Final Opinion

of the

SCIENTIFIC STEERING COMMITTEE

on the

Geographical Risk of Bovine Spongiform Encephalopathy (GBR)

Adopted on 6/July/2000

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1. INTRODUCTION

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

This opinion describes a transparent methodology that the Scientific Steering Committee (SSC) has developed, over about two years, to assess the GBR for any country that provides the information required for the assessment. This methodology is limited to bovines and feed based transmission of BSE. It does not take into account any other initial sources of BSE than the import of infected cattle or contaminated feed. It is assumed that the disease first appeared in the UK from a still unknown initial source. An important characteristic of the methodology is that it does not depend on the confirmed incidence of clinical BSE, which is sometimes difficult to assess due to serious intrinsic limitations of surveillance[1] systems. The other advantage of this methodology is that it allows an easy identification of possible additional measures that in a given situation may improve the ability of a country to cope with BSE.

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 and/or its application to particular countries to be repeated.

In parallel with the work of the SSC, the OIE (Office International des Epizooties) has developed further the BSE-chapter in its Animal Health Code, which makes reference to risk analysis 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 in this opinion.

The present opinion also describes the highly interactive procedure through which the methodology has been applied to those countries that have submitted information and data so far, and the results of this application.

The SSC wants to underline that its main task is to assess whether the presence of one or more infected cattle in a given country is « highly unlikely », « unlikely, but not excluded », « likely, but not confirmed », or « confirmed at lower or higher level » and what the future trend might be. In making this assessment, the SSC has used a reasonable worst-case approach (i.e. a conservative approach) every time data availability was insufficient.

[1] Surveillance should be understood as the process of identifying BSE-cases and animals at risk of being infected.

It should be clear that 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; and
- the ways in which the various tissues that contain infectivity are processed.

Also the risk that animals are exposed to the BSE agent is strongly influenced by a range of other parameters.

The SSC believes that decisions aimed at managing the BSE-risk are the responsibility of the authorities in charge and might need to take into account other aspects than those covered by this risk assessment.

2. THE GEOGRAPHICAL BSE-RISK (GBR) - METHODOLOGY & PROCEDURE

2.1 DEFINITION OF THE GEOGRAPHICAL BSE-RISK (GBR)

The Geographical BSE-Risk (GBR) is 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 specified in the table below.

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 1 - Definition of GBR and its levels

The SSC is well aware that the borderline between GBR level III and IV has to remain arbitrary, as no clear scientific justification can be provided for this differentiation. The SSC adopts for the time being the OIE threshold, i.e. an incidence of more than 100 confirmed BSE cases per million within the cattle population over 24 months of age in the country or zone, calculated over the past 12 months.

The SSC also agrees with the OIE (see also section 2.6 of this document) that, under certain circumstances, countries with an observed domestic incidence between 1 and 100 BSE-cases per million adult cattle calculated over the past 12 months, should be put into the highest risk level if, for example, there are clear indications that the true clinical incidence is in fact higher than 100 per million adult cattle calculated over the past 12 months.

Active[2] surveillance exercises in Switzerland (of adult cattle not notified as BSE or CNS suspect in fallen stock, emergency slaughter, and normal slaughter) and the UK (OTMS-survey[3]) both detected several confirmed BSE-cases that would have remained undetected by normal, passive[4] surveillance, even if targeted at animals with neurological symptoms. The SSC therefore assumed that passive surveillance does not give a true estimate of the existing BSE-cases. The Swiss and UK results indicate that it is likely that passive surveillance, based solely on notification of symptomatic BSE-suspects, will not detect more than half or one third of all clinical cases, or even fewer. However, as long as it is impossible to detect pre-clinical cases in the early phases of the incubation period, active surveillance of apparently healthy animals younger than 24 months cannot be expected to improve the detection level.

At this stage it should be reiterated that the applied 4 GBR-levels are only used to illustrate in qualitative terms different risk levels. Each of these levels includes a range of different potential risks. This range is not detailed in the current classification.

2.2 METHODOLOGY FOR ASSESSING THE GBR

2.21 Basic assumptions

The present application of the SSC-methodology for the assessment of the GBR is based on the assumption that BSE arose in the United Kingdom (UK) and was propagated through the recycling of bovine tissues into animal feed. Later the export of infected animals and infected feed provided the means for the spread of the BSE-agent to other countries where it was again recycled and propagated via the feed chain.

For all countries other than the UK, import of contaminated feed or infected animals is the only possible initial source of BSE that is taken into account. Potential sources such as a spontaneous occurrence of BSE at very low frequency or the transformation into BSE of other (animal) TSEs (scrapie, CWD, TME, FSE[5]) being present in a country are not considered, as they are not scientifically confirmed.

The only transmission mode considered in the model is feed. Contaminated feed is taken as the only possible route of infection because epidemiological research showed clearly that the origin and maintenance of the BSE epidemic in the UK was directly linked to the consumption of infected meat and bone meal by cattle. Blood, semen and embryos are not seen to be effective transmission vectors[6]. Accordingly, blood-meal is not taken into account, neither.

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[2] Active surveillance = testing of cattle that are not notified as BSE-suspects but belong to risk sub-populations.

[3] OTMS=Over Thirty Months Scheme. This scheme excludes all cattle older than 30 months from the animal feed and human food chain. The survey involved sampling about 3000 cattle older than 60 months and which did not show any symptoms compatible with BSE and found 18 BSE-cases.

[4] Passive surveillance = surveillance of notified BSE-suspects, i.e. cattle that are notified because of clinical signs compatible with BSE.

[5] TSE=Transmissible Spongiform Encephalopathy; CWD=Chronic Wasting Disease; TME=Transmissible Mink Encephalopathy; FSE=Feline Spongiform Encephalopathy

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

During the assessment, it became obvious from different sources that cross-contamination of MMBM[7]-free cattle feed with other feeds that contain such ingredients can be a way of propagating the disease. Therefore, it is important to understand that, as long as feeding of MMBM, BM (Bone meal) or Greaves to other farmed animals is legally possible, cross-contamination of cattle feed with animal (ruminant) protein can not be eliminated. Dedicated production lines and transport channels and control of the use and possession of MMBM at farm level would be required to fully control cross-contamination. It should be clear that any cross contamination of cattle feed with MMBM, even well below 0.5%, represents a risk of transmitting the disease[8]. However, the influence of cross-contamination on the GBR has to be seen in the light of the risk that the animal protein under consideration could carry BSE-infectivity.

In the light of the qualitative nature of the exercise, its relatively lesser importance in comparison to feed, and the lack of final scientific confirmation of its existence, the possible impact of maternal transmission on the GBR has not been taken into account[9] in this methodology.

Similarly no "third route of transmission" was taken into account. The existence of a third mode of transmission of BSE, in addition to feed and vertical transmission, such as horizontal transmission via the environment, cannot be excluded. However, to date there is no scientific evidence for such a third potential mode of transmission[10]. The assessment also does not take into account the possibility that sheep and goats may have become infected with BSE[11].

The present GBR risk assessments (see chapter 3 and annex III) are only addressing entire countries and national herds. This is because of the limited availability of detailed, regionalised data. The SSC does not discount the issue of regional differences, for example in the types of animal husbandry e.g. dairy or beef, of feeding or of slaughtering ages. If complete data sets were to be provided on a regional scale, i.e. clearly relating to a defined geographical area, these could be assessed in the same way as data referring to entire countries.

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[7] MMBM = Mammalian MBM

[8] In its opinion on cross-contamination (n° 12 in annex I) the SSC already expressed this position.

[9] There are statistical indications that the disease may be vertically transmitted from dam to calf. It was statistically shown that the risk of maternal transmission occurring is higher if the calf was born within 6 months before the onset of the clinical signs in the dam. Offspring cull and assurance that the dam has survived without BSE for at least six months after calving will thus provide a certain degree of assurance that its offspring is safe (see Opinions N°s 2, 4, 23, 24 and 30 listed in Annex 1).

[10] SeeSSC-opinions N°s 4, 23, and 30 listed in Annex 1

[11] See SSC opinion on the risk of infection of sheep and goats with BSE, 24/25 September 1998

2.22 Information factors and model of the BSE cattle system

The methodology is based on information on 8 factors that were originally identified by the SSC in January 1998. In table 2 the most relevant information is listed that was finally found to be important for carrying out the assessment.

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, productivity of dairy cattle, co-farming of pig/poultry and cattle, geographical distribution of cattle and pig/poultry populations and of different husbandry systems)
Surveillance of BSE Measures in place to ensure detection of BSE-cases: - 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 Results of BSE-surveillance: - 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 birth cohort of the confirmed cases, and – if possible – type of cattle
BSE related culling - Culling schemes, date of introduction & 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 (Note: Blood, semen, embryos or ova not seen as an effective transmission route. MBM is used as proxy for mammalian protein as animal feed) - Imports of live cattle and/or MBM from UK and other BSE-affected 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
Feeding - Domestic production of MBM and use of MBM (domestic and imported) - Domestic production of composite animal feed and its use - Potential for cross-contamination of feed for cattle with MBM during feed production, during transport and on-farm, measures taken to reduce and control it, results of the controls
MBM-bans - Dates 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
SBM-bans (SBM: Specified Risk Material, i.e. material posing the highest risk of infection) - Dates of introduction and scope (definition of SRM, use made of SRM, exceptions from /target animals of the ban, etc.) - Measures taken to ensure and to control compliance - Methods and results of compliance control
Rendering - Raw material used (type: Slaughterhouse offal including SRM or not, other animal waste, fallen stock, etc.; annual amounts by type of raw material) - Process conditions applied (time, temperature, pressure; batch/continuous;) and their share of the annual total domestic production)

Table 2 – Information factors for assessing the GBR *Note: all information should be available for the period from 1980 onwards and be presented on an annual base. For the purpose of the GBR-assessment reasonable worst case assumptions have been used whenever the information was not complete.*

In order to clarify the (often-delayed) interaction between these factors, the SSC has adopted a simplified strictly qualitative model of the cattle/BSE system[12] (Figure 1) which focuses on the feed-back loop that needs to be activated to spark a BSE-epidemic. This feed-back loop consists essentially of the processing of (parts of) cattle that carry the BSE-agent into feed and the feeding of this to cattle who then get infected and multiply the BSE-agent inside their bodies leading to very different concentration of infectivity in different tissues.

This feed-back loop is influenced by a number of factors that, on the one hand, may activate the loop and, on the other hand, might prevent this activation or slow down or reverse the building up of BSE-infectivity within the system.

In the model used by the SSC the initial introduction of the BSE-agent has to come from outside – it is therefore called an external challenge of the system[13]. Two possible routes of

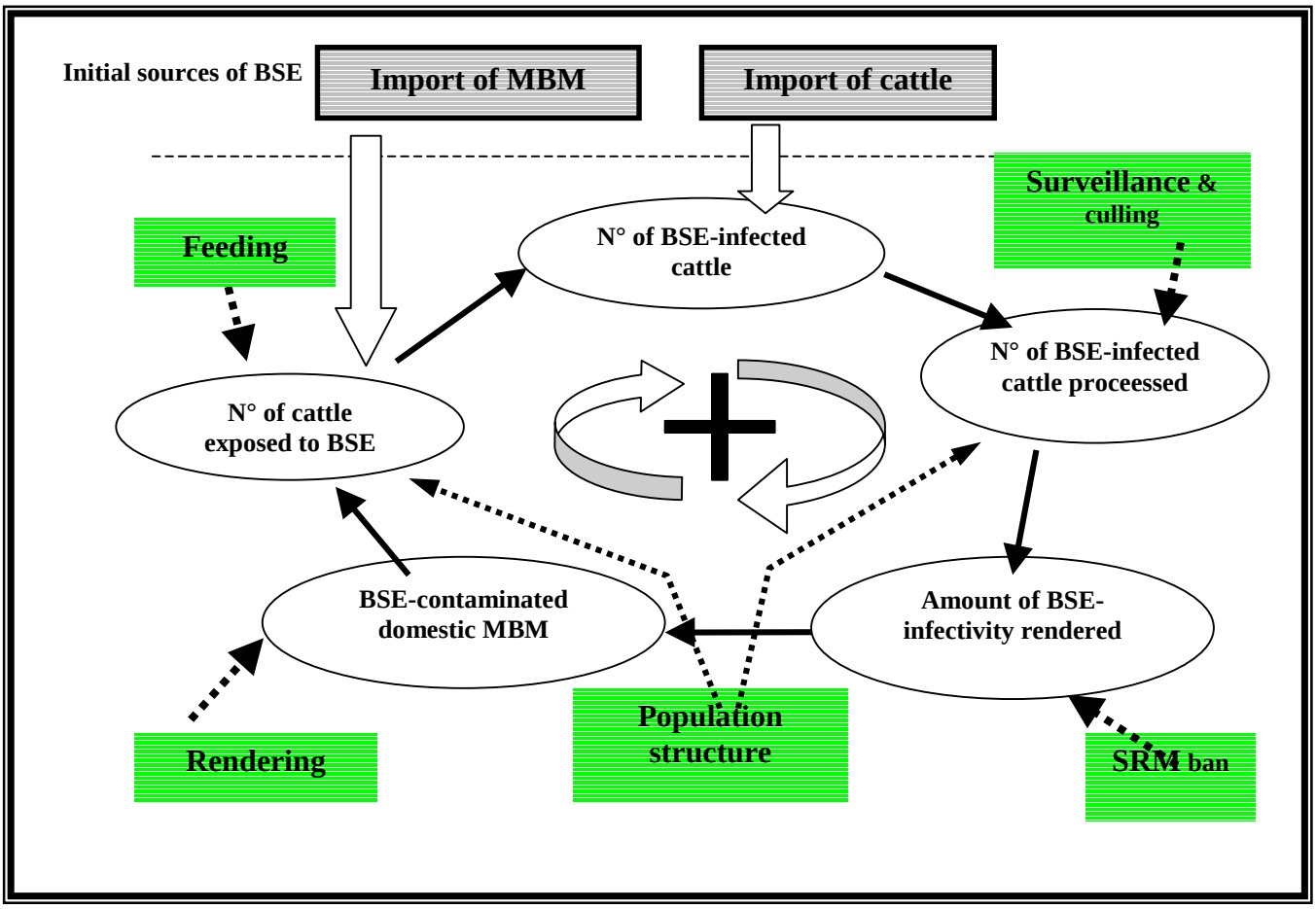

Figure 1: The model of the BSE/cattle system used by the SSC

[12] A BSE/cattle system of a country or region comprises the cattle population and all factors that are of relevance for the propagation of the BSE-agent, should it be present within its boundaries. The model used by the SSC to describe this system is presented in figure 1, it is a deliberately kept simple.

[13] For the UK it is assumed that the initial introduction of the agent happened before the period taken into account in this model.

introduction are considered: import of infected cattle or import of contaminated MBM.

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

- Surveillance and culling. By identifying BSE-cases (by passive and active surveillance including testing and laboratory confirmation) and excluding them and related cattle at risk of being infected from processing (by "culling" and destruction), the risk of introducing the BSE-agent into the feed chain is reduced.
- SRM-removal. By excluding those tissues known to carry the bulk of the infectivity that can be harboured by a (pre-)clinical BSE-case from rendering, it reduces the infectivity that could enter the feed chain. Excluding fallen stock from the feed chain is seen to be equally effective as a "partial" SRM-ban because, according to Swiss experience, the frequency of infective (pre-) clinical cases in fallen stock seems to be higher than in normal slaughter.
- Rendering. Appropriate rendering processes reduce BSE-infectivity that is carried by the raw material by a factor of up-to 1,000 (see footnote[14]).
- Feeding. By ensuring that no feed that could carry the BSE-agent reached cattle this effectively reduces the risk of new infections in the domestic cattle population.

In summary, the model basically can be broken down into two parts relating to challenge (chapter 2.23 and 2.25) and stability (chapter 2.24). The model assumes a mechanism for their interaction.

2.23 External challenge

The term **"external challenge"** is referring to both the likelihood and the amount of the BSE agent entering into a defined geographical area in a given time period through infected cattle or MBM.

2.231 Assessing the external challenge

During the GBR-assessment exercise it became necessary to establish guidelines for assessing the external challenge in order to ensure that comparable challenges were always assessed similarly.

To this end it was first decided to regard the external challenge independent from the size of the challenged BSE/cattle system and in particular the size and structure of the total cattle population (see also section 2.25)

Secondly, it was decided to use the assumed challenge resulting from imports from the UK during the peak of the BSE-epidemic in the UK as the point of reference and to establish the challenge resulting from imports during other periods and from other BSE-affected countries in relation to this baseline.

Therefore, the figures given in table 3 below refer to imports from the country (UK) and the period of time where the risk of contamination of exports with the BSE-agent was regarded to be highest. For live cattle imports this was assumed to be the period 1988 to

[14] See SSC-opinion on the Safety of Meat and Bone Meal, 26/27 March 1998

1993. As a reasonable worst case assumption it was assumed[15] that during this period the average BSE-prevalence of infected animals in exported cattle was around 5%[16], i.e. of 20 animals one could have been infected. Therefore, a moderate external challenge would 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 differences from this level of potentially imported infection.

The assessment of the challenge posed by MBM imports (also table 3) were similarly chosen in accordance with the following events and steps:

- The critical period, i.e. the period of highest risk that MBM imports from the UK were contaminated was set to 1986 –1990. This is the period with the highest case incidence in the birth cohorts.

- The risk peaked in 1988 when SBO[17] were excluded from the human food chain but included into rendering and feed production. It was reduced with the exclusion of SBO[11] from rendering at the end of 1989.

- The table below indicates that the import of one ton of MBM is seen to pose the same challenge as the import of one live animal. This is justified by the fact that available import statistics do not allow the differentiation between different forms of animal proteins and that practically all MBM produced in Europe is always a mixture of ruminant and non-ruminant material. It should also be seen in the context that the probability that more than one infected cattle was processed per ton of final MBM is very low, even in the UK[18].

[15] The period 88-93 was chosen as highest risk period for live cattle imports because it covers the period of roughly one incubation period before the highest incidence (1992/93). Recent data on case incidence in birth cohorts show that this was already high in 1985/86 and 1986/87. However, as cattle are normally exported at an age between 6 (veal) and 24 (breeding stock) months, it was felt justified to keep this range. Nevertheless it might be possible that the risk carried by imports in 1987 was slightly underestimated by this approach.

[16] The value of 5% was used because at normal survival probabilities only one in 5 calves reaches an age of 5 years. If the case incidence in a birth cohort was about 1%, about 5% of the calves in that birth cohort could have been infected.

[17] Specified Bovine Offal = those bovine offal that contain the highest concentration of BSE-infectivity in a clinical BSE-case.

[18] As one cattle carcass is rendered into about 65 kg MBM, 18 carcasses would be needed per ton of MBM.

EXTERNAL CHALLENGE	Cattle (n° of heads) imports			MBM[1] (tons) imports		
	1988 - 93 from UK	UK-imports before 88 and 94-97: *10; after 97: *100	Imports from other countries with BSE: * 100	1986 - 90 from UK	UK-imports before 86 & 91-93: * 10, after 93 *100	Imports from other BSE-countries * 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		

[1] The abbreviation "MBM" refers to different animal meals (MBM, MMBM, BM, Greaves) that could carry the BSE-agent because it contains animal (ruminant) proteins. It does not refer to composite feed that could potentially contain MBM, MMBM, BM or Greaves.

Table 3: Definition of BSE-challenge levels

In other countries affected by BSE and, in the UK at other periods, the risk that exported cattle were carrying the BSE-agent or that MBM was contaminated with BSE was lower. Accordingly, the challenge posed by the same amount of imports would be much lower or the same level of challenge would only occur at higher imports. To adapt the thresholds accordingly, the following multipliers were used:

Import from **UK** in other periods:

Cattle: before 1988 and from 1994 to 1997: multiply all thresholds by **10**;
1998 and after: multiply all thresholds by **100**;

MBM: before 1986 and from 1991 to1993: multiply all thresholds by **10**;
1993 and after: multiply all thresholds by **100.**

Import from other countries than UK affected by BSE: regardless of period and whenever there is reason to assume that BSE was already present at time of export:

Cattle: multiply all thresholds by **100**,

MBM: multiply all thresholds by **10**.

It has to be underlined that the above figures in the table and the multipliers are only indicative. It is obvious that the final external challenge associated with imported cattle and their impact will largely depend of a number of factors including their age at slaughter. Excluding imported animals from the feed chain would reduce the challenge that the excluded animals represent to a negligible level. Accordingly, imported animals that are slaughtered before reaching an age of 24 months would represent a lower challenge than imported animals used for breeding and then rendered at an age high enough to be approaching the end of the incubation period. If available, this and similar information are used to modulate the criteria in the table.

2.24 Stability

Stability is defined as the ability of a BSE/cattle system to prevent the introduction and to reduce the spread of the BSE agent within its borders. Stability relies on the avoidance of processing of infected cattle and the avoidance of recycling of the BSE agent via the feed chain. A "stable" system would eliminate BSE over time; an "unstable" system would amplify it.

The most important stability factors are those which reduce the risk of recycling of BSE, in particular:

- avoiding feeding of MBM to cattle,
- a rendering system ("rendering"), able to largely inactivate BSE-infectivity (e.g. by applying "standard[19]" treatment at $133^{o}/20^{min}/3^{bar}$), and
- exclusion of those tissues/organs from rendering where BSE infectivity could be particularly high ("SRM-removal"). Excluding fallen-stock from the feed chain will also reduce the amount of BSE infectivity that could enter the feed chain and is necessary for a fully efficient SRM-removal. Excluding fallen stock from rendering alone, i.e. without exclusion of SRM from other cattle, would have some effect but is not as efficient as a "reasonably OK"system of SRM-removal.

A comprehensive surveillance system (including passive and active elements) and related activities that ensure detection and isolation (and destruction) of BSE-cases and cattle at risk of being infected would also enhance the stability of the system.

These stability factors were already relevant before their contribution to prevent spreading the BSE epidemic was scientifically understood. It is therefore clear that even compliance with a regulation that at that time was scientifically up-to-date may not always have guaranteed stability.

2.241 Stability levels

A BSE/cattle system can only be regarded to be "**optimally stable"** if all three main stability factors (feeding, rendering, SRM-removal including fallen stock) are in place, well controlled, implemented and audited ("OK"). Ideally such a system would also exclude fallen stock from processing into feed and integrate a highly effective capacity to identify BSE-cases and exclude them together with cattle at risk of being infected from being processed. Such a system would fully prevent propagation of BSE-infectivity and eliminate BSE-infectivity from the system very fast.

If two of the three factors are assessed to be "OK" but one of these factors is only reasonably implemented ("reasonably OK"), the system could at best be assumed to be **"very stable".** Propagation would be largely prevented but the elimination of BSE-infectivity from the system is slower than in an "optimally stable" system.

A system can still be assumed to be **"stable"** as long as two of the three factors are "OK", or one is "OK" and two are "reasonably OK". BSE will be eliminated from the system over time but propagation may still take place – only at a lower rate than the elimination of BSE from the system.

If all three factors are "reasonably OK", the system can nevertheless only be assessed as **"neutrally stable",** i.e. it would neither amplify nor reduce circulating BSE-infectivity over time. The same is true if only one factor is "OK" and two are not present or only badly implemented.

[19] As defined in the SSC-opinion on MBM, see n°8 in annex 1

If only two factors are "reasonably OK", the system is seen to be **"unstable".** It will amplify BSE, should it be introduced. This means the propagation rate is higher than the elimination rate, if there is any.

With only one "reasonably OK" factor in place, the system is assumed to be **"very unstable",** i.e. recycling a large proportion of the BSE-agent and propagating the disease rather fast.

If none of the three factors can even be considered as "reasonably OK", the system would be **"extremely unstable",** quickly propagating the BSE-agent, should it enter, and amplifying the BSE-load of the system.

These considerations are summarised in table 4 below that was used as guidance for ensuring comparability of approaches used for assessing the degree of stability of a given BSE/cattle system between the different country assessments.

STABILITY	**Level**	***Effect on BSE-infectivity***	Most important stability factors		
			Feeding	**Rendering**	**SRM-removal**
Stable: ***The system will reduce BSE-infectivity***	**Optimally* stable**	*Very fast*	Feeding OK, rendering OK, SRM-removal OK		
	Very stable	*Fast*	Two of the three factors OK, one reasonably OK.		
	Stable	*Slow*	Two OK **or** 1 OK and two reasonably OK.		
Neutrally stable		+- *constant*	3 reasonably OK or 1 OK		
Unstable: ***The system will amplify BSE-infectivity***	**Unstable**	*Slow*	2 reasonably OK		
	Very Unstable	*Fast*	1 reasonably OK		
	Extremely Unstable	*Very Fast*	None even reasonably OK		

Table 4: BSE-stability levels (*"Optimally" should be understood as "as good as possible according to current knowledge".)

Explanation concerning the three main stability-factors:

Feeding: OK = evidence provided that it is highly unlikely that any cattle received MMBM.
Reasonably OK = voluntary feeding unlikely but cross contamination cannot be excluded.

Rendering: OK = only plants that reliably operate at $133^{o}/20^{min}/3^{bar}$-standard.
Reasonably OK = all plants processing high-risk material (SRM, fallen stock, material not fit for human consumption) operating at $133^{o}/20^{min}/3^{bar}$ – standard, Low-risk material is processed at more gentle conditions.

SRM-removal: OK=SRM-removal from imported and domestic cattle in place, well implemented and evidence provided. Fallen stock is excluded from the feed chain.
Reasonably OK = SRM- removal from imported and domestic cattle in place but not well implemented or documented. If in addition to a "reasonable OK" SRM-removal fallen-stock is excluded from rendering, the

"SRM-removal" might be considered "OK". Exclusion of fallen stock from rendering alone is regarded to be useful but not as effective as a "reasonably OK" SRM-removal.

Note:

Surveillance and culling are essential for the ability of a system to identify clinical BSE-cases and to avoid that they, and related at-risk animals, enter processing. A good surveillance system can therefore, in combination with appropriate culling, improve the stability by supporting the exclusion of BSE-infectivity from the system. It would, however, not be sufficient to make a system more stable (move it into the next higher stability level) than it would be due to the three main stability factors.

2.25 Internal challenge

The term "internal challenge" is referring to the likelihood and the amount of the BSE-agent being present and circulating in a specific geographical area in a given time period.

If present, the agent could be there in infected domestic animals, where it would be replicated, in particular in SRMs, and in domestic MBM made from the infected domestic cattle. The internal challenge in a given period is a consequence of the interaction of the stability of the system and the combined external and internal challenge to which it was exposed in a previous period.

- If a fully stable BSE/cattle system is exposed to an external challenge, processing and recycling of the BSE-load entering the system will be prevented and the infectivity load will be neutralised over time. No internal challenge will result from this external challenge because the system is able to cope with it.

- 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 start circulating in the system. It will first be present in contaminated domestic MBM and, if this is fed to domestic cattle, these are likely to become infected. After approximately another 5 years (average incubation period) a certain number of them, which have survived until that age, could become clinical-BSE cases. Others might be processed before developing clinical symptoms and the infectivity harboured by them will again be recycled. By this way the internal BSE-load of the system is going to be amplified and a BSE-epidemic could develop (see fig.1 and 2).

The number of domestic cattle that are pre-clinically or clinically infected with the BSE-agent while being alive in the system at a given point in time could be taken as an indicator of the size of the internal challenge. However, 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 an internal challenge to be detected in an unstable country challenged by BSE will normally be at least one incubation period after the initial challenge (approximately 5 years). It may be much longer, depending on a number of factors including the following ones:

- the extent of the BSE challenge (a larger challenge would lead to more new infections with a higher number of cases reaching the clinical phase);
- the extent of the instability of the country (a very unstable system would amplify the infectivity faster and lead more rapidly to a higher number of cases);

- the size of the national cattle population (within a smaller population the same number of cases might be more easily discovered than in a large population, i.e. given a similar initial challenge and similar rates of propagation it would take longer to reach the same incidence level), animal demographics and agricultural and marketing practices of the challenged countries (e.g. if cattle are hardly reaching an age of 5 or more years, the probability that incubating animals turn into clinical cases is reduced); and
- the quality and validity of the BSE surveillance in the challenged country (the better the surveillance the earlier the detection as the risk of missing a case is smaller).

Depending on the many specifications of each case, detection of an internal challenge may take from a minimum of an average of 5 years from the initial challenge (average incubation period) up to several incubation periods. The longer periods might be valid because several cycles of about one incubation-period each are needed to reach numbers of clinical BSE-cases that are detectable by existing surveillance systems.

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 SSC has assumed, as a reasonable worst case scenario, that exposure of an unstable system to the BSE agent would always result sooner or later in an internal challenge. The speed of this development depends on the degree of stability of the system.

2.26 Interaction of overall challenge and stability over time

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

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

- A **"stable"** system that is not or only slightly **"challenged"**: this is obviously the best situation.
- A **"stable"** system that is highly **"challenged"**: this is still rather good because the system will be able remove the BSE, even if this might need some time.
- An **"unstable"** system is not or only slightly **"challenged"**: as long as BSE is not entering the system, the situation is good. However, if BSE would enter the system it could be amplified.
- An **"unstable"** system is **"challenged"**: obviously this is an unfortunate situation. BSE-infectivity entering the system will be amplified and an epidemic will develop.

These "stability" and "challenge" situations are illustrated by the two-dimensional diagram given in Figure 2, where both axes spread between the respective lowest and highest feasible level.

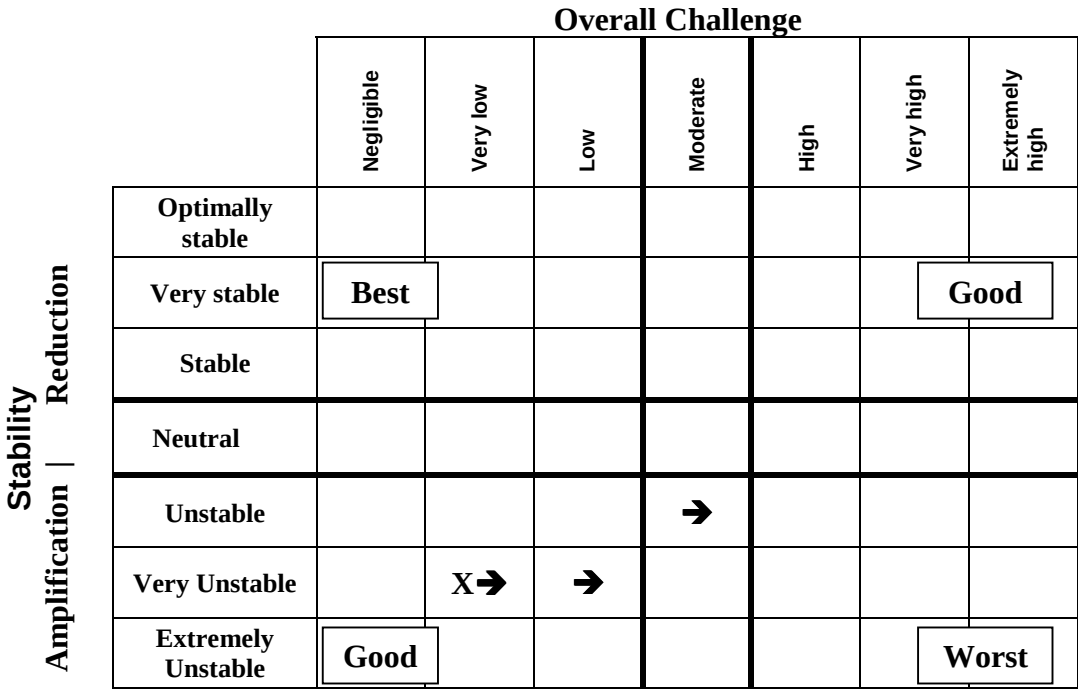

Figure 2: Diagram used in the country reports on the assessment of the GBR to illustrate the development of stability and challenge over time. In this figure four principal situations are indicated and a hypothetical development over time is given

Since the above-mentioned 8 factors, on which challenge (external and internal) and stability depend, change over time, it is necessary to assess the challenge and stability at different periods. These periods might, for example, be determined in function of changes of stability (e.g. by an MBM-ban) and/or challenge (e.g. preventing BSE from entering the system).

The arrows in figure 2 indicate an example for a hypothetical development over time. A very unstable system is exposed to a very low initial (external) challenge. Because of the low stability and as it is assumed that no special measures are taken to prevent the "dangerous" imports from entering the feed cycle, e.g. by putting the imported animals under strict monitoring and prohibiting them to be rendered, the BSE-infectivity is recycled and, over time, amplified. After some time (several years) the challenge (external plus internal) is reaching a moderate level but in the hypothetical example the stability is improving, too, for example by excluding ruminant MBM from cattle feed. The system, however, remains unstable and therefore the BSE-infectivity that is present in the system continues to be recycled and amplified, and a high challenge develops. Fortunately the stability of the system is increasing. As soon as it is stable the system eliminates BSE-infectivity and the challenge decreases (as long as no new external challenges occur). With a further improvement of the stability the decrease of the challenge will be quicker.

From the above explanations it becomes clear that the past stability and overall challenge of the system are the reason for the current internal challenge and hence the current GBR. The impact of most risk management measures on the number of clinical BSE-cases is delayed by at least one incubation period of BSE, in bovines on average 5 years. Therefore measures taken in the last five years may have had an immediate effect on the recycling and amplification of the BSE-agent and hence the internal challenge and the current GBR

but will only be reflected in the number of clinical BSE-cases around one incubation period after their effective implementation.

It is also clear that the future development of the GBR is influenced by the occurrence of additional external challenges and the continued ability of the system to reduce any incoming or already existing BSE infectivity. Assuming that new challenges can be avoided, the current stability determines the slope of the GBR-trend. An optimally stable system will very quickly reduce the GBR-level and an extremely unstable system will very quickly amplify any BSE-infectivity that is already in the system and increase the GBR-level.

2.3 PROCEDURE FOR ASSESSING THE GBR

2.31 Development of the methodology

In January 1998, the SSC established a list of factors on which it would require information for assessing the Geographical BSE-Risk (GBR)[20].

In July 1998, the Commission recommended to Member States and interested Third Countries to provide information on these factors[21].

In December 1998, the SSC issued a draft opinion on a method for assessing the Geographical BSE-Risk of a country or region. This was adopted in February 1999[22], taking into account comments received and the method was first applied in March 1999 to 11 Member States of the European Union (MS) that had supplied dossiers at that time. The methodology and process were repeatedly updated. The basis for these updates was the experience gained with its application to 26[23] countries that had voluntarily and timely submitted information and the comments received from several of these countries on

- the drafts of their reports (April/May and June 1999 and 2000),
- a working document of the SSC on the GBR (April 2000), and
- the preliminary opinion of the SSC on the Geographical risk of BSE and the preliminary country reports on the BSE-risk assessment (May 2000).

2.32 The process

The application of the SSC methodology was carried out with the help of about 50 independent experts, coming from most of the Member States and Third Countries.

More than three independent experts assessed each country and discussed their analyses with the country's experts in order to clarify the available information. These discussions proved to be very valuable. To date, July 2000, twenty-five countries have been assessed.

The assessed countries have openly co-operated in the assessment by sending their country experts and by reacting to the draft reports forwarded to them for comments. During the

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

[21] 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)

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

[23] The reports on the Czech Republic, India and the Slovak Republic are not yet finalised.

process many countries provided additional information that improved the basis for the risk assessment.

The process by which the independent experts[24] assessed the GBR of a given country is outlined in table 5. The report on the assessment of the GBR of each country followed the same scheme. The interaction of the countries was essentially contributing to the tasks in step 1 (data appreciation) and the appraisal of the appropriateness of the conclusions drawn and presented under the points 2-5.

Notwithstanding the efforts made to harmonise the approaches taken by the different experts, a certain degree of difference in appraisal of comparable data could not have been avoided. With a view to harmonise the different country reports and to ensure consistency a final review of all assessments was carried out from January 2000.

1. Appraisal of the quality of the available data
2. Assessment of the Stability of the BSE/cattle system (over time). 2.1 Ability to identify BSE-cases & to exclude cattle at-risk of being infected from processing 2.2 Ability to avoid recycling BSE-infectivity, should it enter processing 2.3 Overall assessment of the stability (over time)
3. Assessment of the challenges to the system (over time) 3.1 External challenge resulting from importing BSE 3.2 Internal challenge resulting from the interaction of external challenge and stability. 3.3 Overall challenge (over time)
4. Conclusion on the resulting risks (over time) 4.1 Interaction of stability and overall challenge (over time) 4.2 Risk that BSE-infectivity enters processing (over time) 4.3 Risk that BSE-infectivity is recycled and the disease propagated (over time)
5. Conclusion on the Geographical BSE-Risk 5.1 The current GBR as function of the past stability and challenge 5.2 The expected development of the GBR as function of past and present stability &challenge. 5.3 Recommendations to influence the expected development of the GBR.

Table 5: - Outline for the assessment procedure established by the SSC and applied by the independent experts. This outline was also used to structure the Country reports.

Having taken account of the draft country reports available in January 2000, the SSC charged 20 independent experts to review them. In order to do so they were asked to establish criteria for determining the respective degrees of stability and challenge of each country, and to apply these consistently to all assessments. The experts were also requested

[24] In order to identify these independent experts the ad-hoc TSE/BSE group discussed the importance of the quality of the experts and developed a set of criteria that was subsequently adopted by the SSC (October 1998). Members of the ad-hoc group and of the SSC were invited to submit names and a list of possible candidates was established, also including experts known to the secretariat from previous work. This list was discussed at the TSE/BSE ad-hoc group and also given to the SSC. There were no objections to the list and it was left to the secretariat to invite the experts taking account of the selection criteria agreed on and the availability of the experts.

to apply a consistent approach to estimating the current and future GBR derived from the past and current interaction of stability and challenge.

In order to do so, the 20 independent experts:

- agreed on practical criteria of assessing challenge and stability to be used as "orientation" to avoid inconsistencies between countries and
- established guidelines for revising and harmonising the reports & their presentation and
- agreed on the current GBR-level and the expected trend for each of the countries assessed on the basis of the information available to them early in February 2000.

The reports that had been prepared by the 20 independent experts were then examined by the TSE/BSE ad-hoc-group and the SSC.

On 2/3 March 2000 the SSC indicated a general agreement with the assessments while still pinpointing to room for improvement in terms of consistency within and between reports and terminology-standardisation. The SSC also recognised the need to up-date them in the light of additional information that became available between May 1999 and early March 2000. It charged a small group of its members and some assessors to carry out this task, taking due account of comments received by the members of the TSE/BSE ad-hoc group, the SSC and the Commission services, which were also invited to comment on the factual correctness of the reports. Subsequently the reports were sent to the respective countries together with a copy of a draft of this opinion. Comments on both documents were requested from the countries by early May 2000. The comments received were taken into account for revising the methodology of the SSC for assessing the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) and preparing preliminary versions of the country reports. It was assumed that countries, which did not submit comments, agreed to the provided documents.

On 25/26 May 2000 the SSC adopted the preliminary opinion and the preliminary GBR-country reports and requested their immediate publication on the Internet, inviting comments on both, the opinion and the reports, until 19 June 2000. Being aware of the sensitivity of the topic, the SSC made it clear that it would only consider comments related to the Risk-Assessment dimension of the issue, not those on the Risk-Management aspects.

The current final opinion and the related final GBR-country-reports take due account of the comments received. These documents now set out the SSC's final views on both the methodology issues and the GBR in each country that has been considered.

In reviewing this opinion and the related country reports it should be understood that in the view of the SSC it is expected that the framework of analysis will need to be revised if novel findings emerge, i.e. this opinion is dynamic in process as more scientific evidence will be available. These may relate to the source of BSE, to the diagnosis and transmissibility of BSE or to the infective dose for man. It can also be expected that novel developments in surveillance and management techniques or new tests to assess the prevalence of sub-clinical BSE conducted in a country may also precipitate the need for a selective re-assessment of a particular GBR.

The SSC's experience in assessing changes in the challenges and stability of countries, however, suggests that trends in incidence figures may allow different conclusions to be drawn only after 3 –5 years. In any case, the current assessments have to be up-dated from time to time.

2.4 AVAILABILITY AND QUALITY OF DATA

The SSC is well aware of the critical importance of the availability and quality of data for any risk assessment. It is, therefore, necessary to appreciate that the current GBR assessments are mainly based on information provided by the assessed countries and that it is essential to assume that the information provided is correct**.** In essence the provision of an appropriate basis for the GBR-assessment was the responsibility of the competent national authorities.

In general the available data were seen to be adequate to carry out the assessment of the GBR. Despite all efforts, however, considerable differences in the availability and quality of data remain of concern.

Additional sources of information, such as reports from the missions of the EC-Veterinary Inspection Services (the Food and Veterinary Office, FVO) and UK trade statistics were also used as available.

To complement insufficient information, and in line with the recommendation of the Commission of July 1998, "reasonable worst case assumptions" were used whenever extrapolation, interpolation or similar approaches were not possible.

A shortcoming in many dossiers, which had to be overcome by reasonable worst case assumptions, was insufficient information on compliance with the preventive measures put in place by the competent national authorities. For most countries additional information on this issue could therefore improve the basis for the risk assessment further.

While for E.U. Member States reports from the missions of the FVO were generally available, this is not the case for Third Countries, with the exception of Switzerland. This is important because in case of conflicting information the FVO-mission reports were generally taken as the authoritative source. Mission reports have also been demonstrated to be very useful sources to fill gaps in the available information.

In addition the information base for third countries could also be improved by extensive exploitation of additional publicly available sources. Given these considerations it might be argued that the foundation on which the assessments for third countries are based is not in all cases fully equivalent to the one for the Member States.

Another problem with data availability was recognised, as some countries did not provide data before 1988. In view of the importance of this period for possible initial challenges and recycling of BSE, and in order to treat all countries equally the independent experts stated the following:

"Whenever the available information does not cover the period 1980 to 1988, an open question remains as to the challenge and stability of the system during that period. To this end the following was generally applied:

> ***Challenge:*** *Given the fact that the UK-epidemic was building up during that period, the implication is that any country that traded live cattle or MBM with the UK in this period could have imported some BSE-infectivity. If the system was unstable during that period (what was frequently the case) the potentially incoming BSE-infectivity could have been amplified.*

In order to have a first approximation of the possible external challenge, UK-export data to the country in question were used. The Commission is also invited to provide the appropriate EUROSTAT data for the same purpose. An analysis of the different import/export figures from different sources would be most useful to improve the information basis for the period in question for all countries.

Stability: *The stability of the system prior to 1988 is estimated on the basis of the available information, if necessary through extrapolation from the last known data.*

If it is not possible to base an assessment of imports on the UK export data or to extrapolate the stability, it will be assumed that the country was subject to a low challenge while its BSE/cattle system was not fully stable. This unfavourable situation is assumed to have lasted until the available data allow assessing the situation differently".

The impact of incoming cattle on the GBR of the receiving country is assessed on appraisal of the BSE situation in the exporting countries at time of export. Should it become apparent that this appraisal was wrong, the assessment of the geographical BSE-risk of the receiving country would have to be reviewed. Imports from not-assessed countries could not be taken into account. It was also in principle impossible to take account of triangular trade as a route for external challenges to develop.

2.5 MONITORING THE EVOLUTION OF THE GEOGRAPHICAL BSE-RISK

In order to monitor the evolution of the GBR, it is very important to improve the ability to identify clinically and sub-clinically BSE-infected animals and potentially infected MBM.

According to field observations in Switzerland, the incidence of BSE is higher in fallen stock and in cows offered for emergency slaughter than in healthy looking animals presented at routine slaughter.

Since the GBR-assessment exercise started, three rapid post-mortem tests for BSE became available. These make appropriate intensive surveillance programmes possible, targeting at-risk sub-populations such as adult cattle in fallen stock or in emergency slaughter, cohorts of confirmed BSE cases. Results from such programmes, applied to statistically justified samples, could improve the basis for future assessments of the GBR, or help to verify the current risk assessment.

Three rapid tests in bovines have been shown by the European Commission (European Commission, 1999, *The Evaluation of Tests for the Diagnosis of Transmissible Spongiform Encephalopathies in Bovines* – see DG-SANCO internet site at http://europa.eu.int/comm/dgs/health_consumer/index_en.htm) to have excellent potential (high sensitivity and specificity) for detecting or confirming clinical BSE for diagnostic purposes or for screening dead or slaughtered animals, particularly casualty animals or carcasses to be used for rendering.

The above tests are:

- *Prionics* : an immuno-blotting test based on a western blotting procedure for the detection of the protease-resistant fragment PrP^{Res} using a monoclonal antibody
- *Enfer* : a chemiluminiscent ELISA, using a polyclonal anti-PrP antibody for detection

- *CEA* : a sandwich immunoassay for PrP^{Res} carried out following denaturation and concentration steps. Two monoclonal antibodies are used.

The currently available rapid post-mortem tests are able to prove the presence of PRP^{res} in the CNS of cattle that are close to the end of the incubation period or already clinically ill. However, these tests cannot be considered to be able to identify pre-clinical cases at earlier stages of the incubation. The SSC, therefore, regards these tests to be useful for complementing existing surveillance efforts based on notification of BSE-suspects and detection of infected cattle with heavy loads of infectivity.

They should not, however, be used to guarantee the absence of the BSE-agent from an individual animal tested and found to be negative. The SSC wants to underline its support for the development of improved rapid BSE-diagnostic tests ultimately aimed at having reliable ante-mortem tests able to detect pre-clinical BSE.

Moreover, for an accurate assessment of the future trends in GBR, compliance data (from farming/slaughtering/rendering[12] industries) will be especially important. This information will be needed to determine the effectiveness of the various preventive measures, including bans, adopted and hence their impact on the GBR.

2.6 RELATION OF THE GBR TO THE OIE CODE ON BSE

2.61 The role of Risk Assessment

The OIE International Animal Health Code, Chapter 3.2.13 related to BSE, adopted May 2000, states that the status of a country or zone can only be determined from the outcome of a risk analysis. The OIE – International Animal Health Code, Section on Risk Analysis (section 1.4) outlines methods for this process as they are related to issues for the importation of animals or animal products. The OIE identifies the components of the risk analysis process as: hazard identification, risk assessment, risk management and risk communication. The risk assessment is the component of a risk analysis that estimates the risk associated with a hazard. Risk assessment methods should be chosen in relation to the specific situation. They may be qualitative or quantitative. The SSC method for the assessment of the Geographical BSE-Risk is one of the possible qualitative methods that can be used for the risk assessment component of this process. It is, however, an innovative approach using terminology somewhat different to those applied in the risk assessment literature and the OIE-section on risk analysis.

The SSC method for the assessment of the geographical BSE-risk is comparable to the OIE-guidance on risk analysis and in particular the chapter on risk assessment. The following points should be taken into consideration when determining the comparability of the SSC-method to other potentially proposed methods:

[12] As a follow-up to its earlier validation studies on appropriate heat treatments of animals meals, the Joint Research Centre has conducted a study on the Prevention of Epidemic Diseases by appropriate Sterilisation of Animal Waste. According to SSC Opinion (20-21 January 2000), the test may become, after further validation, a useful additional part of verification and control protocols for verifying the appropriateness of processing equipment in rendering plants (effective wet sterilisation carried out at least at 133°C/20'/3 bars), provided a sample of appropriate test material is available to be processed.

- The hazard identification is not included in the SSC-method for the assessment of the GBR as it was taken for granted that the BSE-agent is the hazard (see also the SSC-opinion on Human Exposure Risk).

- The release assessment required according to the OIE-guidance could be compared with the assessment of the "external challenge" and the "internal challenge" and their interaction as described in this opinion. The SSC assessment is not completed if the risk of an external challenge has been identified as negligible. This is contrary to the OIE-guidance. This SSC approach is justified by the high degree of uncertainty with the epidemiology and biology of the BSE-agent as well as with its monitoring and surveillance. The SSC method attempts to address the stability of the assessed BSE/cattle systems as a means to establish its capacity to resist future challenges that are currently unknown.

- One might, however, compare the thrust of the SSC-method with an exposure assessment. The assessment of the inherent stability of a given BSE/cattle system with regard to BSE might be compared, to a certain degree with an analysis of the pathways needed to allow the exposure of animals to BSE. In an unstable system the pathways are open and would lead to exposure whereas in a stable system the risk of exposure occurring is much lower because the pathways are closed. Typically, a pathway assessment would depend on the specific situation and could, according to the OIE, vary from country to country. The SSC-method applies systematically one model of the BSE/cattle system that describes the pathways in a fully transparent and standardised manner. This provides a basis for obtaining comparable results in different countries.

  The SSC-method derives a similar end-point as an exposure assessment described in the OIE-guidelines for risk assessment: it provides a qualitative estimation of the likelihood of the exposure to an identified hazard (the BSE-agent), at a given point in time. However, the SSC-method requires assessing the consequences of past exposures, in the SSC-terminology the internal challenges, which together with the external challenges again interact with the stability and create a new exposure situation. Because of the importance of the time dimension in this delayed process the SSC-terminology seems to be more adequate to describe the positive feed-back loop that is responsible for the BSE risk than the more static terms used in conventional Risk Analysis and Risk Assessment.

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

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

The OIE's list of factors that should be taken into account when analysing the BSE-risk includes:

- **importation of meat-and-bone meal (MBM) or greaves potentially contaminated with a transmissible spongiform encephalopathy (TSE) or feedstuffs containing**

either; *(note: MBM-imports are a very important part of the external challenge which is assumed by the SSC to be the only initial source (except in the UK). Due to lack of data the SSC currently did not take account of greaves or feedstuff-imports)*;

- **importation of animals, embryos or ova potentially infected with a TSE;** *(note: while animal imports are an essential element of the external challenge assessment, the SSC does not take account of embryos or ova as the risk of transmitting the disease via these routes is regarded to be insignificant in comparison to the import of MBM and infected live cattle)*;
- **consumption by cattle of MBM or greaves of ruminant origin;** *(note: the use of MBM is a central point of the SSC-assessment and greaves, and bone meal have been addressed whenever data were differentiated enough to allow for this);*
- **origin of animal waste, the parameters of the rendering processes and the methods of animal feed production;** *(note: this is one of the central points of the SSC-method, determining the stability of the system It is covered under the headings SRM-ban, rendering, and cross-contamination in the reports);*
- **epidemiological situation concerning all animal TSE in the country or zone**; *(note: the SSC does not take account of other animal TSEs because (a) the available data were very poor and (b) the link with BSE is not scientifically established, even for scrapie)*; and
- **extent of knowledge of the population structure of cattle, sheep and goats in the country or zone.** *(note: while the information on the population structure – and dynamics- of the cattle population is taken account of, the information on small ruminants is, for the time being, not considered by the SSC).*

The OIE also requests that the following measures, and their date of effective implementation ("relevant period of time"), be considered when determining the BSE-status. The SSC-method, however, considers them together with the other risk factors:

- **compulsory notification and investigation of all cattle showing clinical signs compatible with BSE**; *(note: this factor is taken into account in the SSC-methodology when assessing the capacity of the system to identify clinical BSE-cases and to eliminate animals at risk of being infected before processing);*
- **a BSE surveillance and monitoring system with emphasis on risks identified**; *(note: also taken into account by the SSC when assessing the BSE-surveillance and when assessing the compliance with the feed and SRM bans);*
- **an on-going education programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle, so as to encourage reporting of all cases of neurological disease in adult cattle**; *(note: this is an integral part of the SSC-assessment of the surveillance system);*
- **examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system**; *(note: again taken into account by the SSC in the context of the surveillance assessment)*;
- **treatment of at-risk animals linked to confirmed cases (culling)** *(note: covered by the SSC as a separate point contributing to the ability of the system to identify clinical cases and to eliminate at risk animals).*

From the above it is clear that there is a close similarity between the relevant factors identified by OIE and those being used by the SSC to assess the GBR.

The SSC provides a detailed methodology for assessing the geographical BSE-risk, taking account of all relevant factors, including those listed in the BSE-chapter of the International Animal Health Code of the OIE. The SSC method also involves an external review of the GBR on the basis of information provided by countries and, in view of the long incubation period of the disease and its initially probably slow progress, it tries to cover the last twenty years. As it is based on a prescribed model of the dynamics of the BSE-disease, this methodology can be applied consistently and transparently to available information. The application of the principle of reasonable worst case assumptions and special care to ensure consistency of these assumptions allows a reasonable estimation of the GBR even in cases where the available information is not fully satisfactory.

3. THE GEOGRAPHICAL BSE-RISK (GBR) - RESULTS

3.1 OVERVIEW

An overview of the results of the GBR-assessment of 23 countries (14 E.U. Member States and 9 third countries) analysed so far is presented in table 6. A detailed description of the overall assessment of the GBR for each one of the 23 countries is provided in specific country reports, published separately. Annex II to this opinion contains the overall assessments for each of the 23 countries.

In a nutshell it can be summarised that all Member States of the European Union are faced with a certain risk of having BSE in their national herd. This risk is a probability in **Austria**, **Sweden**, and **Finland**, where presence of BSE is unlikely but cannot be excluded. It is still uncertain but likely in **Germany**, **Italy** and **Spain** where no domestic cases are yet confirmed. In **Belgium, France, Ireland, Luxembourg** and **The Netherlands,** BSE is clearly present but according to the SSC classification at a lower level. In **Portugal** and **The United Kingdom** the SSC shares the general view that the presence of BSE is confirmed at a higher level.

With regard to Third Countries it is apparent that in general the GBR is lower. For six countries (**Argentina, Australia, Chile, Norway, New Zealand, and Paraguay**) it is regarded to be highly unlikely that the BSE agent could be present. In all cases mainly due to the absence of external challenges. As AU, CHL and NZ have rather unstable systems any failure in controlling the external challenge could lead to future problems. The other third countries (**Canada and the USA)**, with the exception of **Switzerland** that is in GBR-level III, are analysed to be unlikely to have BSE in their national herds, albeit it cannot be excluded. The main reasons for this judgement are small, but non-negligible external challenges combined with more or less stable systems.

Table 6 presents this information by referring to the four GBR-levels defined in chapter 2. In studying and interpreting this table the discussion on data quality (point 2.4 in this document) should be kept in mind. Table 6 also indicates the expected development of the GBR in the foreseeable future, the GBR-trend that is assumed if no new external challenges have to be met by the country in question.

Member States	GBR – LEVEL	GBR-TREND* increasing GBR ↓ decreasing GBR ⇨ constant GBR
AT	II	↓
BE	III	
DE	III	
DK	III	↓
FIN	II	↓
FR	III	↓
IRE	III	↓
IT	III	
LUX	III	
NL	III	↓
PT	IV	↓
SP	III	↓
SW	II	↓
UK	IV	↓
Third Countries		
ARG	I	
AU	I	
CAN	II	
CH	III	↓
CHL	I	
NO	I	
NZ	I	
PGY	I	
USA	II	

Table 6: Overview of the result of the GBR-assessment for 23 countries (the assessments for the Czech republic, India and the Slovak Republic are still pending)

***** GBR-Trend: The GBR will start to decrease or to decrease faster in all EU-Member States once the decisions on rendering (according to 99/534/EC foreseen for 01/07/2000) and SRM (according to 2000/418/EC foreseen for 01/10/2000) are appropriately implemented.

3.2 THE EXPECTED DEVELOPMENT OF THE GBR

The increased stability that has been reached in many countries is clearly reflected in the expected development of the probability that domestic cattle are infected (pre-clinically or clinically) with the BSE-agent. The GBR is already moving towards a decline (table 6) in many countries. Once the recent Commission Decision on removal of SRM (2000/418/EC) is appropriately applied in all Member States of the EU, this will be the case in all of them.

With regard to the expected development of the GBR 8 groups can be seen:

- **Countries where BSE is confirmed and the expected prevalence is in the "higher" range, with a declining GBR.**

  This group consists of the **UK** and **PT**. The UK has introduced increasingly effective measures since 1988 and the decreasing probability of cattle to be infected with the BSE-agent can clearly be seen in the development of the confirmed BSE-cases by birth cohorts.

  Portugal introduced risk management measures in the mid-nineties. It is expected that the measures taken since 1998 will, since 1999, have reduced the annual rate of new infections, and hence that the GBR reached its peak in 1998/99 and is now declining. However, due to the long incubation period the incidence figures will only reflect this trend after some time.

  In both cases the rate of decline of the GBR is critically depending of the efficiency of the implementation of the measures taken. Given the high infectivity-load in the two countries already small failures in the implementation of the measures might re-spark the epidemic.

- **Countries where BSE is confirmed in the "lower" range and were a declining GBR is expected.**

  DK, FR, IR, NL, and **CH** have introduced measures that are believed to have already strongly reduced the risk some years ago. They are, therefore, assumed to have a decreasing GBR. Even if this is not yet be reflected in incidence figures, it is assumed that the prevalence is in fact already decreasing because the number of possible new-infections decreased some years ago.

- **Countries where BSE is confirmed in the "lower" range and were a constant GBR is expected.**

  In **BE/LUX** the GBR is still constant - the main reason is the short period since the implementation of appropriate measures. The risk of new infection, however, has decreased only very recently.

- **Countries where it is likely that BSE is present, even if it is not confirmed, and where the GBR is expected to decrease as long as no new external challenges occur and the stability remains as it is.**

  In SP the measures in place since 1998 made the system "stable". As BSE is expected to be already present (albeit not confirmed) in the country, the probability that cattle are infected with the BSE agent will decrease – if nothing is changed. With the implementation of the most recent European ruling concerning SRM and rendering (bringing also low risk rendering up-to standard) this country will become more stable and its GBR will decrease faster.

- **Countries where it is likely that BSE is present, even if it is not confirmed, but where the GBR is expected to remain constant as long as no new external challenges occur and the stability remains as it is.**

  In DE and IT the measures in place make the systems "neutrally stable". As BSE is expected to be already present (albeit not confirmed) in the country, the probability that cattle are infected with the BSE agent will remain constant – if nothing is changed. With the implementation of the most recent European ruling concerning SRM and rendering (bringing also low risk rendering up-to standard) these countries will become stable and their GBR will begin to decrease.

- **Countries where the SSC regards it as unlikely that cattle are infected with BSE, but does not feel confident enough to exclude it and where the probability that cattle could be infected is decreasing.**

  AT, SW, and FIN have had stable systems for some years and therefore show a positive decreasing trend of the GBR.

- **Countries where the SSC regards it as unlikely that cattle are infected with BSE, but does not feel confident enough to exclude it and where the probability that cattle could be infected remains constant.**

  CAN and the USA have systems that would continue the recycling of BSE but probably would not amplify it. If nothing changes, they will remain at the same level of risk.

- **Countries where the SSC regards it as highly unlikely that cattle are infected with BSE.**

  ARG, AU, CHL, NO, NZ and PGY are currently in this category. As long as BSE is not introduced, they will remain at this level of risk, independent from the stability of their system. However, those with a stable system (ARG, NO, PGY) are less vulnerable than those with an unstable or neutrally stable system (AU, CHL, NZ).

The emphasis of the SSC on the stability of the BSE/cattle system even in countries where BSE is apparently absent results from the fact that the stability determines the resilience of the system to unforeseeable future challenges. Moreover it is obvious that a system where all (or most) critical points are controlled as well as possible, is safer than one in which all depends on a single control point, such as imports. On the other hand, it is also obvious that the avoidance of importing the BSE agent, or the total prevention of feeding anything that could contain it to cattle are valid approaches, and in certain cases apparently successful, strategies to manage the risk.

3.3 DYNAMICS OF THE GBR

Taking the earliest birth cohorts with BSE-cases as an indicator for the earliest presence of BSE in a country the following pattern appears.

The BSE epidemic most likely started in the **United Kingdom (UK)**, although there is no certainty on its initial causes.

As indicated by the earliest BSE case, an internal (domestic infected animals) challenge existed in the **UK** already before the 80s (see table 7). It is worth noting that the earliest birth cohort in which eventually a case was detected was 1973/74.This animal was very old (about 15 years) when it developed clinical signs. It, therefore, might have got infected as

an adult animal[25]. However, this would be contradictory to the generally accepted assumption that the age at onset of clinical BSE is a good indication for the incubation period as most infections would take place early in life. Moreover, about 90 cases were detected globally in birth cohorts of 1976, 77, 78 and 79. It is evident, therefore, that BSE was already present in the United Kingdom in the 70s.

This internal challenge was strongly amplified by the extremely unstable system in the United Kingdom where the feed back loop continued to function uncontrolled until 1988, when the first feed ban was introduced. Despite this ban, until May 2000 approximately 40,000 BSE cases were reported among cattle born after the ban, even if the rate of new cases per birth cohort strongly decreased. The epidemic data (confirmed cases per year) clearly reflect this pattern, with a delay of roughly one incubation period (i.e. average 5 years with the majority of cases falling in the range of 4 to 6 years of age at onset). An extremely high incidence of BSE existed from the mid-80s, peaked in 1992/1993 and then declined rapidly. In August 1996 a complete ban of MBM applicable to all farm animals was introduced.

The United Kingdom was then followed by a second group of countries with earliest BSE-birth cohorts in the early and mid 80s: Republic of **Ireland (IRE)** and **France (FR)**, both in 1981, and **Portugal (PT)** and **Switzerland (CH)**, both in 1984.

A third group of countries found BSE-cases in birth cohorts in the mid-90s: **The Netherlands (NL)** and **Belgium** (**BE)** both in 1993, and **Denmark** (**DK)** in 1996.

Country	Earliest birth cohort with a confirmed case
UK	**1973/74**
FR, IRE	**1981**
CH, PT	**1984**
BE, NL	**1993**
DK	**1996**

Table 7: Earliest birth cohorts in countries with confirmed domestic BSE cases

Assuming that these birth cohorts indicate the first appearance of BSE in a given country, this pattern is compatible with the following: BSE infectivity was present in the MBM produced in the United Kingdom already in the 70s and hence also in domestic cattle. If these, or MBM, were exported from the United Kingdom, BSE-infectivity could have reached other countries. This happened before the first case in the United Kingdom was detected but only once the prevalence of cattle in the advanced stages of incubation that were rendered in the United Kingdom was high enough to reach concentrations of the

[25] J.Wilesmith of 1996 "recent Observations on the Epidemiology of Bovine Spongiform Encephalopathy" in "Bovine Spongiform Encephalopathy - The BSE Dilemma" by Clarence J.Gibbs, Jr. (ed.), 1996 Springer Verlag New York, Inc.

agent in the feed able to transmit the disease[26]. By this way **IRE**, **FR, PT** and **CH** got the infection in the early/mid-80s. However, these early external challenges are difficult to trace back with certainty due to the lack of reliable data for the mid-70s and early 80s. It is also not obvious why these countries were particularly vulnerable. The cause that started the feed back loop might have been an unfortunate combination of cattle or MBM-imports with common feeding of animal protein to cattle and inappropriate rendering of ruminant material.

With the high BSE-prevalence in mid-80s and early 90s in the UK, the external challenge that arose through imports from the UK (directly or indirectly) of cattle and MBM increased in a number of European States (table 8). Imports of cattle and MBM from countries like **CH, FR, IRE** and **PT** might have contributed in certain cases to the external challenge. These increased challenges might explain the appearance of BSE in a third group of countries (BE, NL and DK). The delay, in comparison to the second group, being explained by a combination of relative advantages such as less feeding of animal protein to cattle and/or better rendering and/or of not having been exposed to the BSE-agent before.

Following this reflection, a fourth group of countries can be identified where BSE is not yet confirmed but where the combination of stability (table 8) and challenge (table 8) makes it likely that BSE could indeed be already present. This group includes **Germany (DE), Italy (IT)**, and **Spain (SP)**. All these countries have received imports from the United Kingdom or from other countries known to have BSE. The fact that no BSE was discovered so far is explained by a combination of factors, which made the building-up of a domestic prevalence likely and, with the inherent shortcomings of passive surveillance systems it is not possible to discover all clinical BSE-cases. The relative likelihood that BSE is in fact present and the level of possible prevalence depends on the external challenge experienced, the degree of (partial) stability, and the performance of the surveillance system.

A fifth group consists of countries where the presence of BSE is unlikely but cannot be excluded. These countries have typically experienced a small but not negligible external challenge at a time when their system was more or less unstable. Because of the small size of the external challenge and/or the increase of stability realised in the past, these countries are probably free of BSE – but individual BSE-cases may nevertheless occur in the future. However, the development of an epidemic is not likely. This group includes **Austria (AT), Finland (FIN), Sweden (SW), Canada (CAN),** and the **USA**.

Finally there is a sixth group of countries where the presence of BSE is highly unlikely. Typically, these countries have never been exposed to any non-negligible challenge or have been able to control challenges by specific measures – mostly import restrictions and very careful monitoring of imports from at-risk countries. This group can, in fact, be split into two sub-groups. Those who had, in addition to negligible external challenges a certain degree of stability (**Argentina (ARG), Chile (CHL), Norway (NO), Paraguay (PGY)**) and those where the absence of BSE is fully dependent on the absence or efficient control of the external challenges (**Australia (AU), New Zealand**, **(NZ))**.

[26] It is worth noting that this critical concentration might be very small (SSC-HELL-opinion) but that no MBM-feeding experiments have ever been carried out.

At the time of first exposure, most countries were not equipped to prevent BSE-infectivity from entering the feed chain and being recycled (i.e. they were more or less unstable)[**] (table 8). As a consequence, a domestic prevalence of infected animals developed in those countries that experienced challenges, although to a much lower extent than in the UK, with or without a measured incidence.

Overall, these additional challenges have had much smaller impacts not only because they were of minor dimension, but also because stability started to increase in a number of countries as a consequence of risk management measures adopted since the late 80s/early-90s and later (table 8).

Table 8: BSE Stability and Challenge in 23 countries between 1980 and 1999

Stability: -3=extremely unstable; -2=very unstable; -1=unstable; 0=neutral; 1=stable; 2=very stable; 3=optimally stable
Challenge: -3=negligible; -2=very low; -1=low; 0=moderate; 1=high; 2=very high; 3=extremely high

E.U. MEMBER STATES

		YEAR				
COUNTRY		**1980**	**1985**	**1990**	**1995**	**1999**
AUSTRIA	**Stability**	**1**	**1**	**1**	**1**	**1**
	Challenge	**-3**	**-3**	**0**	**-1**	**-2**
BELGIUM	**Stability**	**-3**	**-3**	**-3**	**-2**	**1 (?)**
	Challenge	**-3**	**1**	**2**	**2**	**2**
DENMARK	**Stability**	**?**	**-3**	**-3**	**0**	**2[C/]**
	Challenge	**?**	**-1**	**0**	**1**	**1**
FINLAND	**Stability**	**-2**	**-2**	**-1**	**0**	**1**
	Challenge	**-1**	**-1**	**0**	**0**	**-1**
FRANCE	**Stability**	**-3**	**-3**	**-2**	**-1**	**2**
	Challenge	**?**	**1**	**3**	**3**	**2**
GERMANY	**Stability**	**-2**	**-2**	**-2**	**-1**	**0**
	Challenge	**-1**	**1**	**2**	**2**	**2**
IRELAND	**Stability**	**-3**	**-3**	**-2**	**-2**	**3**
	Challenge	**-3**	**0**	**2**	**3**	**2**
ITALY	**Stability**	**-2**	**-2**	**-2**	**-1**	**0**
	Challenge	**1**	**1**	**2**	**3**	**2**
LUXEMBOURG	**Stability**	**-3**	**-3**	**-3**	**-2**	**1 (?)**
	Challenge	**-3**	**1**	**2**	**2**	**2**
PORTUGAL	**Stability**	**?**	**-3**	**-3**	**-2**	**1-2**
	Challenge	**?**	**1**	**2 or 3**	**3**	**3**
SPAIN	**Stability**	**?**	**-3**	**-3**	**-2 or -1**	**0**
	Challenge	**?**	**-1**	**2**	**2**	**2**
SWEDEN	**Stability**	**?**	**-2**	**-2**	**0**	**1[C/]**
	Challenge	**?**	**-2**	**0**	**0**	**-1**
THE NETHERLANDS	**Stability**	**-2**	**-2**	**-2**	**0**	**1 or 2[C/]**
	Challenge	**1**	**1**	**2**	**3**	**2**
THE UNITED KINGDOM	**Stability**	**-3**	**-3**	**1**	**1**	**3**
	Challenge	**0**	**2 or 3**	**3**	**3**	**3**

[**] At that time only a few countries (ARG, AT, NO and PGY) had some stability due to the fact that MBM was not used as ruminant feed, mainly for economic reasons. Other countries might have had some stability because MBM was only infrequently given to cattle and/or parts of the rendering system were already functioning well.

[C/] Year 2000

A further increase of stability is expected for several countries in the European Union due to the upgrading of all low-risk rendering plants to the 133/20/3-standard (July 2000) and after the implementation of the Commission Decision of 29 June 2000 on SRM (2000/418/EC). This should lead to a general decrease of the GBR throughout the European Union.

THIRD COUNTRIES

		YEAR				
COUNTRY		**1980**	**1985**	**1990**	**1995**	**1999**
ARGENTINA	**Stability**	**0**	**0**	**0**	**0**	**1**
	Challenge	**-3**	**-3**	**-3**	**-3**	**-3**
AUSTRALIA	**Stability**	**-2**	**-2**	**-3**	**-2**	**0**
	Challenge	**-2**	**-2**	**-1**	**-3**	**-3**
CANADA	**Stability**	**-3**	**-3**	**-3**	**-2**	**0**
	Challenge	**-2**	**-2**	**-1**	**-1**	**-1**
CHILE	**Stability**	**-2**	**-2**	**-2**	**-2**	**-2**
	Challenge	**-3**	**-3**	**-3**	**-3**	**-1***
NORWAY	**Stability**	**-3**	**-3**	**0**	**1**	**2**
	Challenge	**-3**	**-3**	**-3**	**-3**	**-3**
NEW ZEALAND	**Stability**	**-3**	**-3**	**-3**	**-3**	**-2**
	Challenge	**-3**	**-3**	**-3**	**-3**	**-3**
PARAGUAY	**Stability**	**2 or 3**	**2 or 3**	**2 or 3**	**2 or 3**	**2 or 3**
	Challenge	**-3**	**-3**	**-3**	**-3**	**-3**
SWITZERLAND	**Stability**	**-3**	**-3**	**-1**	**2**	**3**
	Challenge	**?**	**0**	**3**	**3**	**1**
USA	**Stability**	**-3**	**-3**	**-3**	**-2**	**0**
	Challenge	**-3**	**0**	**0**	**-1**	**-1**

*1998

3.4 THE CASE OF GREECE

The SSC has not received any data from Greece and is unable therefore to provide a scientifically based opinion in this regard. It must be assumed, however, that Greece has been exposed to the BSE-agent. Under these circumstances, the SSC would consider it prudent in risk assessment terms to assume that the geographical BSE risk in Greece is at a high level.

4. IMPLICATION OF THE GBR ON FOOD AND FEED SAFETY

From the definition of the GBR (see section 2.1) it is clear that it refers to the risk situation at the live-animal level.

At a given GBR the risk that food or feed is contaminated with the BSE-agent, depends on three main factors:

1. the likelihood that bovines infected with BSE are processed;
2. the amount and distribution of infectivity in BSE-infected cattle at slaughter;
3. the ways in which the various tissues that contain infectivity are used.

In addition the trading of potentially contaminated foods and feeds also influences this risk.

4.1 LIKELIHOOD THAT BOVINES INFECTED WITH BSE ARE PROCESSED

The likelihood that processed bovines are infected with BSE (processing risk) depends obviously on the GBR. However, the processing risk may differ for different cattle sub-populations, defined on the basis of criteria such as herd history, feeding history, date of birth in relation to identified challenges.[27]

If the difference in processing risk of different sub-populations is known, excluding those that carry a higher specific processing risk would reduce the overall processing risk below the level that is indicated by the overall GBR.

This is for example possible by excluding birth cohorts born before an effective MBM-ban from slaughter[28]. The exclusion of fallen-stock (in particular adult cattle) from rendering also reduces the processing risk. Ensuring that as many as possible of the infected (clinically and pre-clinically) cattle are excluded from processing also reduces the processing risk. The quality of the BSE-surveillance and the related measures (culling) are essential in this context.

4.2 AMOUNT AND DISTRIBUTION OF INFECTIVITY IN BSE ANIMALS

4.21 Amount

The amount of infectivity carried by an infected animal strongly depends on the incubation stage it is in. Assuming that most infection happen close to birth, the age of an animal is a good approximation of the potentially possible incubation stage and hence its infective load.

For instance, the infective load of animals below 24 months of age is in general very much lower than it would be possible for an animal of 60 months, assuming that both were infected shortly after birth.

Reducing the age at slaughter can hence reduce the infective load that potentially could enter the human food chain. Excluding older animals from rendering would have a similar effect on the feed chain.

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[27] See, for example the SSC opinion on “closed herds”, or on the “Date based export scheme” for criteria that are used to define sub-populations with a much lower BSE-risk.

[28] The Date based export scheme, excluding animals born in the UK before the ultimate MBM ban of 01/8/1996 from export, is an example for the application of this principle.

The OTMS (Over Thirty Months Scheme) that excludes in the UK all animals older than 30 months from the human food and animal feed chain makes use of this effect. As, in the meantime, all animals that are allowed to be processed are also born after the latest MBM-ban (01/08/1996), it can be assumed that the combined effect of the OTMS and the feed-ban very effectively reduces the processing risk below the level expected from the current GBR (level IV).

4.22 Distribution

It is known that in an infected cattle that is approaching the end of the incubation period, the BSE infectivity is very unequally distributed. Certain tissues (the so-called SRM – Specified Risk Material) represent a particularly high risk. Their exclusion from further use (food or feed) reduces the infective load that could enter the respective chains. (See also the opinion of the SSC on SRM of Dec. 1997).

4.3 USE OF THE VARIOUS ORGANS AND TISSUES FROM BSE-ANIMALS

Each tissue/organ of a bovine can be used for a range of uses. Some of them require processing that is known to be capable to reduce BSE-infectivity.

The SSC has expressed its opinion on the production of gelatine, tallow, MBM, and a range of other bovine based products that may be used for food, feed or non-food/feed purposes. It has defined the conditions that have to be met to achieve maximal BSE-infectivity reduction and/or the BSE-infectivity reduction that can be expected from the normally applied/applicable processes. It has also included into these conditions considerations of the BSE-risk carried by the raw material with regard to tissues and the geographical origin of the animals.

With regard to process conditions it has been shown that some reduce BSE-infectivity[29], others (e.g. normal cooking, sub-standard rendering) have no measurable impact on it.

5. CONCLUSION AND ACKNOWLEDGEMENTS

The assessment clearly shows that the current GBRs reflect, more than anything else, differences among the commercial and agricultural practices existing between the early 80s and the early 90s, a time when knowledge on BSE, and its public health impact, was very limited. Since then, however, the awareness has tremendously increased and effective measures have been put in place to minimise the impact of BSE on public health.

In fact, at a given GBR, the risk of humans or animals to be exposed to the BSE-agent can be influenced by measures

- before slaughter, that exclude at-risk animals (such as fallen-stock[30]) and/or reduce their age at processing;
- during slaughter by excluding SRM from further processing,
- after slaughter by applying appropriate processes, able to reduce BSE-infectivity.

These measures might also be modulated in view of the intended end use of the meat or other bovine derived products. If control can be ensured, products that are only used for

[29] See the various SSC-opinions on the safety of Gelatine, Tallow, MBM, Hydrolysed proteins, Fertilisers, etc.
[30] See the opinion of the SSC on "fallen-stock"

non-food/non-feed uses (also called industrial uses) could carry a higher risk than food or feed products. The SSC has the intention to address this issue in more detail in a specific opinion.

The GBR-methodology described in the present opinion has been applied to a number of countries that voluntarily submitted the necessary information. Without the efforts of the responsible authorities in these countries in responding to repeated requests for information and the corresponding intensive and open co-operation, the quality of this assessment could not have been achieved. Moreover, a number of comments were received from competent authorities in response to a restricted consultation in March/April 2000 and to the public consultation on the preliminary opinion and country reports that were put on the Internet on 31 May 2000. Requests for details on the latter comments should be requested from the contact addresses listed in annex III.

The SSC wishes to thank the independent experts who were involved in the exercise for their considerable efforts and contributions not only to the country reports but also to the GBR-methodology. The discussions with the country experts and the comments received from the assessed countries also contributed to this final opinion and the quality of the country reports. The SSC therefore expresses its thanks also to the country experts and the many colleagues who compiled the data on which the assessment is based. A list of the independent and country experts who contributed over the last 30 months to the development and the application of the GBR-methodology is added as Annex IV.

However, the SSC wants to underline that the responsibility for this opinion and the related country reports remains entirely with the Committee. By no means the experts listed in Annex IV should be held responsible for individual country reports or specific aspects of this opinion.

ANNEX I : Opinions/Reports adopted by the SSC since November 1997 on questions related to Transmissible Spongiform Encephalopathies (status : 07.07. 2000)

	Date of adoption	Title of the opinion/report
1.	9 December 1997	Listing of Specified Risk Materials: a scheme for assessing relative risks to man
2.		Report on the UK Date Based Export Scheme and the UK proposal on Compulsory Slaughter of the Offspring of BSE Cases
3.	22-23 January 1998	Opinion of the Scientific Steering Committee on defining the BSE risk for specified geographical areas
4.	19-20 February 1998	Opinion on the revised version of the UK Date Based Export Scheme and the UK proposal on compulsory slaughter of the offspring of BSE-cases, submitted on 27.01.98 by the UK Government to the European Commission
5.		Final Opinion on the contents of a "Complete dossier of the epidemiological status with respect to TSEs".
6.	26-27 March 1998	Opinion on BSE risk
7.		Opinion on the Safety of Tallow
8.		Opinion on the Safety of Meat and Bone Meal
9.	25-26 June 1998	The safety of dicalcium phosphate precipitated from ruminant bones and used as an animal feed.
10.		Possible links between BSE and organophosphates used as pesticides against ecto- and endoparaistes in cattle.
11.	24-25 September 1998	Opinion on the risk of infection of sheep and goats with Bovine Spongiform Encephalopathy agent.
12.		Report and Opinion on mammalian derived meat and bone meal forming a cross-contaminant of animal feedstuffs.
13.		Scientific Opinion on the safety of organic fertilisers derived from mammalian animals.
14.		Updated Scientific Report on the safety of meat and bone meal derived from mammalian animals fed to non-ruminant food-producing farm animals, presented to the Scientific Steering Committee on 24-25 September 1998.
15.	22-23 October 1998	Report and Scientific Opinion on the safety of hydrolysed proteins produced from bovine hides.
16.		Opinion on the safety of bones produced as by-product of the Date Based Export Scheme.
17.	10-11 December 1998	Updated Report and Scientific Opinion on the safety of tallow derived from ruminant tissues
18.		Updated Report and Scientific Opinion on the safety of gelatine
19.		Preliminary opinion on a method to assess the geographical BSE-risk of countries or regions
20.	21-22 January 1999	Report and Scientific Opinion on the evaluation of the "*133°/20'/3 bars heat/pressure conditions*" for the production of gelatine regarding its equivalency with commonly used industrial gelatine production processes in terms of its capacity of inactivating/eliminating possible TSE infectivity in the raw material.
21.	18-19 February 1999	Report and Scientific Opinion on the Safety of Gelatine (updated version of opinion adopted on 21-22 January 1999)
22.		Opinion on a method to assess the geographical BSE-risk of countries or regions, including the Manual for the assessment of the geographical BSE-risk.
23.	18-19 March 1999	Opinion on the possible vertical transmission of Bovine Spongiform Encephalopathy (BSE)
24.	22-23 April 1999	Revised opinion on a method for the assessment of the geographical BSE-risk".
25.	27-28 May 1999	Opinion on Monitoring some Important aspects of the evolution of the Epidemic of BSE in Great Britain (Status, April 1999)
26.		Opinion on: Actions to be taken on the basis of (1) the September 1998 SSC Opinion on the risk of infection of sheep and goats with the BSE agent and (2) the April 1999 SEAC Subgroup report on Research and Surveillance for TSEs in sheep.

27.	24-25 June 1999	Opinion on risks of non conventional transmissible agents, conventional infectious agents or other hazards such as toxic substances entering the human food or animal feed chains via raw material from fallen stock and dead animals (including also: ruminants, pigs, poultry, fish, wild/exotic/zoo animals, fur animals, cats, laboratory animals and fish) or via condemned materials.
28.	22-23 July 1999	Opinion on the conditions related to "BSE Negligible Risk (Closed) Bovine Herds".
29.		Opinion on the policy of breeding and genotyping of sheep, i.e. the issue whether sheep should be bred to be resistant to scrapie.
30.	16-17 September 1999	The risk born by recycling animal by-products as feed with regard to propagating TSE in non-ruminant farmed animals.
31.	28-29 October 1999	Opinion on the Scientific Grounds of the Advice of 30 September 1999 of the French Food Safety Agency (the *Agence Française de Sécurité Sanitaire des Aliments*, AFSSA), to the French Government on the Draft Decree amending the Decree of 28 October 1998 establishing specific measures applicable to certain products of bovine origin exported from the United Kingdom.
32.		Summary Report based on the meetings of 14 and 25 October 1999 of the TSE/BSE *ad-hoc* group of the Scientific Steering Committee on the Scientific Grounds of the Advice of 30 September 1999 of the French Food Safety Agency (the *Agence Française de Sécurité Sanitaire des Aliments*, AFSSA), to the French Government on the Draft Decree amending the Decree of 28 October 1998 establishing specific measures applicable to certain products of bovine origin exported from the United Kingdom.
33.	9-10 December 1999	Opinion on the Human Exposure Risk (HER) via food with respect to BSE
34.	20-21 January 2000	Opinion of the SSC on a method for assessing the Geographical BSE-risk (GBR) of a country or region, update
35.		Updated opinion on the Safety of gelatine
36.	13-14 April 2000	Opinion on The Safety of ruminant blood with respect to TSE risks
37.		Opinion on the UK decision to lift the ban on the consumption of meat on the bone
38.		Opinion on specified risk materials of small ruminants. (Follow-up to the SSC opinion of 24-25 September 1998 on *the Risk of Infection of Sheep and Goats with BSE Agent*)
39.		Opinion on Quantitative Risk Assessment on the Use of the Vertebral Column for the production of Gelatine and Tallow.
40.		Preliminary Report on Quantitative Risk Assessment on the Use of the Vertebral Column for the production of Gelatine and Tallow.
41.		Opinion oral exposure of humans to the BSE agent: infective dose and species barrier
42.		The criteria for diagnosis of clinical and pre-clinical TSE disease in sheep and for differential biochemical diagnosis of TSE agent strains
43.	25-26 MAY 2000	Preliminary and incomplete notes on the safe handling, transport and storage of MBM and other bovine derived materials which may be contaminated with the BSE agent or other pathogens **draft, for comments.**
44.		*UPDATED* Report and Scientific Opinion on the safety of hydrolysed proteins produced from bovine hides. Initially adopted by the Scientific Steering Committee at its meeting of 22-23 October 1998 and updated at its meeting of 25-26 May 2000
45.		Considerations on the safety of amino acids from human hair-hydrolysate used in cosmetic products for topical application, with regard to TSE- risks.
46.		Preliminary Opinion of the Scientific Steering Committee on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) and 25 related Country reports. (Final opinion and 23 final country reports adopted on 6/7 July 2000).
47.	6-7 July 2000	Report On "The Inactivation Of BSE-Like Agents By Rendering Procedures".
48.		Report and Scientific Opinion on: "Export from the UKk of bone-in veal."
49.		Updated Report and Scientific Opinion on the safety of hydrolysed proteins produced from bovine hides. Initially adopted by the SSC at its meeting of 22-23 October 1998 and updated at its meetings of 25-26 May and 6-7 July 2000

ANNEX II : Overall Assessments of the Geographical BSE-risk in 23 Countries

1. COUNTRIES WITH CURRENT GBR-LEVEL I

6 countries, **Argentina, Australia, Chile, Norway, New Zealand** and **Paraguay** have a current geographical BSE-risk (GBR) level of I, i.e. it is highly unlikely that domestic cattle in these countries are (clinically or pre-clinically) infected with the BSE-agent.

For each of these countries descriptions of stability, external challenge and stability-challenge-interaction over time are reported in Table 1.

Assuming that measures in place continue to be appropriately implemented and no new external challenge occurs, the probability that cattle are (pre-clinically or clinically) infected with the BSE-agent will remain as low as it currently is.

NO is in this group as long as it can be assumed that cattle imported from Denmark after 1992 were not slaughtered and did not enter the feed chain before 1995, when the Norwegian system became stable. Should this be proven wrong, a GBR level II would have to be assumed.

AU is in this group because the Australian authorities were able to produce additional evidence that the external challenge was significant lower than it had to be assumed on the basis of previously provided data.

CHL is in this group despite of its very unstable system because the Chilean authorities were able to provide information on the MBM and breeding animals that were recently imported from DK where the first domestic BSE-case, born 1996, was confirmed in February 2000. The Chilean authorities have traced down the use made of the MBM and found that it was used for fish-feed, partly exported to Japan. The imported animals are also traced down, most were dead at arrival due to intoxication during transport. The survivors are put under restriction. Hence the external challenges to the Chilean system remained negligible.

TABLE 1 : STABILITY, EXTERNAL CHALLENGE AND STABILITY-CHALLENGE INTERACTION OVER TIME FOR FIVE COUNTRIES WITH GBR IN LEVEL I

	STABILITY	EXTERNAL CHALLENGE	INTERACTION OF STABILITY AND CHALLENGE
ARGENTINA	Before 1995 the Argentinean BSE/cattle system was neutrally stable, i.e. it would have maintained but neither amplified nor reduced incoming BSE-infectivity. After 1995 (surveillance system in place, MBM ban) the BSE/cattle system is assessed to be stable. However, the increased dairy production for a growing Brazilian market hints towards an intensified and, due to increased consumption of supplementary feed, more vulnerable system.. A significant improvement in rendering and with regard to ensuring exclusion of SRM from the feed chain would be required before the system could be assessed as very or optimally stable.	The only external challenges that were identified could have resulted from cattle imports from UK (19), Switzerland (15) and NL(3) between 1980 and 1983. These challenges were assessed as negligible, i.e. it is regarded to be highly unlikely that BSE-infectivity entered the country by these imports.	The neutrally stable, and since 1995 stable Argentinean BSE/cattle system has only been faced with negligible challenges.
AUSTRALIA	In the 1980s the Australian system was very unstable (some MBM feeding to cattle, rendering not able to significantly reduce BSE-infectivity, no SRM ban) and between 1988-90 it became extremely unstable as feeding of MBM to cattle increased. Afterwards the system became somewhat less unstable due to exclusion of cattle imported from UK from processing in 1990 and of all cattle imported from Europe in 1995. A voluntary feed ban (1996), followed by a mandatory feed ban (1997) and improved BSE-surveillance (1998) made the system again less unstable, reaching “unstable” in 1998. It reached neutral stability in 1999 because of the better implementation and control of the mandatory feed ban. However, in view of the still inappropriate rendering system, the lacking SRM-ban and potential cross-contamination of cattle feed with MBM, the system remains unable to reduce BSE-infectivity already circulating or entering it.	The only external challenges that were identified could have resulted from cattle imports from UK before 1988 (99) and in 1988 (15), from Switzerland in 1990 (9) and France in 1990 (113). These challenges were assessed as very low and low, respectively. In 1990 the animals imported from UK were removed from the food and feed chain. Therefore the impact of the challenge was neutralised and it became negligible.	A very or extremely unstable system was exposed to a very low or low external challenge, which was largely mastered by the specific measures, targeted on the imported animals. If BSE-infectivity entered the system, it would have been propagated and amplified but this possibility is regarded to be very unlikely.

	STABILITY	EXTERNAL CHALLENGE	INTERACTION OF STABILITY AND CHALLENGE
CHILE	Until 1996 the system was very unstable, i.e. it would have amplified and propagated incoming BSE-infectivity rather fast. The 1996 improvements of the surveillance increased the stability somewhat but it remained very unstable.	No external challenges were found until the late 90s, when at least 65 breeding cattle and 151 tons of MBM where imported in 1998 from DK, where the first BSE-case, born in 1996, was confirmed in February 2000. However, the Chilean authorities traced down the use made of the MBM, which was used for fish feed, and put the imported animals under restrictions. Therefore the effect of the potential external challenge remained negligible.	A very unstable system was apparently never exposed to a non-negligible external challenge.
NORWAY	The Norwegian BSE/cattle system was assessed to be extremely unstable between 1980-1989 because of an existing potential of cross-contamination of MBM in feedstuffs and the rendering systems not fully in compliance with the EU requirements. The system was neutrally stable during 1990 and 1994 due to the ban of ruminant derived feedstuffs from ruminant feed (RMBM ban) in 1990. Since mid 1994, the system is considered stable because of the improved tracing capacity, the rendering system now operating according to the standard of the EU Directive, and the introduction of mandatory labelling of packaged feedstuffs. Absence of an SRM-ban prevents the system from being very stable or optimally stable.	Norway was exposed to 10 cattle imported from the UK between 1982 and 1986, to 554 cattle imported from DK between 1991 and 1997, and to 14 cattle imported from France in 1997. O the French animals one died from ingestion problems in 1999 and all others are alive and closely monitored. Of the cattle imported from DK there is no indication that any of these animals that could have entered the feed chain before July 1994 was 4 years old or older. Only a few of these animals died or were slaughtered before July 1994, being mostly 3 years old at that time.	Before 1989 the Norwegian BSE/cattle system was extremely unstable, but it is very unlikely that the small number of cattle imported from the UK, also considering their ages at slaughter, may represent any significant risk. Since mid 1994, the Norwegian system became stable, i.e. able to reduce any BSE infectivity entering or circulating in the system. The 554 cattle imported from Denmark (where a BSE-case was identified in 2000) between 1991 and 1997 are considered unlikely to have given origin to any internal challenge. However, should it emerge that part of these cattle entered the feed system before mid 1994, an internal challenge might have built up.

	STABILITY	EXTERNAL CHALLENGE	INTERACTION OF STABILITY AND CHALLENGE
NEW-ZEALAND	Until 1996 the NZ BSE/Cattle system was extremely unstable, i.e. it would have amplified and propagated incoming BSE-infectivity rather fast. The 1996-voluntary ban on feeding RMBM to ruminants could have increased the stability somewhat but no compliance data were available. Hence the NZ system is still seen to be at least very unstable.	Only a very small number (13) of breeding cattle were imported from the UK. All were traced back, 6 came from BSE-affected herds, 1 from an affected birth cohort. Given the fact that all animals were older than the average BSE-incubation period at their death, they only represented a negligible challenge. No other imports were found that could be regarded to be an external challenge.	An extremely or very unstable system was probably never exposed to an external challenge.
PARAGUAY	The system is likely to have always been stable or very stable because a significant part of SRM was always used for human consumption or exported, fallen stock is not rendered and MBM was apparently not fed to cattle. In addition at least the current rendering is efficient with regard to BSE-infectivity reduction. However, optimal stability was ruled out due to realistic worst case assumptions that had to be applied in the absence of certain data; the voluntary and potentially incomplete nature of the “de facto SRM ban”; the lack of information on enforcement and control of the MBM ban; and the insufficient BSE-surveillance.	It is unlikely that Paraguay was ever exposed to any external challenge. No imports could be identified from any country known to be affected by BSE, neither of live cattle nor of MBM or potentially MBM containing feed.	An apparently always stable or very stable system was never challenged with BSE.

2. COUNTRIES WITH CURRENT GBR-LEVEL II

5 countries, **Austria, Finland, Sweden, Canada and the USA** have a current geographical BSE-risk (GBR) level of II, i.e. it is unlikely that domestic cattle in these countries are (clinically or pre-clinically) infected with the BSE-agent, but it cannot be excluded.

For each of these countries, descriptions of stability, external challenge and stability-challenge-interaction over time are reported in Table 2.

Assuming that measures in place in **AT, FIN**, and **SW** continue to be appropriately implemented and no new external challenge occurs, the probability that cattle are (pre-clinically or clinically) infected with the BSE-agent will decrease over time in these countries. However, for the time being it cannot be excluded that single BSE-cases may occur.

In USA and CAN the GBR will remain at its current low level as long as stability is not improved and no new external challenges have to be met.

FIN*:* This assessment is based on the assumption that the MBM imports from the Netherlands or other European Countries in 1988/89 did not pose a very high challenge. Given the fact that thousands of tonnes of MBM were exported at that time from the UK to other European countries, inter alia to the Netherlands, and given the practical impossibility to monitor the trade flows of that MBM, this assumption might be wrong. In that case Finland would have been exposed to a very high external challenge at a moment when the system was unstable. It therefore would have to be seen as GBR-level III.

TABLE 2 : STABILITY, EXTERNAL CHALLENGE AND STABILITY-CHALLENGE INTERACTION OVER TIME FOR FIVE COUNTRIES WITH GBR IN LEVEL II

	STABILITY	EXTERNAL CHALLENGE	INTERACTION OF STABILITY AND CHALLENGE
AUSTRIA	Until 1998, and at least during the last 20 years, the Austrian BSE/cattle system was neutrally stable (the rendering system was good and MBM was not intentionally fed to cattle while cross contamination could not be excluded; SRM and fallen stock were rendered for feed). In 1998, with the improvement of the BSE-surveillance, further improved rendering, and better control of cross contamination, the system became stable.	Austria has imported 234 live cattle from the UK between 1988 and 1990. This high external challenge was largely mastered by the specific surveillance of these cattle from 1990 onwards. From 1993 to 1997, when the first case occurred in the Netherlands, 253 cattle were imported from that country. These imports are still regarded negligible. Also the MBM that was imported for non-ruminant feed, mainly from Germany (5,683 tons in 1988 and about 1,500 tons in 1997/98) is considered a negligible external challenge;	Between 1988-1990 the neutrally stable BSE/cattle system was challenged by a high external challenge but this was largely mastered by the specific surveillance put in place in 1990. Therefore it is unlikely, but cannot be excluded, that some BSE entered the country. The neutrally stable system would have been able to largely control, but not to reduce, the experienced external challenges and the overall challenge would have remained at the level of the external challenge in the early 90s. Since 1998, when the system became stable the overall challenge started to decline, supposing that no new external challenges occurred.
FINLAND	The Finnish BSE/cattle system was “very unstable” until 1988: (a) the rendering was not fully adequate to reduce BSE-infectivity, (b) feeding animal protein to cattle was frequent, (c) SRM and fallen stock was rendered for feed and (d) surveillance was not adequate for BSE. Incoming BSE-infectivity would have been quickly amplified. In 1988/90 the stability increased because of improved surveillance and of banning imported MBM from ruminant feed. However, the system remained “unstable” until 1995 when the MBM-to-ruminant-ban made the system “neutrally stable”. The improvements in rendering (1996/97) made the system stable in 1997, when the systematic checking for BSE of CNS-suspects in emergency slaughter enhanced its stability. However, as long as SRM and fallen stock is still rendered for non-ruminant feed and cross-contamination is not fully mastered the system cannot be “very” or “optimally” stable.	Before 1988 the Finnish system was exposed to a low, and during 1988/89 a moderate or high external challenge. Thereafter the external challenges were negligible. The pre-1990 challenges resulted mainly from import of large amounts of MBM/MM from countries other than the UK (116,547 tons in total between 1980-1990, of which 59,773 tons from The Netherlands) but also from imports of some (84 in total) cattle directly from the UK. Eleven of the cattle imported from the UK and processed in Finland were found being at risk to have been exposed to the BSE-agent prior to export. It is uncertain if the MBM exported in the late 80s from other European countries than the UK to Finland could have been contaminated with the BSE-agent. However, this cannot be excluded because of the export of about 50,000 tonnes of MBM from the UK to other European countries, in particular BE, FR and NL, in 1988/89.	The unstable Finnish system was exposed to a low (1980-87) and moderate to high (1988/89) external challenge. Therefore, it cannot be excluded that the BSE-agent has entered the system in the late 80s, got recycled and amplified, and the disease was propagated. In 1990 the stability increased and the external challenge decreased due to the ban of imported MBM from ruminant feed. However, already circulating BSE-infectivity could have been further recycled and amplified until 1995, when the system became “neutrally” stable. Between 1995 and 1996/97 the neutrally stable system kept the challenge at a constant level, assuming that no new external challenge occurred. Since 1996/97 the stable system reduces the circulating BSE-infectivity and the challenge declines, as long as no additional external challenge occurs.

	STABILITY	EXTERNAL CHALLENGE	INTERACTION OF STABILITY AND CHALLENGE
SWEDEN	During the 80s the Swedish BSE/cattle-system was very unstable. The ban of fallen stock from feed and the voluntary feed ban for dairy cattle in 1987 had some effect but, as dairy calves were still fed MBM, the effect was marginal. The exclusion of fallen stock from rendering since 1986 also increased the stability to some degree but as long as SRM in general is rendered the effect of fallen stock exclusion remains minor. The official RMBM-ban of 1991 improved the situation to "unstable", and with increasing compliance the system became neutrally stable in 1992, i.e. circulating or incoming BSE-infectivity would have neither been amplified nor reduced. This situation was stabilised by the extended official feed ban that was enacted in 1995. In 1997, rendering was improved and the system became stable, i.e. able to reduce BSE-infectivity, should it be present. The remaining cross-contamination risk and inclusion of SRM into the feed chain prevented to assume higher stability.	Prior to 1988 the external challenge was very low, mainly resulting from cattle imported from the UK. In 1988-90 the challenge increased to a low level because of the higher risk carried by the 35 beef cattle imported from the UK in 1988, and the increasing MBM-imports.	Before 1990 a very unstable system was potentially exposed to a low challenge. This would have led to an internal challenge building up. However, in spite of the uncertainty linked to the extent of the initial internal challenge, this development is regarded to be unlikely but cannot be excluded. Since 1997, the system is considered to be stable and able to reduce circulating BSE-infectivity.
CANADA	Before 1992 the Canadian system was extremely unstable as MBM was fed to cattle, SRM was rendered for feed with processes not able to optimally reduce BSE-infectivity, and BSE-surveillance was inappropriate. After 1993, as a result of the improved passive surveillance of BSE, the traceback and removal of cattle imported from the UK, and the culling practices employed after the detection of the single imported BSE case, the stability increased but the system remained unstable. The introduction of the RMBM ban in 1997 and its subsequent implementation increased the stability of the system to neutral in 1998.	Between 1985 and 1987 a very low external challenge resulted from importing cattle from the UK; from 1988 to 1990 these imports represented a low external challenge. Thereafter they were stopped. As a result of the importation and subsequent (time-delayed) processing of some UK-cattle, BSE-infectivity could have entered the Canadian system. Imports of MBM could have added to this challenge and remained a certain (low level) external challenge after 1993.	While extremely unstable the Canadian system was exposed to a very low or low challenge by cattle imports from UK. It cannot be excluded that BSE-infectivity entered the country by this route and was recycled, reaching domestic cattle. A low-level domestic prevalence cannot therefore be fully excluded to exist since the early 90s. However, the level must be below the detection level of the rather good passive surveillance in place.

	STABILITY	EXTERNAL CHALLENGE	INTERACTION OF STABILITY AND CHALLENGE
USA	Before 1990 the system was extremely unstable because feeding of MBM to cattle happened, rendering was inappropriate with regard to deactivation of the BSE-agent and SRM and fallen stock were rendered for feed. From 1990 to 1997 it improved to very unstable, thanks to efforts undertaken to trace imported animals and to exclude them from the feed chain, and to intensive surveillance. In 1998 the system became neutrally stable after the RMBM-ban of 1997.	A moderate external challenge occurred in the period before 1990 because of importation of live animals from BSE-affected countries, in particular from the UK and Ireland. It cannot be excluded that some BSE-infected animals have been imported by this route and did enter the US rendering and feed production system. The efforts undertaken since 1990 to trace back UK-imported cattle and to exclude them from the feed chain reduced the impact of the external challenge significantly.	While extremely unstable, the US system was exposed to a moderate external challenge, mainly resulting from cattle imports from the UK. It can not be excluded that BSE-infectivity entered the country by this route and has been recycled to domestic cattle. The resulting domestic cases would have been processed while the system was still very unstable or unstable and would hence have initiated a number of second or third generation cases. However, the level of the possible domestic prevalence must be below the low detection level of the surveillance in place.

3. COUNTRIES WITH CURRENT GBR- LEVEL III

10 countries, **Belgium, Germany, Denmark, France, Ireland, Italy, Luxembourg, the Netherlands, Spain** and **Switzerland** have a current geographical BSE-risk (GBR) level of III.

- In **DE, IT** and **SP** it likely that domestic cattle countries are (clinically or pre-clinically) infected with the BSE-agent, but this is not confirmed.
- In **BE, DK, FR, IRE, LUX, NL,** and **CH** BSE is confirmed but at a lower level (incidence < 100).

For each of these countries, descriptions of incidence, stability, external challenge, and stability-challenge-interaction over time are reported in Table 3.

Assuming that measures in place in **BE, DK, FR, IRE, LUX, NL, SP** and **CH** continue to be appropriately implemented and no new external challenge occurs, the probability that cattle are (pre-clinically or clinically) infected with the BSE-agent will decrease over time in these countries. However, for the time being it cannot be excluded that (more) BSE-cases may occur. Incidence figures may therefore continue to increase until birth cohorts with a higher risk of being infected will have left the system. The switch of all low-risk material rendering to 133/20/3 batch pressure cooking, in July 2000 and the exclusion of SRM from the feed (and food) cycle (01 October 2000) will make all systems (more) stable and the GBR will start to decline faster.

In **DE** and **IT** the probability that cattle are (pre-clinically or clinically) infected with the BSE-agent will remain constant, as long as no significant further improvements of the stability of the system are achieved. An increase in stability is essential to cope with the potentially existing challenge and eventually reach a situation where the GBR starts to decrease. The switch of all low-risk material rendering to 133/20/3 batch pressure cooking, in July 2000 and the exclusion of SRM from the feed (and food) cycle (01 October 2000) will make the German and the Italian system stable and the GBR will start to decline.

LUX has no rendering facilities and depends on Belgium for rendering its cattle. It does not produce meat and bone meal, importing this mainly from Belgium. Therefore, the classification of Luxembourg is dependent on the classification of Belgium and reference is made to the Belgium situation throughout this report.

In **CH** the observed incidence is generated by a surveillance system based on an effective passive surveillance system targeting clinically-affected animals coupled with an active surveillance of offspring and herd culls since 1996 and advanced[31] active surveillance on fallen stock and emergency slaughter since 1999.

In all countries in this group except Switzerland, the current surveillance system is passive and therefore not able to detect all clinical BSE cases. The probability that BSE is confirmed in those countries that have not yet identified domestic cases within the next years is high, in particular if active surveillance would improve the performance of the surveillance system. In countries with BSE-incidence, except CH, the real incidence of clinical BSE-cases has to be assumed to be higher than the currently reported. In general, additional efforts to ascertain pre-clinical BSE-cases and remove them, and other animals at-risk of being infected by BSE, from processing will assist in reducing the GBR in all countries of this group.

[31] Using a rapid post-mortem testing.

TABLE 3 : INCIDENCE, STABILITY, EXTERNAL CHALLENGE, AND STABILITY-CHALLENGE INTERACTION OVER TIME FOR FIVE COUNTRIES WITH GBR IN LEVEL III

	CURRENT INCIDENCE	STABILITY	EXTERNAL CHALLENGE	INTERACTION OF STABILITY AND CHALLENGE
BELGIUM	**3.4 (16 June 1999-15 June 2000)**	Before 1995 the Belgian BSE/cattle system was extremely unstable. In 1994 the implementation of the MBM ban improved the stability but it was still very unstable largely because of the remaining cross-contamination of feed. The improvements of the rendering system since 1996 combined with the adoption of the SRM-ban since 1998 made the system stable. Sub-optimal compliance with the 1994 MBM and 1998 SRM bans and decision 96/449/EC reduced the initial impact and speed of effect of these interventions in improving the Belgian BSE/cattle system's ability to cope with BSE infectivity.	The Belgian BSE/cattle system was exposed to a high or very high external challenge throughout the 80s due to the import of MBM from UK and from cattle imported from the UK.	Given the low stability of the Belgian system at the time of high or very high external challenge, the incoming infectivity was recycled and amplified and a domestic prevalence developed, as confirmed by the observed incidence. The high challenge to which an unstable system was exposed lead to a situation where increasing numbers of cattle were infected. It seems to be likely that this trend has continued until 1998. However, since good stability levels have only been reached in 1999 and the challenge is still assessed to be very high, a temporary increase of the incidence can not be excluded for the next few years.
GERMANY	**No domestic cases**	Until 1994 the German BSE/cattle system was very unstable, i.e. it would have amplified rather quickly any imported BSE infectivity. The feed ban in 1994 improved the stability, and together with additional measures implemented later the system became neutrally stable in 1996, i.e. it is still not able to reduce the possibly present BSE-infectivity as long as parts of the rendering system are sup-optimal and the risk of cross-contamination remains.	Between 1980 and 1993 Germany has imported over 13,000 cattle from the UK, only 400 of them for immediate slaughter. Five breeding cattle from UK developed clinical BSE. It is likely that additional BSE-infected cattle were imported from the UK and other European countries now known to have BSE. Germany also imported potentially contaminated MBM from the UK, most notably in 1988 and 1989. Import of potentially contaminated MBM via other EU-countries cannot reliably be estimated.	A very unstable system was faced with a 'very high' external challenge and some of the BSE-infectivity that entered the system was most probably amplified. It is hence assumed that BSE entered the system and was amplified. Therefore, it is likely that BSE is currently present in the domestic cattle population, at levels below the detection limits of the passive BSE surveillance system in place.

	CURRENT INCIDENCE	STABILITY	EXTERNAL CHALLENGE	INTERACTION OF STABILITY AND CHALLENGE
DENMARK	1.0 (February 2000)	Until 1990 the system was extremely unstable, i.e. it would have had recycled and amplified rather quickly any incoming BSE-infectivity. In 1990 the system was improved by the implementation of a feed ban but it remained unstable as full compliance with the feed ban could not be assumed, rendering was not according to standard, and SRM and fallen-stock were rendered for feed. In 1997 improvement of the rendering system were realised that made the system stable, i.e. it is since 1997/98 capable of reducing circulating BSE-infectivity. The just introduced SRM-ban, and the exclusion of fallen-stock from rendering, will make the system now very stable.	About 1,000 cattle were imported from the UK in the 1980s, one of which was confirmed as having BSE in 1992. MBM was officially not imported into DK since many years. However, the DK authorities came across some unauthorised imports when investigating the first domestic BSE-case	An extremely unstable system was faced with a moderate external challenge. As demonstrated by the recent BSE-case, some BSE-infectivity entered the system, was amplified and lead to at least one domestic case.
FRANCE	3.4 (16 June 1999-15 June 2000)	Throughout the 80s the French BSE/cattle system was extremely unstable. The feed ban adopted in 1990, but likely not effectively enforced until 1994/1995, improved the situation, but the system was still unstable in 1995. In 1996 the system became stable due to the adoption of the SRM-ban and other preventive measures. Since 1998, after the improvement of the rendering system, the system is regarded to be optimally stable.	The French BSE/cattle system received high challenges from imported MBM and live cattle during the 80s up to themid-90s from the UK. These trade practices led to an increasing and extremely high challenge from the late 80s to the early 90s. Moreover, also the MBM and cattle imports from EU countries other than U.K., which have shown BSE, did increase largely up to 1997.	Because of the insufficient stability until 1995, the external challenge led to a significant domestic prevalence of BSE in the French cattle population (internal challenge) which gave origin to an increasing BSE incidence until 1999. Therefore, the overall challenge has remained extremely high up to 1999. After 1996 the enhanced stability led to a slow decrease in the newly occurring infections. The measures adopted in 1997 (feed controls) and 1998 (improved rendering) enhanced this trend and a further reduction of new infections and of overall challenge is presently expected, although it cannot be excluded that incidence may continue to increase in the next future.

	CURRENT INCIDENCE	STABILITY	EXTERNAL CHALLENGE	INTERACTION OF STABILITY AND CHALLENGE
IRELAND	32.4 (16 June 1999 - 15 June 2000)	According to a reasonable worst case scenario, the Irish BSE/cattle system was extremely unstable until 1990. In 1990 the implementation of an MBM ban and improvements in the BSE surveillance system increased the stability but the system remained unstable, i.e. amplified incoming and circulating BSE-infectivity, until 1996. In 1996/97/98 rendering was improved (reached EU-standard in all plants in mid 1997), an SRM ban installed (enforced in 1997), and the control of the feed ban intensified. All this led to a significant increase in stability and the system became able to reduce BSE-infectivity. It is very stable since 1997 and optimally stable since 1998.	The Irish BSE/cattle system was exposed to increasing external challenges throughout the 80s, mainly by cattle imports from UK that continued until 1990. The external challenge reached extremely high levels at the end of this period.	Given the low stability of the Irish system during the 80th, the incoming infectivity was amplified and a domestic prevalence developed, as confirmed by the observed incidence. The high and extremely high challenge to which an unstable system was exposed lead to a situation where increasing numbers of cattle were infected. It seems to be likely that this trend has continued until 1996 and started to reverse thereafter.
ITALY	No domestic cases	Prior to 1993 the Italian BSE/cattle system was very unstable, i.e. any BSE-infectivity entering it would have been quickly amplified. The 1994 feed ban and the removal of SRMs from animals imported from BSE-affected countries, introduced in 1996, improved the stability but the system remained unstable. The improvement of the rendering system that started after 1996 and were completed in mid 1999 made the system neutrally stable. It is not stable because SRM of domestic cattle are still rendered and the risk of cross-contamination of cattle feed with MMBM is still not negligible.	Italy imported about 10,000 bovines from UK during the period 1985 to 1990, about 90% for fattening and slaughter at 6 or 18 months of age or younger. About 1000 cattle entered the national herd. From 1990, when the age limit for slaughtering UK-imports was set to 6 months, to 1995, roughly another 10,000 calves have been imported from the UK. In 1994 two cases of BSE have been discovered in UK-imported cattle, thus proving that it cannot be excluded that BSE-infectivity entered the Italian BSE/cattle system by this route. In addition Italy imports roughly about 2 million cattle per year for immediate slaughter or fattening. France is a major source but also BE, CH (until 1996), and NL. Italy also imported MBM from BSE affected countries, mostly for pig and poultry feed. It is likely that some of these imports were contaminated and entered, particularly via cross-contamination or inappropriate use, the Italian BSE-cattle system. Together the cattle imports and the MBM imports represented a very high or high external challenge. After 1996 the destruction of SRM from imported animals reduced the effect of the external challenge significantly.	A very unstable or unstable system was exposed to high or extremely high external challenges over a long period of time. It is hence likely that BSE entered the system and was recycled and amplified, leading to a certain domestic prevalence. It is therefore assumed that BSE is currently present in the domestic cattle population, at levels below the detection limits of the passive BSE surveillance system in place, which would not be able to detect all clinical cases of BSE.

	CURRENT INCIDENCE	STABILITY	EXTERNAL CHALLENGE	INTERACTION OF STABILITY AND CHALLENGE
LUXEMBOURG	**0 (Last domestic case observed in 1997)**	Before 1995 the BSE/cattle system of Luxembourg/Belgium was extremely unstable. In 1994 the implementation of the MBM ban improved the stability to very unstable largely because of the remaining cross-contamination of feed. The improvements of the rendering system (in BE) since 1996 combined with the adoption of the SRM-ban since 1998 made the system stable. Sub-optimal compliance with the 1994 MBM and 1998 SRM bans and decision 96/449/EC reduced the initial impact and speed of effect of these interventions in improving the BSE/cattle system's ability of Luxembourg/Belgium to cope with BSE infectivity.	The BSE/cattle system of Luxembourg/Belgium was exposed to a high or very high external challenge throughout the 80s due to the import of MBM from U.K and from cattle imported from the UK.	Given the low stability of the system of Luxembourg/Belgium at that period the incoming infectivity was recycled and amplified and a domestic prevalence developed, as confirmed by the observed incidence. The high challenge to which an unstable system was exposed lead to a situation where increasing numbers of cattle were infected. It seems to be likely that this trend has continued until 1998. However, since good stability levels have only been reached in 1999 and the challenge is still assessed to be very high, a temporary increase of the observed incidence can not be excluded for the next few years.

	CURRENT INCIDENCE	STABILITY	EXTERNAL CHALLENGE	INTERACTION OF STABILITY AND CHALLENGE
THE NETHERLANDS	**0 (16 June 1999 - 15 June 2000, last case observed in early 1999)**	Before 1990 the Dutch BSE/cattle system was very unstable as feeding MBM to cattle was common, rendering was not fully at standard and SRM were rendered for feed. The ruminant MBM-ban of 1989 improved the stability but the system remained unstable, largely because of the risk of cross-contamination of cattle feed with imported and domestic MBM. The MMBM-ban of 1994 made the system neutrally stable in 1995 and the improvements in the rendering system in 1996, combined with the exclusion of SRM from rendering for feed (1997) made the system first stable and then very stable (1998). Suboptimal compliance with the 1994 MBM and 1997 SRM bans reduced their initial impact and the speed of effect of these interventions in improving the Dutch BSE/cattle system's ability to cope with BSE infectivity. The improvements in BSE-surveillance that were realised since 1997 supported the trend towards a higher stability. Recent efforts to further reduce cross-contamination made the system very stable. Depending on the optimal implementation of all measures in place the system may become optimal stable in the near future.	Before 1987 the Dutch BSE/cattle system was exposed to high, and after 1988 very high external challenges due to the import of MBM and cattle from U.K and other countries known to be affected by BSE.	Given the low stability of the Dutch system when it was exposed to high and very high external challenges, it is assumed that BSE-infectivity entered the system and was amplified. A domestic prevalence developed, as confirmed by the observed incidence. Together the continuing very high external challenge and the increasing internal challenge could not be met by the still unstable Dutch system and it is likely that increasing numbers of domestic cattle were infected, this led to an extremely high overall challenge. Since 1996 the system is stable and hence able to reduce the challenge and it is assumed that it down to very high levels since 1998. With the increasing stability the challenge will further decrease, as long as no new external challenges counteract this trend.

	CURRENT INCIDENCE	STABILITY	EXTERNAL CHALLENGE	INTERACTION OF STABILITY AND CHALLENGE
SPAIN	No domestic cases	Before 1994 the Spanish BSE/cattle system was extremely/very unstable. MBM could legally be fed to cattle, even if this was not commonly the case, rendering was unable to reduce incoming BSE-infectivity significantly, and SRM and fallen stock were rendered, also from imported animals. The 1994 feed ban improved the stability to "unstable". The 1996 SRM ban for animals imported from BSE-affected countries, together with improved surveillance (since end 96) and better rendering (since 1997) made the system "neutrally" stable in 1997. With further improved surveillance (1997), rendering (mid 1998) and feed-controls (1999), the system became stable in mid 1998/99; i.e. circulating or incoming BSE-infectivity will be reduced over time.	Between 1980 and 89 nearly 4,000 cattle were imported from the UK, 943 Friesian for breeding and the rest beef cattle for fattening and slaughter at young age. Of the 943 breeding-cattle, 161 were born after 1/1/85, the year when the case incidence of that birth cohort in the UK surpassed 8.000 BSE cases. Of these 161 animals, 56 are seen to be critical because they probably were pre-maturely killed at an age of 4 to 6 years, i.e. an age when they would just be approaching the end of a normal incubation period, if they were infected with BSE before export. These imports posed a high external challenge. Between 1985-1997, more than 350,000 beef cattle were imported from other European countries now known to be affected by BSE, according to the Spanish authorities exclusively for fattening in specialised installations and slaughter at young age. The import of 14,551 cattle from Portugal mostly consisted of fighting bulls that are assumed to be less at risk due to their special upbringing. The imports from BSE-affected countries other than the UK are assumed to have added to the external challenge to some extent until 1996, when the SRM-ban for imported cattle made the effect of this challenge negligible.	An extremely or very unstable system was exposed to significant challenges over a long period of time but particularly during 1989-1993 when the critical UK-imports were pre-maturely killed. It is hence likely that the BSE-agent entered the system and was recycled and, over time, amplified. As the system is only stable since mid-1998/99, it is expected that BSE is currently present in the domestic cattle population, at levels below the detection limits of the BSE surveillance system in place.
SWITZERLAND	52.5 (16 June 1999- 15 June 2000) (This figure is generated by a combination of good passive & active surveillance)	Prior to 1990 the system was extremely unstable as SRM and fallen stock was rendered, rendering was not able to reduce BSE-infectivity and MMBM was regularly fed to cattle. The feed ban in 1990 improved the situation but the system remained unstable until end 1992. The improvement in the rendering system in 1993 made the system stable, i.e. it became able to reduce the circulating BSE-infectivity. In 1996 the system became optimally stable due to excluding the most important SRMs and fallen stock from feed production and the further improvements of the rendering system. Recent active surveillance measures including sampling of adult cattle in fallen stock, emergency slaughter and normal slaughter enhance the stability of the system, not at least because a higher proportion of the infective material is excluded from the feed chain.	The import of bovines and animal proteins from EU-countries, some affected by BSE, others having received imports from the UK, in particular of potentially contaminated MBM during the late 80s represented a high to very high external challenge.	Because of the insufficient stability, the internal challenge that already was present in 1984, at the latest, led to a significant domestic prevalence of BSE in the Swiss cattle population (internal challenge) which gave origin to an exponentially-increasing BSE incidence until 1995. This process was fuelled by the additional external challenges experienced in the late 80s. After 1993, the system became stable and the challenge began to decrease. Today it is still assumed to be high but quickly decreasing due to the optimally stable system.

4. COUNTRIES WITH CURRENT GBR IN LEVEL IV

2 countries, **UK** and **PT** have a current geographical BSE-risk (GBR) level of IV. BSE is confirmed but at a higher level (incidence ≥ 100).

For each of these countries, descriptions of incidence, stability, external challenge, and stability-challenge-interaction over time are reported in Table 3.

Assuming that measures in place in **UK** and **PT** continue to be appropriately implemented and no new external challenge occurs, the probability that cattle are (pre-clinically or clinically) infected with the BSE-agent will decrease over time in these countries. However, for the time being it cannot be excluded that more BSE-cases may occur. Incidence figures may therefore continue to increase, at least in PT, until birth cohorts with a higher risk of being infected will have left the system.

In both countries in this group, the current surveillance system is passive and therefore not able to detect all clinical BSE cases. The real incidence of clinical BSE-cases has therefore to be assumed to be higher than the currently reported.

Additional efforts to ascertain pre-clinical BSE-cases and remove them, and other animals at-risk of being infected by BSE, from processing will assist in reducing the GBR in the countries of this group, in particular in Portugal.

TABLE 4 : INCIDENCE, STABILITY, EXTERNAL CHALLENGE, AND STABILITY-CHALLENGE INTERACTION OVER TIME FOR FIVE COUNTRIES WITH GBR IN LEVEL IV

	CURRENT INCIDENCE	STABILITY	EXTERNAL CHALLENGE	INTERACTION OF STABILITY AND CHALLENGE
PORTUGAL	215.8 (16 June 1999-15 June 2000)	Before 1990 the Portuguese system was extremely unstable. The situation improved to some extends in 1990 by making BSE a notifiable disease and awareness building measures but due to the continued feeding of MBM to cattle and inappropriate rendering, including SRM, the system remained extremely unstable until 1994. In 1994 the implementation of an MBM ban for ruminants improved the stability but the system remained very unstable because of insufficient compliance and continuing shortcomings in rendering and feed production. In 1996 compensation was introduced which increased notification of suspects but the system remained very unstable until late 1997, when improvements in rendering started. Measures taken in 1998 significantly improved the system, which since 1998 is regarded to be stable, i.e. able to reduce, over time, the BSE-infectivity circulating in the system. Most important were the extension of the MBM ban to all farmed animals, the exclusion of SRM from the feed chain, the improvement of rendering and the improvement of the surveillance system. In the year 2000 the system could be regarded as very stable, as all three main stability-building measures are in place but compliance data would be needed to confirm this positive assessment.	Between 1985 and 1989 Portugal was exposed to very high external challenges mainly by imports of cattle from the UK. Within these imports 7 BSE-cases where identified but more than 8,200 cattle entered the Portuguese system and where processed. Imports of cattle from other countries known to have BSE and some imports of MBM added to this external challenge and maintained a certain level of inflow of BSE-infectivity until at least 1996.	Given the extremely unstable Portuguese system the incoming BSE-infectivity was amplified and a domestic prevalence developed at the latest since 1984, the first birth cohort wherein a BSE-case was confirmed. Together the internal and the external challenge are at very high and extremely high levels since the late 80s and early 90s, while the system was still extremely unstable. This challenge/stability combination lead to the observed building-up of an epidemic, where the numbers of newly infected cattle increased every year. It seems to be likely that this trend decreased with the MBM-ban of 1994 but significant numbers of new infections continued to appear until 1998, when the preventive measures taken where finally sufficient to make the system stable. Since stability has only been reached in 1998/99 and the challenge is still assessed to be extremely high, even a temporary increase of the incidence cannot be excluded for the next few years, although so far no new cases of BSE have been registered that were born after January 1996. The incidence will decrease quickly once the pre-1999 birth cohorts will have left the system.

	CURRENT INCIDENCE	STABILITY	EXTERNAL CHALLENGE	INTERACTION OF STABILITY AND CHALLENGE
THE UNITED KINGDOMS	430.2 (16 JUNE 1999-15 JUNE 2000)	The system was extremely unstable before 1988. The implementation of a ruminant MBM ban and mandatory notification of BSE in 1988 improved the situation but the system remained very unstable. The first SRM ban excluding SRM from the human food chain but including it into rendering made the system again somewhat more unstable but this was rectified in 1990. The enforcement of the 1990 SRM ban finally resulted in a stable system, able to slowly reduce the BSE-infectivity circulating in the system. In 1996 feeding MBM to all farm animals was prohibited and animals over thirty months of age were excluded from any processing. Together this feed ban and the Over Thirty Months Scheme (OTMS) have significantly improved the stability of the system, which is regarded to be very stable since 1996. Since 1999 since all animals allowed to be processed were born after 01/08/96 and supported by the improved cattle tracing system and the surveillance of high risk populations (OTMS-survey in 1999) the system is optimally stable, even if the rendering is still not according to standard.	Given the fact that the BSE epidemic most likely started in UK the external challenge concept is not applicable to this country.	The discovery of the first BSE-cases in 1986 and rapid increase in incidence thereafter indicates a high domestic prevalence in the UK cattle herd early in the 80s. Between 1985 and 1988 a very high (internal) challenge was amplified by an extremely unstable system and quickly developed into an extremely high internal challenge as reflected in the incidence figures. The measures taken in 88/89 and 90 increased the stability of the system but the challenge remained extremely high until today, albeit decreasing since 1990, when the system became stable, i.e. able to slowly reduce BSE infectivity circulating in the system. This is also reflected in the incidence figures that continuously decrease since 1993. The drastic measures taken in 1996 can be assumed to have reduced prevalence in the birth cohorts after August 1996 to very low or negligible levels. However, this depends on the efficiency of these measures.

ANNEX III : Sources of comments on the preliminary opinion of the SSC on the Geographical Risk of BSE and/or the related preliminary country reports received in response to the public consultation following the publication on the Internet.

To receive detailed information on the official comments please contact the appropriate address given hereunder:
Argentina: Secretaria de Agricultura, Ganaderia, Pesca Y Alimentacion Servicio Nacional de Sanidad y Calidad Agroalimentaria SENASA Chief Veterinary Officer AV. Paseo Colon 367 – 3er. Piso c.p. 1063 – Capital Federal Republica Argentina Fax: (5411) 4334-4738
Australia: Agriculture, Fisheries and Forestry - Australia Commonwealth Chief Veterinary Officer GPO Box 858 Canberra ACT 2601 Australia
Austria: Bundesministerium für Soziale Sicherheit und Generationen Chief Veterinary Officer Radetzkystr. 2 A-1031 WIEN Fax: (01) 710 41 51
Canada: Government of Canada Canadian food Inspection Agency Disease Control – Policy and Standards Animal Health and Production Division 59 Camelot Drive Nepean, Ontario K1A 0Y9 Fax: 613-228-6620
France: Direction générale de l'alimentation Chief Veterinary Officer 251, rue de Vaugirard F-75732 PARIS CEDEX 15 Fax: (01) 49 55 43 98
Republic of Ireland: Department of Agriculture, Food and Rural Development Chief Veterinary Officer Kildare Street Dublin 2 Fax: +353-1-6072440

Italy: Ministero della Sanita' Dipartimento Alimenti, Nutrizione e Sanità Pubblica Veterinaria, Chief Veterinary Officer Piazza Marconi, 25 00144 Roma Fax: +39 06 5994 3253
New Zealand: New Zealand Mission to the European Communities Square de Meeus 1 B-1000 Brussels Fax: +32-2-513 48 56
Portugal: Direcção Geral de Veterinária Chief Veterinary Officer Largo Academica Nacional das Belas Artes, 2 P-1249-150 LISBOA Fax: +351-21-346 35 18
Spain: Ministerio de Agricultura, Pesca Y Alimentacion Chief Veterinary Officer C/Corazón de Maria 8 S-28071 Madrid Fax: (91)-5943536
Sweden: Ministry of Agriculture, Food and Fisheries Chief Veterinary Officer Fax: +36-308182
United States of America: United States Department of Agriculture USDA Animal and Plant Health Inspection Service APHIS Washington, DC 20050 Fax: +1-202-690-4171
To receive detailed information on private comments or comments from non-governmental organisations, please e-mail your co-ordinates to the Secretariat of the Scientific Steering Committee: joachim.kreysa@cec.eu.int The secretariat will forward it to the originators of the comments who might then get in contact with the person interested in their comment.

ANNEX IV: List of experts who directly or indirectly contributed over the period January 1998 to July 2000 to the development of the GBR-methodology and its application to 25 Countries.

This list contains the names of Independent and Country Experts that have agreed to be included in this list.

In addition to the experts included in this list about 20 other experts have directly or indirectly participated in the process. Their names are not given because they did not respond to the request for agreeing to their name being listed or because they did not want to be listed.

Of the members of the SSC or the TSE/BSE ad-hoc group only those are indicated that actively participated in one or several working-group meetings related to the GBR.

The opinion on the "Geographical Risk of Bovine Spongiform Encephalopathy (GBR)" and the related country reports are the exclusive responsibility of the Scientific Steering Committee who is grateful for the contribution of the numerous experts.

Name	Country of origin	Independent expert	Country expert
Dr. Reinhard Ahl	Germany	**Yes**	
Dr. Lis Alban	Denmark	**Yes**	
Dr. Susanne Ammendrup	Denmark	**Yes**	**Yes**
Dr. Jean Marie Aynaud	France	**Yes**	
Dr. Juan J. Badiola-Diez	Spain	**Yes**	
Dr. Fabrizio Bertani	Italy		**Yes**
Dr. Mart De Jong, M.	Netherlands	**Yes**	
Dr. Aline De Koeijer	Netherlands	**Yes**	
Dr. Alain Dehove	France	**Yes**	**Yes**
Dr. Vittorio Dell'Orto	Italy	**Yes**	
Dr. Linda Detwiler	United States	**Yes**	
Dr. Marcus Doherr	Switzerland	**Yes**	
Dr. Willem Edel	Nederland	**Yes**	
Dr. Claes Enoe	Danmark	**Yes**	
Dr. C. Gómez-Tejedor	Spain	**Yes**	
Dr. Michael Gravenor	United Kingdom	**Yes**	
Dr. Dagmar Heim	Switzerland	**Yes**	**Yes**
Dr. Karel Hruska	Czech Republic	**Yes**	
Dr. William D. Hueston	United States	**Yes**	
Dr. Matthias Kramer	Germany	**Yes**	

Name	Country of origin	Independent expert	Country expert
Dr. Ann Lindberg	Sweden	**Yes**	
Dr. Karin Möstl	Austria	**Yes**	
Dr. A.-L. M. Parodi	France	**Yes**	
Dr. Giorgio Poli	Italy	**Yes**	
Dr. Michael Roberts	New Zealand	**Yes**	
Dr. Mo Salman	United States	**Yes**	
Dr. Marc Savey	France	**Yes**	
Dr. James Sexton	Ireland	**Yes**	
Dr. Gary Smith	United States	**Yes**	
Dr. Martha Ulvund	Norway	**Yes**	
Dr. H.A.P. Urlings	Netherlands	**Yes**	
Dr. E. Vanopdenbosch	Belgium	**Yes**	
Dr. Patrick G. Wall	Ireland	**Yes**	
Dr. Peter Weber	Austria	**Yes**	**Yes**
Dr. John Wilesmith	United Kingdom	**Yes**	
Dr. Preben Willeberg	Denmark	**Yes**	
Dr. Taina Aaltonen	Finland		**Yes**
Dr. Marianne Elvander	Sweden		**Yes**
Dr. Ramiro Mascarenhas	Portugal		**Yes**
Dr. Paul Merlin	France		**Yes**
Dr. Ignacio Sanchez	Spain		**Yes**

For contacting anybody from this list please send your coordinates to the secretariat of the SSC (e-mail: <joachim.kreysa@cec.eu.int>).

The secretariat will forward your request to the respective person who than may get in contact with you.