Report on

the Assessment of

the Geographical BSE-Risk

(GBR) of

THE NETHERLANDS

July 2000

NOTE TO THE READER

Independent experts have produced this report, applying an innovative methodology by a complex process to data that were voluntarily supplied by the responsible country authorities. Both, the methodology and the process are described in detail in the final opinion of the SSC on "the Geographical Risk of Bovine Spongiform Encephalopathy (GBR)", 6 July 2000. This opinion is available at the following Internet address:

<http://europa.eu.int/comm/food/fs/sc/ssc/out113_en.pdf **>**

In order to understand the rationale of the report leading to its conclusions and the terminology used in the report, it is highly advisable to have read the opinion before reading the report. The opinion also provides an overview of the assessments for another 24 countries.

P A R T I

Description of the method and its limitations, and definitions and process used for assessing the GBR of THE NETHERLANDS

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.

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[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 AND 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 considered 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.

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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

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.

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

[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: 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 introduction are considered: import of infected cattle or import

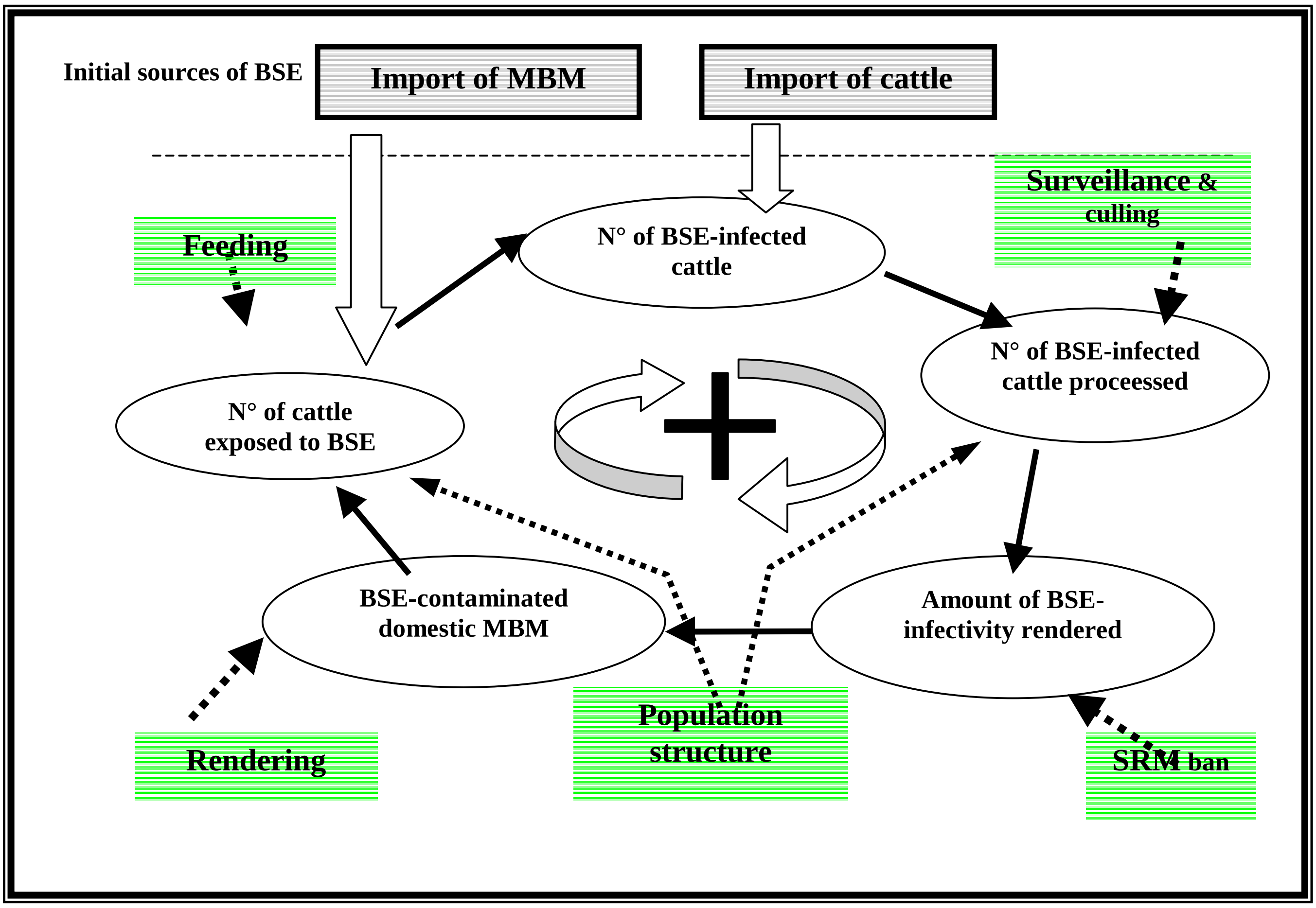

Figure 1: The model of the BSE/cattle system used by the SSC

[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.

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.

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

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

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 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].

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[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

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

BSE-infectivity over time. The same is true if only one factor is "OK" and two are not present or only badly implemented.

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.

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

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.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.

Overall Challenge

Stability: Amplification | Reduction

Stability	Negligible	Very low	Low	Moderate	High	Very high	Extremely high
Optimally stable							
Very stable	**Best**						**Good**
Stable							
Neutral							
Unstable				➔			
Very Unstable		X➔	➔				
Extremely Unstable	**Good**						**Worst**

Figure 2: Stability/challenge combination, four principal situations and a hypothetical development over time

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. 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 who had voluntarily submitted information and the comments received from several of these countries on

- the drafts of their reports (April/May and June 1999 and 2000),

[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 for the Czech Republic, India and the Slovak Republic are still pending finalisation.

- 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-three 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 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.

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

[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.

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.

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 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:

- 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.

[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 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 <u>exposure assessment</u>. 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 <u>pathway assessment</u> 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 lead 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. 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.

3.1 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.[25]

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[26]. 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.

[25] 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.

[26] 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.

3.2 AMOUNT AND DISTRIBUTION OF INFECTIVITY IN BSE ANIMALS

3.21 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.

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).

3.22 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).

3.3 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[27], others (e.g. normal cooking, sub-standard rendering) have no measurable impact on it.

4. CONCLUSION

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[28]) 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 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.

[27] See the various SSC-opinions on the safety of Gelatine, Tallow, MBM, Hydrolysed proteins, Fertilisers, etc.

[28] See the opinion of the SSC on "fallen-stock"

PART II

REPORT ON THE ASSESSMENT OF THE

GEOGRAPHICAL BSE RISK OF

THE NETHERLANDS

EXECUTIVE SUMMARY

OVERALL ASSESSMENT

The current geographical BSE-risk (GBR) level is III, i.e. BSE is confirmed in domestic cattle at a lower level.

However, the observed incidence of clinical cases over the period 1 March 1999 to 29 February 2000 was 0.5 per 1 Million adult cattle. This figure is generated by a passive surveillance system that is not able to identify all clinical cases.

Stability: 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.

External challenge: 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.

Interaction of stability and challenge: 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.

Assuming that measures in place continue to be appropriately implemented and no new external challenge occurs, the GBR is expected to decrease over time. However, this does not exclude that cattle infected by the BSE-agent in the past may be identified as clinical cases in the foreseeable future.

JUSTIFICATION

1. AVAILABLE DATA

The available information was sufficient to assess the Geographical BSE-risk.

2. STABILITY

2.1 Ability to identify BSE-cases and to eliminate animals at risk of being infected before they are processed

- Before 1990, the ability of the system to identify and remove BSE-infected animals before processing was considered very low.
- In 1990 the introduction of the mandatory reporting, a compensation scheme, and of culling, improved this ability to some extent.
- In 1997 intensified surveillance increased the reported number of BSE suspects.
- The system is now relying on a well performing passive surveillance. Without active surveillance, targeting at-risk sub-populations such as fallen-stock and emergency slaughter, there is little potential to improve it further.

2.2 Ability to avoid recycling BSE-infectivity, should it enter processing

- Before 1989, the system was not able to avoid recycling of BSE infectivity since ruminant-derived MBM was fed to cattle of all ages, rendering was not fully at standard, and SRM and fallen stock was rendered for feed.
- The 1989 change from batch to continuous rendering in parts of the industry reduced this ability somewhat more but the change of the entire industry to 133/20/3 in 1990 counter-balanced this.
- Between 1990 and 1997 the ability to avoid recycling improved thanks to the feed bans of 1990 and 1994 but remained insufficient as cross contamination continued to be a problem, rendering was still not fully optimal, and SRM and fallen stock were still rendered for feed.
- Since 1996/1997, all rendering is done with batch processes applying 133/20/3, cross-contamination has been reduced, and an SRM-ban (including fallen stock > 12 months) is in place. Therefore the ability to avoid recycling of BSE infectivity that enters processing is considered to be very good since 1998.

2.3 Overall assessment of the stability

- Until 1990, the system was very unstable, mainly because of an inability to stop cattle from being exposed to MBM via feed, rendering of SRM for feed, and not fully sufficient rendering processes.
- After 1990 stability increased due to the MBM ban and the switch of all rendering plants to 133/20/3. The improvements in surveillance supported this increase in stability.
- Between 1994 and 1997 the system became stable as a result of the second MBM ban in 94, the reintroduction of the batch system in all rendering plants (in 96') and the introduction of an SRM- & fallen stock (>12months)-ban (in 97').

- Since 1998, the system is regarded as being very stable, mainly as a result of the final implementation of the SRM ban and further measures introduced to prevent cross contamination. The 1997 improvements of the surveillance supported the gain in stability.
- If the recent measures against cross-contamination are fully implemented and complied with, the stability is expected to reach optimal stability, thereby quickly removing BSE-infectivity circulating in the system.

3. CHALLENGES TO THE BSE/CATTLE SYSTEM

- The Netherlands have been exposed to high (until 1987) and very high (1988-1997) external challenges, resulting both from cattle and MBM imported from the UK and other countries with BSE.
- Due to the unstable system the incoming BSE-infectivity was recycled to the domestic herd and amplified. An internal challenge developed.
- The overall challenge was first dominated by the high external challenge and is assumed to have been at that level. With an increasing internal challenge the very high external challenge that existed from 1988-1997 lead to an extremely high overall challenge since the early 90s. It remained extremely high until 1996, when the system became stable.
- The now probably optimally stable system is expected to reduce the internal challenge now very fast, supposed that no new external challenges occur.

4. CONCLUSION ON THE RESULTING RISKS

4.1 Interaction of stability and the combined challenges

- Before 1987 a high external challenge had to be met by a very unstable system which was then, from 1988 onwards exposed to a very high challenge. At this time BSE-infectivity most likely entered the system, got amplified and started to circulate leading to an extremely high overall challenge from 1991 onwards.
- Since then the extremely high challenge, mainly resulting from the existing internal challenge, was reduced and reached in 1988/99 very high levels.
- After 1997 the stability was further increased and it is expected that it will further reduce the overall challenge. Over time this will lead to a further decrease of the challenge.

4.2 Risk that BSE-infectivity enters processing

- Between 1985 and 1990 the BSE infected animals, if imported from the UK, would most probably have been processed. This component of the processing risk continued to exist after 1990, due to the imports from other countries, known to have BSE. However, after 1990 this risk was much lower than before as all surviving UK imports were traced and closely monitored.
- Since the late 80 a domestic prevalence is assumed to have existed. When these animals entered processing, in the early 90s, the processing risk increased further. As the rate of new infection surpassed the rate of infected animals leaving the system until 1994 ("unstable system") the processing risk continued to increase until the 1994 birth-cohort entered processing.
- Since 1995 the system was first neutrally stable and then (1996) stable, i.e. the rate of new infections declined and the rate of infected animals leaving the system became bigger. The decreasing prevalence in the birth-cohort since

1996, when the system became stable, the processing risk will significantly decrease once the pre-96 birth cohorts have left the system.

- After 1997 the processing risk is also significantly reduced by the SRM & fallen stock ban which can be expected to reduce the potentially entering BSE infectivity by a factor of 100, even if the number of infected animals entering processing and their age at that moment, would remain constant. (The infectivity load of an infected animal is assumed to exponentially increase with its age.)

4.3 Risk that BSE-infectivity is recycled and propagated

- During the 1980s the risk that the disease was propagated in the Netherlands increased because the feed industry used potentially contaminated imported MBM. This import- dependent propagation risk continued, but at a lower level, after banning rMBM from cattle feed (1989) and imports of rMBM from the UK (1990) due to continuing imports from countries known to have BSE in combination with cross-contamination. It is also impossible to exclude that UK-MBM did reach the Netherlands via other countries.
- The propagation risk was also fuelled by an internal component when infected animals entered the Dutch rendering system and the infectivity harboured by them was recycled.
- During 1989-1994 the propagation risk therefore probably peaked. The external challenges were large, cross contamination a significant problem and the efficiency of a part of the rendering industry was temporarily reduced while there may have been an increase in BSE-infectivity in the raw material rendered due to the increasing internal challenge.
- From 1995 onwards the propagation risk decreased because of the EU MBM-ban introduced in 1994, improvement of rendering, and introduction of an SRM-ban and exclusion from over 1-year-old fallen-stock from feed production in 1997. It is now regarded to be low.
- The measures taken in 1999 regarding cross-contamination are likely to reduce the propagation risk to a negligible level, if implemented properly. However, compliance data were not available at the time of up-dating this report.

5. THE GEOGRAPHICAL BSE-RISK

5.1 The current GBR

The current geographical BSE-risk (GBR) level is III, i.e. BSE is confirmed in domestic cattle at a lower level.

- However, the observed incidence of clinical cases over the last 12 months (1/3/99 to 29/2/2000) was 0.5 per 1 Million adult cattle. This figure is generated by a passive surveillance system that is not able to identify all clinical cases.

5.2 The expected development of the GBR

Assuming that measures in place continue to be appropriately implemented and no new external challenge occurs, the GBR is expected to decrease over time.
However, this does not exclude that cattle infected by the BSE-agent in the past may be identified as clinical cases in the foreseeable future.

5.3 Recommendations for influencing the future GBR

Good implementation of all measures in place would be essential to ensure the continuing decrease of the GBR. In addition to the already well implemented measures an appropriate control of cross-contamination at all levels is of particular importance.

FULL REPORT

JUSTIFICATION

1. AVAILABLE DATA

1.1 Consistency, completeness, and treatment of gaps in the available data

The information provided in the dossier and by the additional sources was largely complete and consistent. Extrapolation, interpolation and realistic worst case assumptions were used to bridge gaps that could not be closed otherwise.

1.2 Sources of information used

- Information provided by the country authorities and the country experts.
- Reports on inspection missions of the European Veterinary Inspection Services from December 1996 and May 1998.
- Dossiers provided by Switzerland (CH), Belgium (B), and United Kingdom (UK).

1.3 Recommendations for improving the basis for assessing the Geographical BSE-Risk

- Detailed compliance data would allow verifying the assumed efficiency of the preventive measures. Of particular importance are data on cattle feeding, the SRM ban and rendering.
- Results from an active targeted surveillance (screening of asymptomatic cattle in "at-risk" sub-populations such as adult (>2 years) fallen stock and emergency slaughter for BSE-infected animals) would allow verification of the current GBR and provide a better basis for assessing the trend of the future GBR.

1.4 Overall assessment of the suitability of the available information for the assessment

- The information available was sufficient to complete the assessment of the GBR.

2. STABILITY

2.1 Ability to identify BSE-cases and to eliminate animals at risk of being infected before they are processed

2.11 Factor 1: Population structure

2.111 Population data

- The cattle population has decreased from 2.4 million adult cattle in 1985 to approximately 1.74 million 1997. The decrease in population size is expected to continue.
- 90% of the cattle are kept for dairy production.

2.112 Age distribution of cattle, alive and at slaughter

- The average Dutch cow is in second parity, indicating a mean age of 3.5 years. It is assumed that this is also the average age at slaughter for adult cows (range 2-7 years). Approximately 45% of the dairy and breeding cows ≥2 years of age are slaughtered annually.

2.113 Husbandry systems

- The predominant cattle husbandry system is intensive dairy production (average milk production 7,900 kg).
- Veal calf production is the second most dominant husbandry system. Input calves come mainly from dairy holdings. The demand for calves is larger than the domestic production, so there is substantial importation from other Member States and non-EU countries. For 90% of the veal calves, the main diet is milk-replacers.
- Approximately 20% of the cattle are held on farms where pigs are kept too. According to the additional information provided, the animals are housed separately. They also have separate feeding systems (e.g. troughs or silos).

2.114 Cattle identification and monitoring system

- In 1990, a computerised identification system was established, recording all cattle and their movements. The transfer/entering of the whole national herd into the database was finalised in 1992.
- All calves are ear-tagged within 3 days after birth. Cross-checking of movements between buyer and seller is automatic within the system.
- Up to November 1998, ear tags were changed from foreign to Dutch on imported animals upon arrival in NL, so called naturalisation. According to the country experts, the naturalisation did not impair the ability to trace animals. The original ID of imported animals as well as their country of origin was always recorded in the central database. Animals imported for direct slaughter were excepted from the practice of naturalisation.
- The change in November 1998 was a result of implementation of the EU directive. According to the country expert it was not caused by problems in the previous system.
- Prior to the introduction of the central database, imported animals were registered with a special identification number, which was linked to a sketch of

the animal. All uniformly coloured animals were in addition identified with a special ear tag.

2.12 Factor 6: Surveillance:

2.121 Description of the surveillance system

- Prior to 1990, there was no surveillance with respect to BSE, since it was not until then that BSE was made notifiable.
- The awareness of veterinarians and farmers has been raised since 1989/1990 by publications in relevant journals. The first two domestic cases in 1997 in together with the information on the possible link between BSE and vCJD is believed to have raised the awareness significantly.
- Prior to 1997, the compensation was full market value for non-confirmed suspect BSE cases, but only 50% if BSE was indeed confirmed. However, since the first case occurred in 1997 it has been 100% in both instances. For the rest of the herd, full market value is paid. Suspect cases are purchased before seizure, and the suspicion is not made public unless confirmed.
- During suspicion, the farm is put under movement restrictions until the definite results from the laboratory are known. According to the country experts, measures (stamping out etc) are taken without delay after confirmation.
- If a BSE case is confirmed, the whole herd is destroyed as well as all other animal species on the farm known to be BSE-susceptible (e.g. cats). It could be anticipated that such an extensive intervention may result in underreporting of cases.
- Since the early 90s, the preconditions for tracing related animals have been good as a result of the implementation of the national animal database. Before, animals imported from the UK could be traced on a regional basis. Records on imports were kept by the farmers themselves, and had to be searched for by on-farm visits.
- Additional to the notification/verification of suspect cases and tracing of associated cohorts, Dutch cattle that have a relation to BSE cases abroad are currently traced and examined.
- In 1996, all traced UK-born cattle had their ear-tags changed to red ones. Two years later, 50 of the adult cattle born in UK were still alive (mainly Scottish Highland/Galloway cattle kept as „hobby cows“ for landscape management). They have been carefully monitored since they were identified in the early 90s.
- Proper diagnostic techniques and pathology competence are in place since 1991.
- The Animal Health Services (Gezondheidsdienst voor Dieren, GD) samples brains from fallen stock and in connection with general post-mortem examinations in cattle older than one year of age. Approximately 10 samples per year were examined up to 1997. This figure rose to 565 and 403 samples in 1997 and 1998, respectively. From end 1997 it was decided to forward all cases where diagnosis could not be established to the ID-DLO.
- From 1990-1995 less than three samples per year were examined at the Institute for Animal Husbandry and Animal Health (ID-DLO), based on BSE suspicion. In 1996, 22 suspected cattle were examined and in 1997-1998, 279 and 610 cattle brains were examined for BSE, respectively.
- At ID-DLO, histopathology is always performed in parallel with immuno-histochemistry. The test procedure includes reconfirmation with Western

blotting in the case of a positive or inconclusive result. In addition, positive and inconclusive results are sent for extra confirmation to the Central Veterinary Laboratory at Weybridge, UK.

- All BSE cases have been positive on both tests, and all other cases that were suspected on clinical ground were negative on both tests. Hence, there have been no inconclusive results.

2.122 Quality of the surveillance system with regard to BSE

- Before 1990, prior to BSE being a notifiable disease, no BSE surveillance existed.
- Between 1990 and 1997, the BSE surveillance was gradually improved.
- Since 1997, BSE surveillance has significantly improved, inter alia by analyzing annually a sufficient number of brains but the hard consequences of having a case (loss of all animals) might render notification of suspects by farmers less likely than the good compensation could indicate.
- Currently, the Dutch BSE-surveillance system is passive, i.e. not able to identify all clinical cases.

2.13 Factor 8: Culling

- In April 1996, a compulsory slaughter regulation was introduced for :
  – All BSE-susceptible animals (e.g sheep, goats and cats) present on a farm with a BSE-case.
  – Direct parents, all descendants, and the year group (birth cohort of cattle born 6 months before and 6 months after the cattle concerned at the farm)

  Animals destroyed under this act are examined with respect to BSE and then taken out of the feed chain.
- In 1996, 59,980 calves, born in the UK, were destroyed along with 230 cattle from Switzerland.

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

- Before 1990, the ability of the system to identify and remove BSE-infected animals before processing was considered very low.
- In 1990 the introduction of the mandatory reporting, a compensation scheme, and of culling, improved this ability to some extent.
- In 1997 intensified surveillance increased the reported number of BSE suspects.
- The system is now relying on a well performing passive surveillance. Without active surveillance, targeting at-risk sub-populations such as fallen-stock and emergency slaughter, there is little potential to improve it further.

2.2 Ability to avoid recycling BSE-infectivity, should it enter processing

2.21 Factor 3 and 4: Domestic MBM production and use

2.212 Domestic production of MBM

Period	Domestic prod. (tons p.a.)	Exports (tons p.a.)	Net domestic prod. (tons p.a.)
1980-89	147,000-186,000	15,000-23,000	132,000-.169,000
1990-97	182.000-283.000	22.000-203.000	10.000-194.000

Table 1: Domestic production of MBM (incl. greaves, bone meal and blood meal) in the Netherlands

- The export has increased significantly since 93/94, when the use of mammalian MBM for cattle feed was banned.

2.213 Description and history of feed bans and their compliance

- In 1989, NL banned the use of ruminant MBM for cattle feed.
- In 1994, the use of mammalian MBM for cattle feed was banned.
- Data on compliance with the respective feed bans are only available from 1995 onwards. However, detailed statistics on MBM-use indicate that at least from 1990/91 onwards MBM was not officially used for cattle feed. As a realistic worst case assumption it has to be assumed, though, that compliance was below the level of compliance that was found in 1995.
- Since 1995, compliance checks have focussed on documentation as well as control of the production process. The incidence of administrative/production irregularities has been low, between 0 and 0,2%.
- Since 1998, feed samples are microscopically analysed. Up to mid-98, 1 out of 93 samples examined were positive for MBM. The analytic sensitivity of this test is not stated in the dossier.
- At present, the system’s compliance is assumed to be good, but not optimal (see 2.24, cross contamination).

2.213 Use of MBM (before and after feed ban)

- According to the dossier, feeding animal protein to cattle or small ruminants was never done officially and intentionally, primarily for economic reasons. The economic aspect is supported by a comparison of prices for expelled soybean and MBM for the years 87-91, where MBM was 16-29% more expensive. However, MBM has been frequently used for pig and poultry feed.
- Up to 1994, approximately 90 % of the domestic production of animal meal went to animal feed. Since then, the proportion has decreased to 80%.
- In 1989/1990 the total use of animal protein in cattle feed increased significantly, according to the available information it was consisting of fish- and feather meal.

- Since 1990/1991 detailed statistics on the use of animal meal in cattle feed are available, indicating that it was not officially used and any use would have been to cross-contamination (or fraud[29]).

2.22 Factor 5: SRM-bans and treatment of SRM

2.221 Description and history of SRM bans

- In April 1996, the Regulation on Designation of High Risk Material (HRM) was used to designate all products from cattle slaughtered in the UK and present in NL at that time as HRM. The products were allowed to be processed as HRMs, but should be incinerated thereafter.
- In August 1997, the Regulation on Designation of High Risk Material was changed to constitute a *de facto* SRM-ban. It includes (with respect to cattle);
- – fallen stock > 12 months of age;
- – Head (including skull, brain, eyes, tonsils; excluding tongue, TRG and other tissues) and spinal cord of all slaughtered cattle > 12 months of age.
- According to the mission report from May 1998, the handling of SRMs still allowed a risk of SRMs entering normal rendering. According to the country experts, this reflected that the ban was not yet fully implemented. The mission group gave constructive criticism and the suggested measures where more or less directly taken. A realistic worst case assumption is that the SRM ban was not fully working up to and including 1998, but well in place thereafter.

2.222 Fate of SRMs

- Fallen stock is collected by a special service and sorted at the rendering plant. Since 1/11/99 SRM carcasses (fallen stock, older than 12 months) are separately collected at the farm level.
- In abattoirs, the SRMs have to be collected and handled separately from the other offal.
- SRMs (carcasses as well as offal) are kept in special containers, which are sealed once they are full.
- All SRMs are rendered to a semi-product on a separate line at one of the two Dutch rendering plants. The product is subsequently incinerated. The separate line is understood to have been in place since 98/99.

2.23 Factor 7: Rendering and feed processing

2.231 Raw material used for rendering

- Raw material for animal meal is mainly non-SRM-carcasses (< 12 months of age) and offal (low and high-risk material).
- In 1997, the total supply in tons to the 2 rendering plants was: Non-SRM carcasses (241.000), offal (702.000), blood (140.000), feathers (92.000), pig bristle (16.000), used restaurant fats & kitchen waste (21.000), and SRMs (9.000).

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[29] Potential fraud is not taken into account in this assessment.

2.232 Rendering processes

- There are currently two rendering plants in the NL. A third plant was active until 1989.
- Up to 1989, batch processes were used at all rendering plants.
- Between 1989 and 1996, a continuous process was used at one of the two plants, and the physical requirements for all processes (continuous and batch) were 130/30/3 in 1989 and 133/3/20 since 1990.
- In 1996, the continuous process was changed into batch. The general process standards remained at 133/3/20.

2.233 Capacity of the rendering system to reduce any potential BSE-infectivity in the raw material

- According to a Dutch study the continuous process as used in the NL in (parameters130/3/30 in 1989 and 133/3/20 since 1990) has not been worse than the batch process. However, according to the Opinion of the Scientific Steering Committee this process is regarded as slightly less efficient in reducing BSE infectivity than a batch process, operating under the same conditions.
- As the Dutch processes had a reasonable potential to reduce BSE-infectivity, the risk that BSE-infectivity could have passed rendering was therefore generally low, but temporarily slightly higher during the period 1989-1996 (due to the continuous process) and in 1989 (due to the slightly different process conditions).

2.24 Cross-contamination

2.241 Possible types of cross-contamination

- Rendering: Prior to 1998 cross-contamination of low-risk MBM with high-risk MBM was possible.
- In feed mills: A large number of compound-feed enterprises in the NL produce ruminant feed on the same line as poultry- and pig feed. Since MBM are used in the latter, carry-over can occur.
- Transport and on-farm: Cross-contamination could have occurred during transportation and at the farm level. However, the economic incentives for deliberate feeding of pig- or poultry feed that contains MBM to cattle do not seem strong.

2.242 Measures undertaken to control cross-contamination

- Since 1993/94 it has been prohibited to produce cattle feed directly after producing feed with more than 6% MBM but is allowed if the MBM content of the previous batch was below 6%.
- In 1997, a microscopic test was introduced that provides a more specific way of checking for the occurrence of cross-contamination. In 1998, 1 out of 93 samples was positive.
- Since March 1999, cattle and poultry-/pig feed have to be delivered with separate transportation and feed is checked both at the feed mill- and at the farm level. If non-approved MBM should be found, the feed would be seized and a decision would be taken to re-process it into pig-/poultry feed or to incinerate it.
- In addition, it is no longer allowed to use poultry meal in ruminant feeds (only fish and feather meals are allowed).

- Also, most of the feed mills now have separate lines for pig-/poultry feed and for cattle feed. Those that do not yet have separate lines use three or more MBM-free flushing charges before the production of cattle feed. These are temporary measures, since also these feed mills are converting to separate lines.

2.243 Assessment of the potential level of cross-contamination

- Prior to 1994 it is assumed that cross contamination was frequent and significant. No restrictions were put on the MBM contents of poultry- and swine feed that were produced on the same lines as cattle feed.
- Between 1994 and 1999, cross contamination has remained a problem, despite measures introduced to control it. According to the dossier, residue levels were estimated to vary between 0-6%.
- Compliance with the measures applied since March 1999 has not yet been assessed. The most crucial measure seems to be the introduction of separate lines in all feed mills that produce feed for both cattle and pigs/poultry.
- As long as feeding of MBM to other farmed animals is legally possible, cross contamination cannot be fully eliminated. However, special measures to reduce cross-contamination reduce the risk.
- The risk of recycling BSE-infectivity must also be seen in the light of the potential infective load of the contaminants.

2.25 Overall appreciation of the ability to avoid recycling BSE-infectivity, should it enter processing

- Before 1989, the system was not able to avoid recycling of BSE infectivity since ruminant-derived MBM was fed to cattle of all ages, rendering was not fully at standard, and SRM and fallen stock was rendered for feed.
- The 1989 change from batch to continuous rendering in parts of the industry reduced this ability somewhat more but the change of the entire industry to 133/20/3 in 1990 counter-balanced this.
- Between 1990 and 1997 the ability to avoid recycling improved thanks to the feed bans of 1990 and 1994 but remained insufficient as cross contamination continued to be a problem, rendering was still not fully optimal, and SRM and fallen stock were still rendered for feed.
- Since 1996/1997, all rendering is done with batch processes applying 133/20/3, cross-contamination has been reduced, and an SRM-ban (including fallen stock > 12 months) is in place. Therefore the ability to avoid recycling of BSE infectivity that enters processing is considered to be very good since 1998.

<u>2.3 Overall assessment of the stability</u>

- Until 1990, the system was very unstable, mainly because of an inability to stop cattle from being exposed to MBM via feed, rendering of SRM for feed, and not fully sufficient rendering processes.
- After 1990 stability increased due to the MBM ban and the switch of all rendering plants to 133/20/3. The improvements in surveillance supported this increase in stability.
- Between 1994 and 1997 the system became stable as a result of the second MBM ban in 94, the reintroduction of the batch system in all rendering plants (in 96’) and the introduction of an SRM- & fallen stock (>12months)-ban (in 97’).

- Since 1998, the system is regarded as being very stable, mainly as a result of the final implementation of the SRM ban and further measures introduced to prevent cross contamination. The 1997 improvements of the surveillance supported the gain in stability.
- If the recent measures against cross-contamination are fully implemented and complied with, the stability is expected to reach optimal stability, thereby quickly removing BSE-infectivity circulating in the system.

3. CHALLENGES TO THE BSE/CATTLE SYSTEM

3.1 External challenge

3.11 Factor 2: Import of live cattle

- According to recent information from the Dutch authorities the following imports of cattle happened. In line with the orientation given in part I of this report, the resulting external challenge would be as indicated in the table below. However, this indication has to be weighted by considerations given hereafter:

Period	**Imports from UK&PT**		**Imports from B,LUX,FR,CH**		**Total external challenge**
	N°	**challenge**	**N°**	**challenge**	
85-87	**1,126**	**high**	**53,721**	**high**	**high**
88-93	**153+98**	**high**	**258,561**	**very high**	**very high**
94-97	**0+30**	**negligible**	**119,229**	**very high**	**very high**

- All imports from UK were apparently traced back around 1990, and those that were still alive were monitored. Thus, the challenge they represented was probably mastered, at least so far that clinically ill animals could most probably not have entered normal slaughtering. They could, however, still have been processed as via emergency slaughter or rendering as fallen stock.
- Since 1990, imports have occurred from countries that are today known to be affected by BSE:
  - **Switzerland**: 173 breeding cattle in 1991-94 and 432 other cattle in 1997.
  - **Belgium and Luxembourg** (only joint statistics): between 146 and 4,181 breeding cattle per year up-to and including 1997. Between 7,500 and 53,000 'other cattle' per year during the same period.
  - **Ireland**: 642 breeding cattle in 1991-94, and 296 to 2,300 'other cattle' per year in 1991-1996.
  - **France**: between 100 and 11,700 breeding cattle per year between 1990 and 1997 and between 3,800 and 27,000 „other cattle" in the same period
  - **Portugal**: 98 'other cattle' in 1992 and 30 in 1996.
- It seems that animals imported from other countries now known to have BSE have <u>not</u> been taken out of the feed chain. However, since 1997, their SRMs are no longer recycled, as all SRMs.
- Taken together, during the period 1988-1997 the external challenge from livestock importation was very high and prior to 1988 it was high.

- During the period 1989-99, large imports of calves occurred in addition to the imports mentioned above. They can be described as follows. UK: 96,000-187,000 per year, until 1997; BE/LUX: 68,000-157,000 per year; FR: 16,000-87,000 per year; IRE: 1,300-40,000 per year. However, if these animals were normally slaughtered, i.e. very young, they could only have carried very low loads of BSE-infectivity, even if they would have been infected at birth, prior to export. The only remaining risk results from calves, imported for slaughter but then used for breeding.
- Calves imported from the UK after 1990 were specifically ear-tagged, transported in sealed vehicles, kept at specially designated farms and only sent for slaughter to designated abattoirs by direct transport. Therefore, the risk is negligible that these calves were included in the national herd. However, calves imported from the UK before 1990 have an unknown fate. As have calves from other BSE-affected countries.
- A realistic worst case assumption regarding the potential external challenge posed by these calf-imports is that they did not add significantly to the external challenge posed by the livestock imports discussed above.

3.12 Factor 3: Import of MBM or feed containing MBM

- According to the country dossier, 1,400 to 5,000 tons of MBM were annually imported to the Netherlands from the UK in the years 1985-1989. If all this would have been mammalian MBM, this would be an extremely high challenge. However, a not specified fraction of these imports were poultry meals. Hence the challenge was most probably lower.
- According to UK export statistics the following amounts of "mammalian flours, meals and pellets" were dispatched to the Netherlands:

year	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97
tons	1.3	.6	135	2095	139	805	1826	6099	7380	1089	814	156	1226	3445	2130	1777
Chall.	High					Extremely high				High			Moderate			

Table 1: Exports of "mammalian flours, meals and pellets" from UK to NL (Source: UK export statistics), and the challenge that would have resulted if all would have been MMBM.

- In 1990, import of ruminant MBM from UK was banned.
- In addition to imports of potentially contaminated "MBM" Imports from other countries now known to be affected by BSE: 25,000 to 56,500 tonnes annually from **Belgium/Luxembourg**. 4,200 to 17,200 tonnes annually from **France**, since 1981. 173 to 36,000 tonnes annually from **Ireland**, since 1985. 47 tonnes from **Portugal** in 1990/91. 102 to 22,500 tonnes annually from **Switzerland**, since 1990. Together these imports amounted to about 35,000 to 130,000 tons annually, representing a very high challenge to the Dutch system, even if parts of it would have been of non-mammalian origin.
- The imported MBM was and is mainly used for incorporation into pig and poultry feed.
- In addition to the MBM-imports significant amounts of compound feed was imported: 1990 – 1994 = 76,000-202,000 tons annually. After 1994, 87,000-397,000 tons p.a.. Only a limited amount of the compound feed for cattle was imported from countries with BSE, in particular Belgium/Luxembourg.

According to the country experts, the volume imported is less than 1% of the total volume of compound feed used.

- There have been no checks of imported feed for presence of MBM. The veterinary mission report from December 1996 states that reliable traceability of feed containing MBM was impossible due to lack of official documents accompanying this product, and that this concerned the trade both within and between Member States.
- The Dutch bans of 1989 (rMBM to cattle) and 1990 (stop of MBM imports from the UK) were not implemented in the other EU-countries before 1994. Therefore BSE-infected MBM, originating from the UK, may have entered NL either as MBM as such or as component of concentrates, during the years 1989-94 (European MMBM-ban) due to triangular trade.
- All together the imports of feed-stuffs constituted a significant, very high challenge of the Dutch system since the late 80s.

3.2 Internal challenge

3.21 Interaction of external challenge and stability, potentially leading to domestic prevalence

- Before 1990 a very unstable Dutch system was exposed to very high external challenges. If BSE-infectivity was imported it was most likely recycled and amplified.
- After 1990 the system became less unstable but the external challenges increased. Therefore it is likely that BSE-infectivity entered the system, reached domestic cattle and lead to the building-up of a certain domestic prevalence.
- Until 1995, when the system became finally stable, domestic and incoming infectivity would have been recycled and amplified.
- After 1995 incoming and already circulating BSE-infectivity would have been reduced by the then stable system.

3.22 Domestic prevalence

- A certain risk that some domestic cattle where infected with BSE existed already in the 80, when a very unstable system was exposed to a high external challenge.
- It can be assume that this domestic prevalence continued to increase until 1995, when the system became neutrally stable.
- The six domestic cases of BSE in 1997 (2), 1998 (2), and in 1999 (2) confirm that BSE infectivity is present in the national herd. It was already present since several years prior to the first case, e.g. in the early 90s, at the latest.

3.3 Overall assessment of the challenges

- The Netherlands have been exposed to high (until 1987) and very high (1988-1997) external challenges, resulting both from cattle and MBM imported from the UK and other countries with BSE.
- Due to the unstable system the incoming BSE-infectivity was recycled to the domestic herd and amplified. An internal challenge developed.
- The overall challenge was first dominated by the high external challenge and is assumed to have been at that level. With an increasing internal challenge the very high external challenge that existed from 1988-1997 lead to an extremely

high overall challenge since the early 90s. It remained extremely high until 1996, when the system became stable.

- The now optimally stable system is expected to reduce the internal challenge now very fast, supposed that no new external challenges occur.

4. CONCLUSION ON THE RESULTING RISKS

4.1 Interaction of stability and the combined challenges

- Before 1987 a high external challenge had to be met by a very unstable system which was then, from 1988 onwards exposed to a very high challenge. At this time BSE-infectivity most likely entered the system, got amplified and started to circulate leading to an extremely high overall challenge from 1991 onwards.

Overall Challenge

Stability	Negligible	Very low	Low	Moderate	High	Very high	Extremely high
Optimally stable							
Very stable						**98-99-2000(?)**	
Stable							**←96/97**
Neutral							**95 ↑**
Unstable							**91-94↑**
Very Unstable					**Pre-87**	**88-90**	
Extremely Unstable							

Figure1: Development of stability of the Dutch BSE/cattle system and the challenge it was exposed to, over time

- The increasing stability was not able to reduce the probably still increasing overall challenge until the combination of measures had lead to a stable system, around 1996.

- Since then the extremely high challenge, mainly resulting from the existing internal challenge, was reduced and reached in 1988/99 very high levels.

- After 1997 the stability was further increased and it is expected that it will further reduce the overall challenge. Over time this will lead to a further decrease of the challenge.

4.2 Risk that BSE-infectivity enters processing

- Between 1985 and 1990 the BSE infected animals, if imported from the UK, would most probably have been processed. This component of the processing risk continued to exist after 1990, due to the imports from other countries, known to have BSE. However, after 1990 this risk was much lower than before as all surviving UK imports were traced and closely monitored.

- Since the late 80 a domestic prevalence is assumed to have existed. When these animals entered processing, in the early 90s, the processing risk increased further. As the rate of new infection surpassed the rate of infected animals leaving the system until 1994 ("unstable system") the processing risk continued to increase until the 1994 birth-cohort entered processing.
- Since 1995 the system was first neutrally stable and then (1996) stable, i.e. the rate of new infections declined and the rate of infected animals leaving the system became bigger. The decreasing prevalence in the birth-cohort since 1996, when the system became stable, the processing risk will significantly decrease once the pre-96 birth cohorts have left the system.
- After 1997 the processing risk is also significantly reduced by the SRM & fallen stock ban which can be expected to reduce the potentially entering BSE infectivity by a factor of 100, even if the number of infected animals entering processing and their age at that moment, would remain constant. (The infectivity load of an infected animal is assumed to exponentially increase with its age.)

4.3 Risk that BSE-infectivity is recycled and propagated

- During the 1980s the risk that the disease was propagated in the Netherlands increased because the feed industry used potentially contaminated imported MBM. This import- dependent propagation risk continued, but at a lower level, after banning rMBM from cattle feed (1989) and imports of rMBM from the UK (1990) due to continuing imports from countries known to have BSE in combination with cross-contamination. It is also impossible to exclude that UK-MBM did reach the Netherlands via other countries.
- The propagation risk was also fuelled by an internal component when infected animals entered the Dutch rendering system and the infectivity harboured by them was recycled.
- During 1989-1994 the propagation risk therefore probably peaked. The external challenges were large, cross contamination a significant problem and the efficiency of a part of the rendering industry was temporarily reduced while there may have been an increase in BSE-infectivity in the raw material rendered due to the increasing internal challenge.
- From 1995 onwards the propagation risk decreased because of the EU MBM-ban introduced in 1994, improvement of rendering, and introduction of an SRM-ban and exclusion from over 1-year-old fallen-stock from feed production in 1997. It is now regarded to be low.
- The measures taken in 1999 regarding cross-contamination are likely to reduce the propagation risk to a negligible level, if implemented properly. However, compliance data were not available at the time of up-dating this report.

5. THE GEOGRAPHICAL BSE-RISK

5.1 The current GBR

The current geographical BSE-risk (GBR) level is III, i.e. BSE is confirmed in domestic cattle at a lower level.

- However, the observed incidence of clinical cases over the period 1/3/99 to 29/2/2000 was 0.5 per 1 Million adult cattle. This figure is generated by a passive surveillance system that is not able to identify all clinical cases.

5.2 The expected development of the GBR

Assuming that measures in place continue to be appropriately implemented and no new external challenge occurs, the GBR is expected to decrease over time.

However, this does not exclude that cattle infected by the BSE-agent in the past may be identified as clinical cases in the foreseeable future.

5.3 Recommendations for influencing the future GBR

Good implementation of all measures in place would be essential to ensure the continuing decrease of the GBR. In addition to the already well implemented measures an appropriate control of cross-contamination at all levels is of particular importance.