EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Scientific Steering Committee

THE ASSESSMENT OF THE GEOGRAPHICAL RISK OF BOVINE SPONGIFORM ENCEPHALOPATHY CARRIED OUT WORLDWIDE BY THE EUROPEAN COMMISSION'S SCIENTIFIC STEERING COMMITTEE

SUBJECT TO EDITORIAL CHANGES

TABLE OF CONTENTS

1 NEED FOR A METHODOLOGY TO ASSESS THE RISK OF GEOGRAFICAL BOVINE SPONGIFORM ENCEPHALOPATHY (GBR) IN CATTLE

Bovine Spongiform Encephalopathy (BSE), initially recognized in cattle in the United Kingdom in 1986, rapidly evolved into a new issue of major public concern. In 1996, evidence was provided that this disease had crossed the species barrier and infected some human beings in the UK with what has become known as "variant Creutzfeld Jakob Disease" (vCJD).

Managing risk, on a day-to-day basis, in an area almost entirely confronted with unknown and uncertainties has been difficult. On the one hand the uncertainties as to the cause of the disease, its transmission and its epidemiology and the absence of any diagnostic test in the live animal, or, indeed, a cure, have justified that the risk be addressed with the highest level of precaution to prevent the disease eventually evolving into a pan-European, or even possibly, a pandemic threat. On the other hand, the precautions taken have needed to be, as far as possible, proportional to the real threat, avoiding whenever possible unnecessary major societal and economic disturbances.

Following the 1996 discovery of vCJD, the European Parliament requested from the European Commission an overhaul of its system of scientific advice to ensure a greater independence of scientific advisers. It was in this situation that the Scientific Steering Committee (SSC), was established in 1997 to advice the Commission on general matters concerning eight specialized scientific Committees concerned with matters of public health, as well as on matters that would not fall into the competence of any single one of these sectoral Committees. To better deal with the BSE- and TSE-related issues, the SSC established an ad hoc working group.

Since then, the SSC has been called upon almost continuously by the European Commission to provide a sound scientific basis for a risk management strategy that aims at the optimal protection of human and animal health and welfare. At the same time, as new scientific data become available, this strategy should be gradually refined and modulated. The SSC has in particular advised the European Commission on all matters relating to Transmissible Spongiform Encephalopathies (human and animal) with the help of very large numbers of experts from many different countries, including non-EU countries.

Among the many successful tasks carried out by the SSC has been the development of a methodology to assess the risk that BSE is present in the domestic cattle herd of a specified geographical area in which it has not yet been detected (the so called Geographical Bovine Spongiform Encephalopathy Risk – GBR). This method allows assessment of the GBR for any country that provides the required information.

Given limitations in the availability and quality of data, the GBR assessment provides a qualitative estimate of the probability that the BSE agent was introduced into the geographical area in question, and if this has occurred, the probability also that the agent has been recycled and amplified within the area. Based on these qualitative estimates the method allows assessment of the current risk that the BSE agent is present in the area.

The Geographical BSE-Risk in cattle (GBR-C) is defined as a qualitative indicator of the likelihood of the presence of one or more cattle within the native population being infected with Bovine Spongiform Encephalopathy (BSE). The infection could be present pre-clinically as well as clinically, at any given point in time, in a country or otherwise defined geographical area. Where its presence is confirmed, the GBR gives an indication of the level of infection.

Given the absence of means to confidently establish the risk in quantitative terms, this qualitative estimate has proven to be a useful basis for risk management decisions, which aim at protecting the human population as well as the cattle population against possible exposure to the BSE agent. Its usefulness has been shown by the results of large scale screening exercises that began in 2000/2001 when rapid post mortem BSE-tests became available.

2 STEPWISE DEVELOPMENT OF THE GBR IN CATTLE

One of the first scientific opinions the SSC dealt with specified risk materials[1] (SRM), i.e. those tissues in BSE infected animals that carry significant levels of infectivity. The SSC regularly updated the list of these tissues in the light of the most recent scientific knowledge. It also stated that the list could probably be modulated in view of the geographical BSE risk (GBR) in the country or region of origin. In other words, in countries with a higher GBR, all tissues that could potentially carry the BSE agent should be treated as SRM, while in countries with a lower risk, it might be acceptable to exclude from the human and animal food chains only those tissues with the highest potential infectivity. Subsequently the SSC was asked to develop a method for assessing the GBR.

In January 1998, the SSC established a list of factors on which it would require information for assessing the GBR[2] and, in July 1998, the Commission recommended to Member States and interested Third Countries to provide the necessary information on the factors to support GBR assessments.[3]

In December 1998, the SSC issued a pre-opinion on a method for assessing the Geographical BSE-Risk of a country or region. This was adopted in February 1999[4], taking into account comments received from competent Authorities in EU-Member States and in reaction to the publication of the pre-opinion on the Internet.

The method was first applied in March 1999 to 11 Member States of the European Union that had supplied dossiers at that time. Since then, it was refined with the opinions adopted on 6 July 2000[5], 11 January and 7 November 2002[6] in the light of the experience made and applied to more than 60 countries.

The repeated refinement of the GBR methodology (Table 1) implied a need for revising some evaluations carried out with an earlier version of the methodology (see also Section 4.6).

[1] Opinion of the SSC on Specified Risk Materials,

[2] Opinion of the SSC on defining the BSE-risk for specified geographical areas. 22/23 January 1998

[3] Commission recommendation of 22 July 1998 concerning information necessary to support applications or the evaluation of the epidemiological status of countries with respect to TSEs. (C(1998)2268); 98/447/EC)

[4] Opinion of the SSC on a method to assess the Geographical BSE-Risk of countries or regions. 18-19/02/99

[5] Opinion of the SSC on the Geographical Risk of BSE – 6 July 2000

[6] Update opinions of the SSC on the Geographical Risk of BSE – 11 January 2002 and 7 November 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.
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

Table 1 – Time-evolution of the methodology to assess the Geographical Bovine Spongiform Encephalopathy Risk (GBR)

This methodology has been widely used as a basis for categorizing countries into different BSE status categories that determine conditions for trade with the European Union.

On the 8 November 2002 this methodology, initially developed for cattle, was adapted to assess the GBR in small ruminants in case BSE would become probable or evident under field conditions; as BSE has not been discovered so far in small ruminant in any country, this methodology has never been applied.

3 THE METHODOLOGY FOR ASSESSING THE GEOGRAPHICAL BOVINE SPONGIFORM ENCEPHALOPATHY IN CATTLE

3.1 Definition of the geographical BSE-risk in cattle

The Geographical BSE-Risk in cattle (GBR-C) is a qualitative indicator of the likelihood of the presence of one or more cattle in the native population being infected with BSE, pre-clinically as well as clinically, at a given point in time, in a country. Where BSE presence is confirmed, the GBR-C gives an indication of the level of infection as specified below.

The SSC defined 4 qualitatively different levels for the GBR (see Table 2):

- At level **"I"** it is highly unlikely that any BSE infected cattle is present.
- At level **"II"** the presence of any BSE infected cattle is still unlikely, but it cannot be excluded.
- At level **"III"** the presence of BSE infected cattle is likely or, if already cases were discovered, the number of BSE cases identified during the last 12 months is below 100 per million adult cattle.
- Level **"IV"** means that more than 100 BSE cases were discovered in the last 12 months per million adult cattle.

GBR level	**Presence of one or more cattle clinically or pre- clinically infected with the BSE agent in a geographical region/country**
I	Highly unlikely
II	Unlikely but not excluded
III	Likely but not confirmed or confirmed, at a lower level
IV	Confirmed, at a higher level

Table 2 – Definition of GBR in cattle and its levels.

As for the differentiation between level III and IV, the SSC adopted the 1999-OIE threshold of 100 BSE cases per million adult cattle over the last 12 months. The significance of this threshold is changing with the progressive development of more sensitive test methods applicable to animals in the field such as the post-mortem tests. However, so far the SSC has not revised its position on this issue.

3.2 Basic assumptions

While consumption of animal proteins by bovines is not a risk per se, it becomes a risk if the protein is potentially contaminated with the BSE agent.

BSE started in the United Kingdom (UK) from an unknown source and was propagated through the recycling of bovine tissues into animal feed. Later the export of infected animals and contaminated feed provided the means for spreading the BSE-agent to other countries where it potentially was again recycled and propagated via the feed chain.

For all the countries other than the UK, import of contaminated feed or infected animals is the only initial source of BSE that is taken into account. A country that has imported potentially infected cattle or potentially contaminated animal proteins was, because of these imports, exposed to an external challenge.

The external challenge is independent from the size of the challenged BSE/cattle system. With other words, there is no dilution effect i.e. a large system cannot tolerate more external challenge than a small system. The reason for this is that it is unrealistic to assume that a given amount of infectivity can be equally spread throughout a large system. In addition it is not scientifically justified to assume that a minimum dose exists, below which no risk of infection occurs. Also for this reason a dilution would not be a solution.

One infected animal can only contaminate a limited amount of MBM and this amount of MBM can realistically only be consumed by a limited number of cattle:

- If MBM is produced in batch mode, one batch is normally around 5 tons of MBM and it is unrealistic to assume that one cattle can contaminate more than one batch. In continuous MBM production systems this value can be higher but will also be limited.

- Cattle compound feed cannot normally have contained more than 5% MBM and may have included traces below 0.5%. Assuming a daily consumption of 25 kg compound feeds per cow, one ton of MBM could theoretically represent between 800 (5%) and 8000 (0.5%) daily cattle rations. As it is unrealistic to assume that a defined amount of MBM is optimally distributed between different daily rations reaching different animals, the number of exposed animals will in reality be much lower. The size of the overall cattle herd of the importing country is therefore not relevant as soon as it is larger than the theoretical maximum number of cattle that could be exposed to a given external challenge.

Potential domestic initial sources of BSE are not considered, because these sources are not scientifically confirmed and no basis exists for assessing their risk potential. This includes sources such as a spontaneous occurrence of BSE at very low frequency, or the transformation into BSE of other (animal) TSEs, including scrapie, Chronic Wasting Disease [CWD], Transmissible Mink Encephalopathy [TME], Feline Spongiform Encephalopathy [FSE]) being present in a country.

Once the agent is present in a country, the only transmission route taken into account is contaminated feed. Epidemiological research showed clearly that the origin and maintenance of the BSE epidemic in the UK was directly linked to the consumption of infected ruminant derived animal protein (other than milk or blood meal) by cattle. Different commodities may contain such potentially contaminated proteins. Within the GBR method and throughout this paper they are referred to by the term "MBM", which in turn refers to meat and bone meal alone, a product distinct from commodities such as Meat Meal (MM), Bone Meal (BM), or greaves that are here included.

Blood as such (and blood meal), semen and embryos are not seen by the SSC to be effective transmission vectors[7].

MBM is prepared from animal remains by a process called rendering. Only one process is known to significantly reduce BSE infectivity, i.e. by a factor of 1000. This process includes a cooking of the animal tissues under 3 bar pressure at 133°C for at least 20 minutes; maximum particle size being 50 mm and the raw material containing about 60% water. Other processes have no or only limited impact on BSE infectivity. However, no process can sterilize BSE.

From European experience it is concluded that already low levels of cross-contamination of cattle feed with other feeds that contain MBM can be spreading the disease. As long as potentially BSE-contaminated MBM exists in the country and feeding of MBM to farmed animals is legally possible, cross-contamination of cattle feed with animal (potentially contaminated ruminant) protein is difficult to be eliminated. This is even more difficult if feeding of non-mammalian MBM to cattle is legal i.e. if only a ruminant to ruminant feed ban is implemented.

The importance of cross-contamination has to be seen in the light of the risk that the animal protein under consideration could carry BSE-infectivity.

The possible impact of maternal transmission is not considered in the assessment process because of the qualitative nature of the method, the relatively lesser importance of this factor in comparison to feed, and the lack of final scientific confirmation of its existence.

Similarly no third route of transmission is considered. While the existence of a third mode of transmission of BSE has been postulated and cannot be excluded, to date there is no scientific evidence to establish its significance[8]

Sheep and goats are assumed not to be infected with BSE[9].

The available assessments only address entire countries without consideration for various zones or regions thereof. If complete data sets were available for other defined geographical areas, these could be assessed in the same way. Limited areas such as very small countries, however, will often not encompass a complete BSE/cattle system (see below) and will therefore depend on the BSE risk in the surrounding BSE/cattle system(s).

3.3 Data

Information on import of cattle and/or MBM from countries/regions where BSE could already have been present at the time of export are essential for assessing the external challenge (see below). The GBR assessment needs information on items and factors listed in Table 3.

Structure and dynamics of the bovine population
- Number and age distribution of beef and dairy cattle, both alive and slaughtered
- Husbandry systems, proportional to the total cattle population (beef/dairy, intensive/extensive,

[7] See SSC-opinion on vertical transmission, 18-19 March 1999 and on *the* safety of ruminant blood (13/14 April 2000)

[8] See SSC-opinion

[9] See SSC-opinion relating to the risk of infection of sheep and goats with BSE

productivity of dairy cattle, co-farming of pig/poultry and cattle)
Surveillance of BSE (Measures in place and results) - Identification system and its tracing capacity - Date since when BSE is compulsory notifiable and criteria for a BSE-suspect - Awareness training (when, how, who was trained) - Compensation (since when, *how much* in relation to market value, payment conditions) - Other measures taken to ensure notification of BSE suspects - Specific BSE-surveillance programs and actions - Methods and procedures (sampling and laboratory procedures used for the confirmation of BSE-cases) - Number of cattle, by origin (domestic/imported), type (beef/dairy), age, method used to confirm the diagnosis and reason why the animal was examined (CNS, BSE-suspect, BSE-related culling, other) - Incidence of reported BSE-cases by year of confirmation, by date of birth, and by type of cattle
BSE related culling - Culling schemes, date of introduction and criteria used to identify animals that are to be culled - Information on animals already culled in the context of BSE
Import of Cattle and MBM - Imports of live cattle and/or MBM from UK and other BSE-risk [10] countries - Information that could influence the *risk* of imports to carry the BSE agent (BSE-status of the herds of origin of imported cattle, precise definition of the imported animal protein, etc.) - Main imports of live cattle and/or MBM from other countries - Use made of the imported cattle or MBM
MBM-bans - Date of introduction and scope (type of animal protein banned for the use in feed in different species, exceptions, etc.) - Measures taken to ensure and to control compliance Methods and results of compliance control
SRM-removal and bans (SRM: Specified Risk Material, i.e. material posing the highest risk of infection) - Use made of SRM from healthy slaughtered animals, from emergency slaughter, from fallen stock (animals dead or killed on farm or dead on arrival), and from animals condemned in ante mortem control) - Dates of introduction and scope of SRM bans (definition of SRM, use made of SRM after the introduction of the ban) - Measures taken to ensure and to control compliance - Methods and results of compliance control
Rendering - Raw material used (type: Slaughterhouse waste including SRM or not, other animal waste, fallen stock, etc.; annual amounts by type of raw material and species) - Process conditions applied (time, temperature, pressure; batch/continuous; their share of the annual total domestic production; control of their correct and reliable application; in case of species specific rendering control of the raw material composition) and their share of the annual total domestic production

Table 3 - Information factors for the assessment of the GBR-C.
(All the information should be available for the period from 1980 onwards)

These items include basic data on structure and dynamics of the domestic cattle population of the country under assessment as well as information on its BSE surveillance. Together with information on the feeding of cattle and the processing of cattle tissues, in particular of SRM, into feed, this information allows assessing the risk that the BSE agent, once introduced, would be recycled and amplified within the country.

The GBR assessment is mainly based on information provided by competent Authorities of the assessed countries and it is assumed that the information provided is correct.

[10] BSE risk countries are all known to have a GBR of III or IV or with at least one confirmed domestic BSE case

In general, the available data were seen to be adequate to carry out a qualitative assessment of the GBR but considerable differences in the availability and quality of data remain of concern.

Given the experienced limitations in data quality and completeness, in case of conflicting data from equally reliable sources, worst-case assumptions are used, as long as they are regarded reasonable. A shortcoming in many dossiers was for example insufficient information on compliance with the preventive measures put in place by the competent national authorities. Compliance, therefore, was often assumed being weak.

Also, to complement insufficient information, "reasonable worst case assumptions" are used whenever extrapolation, interpolation or similar approaches, are not possible. All available additional sources of information, such as reports from the missions of the EC-Veterinary Inspection Services (the Food and Veterinary Office, FVO) and international trade statistics are used.

Another problem with regard to data comes from the slow development of a BSE epidemic. This implies that exports many years before a first BSE case was recognized in the exporting country could already have posed external challenges (see below) to importing countries. It also implies that a GBR assessment must cover about the past 20 years.

3.4 The model of the BSE/cattle system

The BSE/cattle system is defined as the group of factors, and their interaction, which determine recycling and amplification of the BSE agent. A simplified model of this system is described in Figure 1. It focuses on a feedback loop that consists essentially of the processing of (parts of) cattle that potentially carry the BSE-agent into feed and the feeding of this to cattle. These animals then get infected and multiply the BSE-agent inside their bodies over a long period, about 5 years in average, before any signs of the disease appear. To close the loop these animals must again be processed into (cattle) feed.

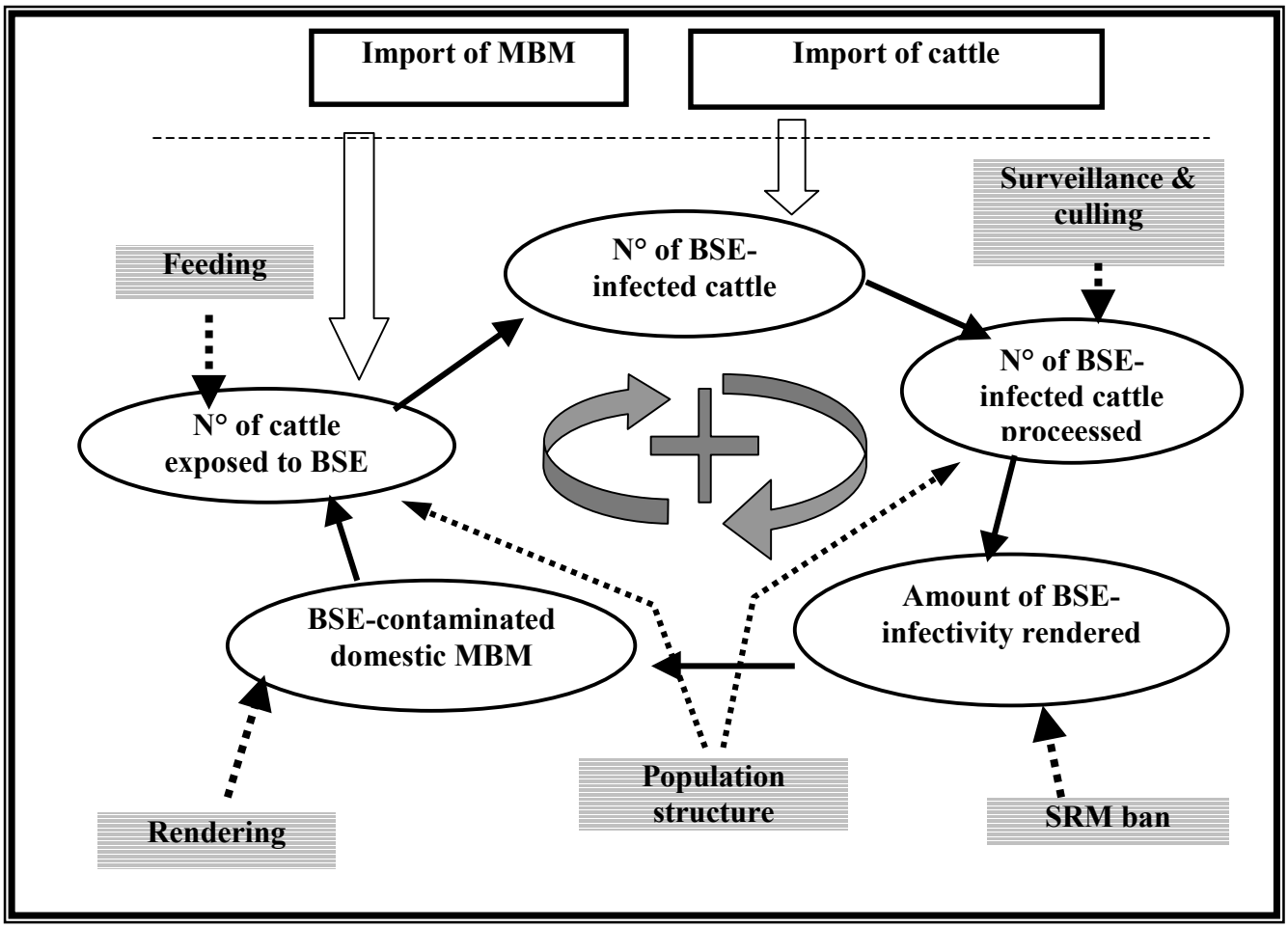

Figure 1: The model of the BSE/cattle system used by the SSC.

The described feedback loop is controlled by a number of factors that may activate the loop, or counteract or even interrupt it. The ability of a system to control the feedback loop is called its stability. A system that has the intrinsic capacity to reverse the building-up of BSE infectivity is "stable" otherwise it is "unstable".

According to the basic assumptions of the GBR method, the initial introduction of the BSE-agent into the system has to come from outside the analyzed BSE/cattle system. Any introduction of the agent into the system's boundaries is an "external challenge", challenging the domestic BSE/Cattle system to cope with it.

3.5 Assessing the GBR

In summary the GBR assessment process consists of three steps. First the risk that the BSE agent was introduced into the country and its BSE/Cattle system, the "external challenge", has to be assessed. Second the ability of the country's BSE/cattle system to avoid recycling and propagating the BSE agent, its "stability", must be evaluated. Third the interaction of external challenge and stability must be looked at, taking due account of the dynamics in the system.

3.5.1 External Challenge

The two possible routes of introduction of the BSE agent into a BSE/cattle system are the import of BSE-infected cattle or of BSE-contaminated "MBM[11]".

[11] For the purpose of the GBR the term MBM is used as a shortcut for all kinds of feed stuffs that may contain ruminant protein, other than milk. It notable includes commodities such as Meat and Bone Meal as such, Meat Meal, Bone Meal, Greaves. As international trade statistics do not have a

- 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.

- BSE risk countries are all countries that are already assessed as GBR III or IV or which have notified at least one domestic BSE case. These BSE risk countries have potentially exported the BSE agent since an internal challenge (see below) was likely to exist on their territory.

- Challenge levels were defined in function of imports from the UK at the time when the risk of BSE-contamination was regarded to be the highest.

- For the imports of live cattle this is the period 1988 to 1993. It was chosen as highest risk period for live cattle imports because it covers roughly one incubation period before the highest incidence (1992/93) and because data on case incidence in UK-birth cohorts show that this was already high in 1985/86 and 1986/87. However, breeding cattle that normally reach an age of 5 or more years in the importing country are normally exported at an age around 24 months (e.g. as pregnant heifers). It, therefore, was felt justified to keep this range. (Even if it might be possible that the risk carried by imports in 1987 was slightly underestimated by this approach, it was kept constant throughout the GBR-exercise to ensure comparability of results). It is assumed that during this period the average BSE-prevalence of infected animals in exported cattle was around 5%, i.e. of 20 animals one could have been infected.

  The value of 5% was used because at normal survival probabilities only one in 5 calves reaches an age of 5 years. As the case incidence in the critical birth cohorts was probably about 1%, at least 5% of the calves in that birth cohort must have been infected. A moderate external challenge was then defined as a challenge resulting from import of between 20 and 100 live cattle from the UK in the period 1988-1993. A moderate external challenge would therefore have made it likely that at least one infected animal was imported. The other levels of external challenge were established with the intention of indicating significant differences in the external challenge. The resulting scale mainly serves as a tool to ensure consistent judgement of the risk resulting from imports, rather than providing an objective measure of the level of risk.

- The period of highest risk that MBM imported from the UK was contaminated with BSE was set to 1986 - 1990. The risk peaked in 1988 when "Specified Bovine Offal" (SBO, more or less synonymous to SRM) were excluded in the UK from the human food chain but included into rendering and feed production. It was reduced with the exclusion of SBO from rendering, and therefore feed, at the end of 1989. As the appropriate application of that ban was delayed for some time, the risk born by MBM imports only declined since 1990 and then again in 1993, when the SBO-ban was better implemented.

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specific category for this type of products category 23010 is used to estimate the amount of imports. It is defined as "flours, meals and pellets made from meat and offal, not fit for human consumption; greaves".

Level of external challenge resulting from import of live cattle or MBM from the UK or other BSE-risk countries						
Level of external challenge	Live cattle from the UK 1988 - 1993	UK	Other countries	MBM import from the UK 1986-1990	UK	Other countries
		UK-imports before 88 and 94-97: *10; after 97: *100	Imports from other countries with a BSE risk: R1*1000, R2* 100		UK-imports before 86 & 91-93: * 10, after 93 *100	Imports from other countries with a BSE-risk: R1*100, R2* 10
Extremely High	≥10.000			≥10.000		
Very High	1.000 - < 10.000			1.000 - < 10.000		
High	100 - < 1.000			100 - < 1.000		
Moderate	20 - < 100			20 - < 100		
Low	10 - < 20			10 - < 20		
Very low	5 - < 10			5 - < 10		
Negligible	0 - < 5			0 - < 5		

Table 4 - Definition of BSE-challenge levels

Table 4 indicates that the import of one ton of MBM is considered to pose the same challenge as the import of one live animal. It is regarded to be unlikely to be higher because the probability that more than one infected cattle was processed per ton of MBM is very low, even in the UK. As rendering can only reduce BSE infectivity but does not eliminate it, the risk from one ton of MBM is regarded unlikely to be lower than from one live cattle.

- Given the much lower incidences in BSE-risk countries other than the UK, or in the UK in other periods, it is assumed that the risk carried by live cattle exported from these other BSE-risk countries or from the UK in other periods is much lower. To reach the same level of risk either 100 times (R2) or 1000 times (R1) more cattle must be imported than from the UK between

1988 and 1993. For MBM 10 (R2) or 100 (R1) times more MBM must be imported than from the UK between 1986 and 1990 to represent a similar external challenge.

- The appropriate value (R1 or R2) was selected by the SSC in function of the qualitative assessment of the likelihood that in the exporting country domestic cattle could already have carried the BSE agent. If this is regarded unlikely, even if not excluded, no risk is assumed to be carried by exports. Once the presence of BSE is regarded being likely, or if a country has notified cases but was not yet assessed with regard to its GBR, it is regarded as a likely source of BSE (R2). For the later a significant risk is assumed since about one incubation period before the earliest birth year of a domestic case and a potential risk (R1) since about 5 years earlier.

- Table 5 indicates from when it is assumed that countries could have exported a BSE-risk. It also indicates the relative level of risk by indicating which factor-(R1 or R2)-should be applied to exports from the respective country in a given year.

Country	GBR	R1	R2
Albania	III	No data	1988
Austria	III	1988	1990
Belgium	III	1983	1987
Bulgaria	III	1980	1986
Croatia	III	No data	1992
Cyprus	III	1980	1990
Czech Republic	III	No data	1988
Denmark	III	1985	1990
Estonia	III	1987	1988
Finland	Ill	1980	1990
France	III	1979	1980
Germany	III	1980	1988
Hungary	III	1981	1982
Ireland (Eire)	III	1980	1980
Israel	III	No data	1980
Italy	III	1983	1990
Latvia	III	No data	1980
Lithuania	III	No data	1994
Luxembourg	III	1983	1987
Malta	III	No data	1980
Netherlands	III	1985	1987
Poland	III	1980	1987
Portugal	IV	1979	1987
Romania	III	No data	1981
San Marino	III	1983	1990
Slovak Republic	III	No data	1988
Slovenia	III	1981	1991
Spain	III	1985	1987
Switzerland	III	1979	1980
Turkey	III	1980	1984
Greece	Ill	1985	1990
Japan	III	1985	1990

Table 5 - Countries in GBR III and IV and the year since when it is regarded as possible (R1=1000 for live cattle and 100 for MBM) or likely (R2=100 for live cattle and 10 for MBM) that exports of life bovine or MBM could have represented an external challenge

to the importing country. For the UK see Table 4. Earliest birth years of domestic BSE cases are given for indicative purposes, whenever a GBR assessment was carried out the date for R2 was established on the basis of the internal challenge assessment (see below).

- Available import/export statistics do not allow differentiation of the various forms of processed animal proteins that are imported. It also does not differentiate between the type of product or by species from which it is produced. The term "MBM" is therefore used in the context of the GBR as a term referring to Meat and Bone Meal (MBM) as such, Meat Meal (MM), Bone Meal (BM), or Greaves made from meat and offal. It is synonymous to "flours, meal, pellets made from meat or offal; greaves" (custom code 23010, EUROSTAT) in the import/export context. As long as no evidence is provided of the contrary, it is assumed that, "MBM" is at least partly made from ruminant material.

- The external challenge that enters the BSE/cattle system in the importing country and that is associated with imported cattle or MBM also depends of their fate after import. The key question is if the BSE-infectivity that could have been carried by these imports did enter the internal BSE/cattle system, as described in figure 1, or not.

- 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, the external challenge is effectively managed and there is no risk that domestic infections could result from imported infected cattle. Another factor is age at slaughter: imported animals slaughtered young (e.g. < 24 months of age) can only carry a 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 years of age therefore represent no or only a very small external challenge.

- 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. The latter is possible during transport, in feed mills and on farms. The ability to avoid cross contamination is essential for the stability of a BSE/cattle system (see below). If imported MBM is reliably only used for non ruminants, e.g. in pet food, it would not represent an external challenge.

- In principle, it cannot be excluded that, under certain circumstances, even an infectious load entering an unstable BSE/cattle- system may have no impact. This may happen if it is unintentionally eliminated, e.g. if contaminated imported MBM is all fed to pigs or poultry and does not reach cattle, even if during that period feeding MBM to cattle was legally possible and generally done. However, the principles of risk assessments require that reasonable worst case scenarios are used whenever the contrary cannot be demonstrated. It is, therefore, assumed that any exposure of an unstable system to the BSE agent would result in domestic cattle being infected with BSE.

3.5.2 Stability

The **GBR Stability** is the ability of a BSE/cattle system to prevent or to reduce the speed of spreading of the BSE agent within its borders. Stability relies on 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.

The factors assumed to be able to prevent the building-up of BSE-infectivity in the system are the following:

- **Surveillance.** The risk of introducing the BSE-agent into the feed chain is reduced if BSE cases are identified and excluded as well as the removal of related cattle at risk of being infected.

- **SRM-removal.** The infectivity that could enter the feed chain can be reduced by excluding from rendering those tissues known to carry the bulk of the infectivity that can be harbored by a pre-clinical BSE-case. Excluding fallen stock from rendering is considered to be equally effective as a "partial" SRM-ban. This is due to the fact that findings from the extensive active surveillance in Europe indicate that the frequency of pre-clinical infection in fallen stock and emergency slaughter 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.

- **Rendering.** According to the SSC opinion on the safety of MBM appropriate rendering processes reduce BSE-infectivity that enters the process with the raw material. The SSC assumes, for all practical purposes, a reduction factor of at least 1,000 for a process known as "batch pressure cooking". Rendering, however, can never be taken as a way to sterilize BSE contaminated material[12].

- **Feeding.** If no feed that potentially carry the BSE-agent reaches bovines the risk of new infections in the domestic cattle population would, under the basic assumptions made for the GBR, be zero. 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-containing pig or poultry feed, e.g. in feed mills that produce both types of feed in the same production lines. Apparently flushing batches, a method that is often used as safeguard against such cross-contamination, is not sufficient. This conclusion from the practical experience is supported by the oral exposure experiments in the UK that have shown that as little as 0.1g, and probably also 0.01g, of infected brain is enough to infect cattle orally, and probably even smaller amounts will do in certain cases.

  The most important stability factors are those which reduce the risk of recycling of BSE, in particular feeding, rendering and SRM-removal.

Assessing the impact of "Feeding":

If feeding MBM to cattle would be completely avoided the only efficient BSE transmission route known would be blocked.

- Feeding is regarded to be **"OK"** if it is highly unlikely that any cattle received mammalian MBM (MMBM) at any time in its life. This assessment has to take into account deliberate feeding of mammalian MBM to cattle as well as accidental administration, e.g. due to cross-contamination of MBM free cattle feed with (traces of) MMBM. Feeding is regarded as **"OK"** if, for example, a total feed ban together with controls by sampling are implemented measures.

[12] See the SSC-opinion on the safety of Meat and Bone Meal adopted on the 26 and 27 March 1998

- If deliberate feeding of MMBM to cattle is unlikely, e.g. because of a feed ban, but cross contamination cannot be excluded (e.g. no controls by sampling in place), "feeding" is considered as **"reasonably OK"**.

- If deliberate feeding is likely to occur, even only at certain periods of the year or of the life of certain cattle, or if cross contamination of cattle feed with MMBM is likely, feeding is then considered as **"not OK"**.

Assessing the impact of "Rendering":

"Rendering" refers to the processing of animal remains or entire animals into processed animal proteins and related by-products such as MBM, bone meal, meat meal, greaves, and tallow. A rendering process is regarded to be able to significantly reduce BSE-infectivity if it complies with the "standard" of sterilization under temperature/pressure of 133°C/3^{bar} for at least 20 minutes "batch pressure cooking". The pressure refers to the pressure of steam in the airless cooker and the material has to have a maximum size of 5 cm and a moisture content of about 60% when entering the cooker. These conditions are referred to by "the 133°C/20^{min}/3^{bar} standard".

- If all rendering plants that process ruminant materials reliably operate the 133°C/20 min/3bar standard, the SSC assumes, for all practical purposes, any infectivity would be reduced by a factor of at least 1000. Under this condition rendering is considered as **"OK"**. As well, if no rendering takes place, rendering is considered as **"OK"**.

- If only rendering plants that process "high risk" material (i.e. fallen stock, condemned materials and animals condemned in ante mortem inspection) reliably operate the standard, rendering is considered as **"reasonably OK"**.

- If high and low risk material is rendered under sub-standard conditions, or if the evidence provided for the reliable application of the standard conditions is insufficient, rendering is considered as **"not OK"**, even if individual rendering plants might comply with the standard.

Assessing the impact of "SRM-removal"

In a BSE infected cattle that approaches the end of the incubation period between 95 and 99% of the infectivity is concentrated in the Specified Risk Materials (SRM). Removing these from the feed cycle reduces the amount of infectivity by up to two logs. However, small breaches of such a removal reduce this factor significantly.

SRM are not only included in slaughter waste but also in fallen stock or cattle dead at arrival or condemned in ante mortem inspection. If BSE is present in a cattle population, the prevalence of infected cattle approaching the end of the BSE incubation period is significantly higher in the sub-population of fallen stock and emergency slaughter than in normal slaughter.[13]

Hence excluding fallen stock from the feed chain is effectively reducing the risk of recycling the BSE agent. However, any occasional rendering of fallen stock could pose a high risk because in that case the incubation period could have been in its finishing stage and high concentration of BSE *infectivity* would enter the rendering process and later the feed chain.

[13] As defined in the SSC-opinion on "Fallen stock", 25-25 June 1999.

- SRM-removal is considered as **"OK"** if SRM are reliably removed from imported and domestic cattle and fallen stock is also reliably excluded from rendering into feed.

- SRM-removal is considered as **"reasonably OK"** if SRM from imported and domestic cattle and fallen stock is not normally rendered but the efficiency of this is not well documented.

- SRM-removal is considered as **"not OK"** if it has to be assumed that SRM and/or fallen stock are normally rendered into feed.

In addition to these three main stability factors, BSE surveillance can contribute to stability by identifying clinical suspects and other high risk related cattle and thereby avoiding them from entering the feed cycle. However, to have an effect at very low BSE prevalence levels requires, as experience from Europe showed, not only a good passive surveillance but also large-scale active sampling of cattle not suspected of BSE.

- A passive surveillance that does not generate at least the annual numbers of BSE suspects required by the OIE (Office International des Epizooties) would reduce stability to a certain degree. It could create an impression of false safety, making other safeguards eventually in place less effective.

- A good passive surveillance would at least identify annually the number of BSE suspects as required by the OIE and test them in appropriate laboratories. It would also indicate a degree of awareness that makes other stability factors more reliable. However, as the detectable clinical incidence of BSE would be rather high, it would not enhance stability either.

- It is currently impossible to detect pre-clinical BSE- cases and early clinical phases of BSE are easily misdiagnosed. Therefore the time frame required for a BSE infection to be detected will normally be at least one incubation period after the initial challenge (approximately 5 years) because cases become detectable only shortly before the end of the incubation period. This time between first infections and detection of first BSE cases may be much longer because small numbers of dispersed clinical cases of BSE might remain undetected for some time.

- A BSE surveillance that combines a good passive with an active sampling of "healthy"/non-suspect cattle (adult cattle in normal and emergency slaughter and in fallen stock) could identify lower levels of BSE incidence and therefore enhance the stability of the system. If numbers of sample tested are high enough such a comprehensive surveillance system could allow detecting at least most clinical cases and avoid that these enter rendering through appropriate culling schemes.

A BSE/cattle system is considered as **"optimally stable"** if recycling of the agent is practically excluded. This requires that all three main stability factors (feeding, rendering, SRM-removal) are in place, well controlled, implemented and audited, i.e. are assessed as "OK". Ideally such a system would also integrate a highly effective BSE surveillance, and control of all imported live cattle and feed stuffs would prevent a potential external challenge, i.e. imported BSE-infected cattle or BSE-contaminated MBM from entering the BSE/Cattle system. Such a system would fully prevent any propagation of BSE-infectivity and eliminate BSE-infectivity from the system very fast.

The different combinations of the three main stability factors accordingly result in different levels of stability, as shown in Table 6. 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.

With 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.

It should be understood that also this table is not meant to provide a semi-quantitative assessment of stability but is rather meant to be guidance for ensuring consistent interpretation of comparable data. This should ensure that similar situations are judged similarly.

STABILITY	**Level**	***Effect on BSEinfectivity***	Most important stability factors		
			Feeding	**Rendering**	**SRM-removal**
<u>Stable</u>: **The system will reduce BSE-infectivity**	**Optimally stable**	*Very fast*	Feeding "OK", rendering "OK", SRM removal "OK".		
	Very stable	*Fast*	2 "OK", one "reasonably OK".		
	Stable	*Slow*	2 "OK" and 1 "not OK" **or** 1 "OK" and 2 "reasonably OK".		
Neutrally stable		*+- constant*	3 "reasonably OK" **or** 1 "OK" and 1 "reasonably OK" and 1 or'2 "not OK".		
<u>Unstable</u> : **The system will amplify BSE-infectivity**	**Unstable**	*Slow*	2 "reasonably OK", I "not OK".		
	Very unstable	*Fast*	1 "reasonably OK", 2 "not OK".		
	Extremely unstable	*Very Fast*	All three "not OK".		

Table 6 - BSE-stability levels ("Optimally" should be understood as "as good as possible according to current knowledge".)

3.5.3 Interaction of stability and external challenge

If a stable BSE/cattle system is exposed to an external challenge, i.e. if the BSE-agent is introduced into the BSE/cattle system, processing and recycling of the BSE-load entering the system will be

fully or partly prevented and the infectivity load will be neutralized, at least over time. The period needed is shorter for a higher stability.

If an unstable BSE/cattle system is exposed to an external challenge, processing and recycling of the BSE-load entering the system will take place and the agent will be amplified, over time.

If BSE- infected cattle are imported, they need to be processed before the agent enters the domestic BSE/cattle system. Only if they are approaching the end of the incubation period when they are processed; their BSE-load is regarded being significant. 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 import 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, less than 8 years after the initial import – even if the importing system is very unstable.

If cattle are imported for immediate slaughter the challenge is strongly depending of their age at import which is largely similar to their age at slaughter. If they are young the likelihood of them approaching the end of the incubation period is very low. Hence the external challenge is significantly reduced. If, however, old 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 shortly afterwards, i.e. normally 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.

3.5.4 Conclusion

The qualitative nature of this methodology and its limitations should be understood in the context of present scientific knowledge on BSE and of the availability and quality of data. As they both evolve, and with the possible advancement of diagnostic methods, the need may arise for the methodology to be revised further and/or its application to particular countries to be repeated.

In parallel with the work of the SSC, the OIE has developed further the BSE- chapter in its Animal Health Code, which makes reference to risk assessment as an integrated part of the procedure to establish the BSE- status of countries or zones. The compatibility of the OIE approach and the SSC methodology for assessing the GBR is extensively discussed by the SSC in its opinion on the GBR of July 2000; an updating of this analysis would be appropriate.

The GBR has no direct bearing on human exposure to BSE. In fact, at a given GBR, the risk that food is contaminated with the BSE agent depends on three main factors:

- the likelihood that infected bovines are processed;
- the amount and distribution of infectivity in BSE- infected cattle at slaughter;
- the ways in which the tissues that contain infectivity are process into food.

The past stability and external challenge of the system are the reason for current probability that BSE infected (pre-clinically or clinically) cattle are present in a country. After a system became stable the rate of new infection is by definition lower than the rate at which infected cattle leave the system. In an optimally stable system the GBR decreases at the same rate by which incubating cattle leave it but even then the risk is only approaching zero once the last cattle born before "optimal stability" is slaughtered.

BSE risk-management measures may have an immediate effect on the risk of introducing the BSE agent into human food (in particular an effective SRM ban) and on recycling and amplification of the BSE- agent, i.e. on the rate of new infections. However, this will only be reflected in the number of clinical BSE- cases around one incubation-period after their effective implementation.

Future external challenges and the ability of the system to reduce any incoming or already existing BSE infectivity determine the future development of the GBR

Assuming that new challenges can be avoided, the current stability determines the slope of the GBR- trend. An optimally stable system will reduce the GBR level and an extremely unstable system will amplify any BSE- infectivity that is already in the system and increase the GBR level.

4 APPLICATION OF THE METHODOLOGY FOR ASSESSING THE GBR IN CATTLE

The GBR methodology is strictly qualitative and requires independent expert judgement which is guided and standardized by the definitions provided by the methodology. The application of the GBR methodology has been a typical multi-step process resulting in the publication of a GBR country report for each country (see Annex 1 for the outline) as a SSC opinion.

The steps are as follows:

a) the dossier with data is provided by the assessed country to the European Commission;

b) the first draft GBR report is prepared by the SSC secretariat in cooperation with external experts participating in ad hoc working groups of the SSC;

c) the first draft GBR report is discussed and approved by the GBR peer group, a standing working group of the SSC with one representative from the SSC itself, one from the TSE/BSE ad hoc group and two external independent experts who are not member in any scientific committee of the EC;

d) the first draft GBR report is sent for comments to the country;

e) the country comments are included in the final draft GBR report;

f) the final draft GBR report is discussed and approved by the GBR peer group

g) the final draft GBR report is sent to:

- the country for final comments;
- the TSE/BSE group for review;
- the SSC for information

h) The TSE/BSE group discusses the final draft GBR report. If appropriate, the group will then forward the report to the SSC and has also to adopt a draft opinion on the GBR of the country under consideration. If country-comments are already available, they will be integrated at that stage. If they arrive later, the GBR peer group will integrate them into the final version of the report and of the opinion going to the SSC and inform the SSC on these changes.

i) The final draft report and the draft opinion will be transmitted to the SSC for adoption at its next meeting. If last minute comments from a country are received that indicate the need for significant modifications, the SSC has to decide if it carries these out by itself. It also may adopt the opinion, subject to modification and delegate this modification to the TSE/BSE group or the GBR peer group. Finally, it may postpone the adoption, sending the file back to the GBR peer group.

Some countries, instead of being assessed according to the GBR methodology, opted to provide their own risk assessment. These assessments have to be checked and translated into a GBR level or, if the own assessment is not based on realistic assumptions, a GBR report has to be produced.

Although the GBR country report is normally produced in close interaction with the assessed country, there is no implication that this report should be agreed upon by the competent Authority of the assessed country.

4.1 The role of the competent Authority of the assessed country

No GBR assessment is possible if the interested country does not provide the necessary data. The receipt of an adequate country dossier marks for the European Commission (Health and Consumer Protection Directorate General) the beginning of the GBR process.

The role of the competent Authority of the assessed country is of paramount importance not only because of data provision, but also because of the systematic interactions taking place when the first draft GBR report and the final draft GBR report are sent out by the European Commission Secretariat for comments. Comments, additional information and clarification elements from the competent Authority have proven to be often fundamental in the process.

4.2 The role of the external experts

Retrieval, analysis and summary of the available information (either provided by the country or from other sources) covering the last 20 years is carried out by a Group of external experts (and particularly by a "primary analyst" identified for each report). These experts are members of an ad hoc working group of the SSC and apply a standardised scheme in line with the GBR methodology to the data sets provided by the country authorities. Information concerning critical imports need to be assessed, cross-checked as far as possible against international trade statistics, and summarised. This includes information on the fate of imported cattle and the use made of imported MBM. The experts also compile and present in a standardised way information on the main stability factors (feeding, rendering and SRM). Also data on the cattle population and information on the BSE

surveillance are put together. The external experts, in collaboration with the SSC-Secretariat, are then responsible for producing the complex import-tables on which the external challenge assessment is based as well as drafting the draft GBR country reports.

4.3 The role of the GBR Peer Group

A group of independent experts (the so-called GBR peer Group), established in the year 2000, then peer-reviews these analyses and provides the necessary judgement. It determines the level of external challenge that was experienced by, and the stability of the analysed BSE/cattle system. The GBR-Peer Group then carries out a qualitative assessment of the interaction of challenge and stability and concludes on the likelihood that at current one or several BSE infected (pre-clinically or clinically) cattle are present in the domestic cattle herd. Finally the Group reflects on the potential development of the GBR and how this could be influenced.

4.4 Role of the BSE/TSE Group

The BSE/TSE Group is a specialised body consisting of a number of experts who are active in the field of the BSE research and management. The role of this Group is to advise the SSC on all the BSE- and TSE- related issues.

The review of the final draft GBR country reports by the BSE/TSE ad hoc Group mainly aims at ensuring that all new scientific developments are properly taken into account. This input is of particular importance for ensuring the permanent up-date of the GBR-methodology itself.

4.5 Role of the SSC

Not only the SSC developed and updated the methodology to assess the GBR, but it also examined and evaluated all the GBR country reports before it adopted an opinion on the GBR of the assessed country. The SSC also carries the responsibility of guiding and supervising the entire process through which the GBR methodology was applied to individual countries.

Both, the GBR reports and the SSC opinions, have been made publicly available on the web site of the European Commission as soon as they were adopted by the SSC.

4.6 The revision of specific GBR country reports

As mentioned in section 2, the GBR methodology has been repeatedly refined.

A very large number of GBR country reports were produced with the methodology described in the 6 July 2000 SSC opinion. In this methodology, the challenge was represented by imports of live cattle and MBM only from countries with at least one confirmed case of BSE. The development of the BSE epidemic in some countries afterwards, however, indicated that this approach was too optimistic. A more prudent assessment would have required considering as a challenge all imports of live cattle and MBM from countries with notified cases of BSE and from those countries already assessed as being likely affected by BSE even in the absence of notified BSE cases (Table 1).

Therefore, an update of the GBR methodology was adopted by the SSC on 11 January 2002. This updating called upon for a revision of the assessment of the GBR for all the countries which had been already evaluated with the methodology of the 6th of July 2000, also in the light of the latest epidemiological information.

This revision has been carried out with the same interactive procedure described in the present chapter.

5 THE PRESENT STATUS OF THE GBR ASSESSMENT IN CATTLE WORLDWIDE AND ITS IMPLICATIONS IN TERMS OF PUBLIC HEALTH

5.1 GBR Status

So far 63 countries have been assessed with regard to their GBR, some of them already for a second time, and more than 25 other have requested an assessment.

An overview of the available results is provided in Table 7.

In certain cases the result of the second assessment has deviated from the first one. The reason is usually that in a GBR II country a BSE domestic case was detected due to strongly enhanced surveillance. It is also worth noting that since 2000 eleven countries have detected a first BSE case. Of these 3 were previously classified as GBR II (AT, FIN, SL), and 6 were previously classified as GBR III (CZR, DE, IT, SK, SP, PO). Moreover, Israel detected a first case before the assessment was finalised while the draft report already indicated GBR III. Similarly, in Denmark the first BSE case was detected shortly before the finalisation of the SSC Opinion of 6 July 2000 already indicating the classification of Denmark in GBR level III.

A clear pattern can be seen in the development of the GBR. Only after the first BSE case is detected, measures that are already in place are appropriately implemented and controlled and additional measures are taken. This often significantly improves the situation but as already explained above cases will continue to appear until the last cattle born before the system became stable has disappeared.

n°	Country name	current GBR	Remarks
1.	Andorra	III	
2.	Albania	III	Re-assessment ongoing
3.	Argentina	I	
4.	Australia	I	Re-assessment ongoing
5.	Austria	III	
6.	Belarus	III	
7.	Belgium	III	
8.	Botswana	I	Re-assessment ongoing
9.	Brazil	I	
10.	Bulgaria	III	
11.	Canada	II	Re-assessment ongoing
12.	Chile	I	
13.	Colombia	II	Re-assessment ongoing
14.	Costa Rica	II	
15.	Croatia	III	

16.	Cyprus	III	
17.	Czech Republic	III	Re-assessment ongoing
18.	Denmark	III	
19.	El Salvador	I	Re-assessment ongoing
20.	Estonia	III	
21.	Finland	III	
22.	Former Yugoslav Republic of Macedonia	III	
23.	France	III	
24.	Germany	III	
25.	Greece	III	
26.	Hungary	III	Re-assessment ongoing
27.	Iceland	I	
28.	India	II	Re-assessment ongoing
29.	Ireland	III	
30.	Israel	III	
31.	Italy	III	
32.	Kenya	II	Re-assessment ongoing
33.	Latvia	III	
34.	Lithuania	III	
35.	Luxembourg	III	
36.	Malta	III	
37.	Mauritius	II	No application for re-assessment
38.	Namibia	I	Re-assessment ongoing
39.	Netherlands	III	
40.	New Caledonia	I	
41.	New Zealand	I	
42.	Nicaragua	I	Re-assessment ongoing
43.	Nigeria	II	No application for re-assessment
44.	Norway	I	Re-assessment ongoing
45.	Pakistan	II	Re-assessment ongoing
46.	Panama	I	Re-assessment ongoing
47.	Paraguay	I	
48.	Poland	III	Re-assessment ongoing
49.	Portugal	IV	
50.	Romania	III	Re-assessment ongoing
51.	San Marino	III	
52.	Singapore	I	
53.	Slovak Republic	III	Re-assessment ongoing
54.	Slovenia	III	
55.	Spain	III	
56.	Swaziland	I	Re-assessment ongoing
57.	Sweden	II	Re-assessment ongoing
58.	Switzerland	III	Re-assessment ongoing
59.	Turkey	III	
60.	United Kingdom	IV	
61.	Uruguay	I	
62.	USA	II	Re-assessment ongoing

63.	Vanuatu	I	

Table 7 – Status of the GBR-Assessment in 63 countries

The country reports adopted by the SSC have also provided for each country an evaluation of the expected development of the GBR.
For most countries with GBR level other than I, the analysis indicated a decrease of the risk over time as a consequence of the many measures adopted. Some recommendations were provided for further reducing the GBR by increasing the stability of the country's BSE/cattle system. Optimal stability would be needed to ensure the elimination of any recycling of BSE-infectivity, and hence to maximise the rate of decrease of the GBR. Optimal stability can only be assumed if evidence is provided that:

(i) it is highly unlikely that any cattle is exposed to ruminant MBM or other potentially contaminated feedstuffs, either deliberately or via cross-contamination;

(ii) rendering is carried out only in plants that reliably operate at $133°C/20^{min}/3^{bar}$ or no rendering takes place;

(iii) SRM-removal and safe disposal[14] is ensured both from imported and domestic cattle;

(iv) fallen stock is excluded from the feed chain.

If adequate active surveillance is carried out[15], optimal stability is further confirmed.

It is reasonable to assume that, in a country in which all the above-mentioned optimal stability conditions are met, no further domestic cattle can be infected by BSE through the oral route. This is the case of the European Community that has adopted a series of legislative acts that put the obligation on all Member States to comply with all the above-mentioned conditions needed for optimal stability. The key issue is, therefore, to comply with the Community legislation and the optimal stability conditions. Obviously, partial compliance and even occasional breaches and leaks in the system would favour a recycling of BSE-infectivity and generate new domestically-infected animals. This would slow down the decline of the GBR considerable. The significance of breaches and leaks in terms of BSE-amplification is obviously dependent, among other factors, on the BSE-infectivity load present in the country. A reliable, national, well-structured management and control framework is crucial to ensure that optimal stability is achieved and maintained throughout.

After several years (e.g. 5 years corresponding to one average incubation period) with no new BSE-cases detected in the cattle population born after the achievement of the optimal stability conditions, it would, therefore, be reasonable to reconsider the GBR-assessment. It is suggested to establish a set of indicators and criteria that should be regularly monitored for providing an adequate base for such a future revision of the GBR. Even if there is excellent surveillance, these indicators should include all those of critical importance for optimal stability.

[14] This may include a rendering step that should, whenever immediate incineration is not guaranteed, also comply with the 133/20/3.

[15] The increase in BSE numbers, revealed by the better surveillance, should be taken into account in reclassifying countries from GBR III to IV. Already the surveillance system has confirmed the GBR III classification of many countries and revealed that Austria and Finland Should be transferred from GBR II to III; Greece is also now in GBR III.

[16] http://europa.eu.int/comm./food/fs/bse/bse30-en.pdf.

The guidance for third countries on the conditions for an "effective feed ban" that can be found on the internet site of the European Commission[16] gives a good orientation for the practical requirements that should be met.

Countries where the presence of BSE is highly unlikely (GBR level I) can be split into two sub-groups. Those who had, in addition to negligible external challenges, a certain degree of stability and those where the absence of BSE is fully dependent on the absence or efficient prevention of external challenges. These countries which apparently have never been exposed to any non-negligible challenge or have been able to prevent challenges by specific measures (mostly import restrictions and very careful monitoring of imports from at-risk countries) must be very careful in order to maintain their very favourable GBR status. This is particularly true if their stability remains low. In principle, certainty of maintaining level I GBR can best be acquired by implementing the preventive measures needed for optimal stability.

5.2 Public health implications

From the public health standpoint the usefulness of the GBR methodology is multiple.

Firstly, the GBR allows prediction of presence of BSE in the bovine population long before BSE-infected animals can be discovered through passive (or even active) ad hoc surveillance programmes; so far this has proved to be the case for several countries (i.e. Czech Republic, Germany, Italy, Slovakia, Slovenia, Spain, Poland and Israel). Clearly this offers the possibility of much earlier awareness of the potential presence of BSE in the country and of the need for associated and appropriate measures to manage the risk adequately.

Secondly, the GBR allows the understanding of the weakness of any specific country's system with respect to the BSE risk and therefore is an effective guidance for the identification of the additional control measures needed to prevent BSE from entering the country and being amplified. This analysis, carried in a standardised and transparent manner, has proven to be of a considerable help to the assessed countries.

Thirdly, the work carried out so far has produced the most powerful world-wide data collection on ruminant husbandry and feeding as well as on animal waste recycling and disposal. If properly exploited, these data are likely to prove helpful for the control of other ruminant diseases and other animal health problems.

However, the most relevant implication in public health terms of the GBR methodology has been the translation of this scientific information into BSE safety criteria for a number of ruminant-derived products sourced from different countries (Table 7). Materials sourced from GBR level I countries are in principle safe with regard to BSE risks (however, according to the SSC, sourcing from fallen ruminant stock should be avoided even in GBR level I countries because of the higher probability of manifestation of BSE in this group of animals). Table 7 shows, as an example, how the GBR classification has influenced the definition of Specified Risk Material (SRM) and has provided a very helpful public health instrument to decision-makers. Similar preventive and pro-active approaches have been adopted by the SSC for several materials including tallow, gelatine, collagen, hydrolysed proteins, amino acids, blood and phosphates from ruminants. These scientific approaches have been widely implemented in the E.U legislation.

	Animals fit for human consumption	Specified risk materials (for animals fit for human consumption)
GBR I	*Ante* and *post mortem* inspection	**Cattle:** none **Small ruminants:** none
GBR II and GBR III	*Ante* and *post mortem* inspection	**Cattle:** The skull, including the brain and eyes, tonsils, the vertebral column excluding the vertebrae of the tail and the transverse processes of the lumbar and thoracic vertebrae and the wings of the sacrum, but including dorsal root ganglia, and spinal cord of animals above 12 months. Intestine from duodenum to rectum and the mesentery of animals of all ages. **Small ruminants:** The skull, including brain and eyes, the tonsils, the spinal cord of ovine and caprine animals aged over 12 months or which have a permanent incisor erupted through the gum; The spleen of ovine and caprine animals of all ages.
GBR IV	*Ante* and *post mortem* inspection*	**Cattle in addition to the above:** the entire head excluding the tongue, including the brain, eyes, trigeminal ganglia and tonsils; the thymus, the spleen and the spinal cord of animals above 6 months **Small ruminants:** as above

Table 8 – Impact of the GBR-C methodology on the definition of specified risk materials

* For the United Kingdom, a number of special schemes exist, for example the Date-based Export Scheme, the Over Thirty Months Scheme and the Beef Assurance Scheme.

6 THE GEOGRAPHICAL BSE RISK OF BSE IN SMALL RUMINANTS

BSE in sheep has not been proven under field conditions, but information obtained so far can be used as a scientific plausible stepping-stone for a hypothetical model for the occurrence and spreading of a BSE epidemic in small ruminants, if indeed it would occur. This model for hypothetical BSE in sheep, combined with the experiences from the assessment of the geographical BSE risk in cattle, has led to the framework for assessing the geographical BSE risk in sheep and goats (GBR-S) described in the SSC report adopted on 8 November 2002.

6.1 Definitions and methodology

A stepwise approach was developed to assess the geographical BSE-risk for sheep and goats (GBR-S) based on the exploitation of the geographical BSE-risk for cattle (GBR-C) in order to make possible public health decisions while the very time consuming tests now being proposed for the reliable discrimination of BSE from scrapie are carried out.

For sheep, the same classification of GBR already in use for cattle, i.e. Levels from I to IV with exactly the same definitions after substitution of the word “cattle” with the word “sheep” is used. The GBR-S methodology acknowledges the peculiarities of sheep, as compared to cattle, concerning:

a) routes of infection (not only contaminated feed, but also direct and indirect contact);

b) prevalence of BSE in a sheep scrapie population (the upper bound for BSE prevalence among scrapie-positive sheep assumed to be 1%);

c) **prevalence of scrapie in small ruminants** (as a reasonable worst case hypothesis a prevalence of 0.5% of scrapie is assumed in small ruminants);

d) prevalence of BSE in small ruminants (as a reasonable worst case hypothesis a prevalence of 0.005% is assumed in small ruminants).

e) information factors and model of the BSE sheep system.

The methodology for assessing the data provided by a country to show that small ruminants were not exposed since 1980 to significant levels of potentially-infected MBM would be the one already developed for cattle by making use of the available information highlighted in Table 9.

The methodology proposed to assess the GBR-S is a stepwise systematic process.

6.2 Step one - Countries in GBR-C levels III and IV

Based on the above mentioned assumptions, it is concluded that countries with GBR-C levels III or IV should be classified, even in the absence of notified BSE or scrapie-cases among small ruminants, into GBR-S level III unless data can be provided showing that, since 1980, it was very unlikely or unlikely that significant levels of potentially-infected MBM reached small ruminant through the feed chain.

All information should be provided, as far as feasible, on an annual basis and for the last 21 years (1980 to 2000). Information that is stable for several years might be provided only once together with a specification of the period it refers to.

Structure and dynamics of the ovine/caprine population

- Number and age distribution of sheep and goats, both alive and slaughtered
- Information on husbandry systems used for sheep and goats
  - type of main product: wool/meat/milk,
  - intensive/extensive,
  - productivity of milk-sheep/goats,
  - co-farming of pig/poultry/cattle with sheep/goats,
  - geographical distribution of sheep/goats, cattle and pig/poultry populations,
  - size distribution of sheep flocks and goat herds,
  - Internal animal trade: (n° and age distribution of sheep/goats annually traded between flocks/herds, and between different husbandry systems and/or between different regions of the country.

Surveillance of TSEs in small ruminants

Measures in place to ensure detection of TSE (scrapie)-cases:

- Identification system and its tracing capacity (for sheep and goats)
- Date since when TSEs are (scrapie is) compulsory notifiable and criteria for a TSE (scrapie)-suspect
- Awareness training with regard to TSEs (scrapie) in small ruminants (when, how, who was trained)
- Compensation for animals culled in the context of scrapie eradication (since when, how much in relation to market value, payment conditions)
- Other measures taken to ensure notification of scrapie suspects
- Specific TSE/scrapie-surveillance programs and actions (detailed description, plans)
- Methods and procedures (sampling and laboratory procedures) used for the confirmation of TSE-cases

Results of TSE/scrapie-surveillance:

- Number of examined sheep and goats, by origin (domestic/imported), type (wool/milk/meat), age, method used to confirm the diagnosis and reason why the animal was examined (CNS, TSE-suspect, TSE-related culling, other)
- Result of the surveillance efforts
- Incidence of reported TSE-cases/n° of newly infected flocks by year of confirmation, by birth cohort of the confirmed cases, and – if possible – type of use (wool/meat/milk).

TSE related culling

- Eradication measures, including culling schemes, date of introduction & criteria used to identify animals that are to be culled
- Information on animals already culled in the context of TSE

Import/export of live animals (bovine/ovine/caprine) and of MBM (Note: Blood, semen, embryos or ova not seen as an effective transmission route. MBM is used as proxy for mammalian protein (other than milk) as animal feed)

- Imports/export of live animals (cattle/sheep/goats and/or MBM from/to UK, from/to other BSE-affected countries[1] and from/to other "BSE-free" countries; provide annual data per partner-country)
- Information that could influence the risk of imported live animals or MBM to carry the BSE agent (BSE-status of the herds/flocks of origin of imported cattle/sheep/goats, precise definition of the imported animal protein, information on the process conditions and raw material used for imported MBM, etc.)
- Use made of the imported animals and of the imported MBM.

[1] BSE-affected countries are all countries with confirmed BSE-cases and all countries classified by the SSC as GBR III, even if they have not notified any cases.

Feeding and cross-contamination

- Composition of the feed for ruminants (for cattle/sheep/goats give the percentage of grass/pasture, roughage, industrial feeds, protein concentrates used in on-farm preparation of compound feed for ruminants, feed additives, … per species) and measures taken to control this composition
- Use of MBM (domestic and imported: for farmed animals (ruminant/non-ruminant), in pet food, fertilizer, or in other uses (please specify); information on how this use was controlled)
- Domestic production of composite animal feed and its use (type of feed mills (single line/multiple line plants, single/multiple species production), annual production of feed by target species and by feed mill, information on how the use of the produced feed was controlled).
- Potential for cross-contamination of feed for ruminants with MBM or blood during feed production, during transport and on-farm,
  - measures taken to reduce it (labeling, awareness raising, technical installations);
  - measures taken to control it (feed sampling (specify n° of samples taken from compound feed for ruminants per year and species, method of examination, place of sampling (feed mills, during transport, on-farm), other controls in feed mills, during transport or on-farm);
  - results of the controls, handling of breaches.

Table 9 - Information elements for assessing the GBR for sheep and goats(a)

Level of external challenge	Live small ruminants from the UK 1988 - 1993	UK	Other countries
Extremely High	>10.000.000	**UK-imports before 88 and 94-97: *10; after 97: *100**	**Imports from other countries with a BSE risk: R1*1000, R2* 100**
Very High	1.000.000-<10.000.000		
High	100.000-<1.000.000		
Moderate	20.000-<100.000		
Low	10.000-<20.000		
Very low	5.000-<10.000		
Negligible	0-<5.000		

Table 10 - Level of external challenge resulting from import of live small ruminants from the UK or other BSE-risk countries

6.3 Step one - Countries in GBR-C level I and II

To assess the GBR-S of countries with GBR-C levels I or II, it would be necessary to check that the challenge deriving from potentially-BSE-infected materials, already assessed for cattle as being negligible or very low, remains as such even after consideration of the additional challenge for the feed chain that might have occurred since 1980 through live sheep imported from BSE risk countries (this import, in fact, might have given origin to an internal production of potentially-infected MBM which could have reached both small ruminants and cattle). Should the challenge through the feed chain due to live small ruminants be found to be negligible throughout, the GBR-S classification would remain identical to the GBR-C classification. Otherwise the combined external challenge should be assessed and a stability analysis conducted for the sheep feeding system since

1980, resulting most likely in a higher GBR-S level. The issue depends crucially on the stability of the system with the exclusion of any possibility that BSE infectivity can contaminate the feeding systems for small ruminants.

In order to apply to small ruminants the methodology already developed for cattle, one could use the same external challenge categories in use in the GBR-C, taking advantage of the available information on the imports of live small ruminants (this is potentially very important as the EUROSTAT data reveal very large number of animals being traded every year) from BSE-risk countries and on the reasonable worst case assumption for the prevalence of BSE in small ruminants. The date reported in Table 10 should be fed, as applicable, to the GBR model and examined consequently.

6.4 Step two

For countries that at the end of step one remain classified as GBR-S level I or II, it would be necessary to estimate whether BSE might have entered the country through live small ruminants and transmitted through horizontal or vertical routes. To this end, use should be made of the information, when available, on the numbers of imported live small ruminants from BSE-risk country and dates. The intended use of these animals is important because it is expected that a substantial proportion of these animals are scheduled for slaughter but experience suggests that an appreciable proportion of the animals imported into one country may be rapidly exported to another country. This will reduce the risk in the first country, but amplify the potential spread of BSE infectivity.

In order to develop different challenge levels for the horizontal transmission of BSE in small ruminants, it could be considered, as a starting point, that information derived from scrapie indicates that even a small number of infected sheep (according to a worst case hypothesis, even one animal can be at the origin of disease spread within a flock) is sufficient to generate and sustain an epidemic and that such a probability increases with the number of potentially–infected animals imported. This evaluation should be based on the same prevalence factor reported above. Therefore, a significant probability of a BSE epidemic in small ruminants would be associated, for example, with the import into a given flock of a few thousands breeding or milking sheep, whereas sheep imported for immediate slaughter are not expected to give any major contribution to this risk of spreading BSE via horizontal transmission.

The SSC stressed that this GBR-S model will need adjustments when new scientific data regarding probable/possible presence of BSE in small ruminants under field conditions become available, but supports the further development (and its application) of the present model if an acute situation concerning discovery of BSE in sheep under field conditions would occur. Obviously, the possibility should be considered that the results of the GBR-S assessment may require a reassessment of the GBR also in cattle.

7 RECOMMENDATIONS FOR FUTURE WORK

The main purpose of this report is to contribute to continuity of the GBR-C assessments at a European level once the mandates of the SSC, the TSE/BSE Group and the GBR peer Group will have expired. In fact, in spite of the very large amount of work that has been carried out so far on many countries worldwide, work is still pending on some countries which have already applied but have not been assessed yet and on other countries for which the re-assessment of the GBR is still on-going (see Table 7). Therefore, a first recommendation of the SSC is that the GBR-C assessment

process be completed according to the current model and that consistency is guaranteed throughout the entire process.

A second recommendation deals with the opportunity of gathering additional data particularly on some third countries which have been classified in GBR level I. The main difference between the European Union Member States and most Third countries is the availability of the FVO reports that are in general only available for EU-Member States and some accession countries. As the FVO reports are very important sources of highly reliable information, it should be carefully considered if similar reports could be produced for third countries, at least those with a favourable assessment depending on certain not fully verified data.

A third recommendation deals with the reiteration of the application of the GBR methodology to review the decline of the GBR in countries presently classified in GBR levels other than I or the maintenance of GBR level I. In this context, it is particularly important to further update the current GBR methodology to make optimal use of the presently available active surveillance tools and data in addition to the three fundamental stability parameters and other factors. By the beginning of 2003, cases of BSE in domestic cattle have been detected in 21 countries world wide. Infection was confirmed in 10 of these following the EU-sponsored validation study of post-mortem field tests, in active surveillance carried out through testing animals at routine slaughter, fallen stock and casualty slaughtered animals. Therefore, while so far the results of active surveillance have widely confirmed the value of the GBR assessment (see also Section 5.1), for the future it is essential to develop appropriate surveillance strategies (also taking into account countries with different abilities and budgets) to be effectively incorporated in a revised GBR-C methodology to speed up the evaluation of the positive trend in the decline of the GBR and to certify the achievement of the GBR level I status of individual countries.

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ANNEX 1

OUTLINE OF THE COUNTRY GBR REPORT

1. **DATA**

2. **EXTERNAL CHALLENGES**

   2.1. Import of cattle from BSE-Risk countries

   2.2. Import of MBM or MBM-containing feedstuffs from BSE-Risk countries

   2.3. Overall assessment of the external challenge

3. **STABILITY**

   3.1. Overall appreciation of the ability to avoid recycling of BSE infectivity, should it enter processing

   3.2. Overall appreciation of the ability to identify BSE-cases and to eliminate animals at risk of being infected before they are processed

   3.3. Overall assessment of the stability

4. **CONCLUSION ON THE RESULTING RISKS**

   4.1. Interaction of stability and challenges

   4.2. Risk that BSE infectivity entered processing

   4.3. Risk that BSE infectivity was recycled and propagated

5. **CONCLUSION ON THE GEOGRAPHICAL BSE-RISK**

   5.1. The current GBR as function of the past stability and challenge

   5.2. The expected development of the GBR as a function of the past and present stability and challenge

   5.3. Recommendations for influencing the future GBR

ANNEX II

LIST OF OPINIONS AND REPORTS ON THE GEOGRAPHICAL BSE RISK ADOPTED BY THE SCIENTIFIC STEERING COMMITTEE IN THE PERIOD 1997-2003.

Geographical BSE risk: methodological aspects.

1. Opinion on the Geographical BSE risk for sheep and goats (GBR-S): adaptation of the cattle GBR methodology to small ruminants, in case BSE in small ruminants would become probable or evident under field conditions. Adopted on 7-8 November 2002.
2. Update of the opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR). Adopted on 7 November 2002.
3. Opinion on the geographical BSE-risk (GBR) and its evolution over time in the European Union Member States (adopted by the SSC at its plenary meeting of 21/22 February 2002. Endorsed on 7 July 2002.
4. Updated opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR). Adopted on 11 January 2002.
5. Final opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR). Adopted on 6 July 2000.
6. Opinion of the Scientific Steering Committee on a method for assessing the Geographical BSE-Risk (GBR) of a country or region. Up-dated on January 2000.
7. Opinion on a method to assess the Geographical BSE-Risk (GBR) of Countries or Regions. Revision adopted on 22-23 April 1999.
8. Preliminary-opinion on a method to assess the geographical BSE-Risk of Countries or Regions. Adopted on 10 December 1998.
9. Opinion on BSE risk. Adopted on 26-27 March 1998.
10. Opinion on defining the BSE risk for specified geographical areas. Adopted on 23 January 1998.
11. Preliminary Opinion on BSE risk. Adopted on 19-20 February 1998.
12. Final Opinion on the contents of a "Complete dossier of the epidemiological status with respect to TSEs". Adopted on 19-20 February 1998. Adopted on 19-20 February 1998.

Geographical BSE risk (GBR): Opinions on the GBR of countries

13. Opinion on the Geographical risk of bovine spongiform encephalopathy (GBR) in Paraguay. Adopted on 10-11 April 2003.
14. Opinion on the Geographical risk of bovine spongiform encephalopathy (GBR) in Uruguay. Adopted on 10-11 April 2003.
15. Opinion on the Geographical risk of bovine spongiform encephalopathy (GBR) in Brazil. Adopted on 10-11 April 2003.
16. Opinion on the Geographical risk of bovine spongiform encephalopathy (GBR) in Argentina. Adopted on 10-11 April 2003.
17. Opinion on the Geographical risk of bovine spongiform encephalopathy (GBR) in Chile. Adopted on 10-11 April 2003.
18. Opinion and report on the Geographical risk of bovine spongiform encephalopathy (GBR) in Costa Rica. Adopted on 10-11 April 2003.
19. Opinion on the Geographical risk of bovine spongiform encephalopathy (GBR) in Belarus. Adopted on 10-11 April 2003.

20. Opinion on the Geographical risk of bovine spongiform encephalopathy (GBR) in FYR Macedonia. Adopted on 10-11 April 2003.
21. Opinion on the Geographical risk of bovine spongiform encephalopathy (GBR) in Estonia. Adopted on 10-11 April 2003.
22. Opinion on the Geographical risk of bovine spongiform encephalopathy (GBR) in Lithuania. Adopted on 10-11 April 2003.
23. Opinion on the Geographical risk of bovine spongiform encephalopathy (GBR) in Cyprus. Adopted on 10-11 April 2003.
24. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Singapore. Adopted on 06 March 2003.
25. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in New Caledonia. Adopted on 06 March 2003.
26. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Greece. Adopted on 06 December 2002.
27. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in the Principality of Andorra. Adopted on 06 December 2002.
28. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in New Zealand. Adopted on 07 November 2002.
29. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Israel. Adopted on 13 September 2002.
30. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Malta. Adopted on 13 September 2002.
31. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Slovenia. Adopted on 13 September 2002.
32. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Vanuatu. Adopted on 27 June 2002.
33. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Turkey. Adopted on 27 June 2002.
34. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in the Republic of San Marino. Adopted on 27 June 2002.
35. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Latvia. Adopted on 27 June 2002.
36. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Iceland. Adopted on 27 June 2002.
37. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Croatia. Adopted on 27 June 2002.
38. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Bulgaria. Adopted on 27 June 2002.
39. Opinion on the geographical risk of Bovine Spongiform Encephalopathy (GBR) in Finland. Update adopted on 16 May 2002.
40. Opinion on the geographical risk of Bovine Spongiform Encephalopathy (GBR) in Austria. Update adopted on 16 May 2002.
41. Opinion the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in El Salvador. Adopted on 29 June 2001.
42. Opinion the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Nigeria. Adopted on 29 June 2001.
43. Opinion the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Panama. Adopted on 29 June 2001.
44. Opinion the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Costa Rica. Adopted on 11 May 2001.

45. Opinion the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Kenya. Adopted on 11 May 2001.
46. Opinion the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Romania. Adopted on 11 May 2001.
47. Opinion the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Slovenia. Adopted on 11 May 2001.
48. Opinion the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Albania. Adopted on 30 March 2001.
49. Opinion the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Brazil. Adopted on 30 March 2001.
50. Opinion the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Colombia. Adopted on 30 March 2001.
51. Opinion the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Cyprus. Adopted on 30 March 2001.
52. Opinion the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in the Czech Republic. Adopted on 30 March 2001.
53. Opinion the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Estonia. Adopted on 30 March 2001.
54. Opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Hungary. Adopted on 30 March 2001.
55. Opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in India. Adopted on 30 March 2001.
56. Opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Mauritius. Adopted on 30 March 2001.
57. Opinion the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Pakistan. Adopted on 30 March 2001.
58. Opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Poland. Adopted on 30 March 2001.
59. Opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in Singapore. Adopted on 30/03/2001.
60. Opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) in the Slovak Republic. Adopted on 30 March 2001..
61. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Botswana. Adopted on 09 February 2001.
62. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Lithuania. Adopted on 09 February 2001.
63. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Namibia. Adopted on 09 February 2001.
64. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Nicaragua. Adopted on 09 February 2001.
65. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Swaziland. Adopted on 09 February 2001.
66. Opinion on the Geographical risk of Bovine Spongiform Encephalopathy (GBR) in Uruguay. Adopted on 12 January 2001.

Geographical BSE risk (GBR): Reports on the GBR of countries

67. Report on the Geographical risk of bovine spongiform encephalopathy (GBR) in Paraguay. (April 2003).
68. Report on the Geographical risk of bovine spongiform encephalopathy (GBR) in Uruguay. (April 2003).

69. Report on the Geographical risk of bovine spongiform encephalopathy (GBR) in Brazil. (April 2003).
70. Report on the Geographical risk of bovine spongiform encephalopathy (GBR) in Argentina. (April 2003).
71. Report on the Geographical risk of bovine spongiform encephalopathy (GBR) in Chile. (April 2003).
72. Report and report on the Geographical risk of bovine spongiform encephalopathy (GBR) in Costa Rica. (April 2003).
73. Report on the Geographical risk of bovine spongiform encephalopathy (GBR) in Belarus. (April 2003).
74. Report on the Geographical risk of bovine spongiform encephalopathy (GBR) in FYR Macedonia. (April 2003).
75. Report on the Geographical risk of bovine spongiform encephalopathy (GBR) in Estonia. (April 2003).
76. Report on the Geographical risk of bovine spongiform encephalopathy (GBR) in Lithuania. (April 2003).
77. Report on the Geographical risk of bovine spongiform encephalopathy (GBR) in Cyprus. (April 2003).
78. Final Report on the assessment of the Geographical BSE-Risk (GBR) of Singapore – 2003 (March 2003)
79. Final Report on the assessment of the Geographical BSE-Risk (GBR) of New Caledonia – 2003 (March 2003)
80. Final Report on the assessment of the Geographical BSE-Risk (GBR) of Greece – 2002 (December 2002)
81. Final Report on the assessment of the Geographical BSE-Risk (GBR) of the Principality of Andorra – 2002 (December 2002).
82. 111. Final report on the updated assessment of the Geographical BSE-Risk (GBR) of New Zealand – 2002 (November 2002).
83. Final Report on the assessment of the Geographical BSE-Risk (GBR) of Israel – 2002 (September 2002).
84. Final Report on the assessment of the Geographical BSE-Risk (GBR) of Malta – 2002 (September 2002).
85. Final Report on the assessment of the Geographical BSE-Risk (GBR) of Slovenia – 2002 (September 2002).
86. Final Report on the assessment of the Geographical BSE-Risk (GBR) of Vanuatu – 2002 (June 2002).
87. Final Report on the assessment of the Geographical BSE-Risk (GBR) of Turkey – 2002 (June 2002).
88. Final Report on the assessment of the Geographical BSE-Risk (GBR) of the Republic of San Marino – 2002 (June 2002).
89. Final Report on the assessment of the Geographical BSE-Risk (GBR) of Latvia – 2002 (June 2002).
90. Final Report on the assessment of the Geographical BSE-Risk (GBR) of Iceland – 2002 (June 2002).
91. Final Report on the assessment of the Geographical BSE-Risk (GBR) of Croatia – 2002 (June 2002).
92. Final Report on the assessment of the Geographical BSE-Risk (GBR) of Bulgaria – 2002 (June 2002).
93. Final report on the updated assessment of the Geographical BSE-Risk (GBR) of Finland - 2002 (May 2002).

94. Final report on the updated assessment of the Geographical BSE-Risk (GBR) of Austria - 2002 (May 2002).
95. Final report on the Assessment of the Geographical BSE - Risk of El Salvador (June 2001).
96. Final report on the Assessment of the Geographical BSE - Risk of Nigeria (June 2001).
97. Final report on the Assessment of the Geographical BSE - Risk of Panama (June 2001).
98. Final report on the Assessment of the Geographical BSE - Risk of Costa Rica (May 2001).
99. Final report on the Assessment of the Geographical BSE - Risk of Kenya (May 2001).
100. Final report on the Assessment of the Geographical BSE - Risk of Romania (May 2001).
101. Final report on the Assessment of the Geographical BSE - Risk of Slovenia (May 2001) .
102. Report on the Assessment of the Geographical BSE - Risk of Albania (March 2001).
103. Report on the Assessment of the Geographical BSE - Risk of Brazil (March 2001).
104. Report on the Assessment of the Geographical BSE - Risk of Colombia (March 2001).
105. Report on the Assessment of the Geographical BSE - Risk of Cyprus (March 2001).
106. Report on the Assessment of the Geographical BSE - Risk of the Czech Republic (March 2001).
107. Report on the Assessment of the Geographical BSE - Risk of Estonia (March 2001).
108. Report on the Assessment of the Geographical BSE - Risk of Hungary (March 2001).
109. Report on the Assessment of the Geographical BSE - Risk of India (March 2001).
110. Report on the Assessment of the Geographical BSE - Risk of Mauritius (March 2001).
111. Report on the Assessment of the Geographical BSE - Risk of Pakistan (March 2001).
112. Report on the Assessment of the Geographical BSE - Risk of Poland (March 2001).
113. Report on the Assessment of the Geographical BSE - Risk of Singapore (March 2001).
114. Report on the Assessment of the Geographical BSE - Risk of the Slovak Republic (March 2001).
115. Report on the Assessment of the Geographical BSE - Risk of Botswana.
116. Report on the Assessment of the Geographical BSE - Risk of Lithuania.
117. Report on the Assessment of the Geographical BSE - Risk of Namibia.
118. Report on the Assessment of the Geographical BSE - Risk of Nicaragua.
119. Report on the Assessment of the Geographical BSE - Risk of Swaziland.
120. Report on the Assessment of the Geographical BSE - Risk of Uruguay.
121. Report on the Assessment of the Geographical BSE - Risk of Austria (July 2000).
122. Report on the Assessment of the Geographical BSE - Risk of Belgium (July 2000).
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130. Report on the Assessment of the Geographical BSE - Risk of The Netherlands (July 2000).
131. Report on the Assessment of the Geographical BSE - Risk of Portugal (July 2000).
132. Report on the Assessment of the Geographical BSE - Risk of Spain (July 2000).
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140. Report on the Assessment of the Geographical BSE - Risk of Norway (July 2000).
141. Report on the Assessment of the Geographical BSE - Risk of Paraguay (July 2000).

142. Report on the Assessment of the Geographical BSE - Risk of Switzerland (July 2000).
143. Report on the Assessment of the Geographical BSE - Risk of USA (July 2000).