIE code. There it is requested to include all factors that could have led to a risk of introducing or propagating the BSE agent in the country/region under consideration. This list is in fact very similar to the list of risk factors used by the SSC.

According to the BSE-chapter of the Terrestrial animal health code of the OIE, it has to be evaluated whether potentially infected material was imported, and, in such a case, whether the conditions in the country were/are sufficient to cope with potentially infected material, i.e. to prevent the disease being propagated. This is, indeed, exactly the objective of the GBR-method.

The points to consider for the BSE-risk assessment are described in the BSE-chapter and in detail in the “OIE-Guidelines on the factors to consider in conducting the bovine spongiform encephalopathy risk assessment”. However, since the adoption of the new BSE-chapter, these guidelines are not up-to date.

The OIE’s list of factors that should be taken into account when analyzing the release-risk includes some more factors than the GBR approach (Table 1). The list of factors for the exposure risk shows no differences.

From Table 1 below it appears that there is a close similarity between the relevant factors identified by OIE and those being used by the SSC to assess the GBR. Some factors are not addressed by the (SSC/EFSA) GBR-method because they are either judged insignificant compared to the other factors or reliable data are not available.

84 Table 1. **Factors to consider in the release assessment; comparison of OIE and GBR**

OIE	GBR	Remark
Release assessment		
the presence or absence of animal TSE agents in the country or zone or compartment and, if present, their prevalence based on the outcomes of surveillance		the SSC does not take account of other animal TSEs because (a) the available data were very poor and (b) the link with BSE is not scientifically established, even for scrapie;
meat-and-bone meal or greaves from the indigenous ruminant population	Taken into account in the exposure assessment and not in the release assessment	
Imported meat-and-bone meal or greaves	imported meat-and-bone meal or greaves (only taken into account : custom code 2301) not other codes…*e.g.* giving bones to animal as a source of phosphorus eg South Africa, dried bones, clean…if pure not risk – is basically a control issue. *E.g.* if VC is included, or skull with brain is included.	MBM-imports are the most important part of the external challenge which is assumed by the GBR to be the only initial source
While cattle imports are an essential element of the external challenge assessment, the GBR does not take account of other animals like sheep and goats as the risk via these animals is regarded to be insignificant in comparison to the import of MBM and infected live cattle + the SSC does not take account of other animal TSEs because (a) the available data were very poor and (b) the link with BSE is not scientifically established, even for scrapie);		
Imported animal feed and feed ingredients – no clear custom codes so nearly impossible to found out the real commodity.		Due to lack of data the GBR currently did not take account of feedstuff-imports
Imported products of ruminant origin for human consumption, which may have contained (SRM) tissues listed in Article 2.3.13.13., and may have been fed to cattle;		The GBR did not take into account, because it is nearly impossible to find out
Imported products of ruminant origin for in vivo use in cattle – no idea what is meant here by OIE – probably vaccines, hormones…		The GBR did not take into account, because it is nearly impossible to find out
Surveillance and other epidemiological investigations (especially surveillance for BSE conducted on the cattle population) relevant to the above	Surveillance and other epidemiological investigations	

4. Additional parameters for OIE status

The OIE requests moreover to the risk assessment that several measures, and their date of effective implementation ("relevant period of time"), should be considered when determining the BSE status (Table 2).

Table 2: **Comparison of OIE status and GBR**

	OIE	**GBR**
Objective	Status	Risk assessment
To consider	Risk assessment **and** - on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Appendix on BSE surveillance - the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE; - the examination in an approved laboratory of brain or other tissues collected within the framework of the surveillance and monitoring system. - Surveillance* (Type A or B)	Risk assessment

*When the risk assessment (which takes into account the surveillance referred to in the release and exposure assessments above) demonstrates non-negligible risk, the country should conduct Type A surveillance in accordance with Appendix on BSE surveillance.

*When the risk assessment (which takes into account the surveillance referred to in the release and exposure assessments above) demonstrates negligible risk, the country should conduct Type B surveillance in accordance with Appendix on BSE surveillance.

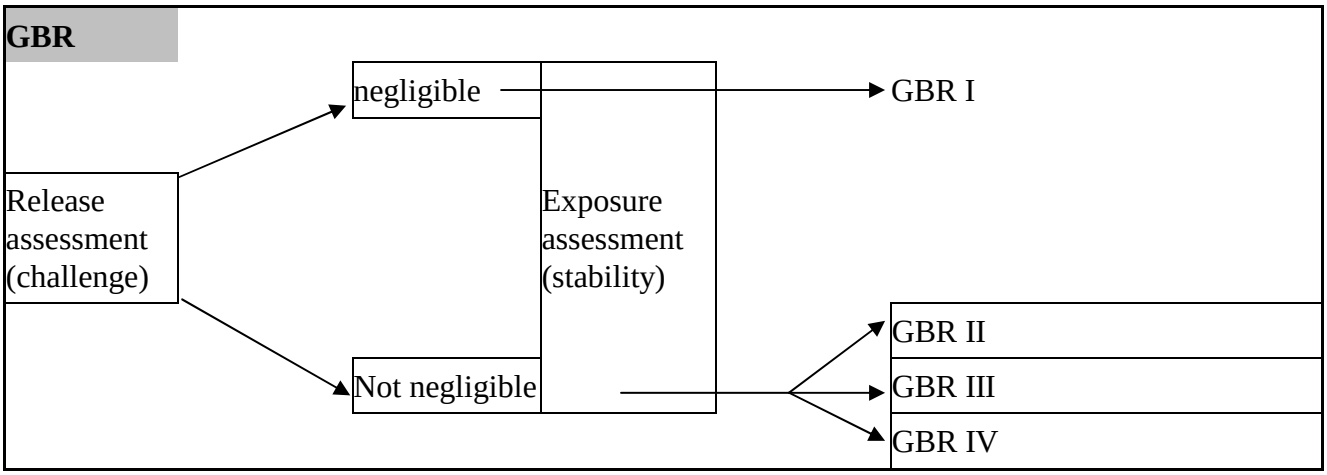
The (SSC/EFSA) SSC-method, however, considers them together with the other risk factors as part of the risk assessment.

5. Foreseen use of GBR in the OIE context

The GBR-risk assessment takes into account most of the parameters described by the OIE.

Additionally to the risk assessment part, the OIE considers several other factors to determine the BSE-status. Therefore, countries assessed as "negligible risk" (according to GBR, GBR I countries) could be categorized based on the OIE-chapter, taken into account further parameters *i.e.* controlled or undetermined risk.

106 **Figure 1**



107

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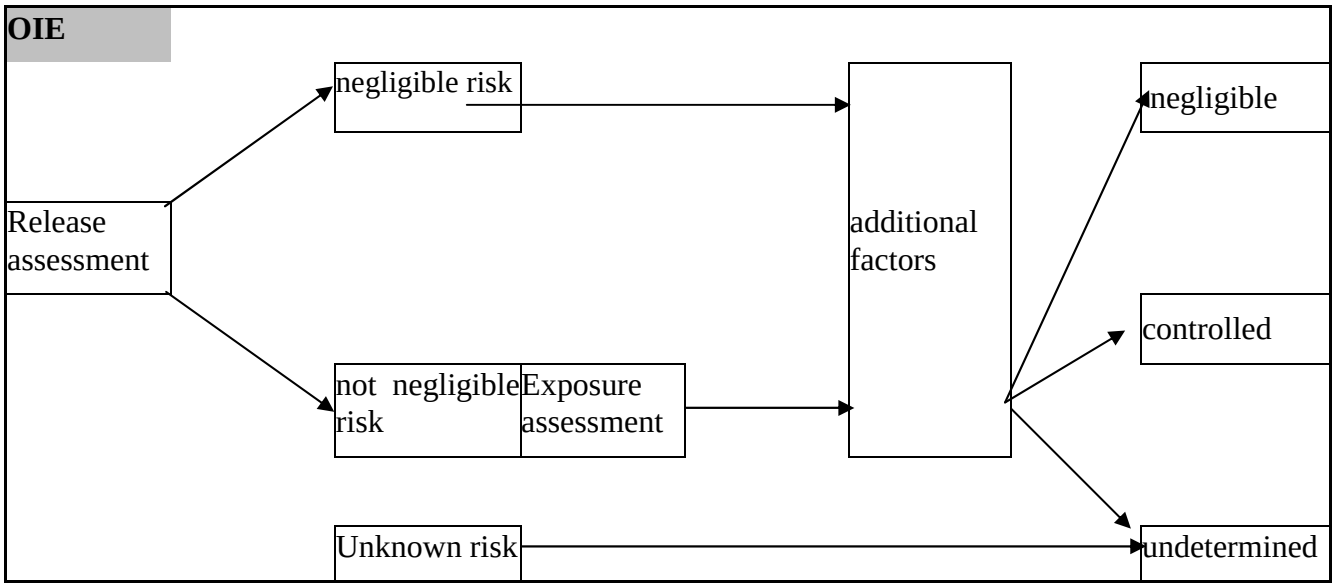
109 **Figure 2**



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ANNEX III

EFSA GBR – compared to SSC GBR

In the EFSA GBR the gist of the change in comparison with the SSC GBR is to analyse the data whenever possible quantitatively, while the rules based assessment is a fallback procedure if a quantitative assessment is not possible *i.e.*, relevant data is not available..

1. Changes of external challenge assessment

In the SSC GBR methodology the magnitude (indicated as R values) of the external challenge was regarded independent from the size of the challenged BSE/cattle system and in particular the size and structure of the total cattle population.

In the EFSA GBR methodology, this aspect is taken into account by using different weighting factor (*w*) values (instead of the R values used in the SSC GBR) depending on the size of the challenged bovine population, including two population sizes: (1) more than 20 million cattle and (2) less than 20 million cattle. For a not very high challenge with no change in the stability in the exporting country, the progression period to a higher *w* value is extended by one 5 year period for countries with a very large cattle population (more than 20 million of cattle): so the *w* weighting factor increases in that case only after two 5 year periods instead of one 5 year period (*i.e.*, from R1 to R2) in the former SSC GBR methodology.

In the SSC GBR methodology, the external challenge was assessed in a global way. In the EFSA GBR methodology, the external challenge is assessed in three clearly defined steps:

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

The same approach as in the SSC GBR methodology is followed, but imports from countries that have not been assessed before might be considered as posing a risk due to imports from BSE risk countries and this can be taken into account as external challenge.

- Step 2: Determination whether the imports entered the BSE/cattle system.

Although in the former SSC GBR methodology, some possibility for deduction were mentioned (i.e. cattle slaughtered under the age of 24 months), now it is clearly stated that 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 for deduction. In cases where the available information indicates but does not conclusively show that the animals or MBM did not enter the fed chain, only a proportion of the imports may be deducted depending on the quality of the data. This was not possible under the SSC methodology.

The acceptable and unacceptable reasons for the exclusion are in the EFSA GBR methodology clearly defined, both for live cattle and MBM.

- Step 3: Estimation of the level of infectivity in the imported material.

In the EFSA GBR methodology, not only the number of live cattle exported from BSE risk countries is taken into account, but also the type of intervention measures that are taken by the exporting country to prevent the spread of the agent to live animals ad subsequent to the animal products. A new terminology , instead of the “R” values used in the SSC GBR methodology, for the scaling of the external challenge is introduced; *w* or weighting factor, whereby if *w* =1, this represents 1 “Risk Unit”. This *w* value can be estimated using BSurvE or another appropriate method if yearly prevalence estimates are available for the exporting country. Otherwise an estimation based on a rules system is proposed. Weighting factors are calculated taken into

account the risk from imported live cattle and MBM, ranging from 0 (very low) up till = or > 10.000 (very high)

2. Changes of stability assessment

As for the assessment of the impact of SRM removal, fallen stock and feeding in the EFSA GBR methodology a semi-quantitative approach is proposed, using the most recent data on BSE infectivity distribution in an infected bovine, as well as the updated results from the attack rate studies are taken into account, i.e. the fact that as little as 0.1 g and probably also 0.01 g of infected brain is enough to infect cattle orally. In the SSC GBR methodology, only a qualitative approach was used (OK, reasonable OK, not OK).

In contrast with the SSC GBR methodology, in the EFSA GBR methodology, also the basic reproduction ratio of infection of BSE is assessed, taking into account the three main stability factors SRM removal, rendering and feeding.

A tree approach is developed, in which a reduction factor for each of the main control measures is multiplied, resulting in the calculation of the total effect of all the control measures together. This result represents basically the basic reproduction ratio.

The reduction factors are defined for the different levels of application of the three control measures:

- SRM removal: reduction factor between 1 (no SRM removal) and maximum 0.01 (full compliance, including control measures, of OIE or EU SRM list and exclusion of fallen stock).
- Rendering: reduction factor between 0.1 (atmospheric pressure) and maximum 0.001 (133/20/3 fully applied or no rendering).
- Feeding: reduction factor between 0.2 (= UK pre 86, 20% of MBM production fed to cattle) and 0.001 (optimal feed ban).

3. Changes in categories of assessments

The table below provides an overview on the evolution of the SSC GBR methodology over time (1998-2002) based on revisions carried out by the Scientific Steering Committee (SSC)

72 Table: **Overview on the evolution of the SSC GBR methodology over time based on revisions carried out by the SSC (1998-2002)**

	January 1998	April 1999	July 2000	January 2002
GBR-definition	No definition provided	The combined probability that the BSE-agent is currently and in the foreseeable future present in the native cattle herd, and currently and in the foreseeable future one or more BSE-infected native animals per year enter processing in that geographical area.	A qualitative indicator of the likelihood of the presence of one or more cattle being infected with BSE, pre-clinically as well as clinically, at a given point in time, in a country. Where presence is confirmed, the GBR gives an indication of the level of infection	As in July 2000
GBR-levels	No levels provided	No levels provided	GBR levels I-IV introduced	As in July 2000
Factors assessed	1. Structure and dynamics of the cattle, sheep and goat populations; 2. Animal trade; 3. Animal feed; 4. Meat and bone meal (MBM) bans; 5. Specified bovine offals (SBO) and specified risk materials (SRM) bans; 6. The surveillance of TSE, with particular reference to BSE and scrapie; 7. Rendering and feed processing; 8 BSE and scrapie related culling	1. Structure and dynamics of the cattle population; 2. Cattle trade; 3. Cattle feed; 4. Meat and bone meal (MBM) bans; 5. Specified bovine offals (SBO) and specified risk materials (SRM) bans; 6. The surveillance of BSE; 7. Rendering and feed processing; 8. BSE related culling	Clarification that -semen and embryos - other TSE are not (and never were) taken into account. Clarification of the importance of cross- contamination.	As in July 2000
Definition of "external challenge"			Imports via infected MBM or live cattle from BSE affected countries (where BSE-cases have been reported). Guidelines for external challenge assessment introduced.	Imports from all BSE-Risk countries. BSE-Risk countries are all countries already assessed as GBR III or IV or with at least one confirmed domestic BSE case. Guidelines for external challenge assessment updated to take account of different BSE-risk levels in exporting countries and at the moment of export.

	January 1998	April 1999	July 2000	January 2002
Definition for "stability"			Ability to reduce BSE infectivity circulating in the BSE/cattle system under assessment. The degree of stability is depending on the ability to identify BSE-infected cattle and exclude them from processing and the ability to avoid recycling of the BSE agent via feed. Guidelines for stability assessment introduced.	As in July 2000

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ANNEX IV

QUESTIONNAIRE FOR THE PROVISION OF INFORMATION NEEDED FOR THE ASSESSMENT OF THE EFSA GEOGRAPHICAL BSE RISK (GBR) OF A GIVEN COUNTRY OR REGION

Explanatory note:

To put this questionnaire into context, consideration of the following documents is recommended:

1. Commission Recommendation of 22 July 1998 concerning the information necessary to support applications for the evaluation of the epidemiological status of countries with respect to transmissible spongiform encephalopathy (98/477/EC)
   http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_212/l_21219980730en00580061.pdf
2. Annex II to the TSE-Regulation (EC) No 999/2001.
   http://europa.eu.int/comm/food/fs/bse/bse36_en.pdf
3. Opinion of the Scientific Steering Committee (SSC) on the GBR of 6 July 2000:
   http://europa.eu.int/comm/food/fs/sc/ssc/out113_en.pdf
4. Update of the SSC Opinion on the GBR of 11 January 2002:
   http://europa.eu.int/comm/food/fs/sc/ssc/out243_en.pdf
5. EFSA Opinion on an updated GBR methodology:
   http://www.efsa.eu.int/science/biohaz/biohaz_opinions/No_en.html

- A chronological list and overview on the EU legislation on BSE can be found at:
  http://europa.eu.int/comm/food/fs/bse/legislation_en.html#general%20framework
- Previous outcome of the GBR assessment on countries assessed by the former SSC:
  http://europa.eu.int/comm/food/fs/sc/ssc/outcome_en.html
- The outcome of the GBR assessment on countries assessed by EFSA:
  http://www.efsa.eu.int/science/tse_assessments/gbr_assessments/catindex_en.html

Information useful when completing this questionnaire:

- It would be appreciated if all information could be provided in English. This will allow timely consideration of the information and finalisation of the assessment.

- This questionnaire may be requested electronically from, and response to this questionnaire would be preferable also be submitted in electronic form to, the following e-mail address: *efsa-gbr@efsa.europa.eu*

- Please supply a contact address of the responsible authority for the applicant country using the following template:

Country:
Responsible Authority for filing this questionnaire (Please specify the complete name of the authority or agency and postal address):
Contact Person(s) (name and postal address) for additional clarifications/information:
Telephone:
Fax:
E-Mail:

Please send an electronic copy of the completed questionnaire to efsa.gbr@efsa.europa.eu

Information other than in electronic format can be sent to the following address :
European Food Safety Authority (EFSA)
BSE/TSE Unit, GBR assessments
Largo N Palli, 5/a
43100 Parma, Italia
Fax number : +39 0521 036 153
In case information is needed this can be obtained from :
Dr. Bart Goossens, +39 0521 036 218
Bart.Goossens@efsa.europa.eu
Or via efsa.gbr@efsa.europa.eu

1. INFORMATION ON "EXTERNAL CHALLENGE"

1.1. Imports of cattle

The GBR is based on the assumption that the BSE agent has to be imported, i.e. a domestic system has to be exposed to an external challenge. Live bovines are one of the imports that could carry the agent. It is therefore important to have as much as possible complete data of the imports

The assessment of the external challenge is carried out in three stages. In the first stage, information is compiled on all cattle imports from BSE risk countries. In the second stage, only those cattle that could have contributed to the exposure of domestic cattle are included. In the third stage, an assessment is made of the level of infectivity in the imported material.

Please provide information on the importation of

- all live bovine animals from all countries from 1980 if possible (at least from 1986) and in addition
- fill in the excel sheet named: "**ANNEXES 1-3_IMPORTS from BSE risk countries.xls**"

In sheet 1 ("cattle raw data") of this excel file, please provide information on the number of cattle imported from the countries listed (BSE risk countries) in this sheet. This information should be grouped by country of origin and year of import. The numbers in each cell should correspond with EUROSTAT cattle export data if the animals originated from an EU country and with the official cattle export figures for other countries of origin. If the numbers do not correspond, please provide a detailed explanation for the difference with documentary evidence if available.

Please note that if you have already provided information on the number of imported cattle for a previous assessment, it is included in sheet 1 and it is only necessary to provide additional data that has become available since the previous assessment.

In sheet 2 ("cattle final data"), please insert in each cell, the number of cattle for which rendering into feeding stuffs cannot be excluded and which could have led to the exposure of domestic cattle to the BSE agent. Reasons for exclusion should be provided, with documentary evidence where available, for each group of cattle that are excluded from this sheet. Acceptable reasons for the exclusion of cattle from sheet are provided in section 6.4.2.1 of this EFSA GBR methodology.

If you have had a previous assessment, the number of cattle that contributed to the exposure of domestic cattle has already been estimated. In that case, it is only necessary to provide additional data for recent years that has become available since the previous assessment.

1.2. Export of cattle

Please use Sheet 1 of the provided excel file named "EXPORTS to other countries-EFSA.xls"

Please include, as far as possible, information on the type of the exported cattle.

1.3. Import of Meat and Bone Meal

Processed ruminant protein is considered to be the most important, if not the only transmission vehicle for BSE. It is therefore important to have as much as possible complete data of the imports.

In the international customs statistic there is only one category (230110) that clearly refers to material of the above-mentioned type: "Flours, meals and pellets made from meat and offal, greaves; not fit for human consumption". For the purpose of the GBR all materials listed under this category are called "MBM". This term therefore refers hereunder to Meat and Bone Meal as such, but also to Meat Meals, Bone Meals, and greaves.

Please provide information on the importation of

- MBM from all countries from 1980 if possible (at least from 1986) and in addition
- fill the excel sheet named:
  "ANNEXES 1-3_IMPORTS from BSE risk countries-EFSA.xls"

In sheet 3 ("MBM raw data"), please attach information on the quantity of MBM imported from the countries listed (BSE risk countries) in this sheet. This information should be grouped by country of origin and year of import. The quantities should correspond with EUROSTAT export data under code 230110 if the MBM originated from an EU country and with the official export figures under code 230110 for other countries of origin. If the numbers do not correspond, please provide a detailed explanation for the difference with documentary evidence, if available.

Please note that if you have already provided information on the quantity of imported MBM for a previous assessment, it is included in sheet 3 and it is only necessary to provide additional data that has become available since the previous assessment.

In sheet 4 ("MBM final data"), please insert in each cell, the number of tons of MBM that could not be excluded, with certainty, from use as a cattle feed. Reasons for exclusion should be provided, with documentary evidence where available, for each quantity of MBM that is excluded from this sheet. Acceptable reasons for the exclusion of MBM from sheet 4 are provided in section 6.4.2.3 of this EFSA GBR methodology.

Please note that if you have had a previous assessment, the number of tons of MBM that could not be excluded from use as a cattle feed has already been estimated and is inserted in the appropriate cells in sheet 4. In that case, it is only necessary to provide additional data that has become available since the previous assessment.

1.4 Export of MBM

Please use Sheet 2 of the provided excel file named "EXPORTS to other countries-EFSA.xls"

Please include, as far as possible, information on the type and composition of the exported MBM.

2. INFORMATION ON "STABILITY"

The second element that the EFSA GBR method takes into consideration is the stability of a domestic system. This is defined as its ability to avoid the BSE agent being recycled and amplified.

2.1. Feeding

Given the fact that feed is assumed to be the most important, if not the only transmission route of BSE, a complete view on the feeding of bovines in the assessed countries is essential.

It is assumed, for the purpose of the GBR assessment, that all bovines received some feed that contains MBM unless demonstrated otherwise.

In order to better estimate the probability that cattle were exposed to such feeds, please provide the information requested below.

2.1.1. Composition of bovine feed

Give a detailed description of the composition of the diet consumed by dairy calves and cows, by other non dairy bovines, including, if possible, the period 1980 to the present. If this composition was regulated by the government, please summarise the relevant regulations and attach a copy to this questionnaire.

2.1.2 Feed industry, structure and output

Table 2.1.2 **Structure of the feed industry in the country**

	Number of mills operational in the country per period by type of feed mill					
Type of feed mill:	**1980-85**	**1986-90**	**1991-95**	**1996-2000**	**2001-2005**	**2006-**
Dedicated to pig feed						
Dedicated to poultry feed						
Dedicated to poultry and pig feed						
Dedicated to ruminant feed						
Mixed feed mills producing feed for ruminant and non-ruminant animals						

Dedicated plants do not produce feed for ruminant and non-ruminant animals on the same premises.

2.1.3 Output of the feed industry in the country by type of feed mill, type of feed and period

		Feed output of mills operational in the country per period by type of feed mill (tons)					
Type of feed mill	**Type of feed**	**1980-85**	**1986-90**	**1991-95**	**1996-2000**	**2001-05**	**2006-**
Mills dedicated to producing feed for ruminants or non-ruminants							
	Pig feed						
	Poultry feed						
	Ruminant feed						
Mixed feed mills (ruminant and non-ruminant feed produced on same premises)							
	Pig feed						
	Poultry feed						
	Ruminant feed						

2.1.4 Feed regulations. Feed Ban: Is there an official feed ban in your country ?

☐ **YES** ☐ **NO** ➔ go to **2.2.**

↓

Type of feed-ban			Date of adoption	Start of controls
☐	BMBM*	to Bovines	…….	…….
☐	BMBM*	to Ruminants	…….	…….
☐	RMBM*	to Bovines	…….	…….
☐	RMBM*	to Ruminants	…….	…….
☐	RMBM*	to all farmed animals	…….	…….
☐	MMBM*	to Bovines	…….	…….
☐	MMBM*	to Ruminants	…….	…….
☐	MMBM*	to all farmed animals	…….	…….
☐	other	*explain* ……..…….…….		

* BMBM = Bovine MBM ; * RMBM = Ruminant MBM;
* MMBM = Mammalian MBM

2.1.5 Overview of measures taken to prevent cross-contamination of bovine feed with MBM

Provide information on any additional control measures that were used to reinforce the feed ban in the table below including the measures taken in the case of a mill that changes from producing non ruminant to ruminant feed.

Check point	Measures* and results of audits	Date of implementation	Details of legal basis (if any)
Feed-mills			
Transport			
Farms			

*Measures may include flushing batches between non-ruminant containing MBM and ruminant feed, separated production lines for ruminant feed and other feed, separated transport systems for different feeds, labelling of non-ruminant feed as “not for ruminant consumption”, etc. Information already given under 2.1.1 does not have to be repeated.

2.1.6 Results of the examination of bovine feed samples with regard to contamination with MBM or animal protein in general other than milk

Provide information on feed sampling in the table below:

Year	*Test method**			*n° tested*	*n° of contaminated samples*	*n° positive*	*Criteria for a positive sample***
	M	*E*	*O*				
1990							
1991							
1992							
1993							
1994							
1995							
1996							
1997							
1998							
1999							
2000							
2001							
2002							
2003							
2004							
2005							

* Test methods: **M**= microscope, **E**= ELISA, **O**= other (specify)

** Give minimum contamination above which a sample is declared being "positive", e.g. >0.5%, >0.1%, >0% and/or any other criteria used.

Describe in detail the sampling procedure (size of batch and number of samples per batch and fraction of batches sampled; place of sampling, i.e. end of line in feed mill, after packing/loading, at retailers, on the farm) and the method of examination. Indicate the sensitivity of the examination method.

Give information on the follow-up taken by the authorities in cases where breaches of the feed ban were found.

2.2. Rendering (please include data from 1980 up to the present)

Rendering of BSE-contaminated material can reduce BSE infectivity by a factor of 10^3. To have this effect, material of a particle size of no more than 50mm and a moisture content of about 60% must be exposed to a pressure of 3bar reaching a core temperature of 133°C for at least 20min.

Structure of the rendering industry

2.2.1. Number of rendering plants by type of raw material that is processed and by product and period

	Number and accumulated MBM-output (tons) of rendering plants operational in the country per period and by type of plant											
Type of rendering plant by raw material that is processed	**1980-85**		**1986-90**		**1991-95**		**1996-2000**		**2001-05**		**2006**	
Dedicated to:	N°	Tons	N°	Tons	N°	Tons	N°	Tons	N°	Tons	N°	Tons
Poultry material												
swine material												
Swine and poultry material												
bovine material												
any **other mammalian species***												
Processing material from **different mammalian species,** including bovine waste material												

Include all plants that were operational in a given period, even if they were only operational for a part of that period. Please note that bone meal production plants are to be included.

198 * specify which other mammalian species the rendering plants were/are dedicated to.

199

200 Provide additional explanations if rendering plants were newly started, changed or closed during a specified period. Describe if rendering plants existed
201 that only processed material selected on the basis of other criteria, such as a higher risk of potential contamination with high-risk biological agents,
202 toxins, etc. Give details on raw material intake and product output of these plants as well as on the use made of these products.

203 Explain how (and why) dedicated rendering plants ensured that no other raw material entered their process. Describe procedures for ensuring avoidance
204 of contamination with raw materials entering the process in dedicated rendering plants.

205 Assuming that bovine material could only be rendered in plants dedicated to bovine material or processing material from a variety of species (including
206 cattle), the following details are only required for these two types of rendering plants.

207

2.2.2. Production (metric tons) of the rendering industry in the country by type of rendering plant, type of process, process conditions and use of product, over the periods indicated

			MBM output of rendering plants operational in the country per period and type of plant (metric tons)					
Type of rendering plant	**Type of process**	**Process conditions***	**1980-85**	**1986-90**	**1991-95**	**1996-2000**	**2001-05**	**2006-**
Dedicated to ruminant	Continuous	System 1						
		System 2						
	Batch	System 1						
		System 2						
Mixed plants	Continuous	System 1						
		System 2						
	Batch	System 1						
		System 2						

**Please provide details (temperature, duration, pressure) for each processing system and amount produced per system. (If necessary please add lines for additional systems).*

2.2.3. Average number of bovines annually slaughtered for human consumption

	Average number of bovines annually slaughtered					
Age at slaughter [months]	**1980-85**	**1986-90**	**1991-95**	**1996-2000**	**2001-05**	**2006-**
< 30						
> 30						

2.2.4. Specified Risk Materials (SRM) and fallen bovine stock

Please describe the treatment in your country of SRM[1] and of material from fallen stock (animals dead/killed on farm, dead at arrival, condemned in ante mortem inspection), or of bovine material condemned in post mortem inspection.

Use made of bovine brains, spinal cords/vertebral and fallen stock

Rendering of brain and spinal cord of cattle and of bovine fallen stock (dead/killed on farm or in transport),emergency slaughter animals or bovine animals condemned at ante mortem inspection) by period, and process

	Brain and spinal cord/vertebral column of healthy bovines (1)		**Fallen bovine stock, emergency slaughter animals or bovines condemned at ante mortem (2)**	
Period	**Rendered** *(in %; specify its fate)*	**Not rendered** *(in %; specify its fate)*	**Rendered** *(in %; specify its fate)*	**Not rendered** *(in %; specify its fate)*
1980-1985				
1986-1990				
1991-1995				
1996-2000				
2001-2005				
2006-				

[1] SRM=Specified Risk Materials. For the purpose of the GBR assessment this is, in case of bovines, mainly the brain and spinal cord and vertebral column of cattle over 12 months of age.

If only a fraction of the mentioned materials (1) or (2) is rendered, explain how this fraction is determined and how large it was in the different periods. If brain and spinal cord are/were consumed by humans, estimate the fraction of brains and spinal cord that was not regarded edible and was therefore rendered. If only a part of the animals dead on farm is/was collected for rendering, estimate the fraction and explain what happened to the non-rendered carcases. (Please extend the table if required).

2.3. Bovine population structure

Knowledge of the bovine population structure is necessary background information for the rest of the questionnaire.

2.3.1. Key data on the bovine population

		All ages [n°]	Less or equal 24 months old [n°]	Over 24 months old				
				Male		Female		
Year				Beef	Breeding	Beef	Dairy	Breeding
1980	n°							
	age*							
1985	n°							
	age*							
1990	n°							
	age*							
1995	n°							
	age*							
2000	n°							
	age*							
2005	n°							
	age*							

(age*: average age at slaughter)

Double purpose cows are to be included in the dairy column. In addition attach information on other types of bovine, such as working animals, as appropriate.

2.3.2. Co-farming of bovines with pigs and/or poultry and/or horses. Includes also farms with only dairy cows as economic activity but having some poultry and/or pigs and/or horses for their own use or as secondary business

	Number and percentage of all bovine holdings									
Co-farming	**1985**		**1990**		**1995**		**2000**		**2005**	
	n°	**%**	**n°**	**%**	**n°**	**%**	**n°**	**%**	**n°**	**%**
Bovines & non ruminant farmed animals (pigs, poultry)										

2.3.3. Cattle identification and traceability

Please describe in detail the system for identifying cattle. How long has this system in operation? Who is responsible for cattle identification on the farms and who carries out the supervision? If available, please provide compliance figures (e.g. on spot checks of veterinary authorities, plausibility checks etc.)

Please describe in detail the system for tracing the movement of imported and indigenous cattle. If appropriate, please, give some information on the structure and the maintenance of the cattle movement database.

Please provide details of the system, if implemented, for registering cattle herds. Does this involve the recording of individual animals? Are BSE test results recorded in the database?

2.4. BSE-surveillance

Notification

- Date since BSE was officially defined as a notifiable disease: ……

- Attach a description of the criteria for a notifiable BSE-suspect, and describe their development over time.

- Measures taken to ensure/enforce notification (incl. their development over time and attach a detailed description including their development over time):

- awareness training: ☐ **YES**, since ……☐ NO

- compensation for cases: ☐ **YES**, since ….. ☐ NO

amount paid: ……

for BSE-suspects: ☐ **yes**; amount paid: …… ☐ NO

for BSE related culled animals: ☐ **yes**; amount: …… ☐ NO

- incentives for reporting suitable surveillance candidates (fallen stock, clinical suspects),

specify:

- lab-personal trained: ☐ **YES**, since…….. ☐ NO

where: ……

- other (specify): …….

……

Attach a detailed description of the methods used for the examination of BSE-suspects (past and present).

Attach a detailed description of the criteria used for the confirmation of BSE-<u>cases</u> (past and present).

271 Table **TSE testing in bovine animals above 30 months of age**

	BSE Eradication (1)		Healthy Slaughter (2)		Fallen Animals (3)		Casualty slaughter (4)		Suspect (5)	
	Number	Positives	Number	Positives	Number	Positives	Number	Positives	Number	Positives
1990										
1991										
1992										
1993										
1994										
1995										
1996										
1997										
1998										
1999										
2000										
2001										
2002										
2003										
2004										
2005										

	BSE Eradication (1)		Healthy Slaughter (2)		Fallen Animals (3)		Casualty slaughter (4)		Suspect (5)	
	Number	Positives	Number	Positives	Number	Positives	Number	Positives	Number	Positives
2006										
Total										

(1) Birth and rearing cohorts, offspring of BSE cases, animals from herds with BSE

(2) Bovine animals subject to normal slaughter for human consumption and animals without clinical signs of disease slaughtered in the context of a disease eradication campaign other than BSE

(3) Bovine animals which have died or have been killed on the farm or in transport, but not slaughtered for human consumption nor killed in the framework of an epidemic

(4) Casualty slaughter

(5) Animal reported as BSE clinical suspects of TSE

A detailed definition of the different categories can be found at appendix 3.8.4 (OIE terrestrial animal health code

ANNEX V

GUIDELINES TO THE USE OF THE INTERACTION CHART

Table 1. **Country A with an improved stability over time**

Onto the following graph are reported all the external challenges (EC) that took place in this country from 1980 onward.

Levels of challenge	1980-1985	1986-1990	1991-1995	1996-2000	2001-2005	2006-2010
extremely high						
very high						
high			**IC=OC**	**IC=OC**		
moderate		**IC=OC** */EC*		*EC*	**IC=OC**	
low	*EC*		*EC*		*EC*	**IC=OC**
very low						
extremely low						
Stability	Extremely unstable	Very unstable	Very unstable	Neutrally stable	Extremely stable	

Step 1: In this example, the country is very unstable between 1986 and 1990, and an external challenge arises at a **low level** in 1980. On the 1986-1990 period, we can expect the BSE-infectivity to be recycled over time and amplified. The internal challenge for the period 1986-1990 will therefore result from the increase of one risk level since 1980-1985. The internal challenge (IC) will then be considered as: low + 1 level upgrade, that is **moderate**, as shown below.

Step 2: From 1986 to 1990, a moderate external challenge (EC) takes place in a very unstable system. Both internal and external challenges are at the same level, i.e. moderate. Therefore we can infer the overall challenge (OC) as being moderate. Because of the very unstable system in the 1991-1995 period and this moderate OC, the internal challenge (IC) for the 1991 to 1995 period will then be considered to be one step higher than this moderate overall challenge: it is said to be **high**.

Step 3: From 1991 to 1995, a low external challenge (EC) takes place and the country is neutrally stable for the following period. The internal challenge for this period being higher than the external challenge (high level of challenge), we can infer the overall challenge (OC) as being equivalent to the level of the IC, i.e. high. Because of the neutrally stable system and the high OC, the internal challenge (IC) for the 1996 to 2000 period will then be considered to be at the same level as this high overall challenge: it is said to be **high**.

Step 4: From 1996 to 2000, a moderate external challenge (EC) takes place and the country is extremely stable the next period. The internal challenge for this period being higher than the external challenge (high level of challenge), we can infer the overall challenge (OC) as being equivalent to the level of the IC, i.e. high. Because of the extremely stable system and the high OC, the internal challenge (IC) for following time period will then be considered to decrease by one risk level: **moderate**.

Step 5: From 2001 to 2005, a low external challenge (EC) takes place and the system is still optimally stable between 2006 and 2010.. The internal challenge for this period being higher than the external challenge (moderate level of challenge), we can infer the overall challenge (OC) as being equivalent to the level of the IC, i.e. moderate. Because of an extremely stable system and the moderate OC, the internal challenge (IC) for the 2006-2010 period will then be considered to decrease by one level: **low**.

Table 2. **Country B with a large cattle population and extremely unstable system over time**

Onto the following graph are reported all the external challenges (EC) that took place in the USA from 1980 onward.

Levels of challenge					
extremely high			*EC*		**IC=OC**
very high				**IC=OC**	
High		*EC*	**IC=OC**		
Moderate	*EC*				
Low					
very low				*EC*	*EC*
extremely low					
	1980-1985	1986-1990	1991-1995	1996-2000	2001-2005
Stability	Extremely unstable	Extremely unstable	Extremely unstable	Extremely unstable	Extremely unstable

Step 1: In this example of country B, an external challenge arises at a **moderate level**. On the next 10-year period, regarding the size of the country, we can expect the BSE-infectivity to be recycled over time and amplified. Moreover, the country is considered as extremely unstable for the period 1991-1995. The internal challenge for the period 1991-1995 will therefore result from the increase of one risk level since 1980-1985. The internal challenge (IC) will then be considered as: moderate + 1 level upgrade, that is **high**, as shown below.

Step 2: From 1986 to 1990, a high external challenge (EC) takes place. On the next 10-year period, regarding the size of the country, we can expect the BSE-infectivity to be recycled over time and

amplified. The internal challenge for the period 1996-2000 will therefore result from the increase of one risk level. The internal challenge (IC) will then be considered as: high + 1 level upgrade, that is **very high**, as shown below.

Step 3: From 1991 to 1995, an extremely high external challenge (EC) takes place. On the next 10-year period, regarding the size of the country, we can expect the BSE-infectivity to be recycled over time and amplified. The internal challenge for the period 2001-2005 will therefore result from the increase of one risk level. The internal challenge (IC) will then be considered as: very high + 1 level upgrade, that is **extremely high**, as shown below. Between 1991 and 1995, the EC level being higher than the IC's at the same period, the OC can be considered as equivalent to the EC, i.e. **extremely high.**

Step 4: Between 1996 and 2000, the EC level being lower than the IC's at the same period, the OC can be considered as equivalent to the IC, i.e. **very high.**

Step 5: Between 2001 and 2005, the EC level being lower than the IC's at the same period, the OC can be considered as equivalent to the IC, i.e. **extremely high.**

Table 3. **Country C with a small cattle population and an extremely unstable system over time**

The same methodology is applied for this country and leads to the following results.

Levels of challenge						
extremely high					**IC=OC**	**IC=OC**
very high				**IC=OC**		
high			**IC=OC**	*EC*		
moderate		*EC*=**OC**			*EC*	
low		**IC**				
very low	*EC*		*EC*			
extremely low						
	1980-1985	1986-1990	1991-1995	1996-2000	2001-2005	2006-2010
Stability	Extremely unstable	Extremely unstable	Extremely unstable	Extremely unstable	Extremely unstable	

Step 1: In this example, the country is extremely unstable between 1986 and 1990, and an external challenge arises at a **very low level** in 1980. On the 1986-1990 period, we can expect the BSE-infectivity to be recycled over time and amplified. The internal challenge for the period 1986-1990 will therefore result from the increase of one risk level since 1980-1985. The internal challenge (IC) will then be considered as: low + 1 level upgrade, that is **low**, as shown below.

Step 2: From 1986 to 1990, a moderate external challenge (EC) takes place in a very unstable system. The external challenges for that particular period is higher than the internal challenge, i.e. moderate. Therefore we can infer the overall challenge (OC) as being equivalent to the higher of the two, i.e. moderate. Because of the extremely unstable system in the 1991-1995 period and this moderate OC, the internal challenge (IC) for the 1991 to 1995 period will then be considered to be one step higher than this moderate overall challenge: it is said to be **high**.

Step 3: From 1991 to 1995, a very low external challenge (EC) takes place and the country is still extremely unstable for the following period. The internal challenge for this period being higher than the external challenge (very low level of challenge), we can infer the overall challenge (OC) as being equivalent to the level of the IC, i.e. high. Because of the extremely unstable system and the high OC, the internal challenge (IC) for the 1996 to 2000 period will then be considered to be one step higher than this moderate overall challenge: it is said to be **very high**.

Step 4: From 1996 to 2000, a high external challenge (EC) takes place and the country is still extremely unstable the following period. The internal challenge for this period being higher than the external challenge (very high level of challenge), we can infer the overall challenge (OC) as being equivalent to the level of the IC, i.e. very high. Because of the extremely unstable system and the very high OC, the internal challenge (IC) for following time period will then be considered to be one step higher than this moderate overall challenge: it is said to be **extremely high**.

Step 5: From 2001 to 2005, a moderate external challenge (EC) takes place and the system is still extremely unstable between 2006 and 2010.. The internal challenge for this period being higher than the external challenge (extremely high level of challenge), we can infer the overall challenge (OC) as being equivalent to the level of the IC, i.e. extremely high. Because of an extremely unstable system and the extremely high OC, the internal challenge (IC) for the 2006-2010 period will then be considered to remain as for the former period: **extremely high**.