Report on

the assessment of

the geographical BSE-risk of

ITALY

May 2000

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P A R T I

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

1. INTRODUCTION

Currently, BSE risk management measures, including import[1] restrictions, are often based on the incidence of clinical BSE in bovines. But, as already noted at several occasions by the SSC, this incidence of clinical BSE depends heavily on the quality and effectiveness of the country's surveillance and notification systems. Both are not only difficult to judge, but also constrained by serious intrinsic limitations in detecting small numbers of clinically infected animals; moreover, incidence of clinical BSE cannot take into account pre-clinically infected cattle.

Therefore, in the view of the SSC, a risk assessment should underpin the reliability of the reported number of clinical BSE-cases to improve the decision basis. To this end, the SSC has developed the concept of Geographical Risk of Bovine Spongiform Encephalopathy (GBR) as well as a transparent methodology and procedure to assess the GBR for any country that would provide the information required for the assessment.

Since three rapid post-mortem BSE-tests are available, it is now possible to implement intensive large scale surveillance programmes. Results from such programmes could significantly improve the basis for future assessments of the GBR. Any assessment should be regularly repeated.

This opinion describes the application of the current methodology and procedure and briefly discusses in the light of previous SSC opinions the implications of the GBR on the safety of food and feed.

2. The Geographical BSE-risk (GBR) ; methodolgy and process

2.1 Definition of the Geographical BSE-Risk (GBR)

The SSC wants to underline that its opinion is only a contribution to the final categorisation of countries with regard to BSE for risk management purposes. This final categorisation is the responsibility of the authorities responsible for risk management and might take into account other aspects than those covered by this risk assessment.

The Geographical BSE-Risk (GBR) is an indicator for the probability of one or more cattle to be infected clinically or pre-clinically with the BSE-agent, at a given point in time, in a geographical region/country[2] and, where presence is confirmed, the level of incidence[3]. As shown in Table 1, the GBR is classified into 4 levels**.**

[1] Within the EU "imports" might not be the right term for referring to inter-state trade within the internal market. However, in this context the term is used as a synonym to introducing bovine or bovine-based products into the BSE/cattle system of a given country or region.

[2] GBR should not be confused with the risk that human food or animal feed is contaminated with the BSE-agent. These risks are in addition to the BSE dependent of several other factors (see chapter 4). The SSC will address this issue in a future opinion.

[3] Incidence is defined as "N° of 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"

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

With regard to the borderline between GBR level III and IV the SSC is well aware that it has to remain arbitrary, as no clear scientific justification can be provided for it. For this reason the SSC did not follow the proposal of the independent experts to use 100 clinical or pre-clinical infected cattle per million adult cattle as threshold between GBR-level III and IV. It adopts, for the time being, the OIE threshold (OIE, International Animal Health Code, Appendix XI, chapter 3.2.13., Article 3.2.13.2.), 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 3.1.5 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 also be put into the highest risk level, for example if 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[4] screening exercises in Switzerland (of adult cattle of fallen stock and emergency slaughter and normal slaughter) and the UK (OTMS-survey) both detected significant numbers of confirmed BSE-cases that would have remained undetected by normal, passive[5] surveillance, even if targeted at animals with neurological symptoms. The SSC therefore assumes, for indicative purposes, that passive surveillance cannot identify all clinical BSE-cases. The Swiss and UK results seems to indicate that more likely passive surveillance, based alone on notification of symptomatic BSE-suspects, will not detect more than half or one third of all clinical cases, or even less. However, as long as it is impossible to detect pre-clinical cases in early phases of the incubation period, active surveillance of apparently healthy animals younger than 24 months cannot be expected to improve the detection level.

[4] Active surveillance = sampling of at-risk sub-populations of cattle that are not notified as BSE-suspects.
[5] Passive surveillance = surveillance of notified BSE-suspects, i.e. cattle that are notified because of clinical signs compatible with BSE.

At this stage it should be reiterated that the applied 4 GBR-levels are only used to illustrate in qualitative terms significantly different risk situations, each level including a range of different risks.

2.2 Methodology for assessing GBR

2.21 Methodology for GBR Assessment

The current methodology for assessing GBR has been first adopted by the SSC in February 1999, taking account of comments received in response to a draft opinion issued in December 1998. This methodology has evolved since then, based on the experience of its practical use. This evolution of the method has been recognised by the SSC in two up-dates of April 1999 (after the first assessment exercise) and in January 2000 (after the second and third assessment exercise).

Note: The GBR is, for the time being, limited to the situation in the national bovine herd. It does not indicate the probability for sheep and goats to be infected with BSE. Such an assessment would require other basic data, which are currently not available.

2.211 Information factors and model of the BSE cattle system

The methodology is based on information on the 8 factors listed in Table 2, which were identified by the SSC in January 1998.

Structure and dynamics of the bovine, ovine and caprine animal population.
1) Animal trade *(Embryos or ova not seen as an effective transmission route).*
2) Animal feed and import of animal feed (*greaves and feed stuffs containing MBM or greaves not explicity mentioned, but considered*)
3) MBM-bans (*greaves and feed stuffs containing MBM or greaves not explicitly mentioned, but considered).*
4) SRM-ban(s).
5) Surveillance of TSE, with particular reference to BSE and scrapie.
6) Rendering and feed processing.
7) BSE-or scrapie related culling.

Table 2 – Information factors for assessing the GBR, numbers as in the SSC's opinion of February 1998.

In order to clarify the (often-delayed) interaction between these factors, the SSC has adopted a simple strictly qualitative model of the cattle/BSE system (Figure 1) which focuses on the feed-back loop that needs to be activated to spark a BSE-epidemic.

This BSE/cattle-system can be "challenged" by incoming and/or circulating BSE infectivity. It then has to remove the BSE-agent as quickly as possible. Its ability to do so is called hereafter its "stability".

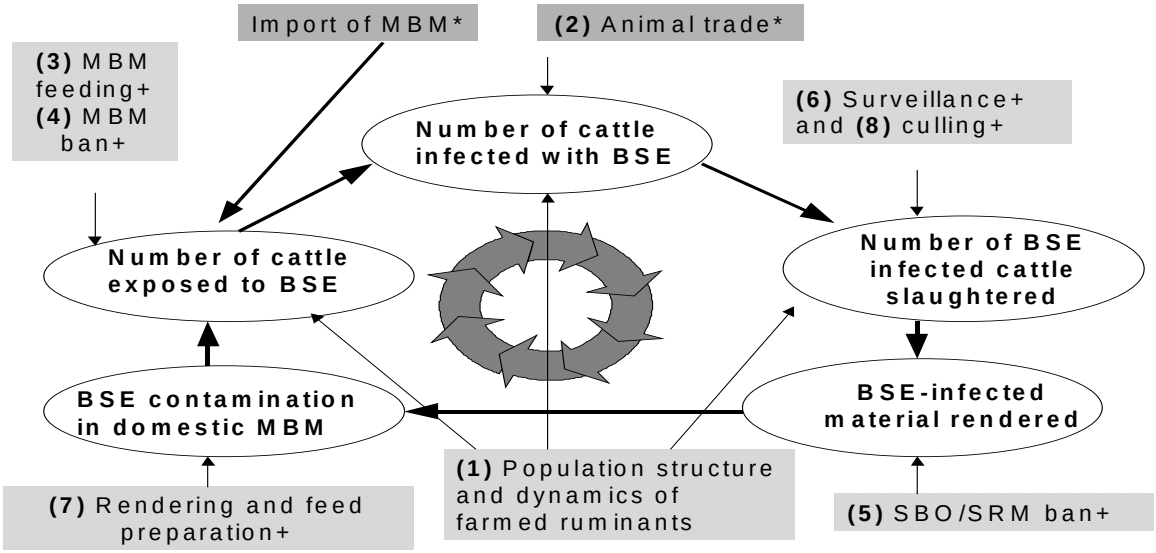

Figure 1:The SCC model of the BSE/Cattle system
*** external challenge, + stability factors, numbers as in SCC, February 1998, "animal trade" refers to importing/exporting animals into/from the system.**

2.212 External challenge

In this simplified model, imports of contaminated feed ("import of MBM" in fig.1) or of infected live cattle (factor 2 in fig.1 called "animal trade") into the system are the only initial sources of BSE ("external challenge") taken into account[6]. Without an initial source the feedback, which ultimately could lead to an epidemic, will not be started.

Possible, but not confirmed, initial sources of BSE such as other TSEs including Scrapie, exotic diseases, etc. are currently ignored. Moreover, while trade of live animals and MBM or MBM-containing feed stuffs are regarded to be effective vectors for introducing the BSE-agent, semen and embryos are not (see SSC-opinion on vertical transmission, listed as n° 23 in annex 1). Obviously, should any other initial sources of BSE be confirmed, the risk assessment would have to be repeated. This is particular relevant for countries or regions where stability is insufficient and for which the favourable GBR assessment mainly depends on a negligible initial challenge.

The more BSE-infectivity comes-into or circulates in a system, the bigger the challenge.

[6] In the UK BSE was present throughout the assessment period (1980-1998)

For orientative purposes the numbers given in table 3 were applied to support assessing the order of magnitude of a challenge consistently:

CHALLENGE	**External Challenge** through imports			**Internal challenge** [Expected number of domestic infected cattle being alive at a given point in time.]
	Cattle imported in the period 1988 and 1993 from UK	MBM[1] (tons) imported in the period 1986 to 1990 from UK		
Extremely High	≥10.000	≥10.000	For feed imports multiply by **50**	≥500
Very High	1.000 - < 10.000	1.000 - < 10.000		50 - < 500
High	100 - < 1.000	100 - < 1.000		5 - < 50
Moderate	20 - < 100	20 - < 100		1 - < 5
Low	10 - < 20	10 - < 20		< 1
Very low	5 - < 10	5 - < 10		
Negligible	0 - < 5	0 - < 5		

[1] The abbreviation "MBM" refers to all kinds of animal meals (MBM, MMBM, BM, Greaves) that could carry the BSE-agent because it contains animal (ruminant) proteins.

Table 3: Definition of BSE-challenge levels

The figures given in the table refer to the country (UK) and the period of time where the risk of contamination was regarded to be highest. For live cattle that could have received MBM from UK and were exported from this country this was the period 1988 to 1993. During this period the UK-prevalence of infected animals was assumed to have been around 5%, 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.

For MBM in the UK, the highest risk of being contaminated is assumed to exist from 1986 to 1990. It reached a peak in 1988 when SBO were excluded from the food chain but included into rendering. It was significantly reduced with the exclusion of SBO from rendering end 1989.

In order to take account of the lower BSE-risk in other countries and periods, the figures in the table should be higher for imports from the UK at other periods and for imports from other countries affected by BSE at any period. To adapt the thresholds accordingly, the following is proposed:

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 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**.

The figures in the table and the multipliers are only indicative. It is obvious that the challenge associated with imported cattle and their impact will largely depend of a

number of factors including their age at slaughter. Imported animals that do not enter the national herd and are slaughtered before reaching an age of 24 months would represent a lower challenge than imported animals used for breeding. If available, this information should be used to modulate the criteria in the table.

Note: The values given in the table are arbitrarily chosen in order to represent challenge levels that are regarded to be significantly different. In deciding on the challenge level, these figures are taken as starting point. Other available information could/should be taken into account and might justify deviation from the indicative level. In case of imports from other countries than UK a reasoned judgement is needed on the likelihood that BSE could have been present in the moment of export. The categories are additive and may be combined.

2.213 Stability

The ability of the system that is described by the SSC's model to reduce BSE-infectivity over time is called its "stability". It depends on its ability to identify BSE-infected cattle and exclude them from processing (factors 1, 6, and 8 in fig. 1) and its ability to avoid recycling of the BSE-agent via feed (factors 1, 3, 4, 5 and 7 in fig. 1). A "stable" system would eliminate BSE over time, an "unstable" system would amplify it.

The only transmission vector considered in the model is feed. Contaminated feed is taken as only possible source 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.

During the assessment, it became obvious from different sources that cross-contamination of MMBM-free cattle feed with other feeds that contain such ingredients can be a significant cause of propagating the disease, in particular at lower prevalence levels. Therefore, it is important to understand that, as long as feeding of MMBM (mammalian MBM), BM (Bone meal) or Greaves to other farmed animals is legally possible, cross-contamination of cattle feed with animal protein can not be fully eliminated, unless clear evidence is provided for the use of dedicated production lines, transport channels and control of the use and possession of MMBM at farm level. 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[7]. However, this effect 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 and its relatively lesser importance in comparison to feed, the possible impact of maternal transmission on the GBR has not been taken into account[8].

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

[8] 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 occurred is significantly 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).

Similarly no "third route of transmission" was taken into account. The existence of a third route/mechanism of transmission of BSE, in addition to feed and vertical transmission (for example: horizontal transmission via the environment), cannot be excluded a priori. However, to date there is no scientific evidence for such third mechanism, even not in the recently decreasing rate of decline of the BSE epidemic in the UK (see Opinions N°s 4, 23, and 30 listed in Annex 1).

If the system is not able effectively to prevent processing and recycling of a BSE-load that enters the system (i.e. if it is not "stable" with respect to BSE) a certain number of domestic cattle will be pre-clinically infected after the initial BSE-load has reached the feed chain. After approximately 5-years (average incubation time) a certain number of them would become clinically infected with BSE (unpublished data indicated that 270 animals infected would finally result in 50 clinical cases, assuming normal survivial probabilities). The infected animals represent an "internal challenge" and if the system is not able to identify and eliminate them and to avoid recycling the infectivity harboured by them, they might give origin to a further building-up of the BSE-load of the system.

The most important stability factors are those which reduce the risk of recycling of BSE. This are in particular avoiding MBM feeding to cattle ("feeding"), a rendering system able to largely inactivate BSE-infectivity (e.g. "standard[9]" treatment at $133^{o}/20^{min}/3^{bar}$) and exclusion of those tissues/organs where BSE infectivity could be particularly high (SRM) from rendering. Excluding fallen-stock from the feed chain will also reduce significantly the amount of BSE infectivity that could enter the feed chain.

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

2.213.1 Stability levels

A BSE/cattle system can only be "**optimally stable"** if all three main stability factors (feeding, rendering, SRM-ban) are in place, well controlled, implemented and evidenced ("OK"). Such a system would fully prevent propagation of BSE-infectivity and eliminate BSE-infectivity from the system very fast.

If two factors are "OK" but one of these factors is only reasonably but not satisfactorily implemented ("reasonably OK"), the system could at best be **"very stable".** Propagation would be largely prevented but the elimination of BSE-infectivity from the system is slower than in a "optimally stable" system.

However, a **"stable"** system can still be assumed as long as two factors are "OK" while one factor is not in place, or one is "OK" and two are "reasonably OK". Still 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 only be **"neutrally stable",** i.e. it would neither amplify nor reduce circulating BSE-infectivity over time. The same is true if only one factor is "OK" and two are not present or or only badly implemented.

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

If only two factors "reasonably OK", the system will be **"unstable"** and amplify BSE, should it enter. 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 will be **"very unstable"**.

If non of the three factors can even be considered as "reasonably OK", the system would be **"extremely unstable",** quickly propagating the BSE-agent, should it enter, and amplifying the BSE-load of the system.

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

STABILITY	**Level**	***Effect on BSE-infectivity***	Most important stability factors		
			Feeding	**Rendering**	**SRM-removal**
Stable: ***The system will reduce BSE-infectivity***	**Optimally* stable**	*Very fast*	Feeding OK, rendering OK, SRM-removal OK		
	Very stable	*Fast*	Two of the three factors OK, one reasonably OK.		
	Stable	*Slow*	Two OK (and one not OK) **or** 1 OK and two reasonably OK.		
Neutrally stable		+- *constant*	3 reasonably OK or 1 OK		
Unstable: ***The system will amplify BSE-infectivity***	**Unstable**	*Slow*	2 reasonably OK		
	Very Unstable	*Fast*	1 reasonably OK		
	Extremely Unstable	*Very Fast*	None even reasonably OK		

Table 4: Definition of 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

SRM-removal: OK=SRM-removal from imported and domestic cattle in place, well implemented and evidence provided
Reasonably OK = SRM- removal from imported and domestic cattle in place but not well implemented

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 significantly more stable than it would be due to the three main stability factors.

The exclusion of fallen-stock from feed production would significantly contribute to stability. In combination with a reasonably OK SRM-removal it could be as effective as an OK SRM-removal.

2.214 Interaction of challenge and stability over time

2.214.1 Interaction of external challenge and stability over time

If a stable system is exposed to an external challenge, the resulting internal challenge will be lower than the original external one and eventually disappear. On the contrary if an unstable system is exposed to an external challenge the resulting internal challenge will be bigger than the original external one and will continue to grow until the system remains unstable

The "internal challenge" depends on to the amount of BSE-infectivity circulating in the system. As indicator for its level the number of BSE-infected domestic cattle is taken that is alive in the system at a given point in time and would present a certain level of challenge to the system (see table 3).

2.214.2 Interaction of overall challenge and stability over time

The overall challenge is a combination of the external and internal challenges being present 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 significantly **"challenged"**: this is still rather good because the system will be able remove the BSE, even if this might need some time.

An **"unstable"** system is not or only slightly **"challenged"**: as long as BSE is not entering the system, the situation is good. However, if BSE would enter the system it could be amplified.

An **"unstable"** system is **"challenged"**: obviously this is an unfortunate situation. BSE-infectivity entering the system will be amplified and an epidemic will develop.

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

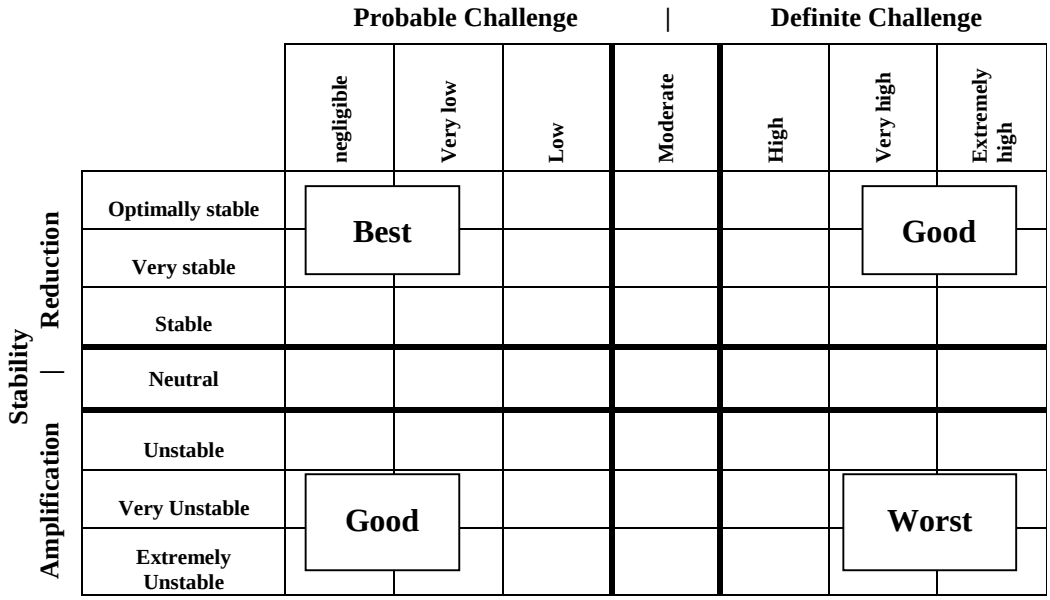

Figure 2: Stability/challenge combination, four principal situations

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

A hypothetical example of a chart showing the development over time is given in fig.3.

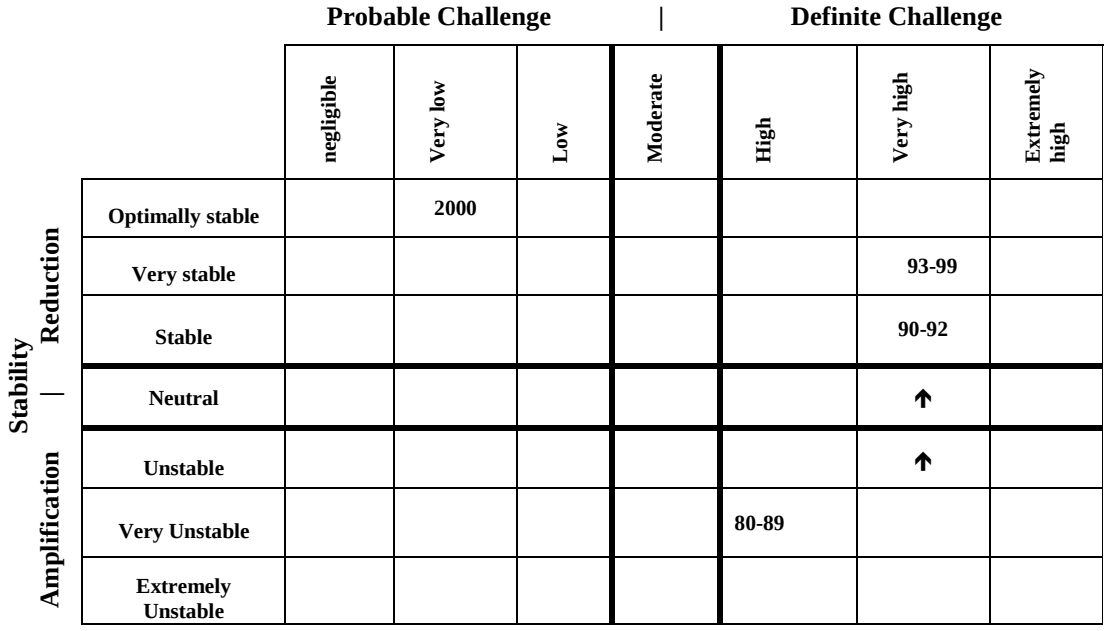

Figure 3: Hypothetical development of stability and challenge over two decades

The hypothetical example described in figure 3 would correspond with the following:

In the eighties, the situation was rather bad, characterised by a low stability and a high (internal or external) challenge.

The amplification lead to increasing (internal) challenge but fortunately the stability started to improve.

Once the system became stable enough to reduce the BSE infectivity, the internal challenge started to decrease, while the stability increased further.

Between 1993 and 1997 the impact of the high stability became visible and lead to a significant decrease of the challenge and hence a rather good situation in 2000.

The diagram helps to understand the conclusion on:

- the risk that infected cattle could enter processing (processing risk, over time)
- the risk that the disease could be propagated (propagation risk, over time)
- the risk that a cattle could be pre-clinically or clinically infected (Geographical BSE-risk), and its development over the coming 4-6 years (one incubation period).

The past stability and challenge of the system are the reason for the current GBR, due to the fact that the impact of most risk management measures is delayed by one incubation period of BSE, in bovines on average 5 years.

The future developments of the GBR is influenced by the occurrence of additional external challenges and the ability of the system to reduce any incoming infectivity or existing BSE infectivity, i.e. its stability. 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, an extremely unstable system will very quickly increase the GBR-level (if any BSE circulates already).

Therefore, its expected development more than the current GBR is the important indicator to evaluate the adequacy of preventive measures currently adopted by a country to control BSE.

The current GBR is mainly the result of past events, largely dependent on trade and agricultural practices, at times when nobody was aware of BSE and its potential impact on public health.

The SSC recognises that more sophisticated approaches could be possible if more extensive data bases would be available. Therefore, it should be understood that the above described methodology has also been adopted on the basis of the limitation with regard to the availability and quality of data and of the need to apply it uniformly to all countries.

2.2 Relation of the GBR to the OIE Code on BSE

The OIE has adopted a BSE-classification of countries using four[10] categories:

BSE-free

Provisionally free of BSE

Low incidence of BSE

High incidence of BSE.

It should be noted that the International Animal Health Code, BSE, Chapter 3.2.13, adopted May 1999, foresees that countries with and without incidence could be placed in "provisionally free" or "low incidence", depending, inter alia, on the outcome of the risk assessment required by the OIE.

Although it is possible to understand that the names of the categories suggest that these are based on incidence alone, one of the criteria always taken into account is a risk analysis. This risk analysis is based on a list of 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 factors used by the SSC.

According to the OIE, such a risk analysis has to evaluate whether potentially infected material (i.e. infected animals or MBM/Greaves or MBM/Greaves containing feed stuff) was imported and, in such case, whether the conditions in the country were/are sufficient to cope with potentially affected material, i.e. to prevent the disease to be propagated:

- importation of meat-and-bone meal (MBM) or greaves potentially contaminated with a transmissible spongiform encephalopathy (TSE) or feedstuffs containing either;
- importation of animals, embryos or ova potentially infected with a TSE;
- consumption by cattle of MBM or greaves of ruminant origin;
- the origin of animal waste, the parameters of the rendering processes and the methods of animal feed production;
- the epidemiological situation concerning all animal TSE in the country or zone; and
- the extent of knowledge of the population structure of cattle, sheep and goats in the country or zone.

Moreover, the OIE requests the following measures, and their date of effective implementation ("relevant period of time"), to be considered when determining the BSE- category:

- compulsory notification and investigation of all cattle showing clinical signs compatible with BSE;
- a BSE surveillance and monitoring system with emphasis on risks identified;

[10] The current proposal for the BSE-chapter, that is going to be discussed in May 2000, foresees 5 categories, including two categories "provisionally free": one where no indigenous case has been reported and one where at least one indigenous case has been reported.

- 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;
- examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system;
- treatment of at-risk animals linked to confirmed cases (culling).

With regard to the borderline between its category "low incidence" and "high incidence", the OIE foresees on the one hand a threshold-incidence of 100 BSE-cases per million within the cattle population over 24 months of age, calculated over the past 12 months. On the other hand it requests that a country with a BSE-incidence between 1 and 100 BSE-cases per million within the population of cattle above 24 months of age, calculated over the past 12 months, is put into the "high incidence" category if at least one of the criteria listed (see above) is not complied with. (OIE, Animal health code, Appendix XI, chapter 3.2.13, Article 3.2.13.2).

From the above appears a close similarity of the relevant information factors identified by OIE with those used by the SSC to assess the GBR.

The SSC is therefore not contradicting the OIE approach but adds to it a detailed methodology for assessing through an external review the GBR on the basis of information provided by countries. This methodology is applied consistently and transparently to the information provided by the different countries and includes scrutinising the available information for the time period covering the last twenty years. Whenever evidence is not convincingly provided, the principle of realistic worst case assumptions is applied and special care has been taken to ensure consistency of these assumptions.

Another amendment to the OIE approach is the introduction of an indicator of the probability of one or more cattle to be infected clinically or pre-clinically with the BSE-agent, at a given point in time, in a geographical region/country – the GBR. This indicator is felt to be necessary to overcome the intrinsic limitations of incidence figures alone, as explained in the introduction. It is not meant to qualify the risk with regard to acceptability. This is the responsibility of the risk managers at national and international level.

2.4 GBR assessment procedure

In January 1998, the SSC established a list of factors on which it would require information for assessing the Geographical BSE-Risk (GBR)[11]. In July 1998, the Commission recommended to Member States and interested Third Countries to provide information on these factors[12].

In December 1998, the SSC issued a draft opinion on a method for assessing the Geographical BSE-Risk of a country or region, which was adopted in February 1999[13], taking into account the comments received, and amended it in April 1999[14] and in January 2000[15] on the experience gained with its application.

1. Appraisal of the quality of the available data (completeness and reliability)
2. Assessment of the Stability of the BSE/cattle system (over time) *Note: Stability is independent of the presence of BSE.* 2.1 Ability to identify BSE-cases and to exclude animals at-risk of being infected from processing (factors 1, 6 & 8; surveillance (6) is of critical importance) 2.2 Ability to avoid recycling BSE-infectivity, should it enter processing (factors 3,4,5,&7). 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 (factor 2 & 3) 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 GBR as function of past & present stability & challenge. 5.3 Recommendations to influence the expected development of the GBR.

Table 5: - Outline of the sequence of the assessment procedure

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.

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

[12] 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).

[13] Opinion of the SSC on a method to assess the Geographical BSE-Risk of countries or regions; 18-19 February 1999, adopted after taking account of comments received on a preliminary opinion, issued in December 1998.

[14] Opinion of the SSC on a method to assess the GBR of countries or regions, adopted on 18 February 1999, revised on 22 April 1999 in the light of the experience gained during the first risk assessment exercise in March 1999.

[15] Opinion of the SSC on a method to assess the GBR of a country or region, an update in the light of the experience gained during the GBR assessment of 26 countries. January 2000.

More than three independent experts assessed each country and discussed with country experts in order to clarify the available information. These discussions proved to be very valuable. To date 25 countries are assessed.

The assessed countries have openly co-operated in the assessment by sending their country experts and by reacting on the draft reports forwarded to them for comments. During the process many countries provided additional information that improved significantly the basis for the risk assessment.

The SSC wants to thank the independent experts[16] who were involved in the exercise for their considerable efforts and the countries for their open co-operation. Without the efforts of the countries to respond to the requests of the independent experts and the intensive dialog that developed between the independent experts and the country experts, the quality of this assessment could not have been achieved.

A final review was undertaken since January 2000.

Having taken account of the draft country reports as available in January 2000, the SSC charged the 20 independent experts invited for the final review, to agree on 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 asked to apply a consistent approach to estimating the current and future GBR derived from the past and current interaction of stability and challenge.

In order to do so, the independent experts:

- agreed on practical criteria of assessing challenge and stability to be used as "orientation" to avoid inconsistencies between countries (tables 3 and 4) and
- established guidelines for revising and harmonising the reports & their presentation (Tab. 5) and
- agreed on the current GBR-level and the expected trend for each of the countries assessed.

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

On 2/3 March the SSC indicated a general agreement to the assessments while still pinpointing to significant room for improvement in terms of consistency and terminology-standardisation, once the need to up-date them in 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 also were invited to comment on the factual correctness of the reports. Subsequently the reports were sent to the respective countries

[16] In order to identify these independent experts the ad-hoc TSE/BSE group discussed on 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 in function of their availability and taking account of the selection criteria agreed on.

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. It was assumed that countries which did not submit comments agreed to the provided documents.

2.5 Availability and Quality of data

The SSC is well aware of the critical importance of the data availability and quality 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 a priori assumed that the information provided is correct**.** In essence the provision of an appropriate basis for the GBR-assessment was therefore 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. However, despite all efforts, there remain considerable differences in the availability and quality of data.

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

To complement insufficient information, and in line with the recommendation of the Commission of July 1998, "realistic worst case assumptions" were used whenever extrapolation, interpolation or similar approaches were not possible. Therefore, provision of consistent and substantiated facts that significantly differs from the assumptions made, could affect the outcome of the GBR-assessment.

A shortcoming in many dossiers, which had to be overcome by realistic 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 were also useful sources to fill gaps in the available information. It is, therefore, recommended that missions be sent to Third Countries applying for BSE-free status.

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 is 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.

2.6 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 the SSC and to field observations in Switzerland, the incidence of BSE is higher in fallen stock and in cows offered for emergency slaughter than that 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 and culls from the dairy herds. Results from such programmes, applied to statically justified samples, could significantly 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 fro 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 absence of the BSE-agent from an individual animal tested and found to be negative. The SSC wants to underline its support to the development of improved rapid BSE-diagnostic tests ultimately aiming for reliable ante-mortem tests able to detect pre-clinical BSE.

In order to make optimal use of the available tools, the SSC therefore suggests a combination of the qualitative assessment of the GBR, as described above in the present paper, with the results of conventional surveillance efforts and targeted application of the rapid post mortem tests. Whenever it is not highly unlikely that infected cattle, approaching the end of the incubation period, is present, the finding of the GBR could be confirmed. Any assessment should be regularly repeated in order to verify the expected trends of GBR and, where appropriate, the incidence figures.

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.

[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.

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P A R T II

Report on the assessment of the GBR of ITALY

May 2000

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Executive Summary

Overall assessment

The current geographical BSE Risk (GBR) level is III, i.e. it is likely that cattle are infected (pre-clinically or clinically) with the BSE-agent but it is not confirmed.

Stability: Prior to 1993 the Italian BSE/cattle system was very unstable, i.e. any BSE-infectivity entering it would have been quickly amplified. The 1994 feed ban and the removal of SRMs from animals imported from BSE-affected countries, introduced in 1996, improved the stability but the system remained unstable. The improvement of the rendering system that started after 1996 and were completed in mid 1999 made the system neutrally stable. It is not stable because SRM of domestic cattle are still rendered and the risk of cross-contamination of cattle feed with MMBM is still not negligible.

External Challenge: Italy imported about 10,000 bovines from UK during the period 1985 to 1990, about 90% for fattening and slaughter at 6 or 18 months of age or younger. About 1000 cattle entered the national herd. From 1990, when the age limit for slaughtering UK-imports was set to 6 months, to 1995, roughly another 10,000 calves have been imported from the UK,. In 1994 two cases of BSE have been discovered in UK-imported cattle, thus proving that it cannot be excluded that BSE-infectivity entered the Italian BSE/cattle system by this route. In addition Italy imports roughly about 2 million cattle per year for immediate slaughter or fattening. France is a major source but also BE, CH (until 1996), and NL. Italy also imported MBM from BSE affected countries, mostly for pig and poultry feed. It is likely that some of these imports were contaminated and entered, particularly via cross-contamination or inappropriate use, the Italian BSE-cattle system. Together the cattle imports and the MBM imports represented a very high or high external challenge.

Interaction of stability and challenge: A very unstable or unstable system was exposed to high or extremely high external challenges over a long period of time. It is hence likely that BSE entered the system and was recycled and amplified, leading to a certain domestic prevalence. It is therefore assumed that BSE is currently present in the domestic cattle population, at levels below the detection limits of the passive BSE surveillance system in place, which would not be able to detect all clinical cases of BSE.

It is expected that the GBR will remain constant as long as no significant improvements of the stability are achieved and no new external challenges occur.

Additional efforts to increase the stability (excluding domestic SRM from the feed chain, improved feed control) and to ascertain pre-clinical BSE-cases and remove them, and other animals at risk of being infected by BSE, from processing, will assist in reducing the GBR.

Justification

1. Available data

The information available was largely sufficient to complete the assessment.

2. Stability

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

- Until today the Italian system is regarded as not being able to identify small numbers of clinical BSE-cases, should they occur. The system's ability to back-trace cases is assessed to be low. Consequently, elimination of other at-risk animals with a relation to a case seems unlikely.

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

- Until 1994 BSE infectivity that would have entered the Italian BSE/cattle system would have been recycled and amplified, because rendering was not appropriate, SRM were not destroyed and feeding of MBM to cattle was possible.
- Also after the feed ban of 1994 BSE-infectivity could have been recycled, in particular because of cross-contamination.
- The improvements of the rendering system, that started in 1996 and the SRM-ban for imported animals of the same year, reduced the risk that BSE-infectivity would be recycled to some extend.
- Since mid 1999 recycling is much less likely but as long as domestic SRM are still rendered for feed production and cross-contamination remains possible, recycling will continue to occur. However, amplification is now regarded to be unlikely.

2.3 Overall assessment of the stability

- Until 1993, the Italian BSE/cattle system is assumed to have been very unstable. Although feeding MBM to cattle was not common, no formal feed ban existed, rendering was mostly inappropriate, and SRM were processed into feed.
- From 1994 to 1998 the system was unstable, even if the effect of the MBM ban of 1994 was reduced by cross-contamination. The removal of SRMs of imported cattle (since 1996) contributed to the stability, as did the improvements in the rendering system that began in 1996.
- Since mid 1999 the system is regarded to be neutrally stable, thanks to the confirmed compliance of all rendering facilities with the 133/20/3-standard and the apparent improvements in the MBM-ban implementation. It is not yet stable because domestic SRM are still rendered and included into animal feed while cross-contamination is apparently still non-negligible (in 1999 4.4% of all cattle-feed samples were found to include MBM).

- As long as domestic SRM are rendered and cross-contamination of cattle feed with MBM cannot be excluded, the system will not become stable.

3. Challenges to the BSE/Cattle-system

- From 1980 to 1996 Italy had to face high external challenges due to importation of potentially BSE-infected animals and feed stuffs from the UK and other BSE-affected countries. The external challenge have probably reached very high levels in 1988-1990 and then returned to high levels.
- Given the limited stability of the system it is therefore likely that domestic cattle were exposed to and subsequently infected by BSE already in the late 80s/early 90s and an internal challenge gradually built up.
- This internal challenge grew fast enough to over-compensate the decrease in external challenge after 1990 and hence the combined challenge stayed at very high levels even after the external challenges were reduced.
- From 1994 to 1996, before the external challenge was largely reduced due to import restriction and better controlled due to the SRM-ban, the combined challenge even reached extremely high levels. It returned to high levels in 1997 when the external component became much smaller.

4. Conclusion on the resulting risks

4.1 Interaction of stability and the combined challenges

- Until 1993 a very unstable Italian BSE/cattle system had to face high challenges, firstly resulting from imports of potentially BSE-infected animals and feed stuffs, and later also resulting from an internal challenge.
- The gradual improvements of the stability of the system in 1994 (MBM-ban) was not enough to prevent the internal challenge growing and from 1994 to 1996 the overall challenge was extremely high, even if the stability of the system was regarded to be improved to “unstable”.
- After 1997 the external component of the challenge decreases significantly and the challenge was returning to high, even if the unstable system would still have recycled and amplified the BSE-infectivity that was already circulating.
- As the system is now, since mid 1999, considered to be neutrally stable, the challenge will remain at this very high level, as long as the stablitity is not further increased and no new external challenges will introduce more BSE-infectivity into the system.

4.2 Risk that BSE-infectivity enters processing

- The risk that BSE-infectivity enters processing (processing risk) was highest when the roughly 1.000 cattle imported from the UK in the 80s and introduced into the Italian cattle-herd were processed, probably in the late 80s or early 90s. The imports slaughtered at an age below 6 or 18 months are not considered as posing a significant processing risk.

- Assuming that BSE-infectivity was introduced to Italy in the late 80s and domestic cattle were infected at that period, a processing risk would have resulted when these domestic cases entered processing, be it as "healthy" (pre-clinical) animals at normal or in emergency slaughter or as fallen stock with or without diagnosis.
- Hence a certain processing risk existed since the late eighties, first due to import animals, later from domestic cattle.

4.3 Risk that BSE-infectivity is recycled and propagated

- Given the fact that BSE probably entered the Italian system in the late 80s and is present since, and given the low stability of the system, a high risk existed since then that BSE-infectivity was recycled and propagated.
- Since 1994, with the introduction of a feed ban, and since 1996/97 with a beginning improvement of the rendering system, the propagation risk started to decline.
- Today, since mid 1999, the propagation risk is regarded to be small enough to assume that the amount of BSE-infectivity already circulating in the system will not be amplified. It is, however, still high enough to ensure that the circulating BSE-infectivity will remain fairly constant.

5. Conclusion on the geographical BSE-risk

5.1 The current GBR

- **The current geographical BSE-risk (GBR) level is III, i.e. it is likely that domestic cattle are infected with the BSE-agent but it is not confirmed.**

5.2 The expected development of the GBR

- Without further improvements of the stability of the Italian BSE/cattle system, the GBR will remain at its current level.

5.3 Recommendations for influencing the future GBR

- Incineration of the domestic SRMs and exclusion of fallen stock from rendering would significantly increase the stability and hence lead, over time, to a decrease of the GBR.

- In addition, expanding the surveillance system to target high risk populations such as adult fallen dairy stock and adult cattle presented for emergency slaughter will allow verification of this GBR assessment and its trend.

Full report

1. Available data

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

- The information provided in the dossier and by additional sources was not fully complete and some inconsistencies were discovered between the Italian dossier and the mission reports from the European Veterinary Inspection service. 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 authority and the Country Experts.
- Export figures in the UK dossier for live imports.
- Reports of an EC-veterinary missions to Italy, 25-29 November 1996 and 14-18 September 1998.

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

To get a better appreciation of the challenge imposed by imports, it would be valuable to have:

- more detailed information on their origin, age and final fate within the system (including any efforts to trace and examine imported animals). This is particularly valid for the 14.976 animals imported in the period 1985-1989 from the UK, but also for livestock imported from other BSE-affected countries, in particular CH, FR, BE and NL since 1990.
- more detailed documentation on importations from BSE-affected countries of MBM, or feed stuffs containing MBM.
- more detailed information on feed production and feeding of cattle, including efforts to check any compliance, that allows a better judgement of the probability that BSE-infected material ended up in cattle feed.

To get a better appreciation mainly of the quality of the surveillance system, it would be valuable to have:

- a better understanding of the size of the challenge from possibly infected animals rendered as “fallen stock” or after emergency slaughter.
- a demonstration of the current performance of the identification system, e.g. documentation on the origin and fate of recent imports.
- information on the number of BSE suspect cases > 24 months old that were notified and investigated before 1997 and on the notification of CNS- and progressive disorders in cattle.

To allow for a better appreciation mainly of the quality of the (past and current) rendering system, it would be valuable to have:

- Detailed description, covering at least the last ten years, of the rendering processes used in all rendering facilities of Italy together with clear documentation of the raw materials used (type and origin).

- Statistics for the output from the individual rendering plants.
- Detailed information on the control measures applied throughout the same period.

In addition, results of an intensive surveillance program, actively sampling non-suspects in at-risk sub-populations such as adult cattle in fallen stock and emergency slaughter (including buffalo), could help to verify the outcome of this assessment and to monitor the trend of the GBR.

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

- The information available was largely sufficient to complete the assessment. However, where worst case assumptions have been used to account for gaps or inconsistencies in the information, the provision of substantiated facts could affect the outcome.

2. Assessment of the stability of the BSE/cattle system

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

2.1.1. Factor 1: Population data

2.1.1.1. Total size of the cattle herd; relative share of dairy, beef and dual use cattle

- The total cattle population in Italy is about 7 millions, of which two millions are dairy cattle older than 2 years.
- The dairy cow population has fallen from 3 million in 1988 to 2 million in 1998.

2.1.1.2. Age distribution of cattle, alive and at slaughter

- The average age at culling of dairy cows is currently estimated to be about 5 years (having been reduced from 8 years in 1988). This estimate is based on information received from the Country Expert and interpolation.
- The total number of cattle slaughtered annually in Italy is about 4.6 million, 16% being dairy cattle that are taken out of production.

2.1.1.3. Husbandry systems

- Italy has a relatively intensive dairy cattle industry with large herds (average herd size = 200) concentrated in the north of the country. Less intensive beef production is found in the southern parts of the country.
- Most of the dairy cows are managed for a dual purpose, i.e. after their productive life as dairy cow they are fattened for some time before final slaughter.
- Typically dairy cattle will receive calf starters, consisting of powder milk or milk surrogates. They will also receive significant amounts of supplementary (compound) feed during their productive live as dairy cows and, in certain cases in the subsequent fattening period.
- It is worth noting that about 1/3 of the dairy population is likely to deviate from this pattern. Those are in herds where certain product (cheese) quality requirements have lead to special regulations for and control of feeding. Cows in these herd will not have received any MBM.

2.1.1.4. Cattle identification and monitoring system

- A cattle identification system including all animals older than 6 months has existed since 1991. It consisted of a tattoo in the left ear, with the province code and a sequential number. These were recorded in a herd file maintained by the Veterinary Service.
- Data on the importation status of slaughtered animals could not be provided, and therefore the old system was judged to be insufficient in terms of tracing capacities.
- An identification system including all cattle has been in place since the EU directive in 1992. However, its performance before 1996 (based on the earliest mission report available to the assessors) could not be assessed. In November 1996 the mission of the European Veterinary Inspection Service found it was not fully implemented. However, according to the CE, the cattle identification system is now fully operational.
- The assessors conclude that until 1996, the identification system was not able to trace back all imported animals but assumed that this ability gradually improved since then. However, the current performance of the existing system has yet to be confirmed.

2.1.2. Factor 6: Surveillance

2.1.2.1. Description of the surveillance system[17]

- BSE is a notifiable disease since May 1991.
- The Italian BSE-surveillance system is passive in nature, i.e. it is depending on the notification of all suspect cases to the responsible services.
- Awareness raising campaigns have been, and are carried out in order to make relevant professionals aware of the symptoms of BSE and the need to notify any suspect case.
- Before 1997 compensation was provided for confirmed cases only – not for suspects that are finally not confirmed. After 1997, compensation corresponding to full market value is paid for all suspect cases.
- Sufficient laboratory facilities, well equipped and with trained personnel, are available for the examination of suspects. The applied methodology is assumed to be appropriate.
- Until 1995, 1,149 brains from healthy cattle of unknown age, most of them from imported animals, have been examined. The samples were taken at slaughterhouses. This target population is not regarded as appropriate for BSE surveillance.
- The number of brains examined from neurological cases and progressive disease from cattle > 24 months was low since 1990 (6 in 1997, 12 in 1998). This level did not meet the minimum requirements of the OIE guidelines. According to the CE rabies is not a relevant health problem for domestic animals in Italy and therefore samples submitted for such examinations can not be used.
- In 1999, 101 samples have been examined, thus meeting the requirements of decision 98/273/EC and of OIE.

[17] (The 1998 and 1999 reports on epidemio-surveillance were not available to the assessors at the time of evaluating the Italian Country Dossier).

- On 7 January 2000 an ad-hoc decree was adopted establishing the Italian system of BSE epidemiological surveillance. When fully implemented it will significantly improve the surveillance system.

2.1.2.2. Quality of the surveillance system with regard to BSE

- The Italian BSE-surveillance system is passive, and depending on notification while incentives for reporting have been insufficient in the past.
- Until 199 the number of examinations of cases of neurological and progressive disease from cattle > 24 months did not meet the minimum requirements of the OIE guidelines.
- Therefore, it is assessed that the surveillance system, could and probably cannot be expected to identify low incidence of clinical BSE nor to identify all clinical BSE cases if present at a higher level.
- The Ability to identify animals being at risk because of established links to domestic or foreign BSE-cases is regarded as limited.

2.1.3. Factor 8: Culling

- According to the Country Expert, cattle originating from BSE-affected herds in the UK were traced and culled after Nov. 1994.
- The culling policy towards affected herds is stamping out, no cohort culling was foreseen.
- Since 7 January 2000, additional to the herd culling cohort culling is foreseen.

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

- Until today the Italian system is regarded as not being able to identify small numbers of clinical BSE-cases, should they occur. The system's ability to back-trace cases is assessed to be low. Consequently, elimination of other at-risk animals with a relation to a case seems unlikely.

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

2.2.1. Factors 3 and 4: Domestic MBM production and use

2.2.1.1. Domestic production of MBM

- The annual Italian production of MBM is around 450.000 tons.
- Italy exports about 90,000 tons of MBM each year, mainly to Africa and the Middle East. This represents approx. 20 % of the domestic production.

2.2.1.2. Description and history of feed bans and their compliance

- A feed ban was implemented in 1994, in response to the European MBM to ruminants-ban.
- Data on compliance were available for 1998 and 1999. In 1998 of 730 microscopically tested cattle feed samples 109 (14.1%) were positive for MBM, most with less than 0,01%. In 1999, 27 out of 613 (4.4%) samples were positive. This indicates a significant improvement but still shows a non-negligible degree of cross-contamination (see also point 2.2.4).
- The low levels that were found (<0.01%) are regarded more to be a result of cross-contamination than actual non-compliance.

2.2.1.3. Use of MBM (before and after feed ban)

- There was no tradition to feed cattle with MBM. Nevertheless, ruminant MBM could be fed to cattle until 1994, when the European MMBM to ruminants-ban was implemented.
- Dairy herds producing milk for certain cheese production have for a long time been specifically excluded from being fed with MBM, for quality reasons.
- Since 1994, feed concentrates are still fed to >90 % of bovines over 1 year. It is assumed that significant amounts of these feed concentrates have been domestically produced.
- MBM is currently allowed for inclusion in feed preparations for pig and poultry.

2.2.2. Factor 5: SRM-ban and treatment of SRM

2.2.2.1. Description and history of SRM bans

- There is no SRM ban in place for domestic cattle.
- Since 1996, there is an SRM ban (including skull, brain, eyes and spinal cord from cattle > 6 months of age) for imported animals from BSE affected countries.
- Compliance with this ban could not be verified on the basis of the available information. However, according to the Italian authorities, a recent FVO mission (Jan.2000, report not yet finalised) confirmed appropriate implementation.

2.2.2.2. Fate of SRMs

- The Country Expert informed the assessors that the SRMs of imported animals are incinerated.
- Domestic SRMs are rendered.

2.2.3. Factor 7: Rendering and feed processing

2.2.3.1. Raw material used for rendering

- Most of the raw material is sourced from within Italy. It includes low and high risk material, fallen stock and domestic SRM.
- Suspect TSE cases are excluded, as are SRMs from imported cattle (since 1996).

2.2.3.2. Rendering processes

- According to the mission report of 1996, about 55 % of the registered plants met the 133/20/3 standard. The rest were assumed to apply lower standards.
- There was uncertainty about the number of plants, their respective raw material supply and relative share of the domestic production. According to the Ces (May 1999), the number of registered plants was decreasing and the rendering standard was improving and under control. However, this could not be substantiated from the documentation available at that time.
- The mission report of 1998 showed some improvements of the rendering systems, but there were still serious shortcomings in the 4 inspected plants.
- In the meantime the Italian authorities confirmed that since June all rendering facilities, including those processing low-risk material, work in batch modus and apply the 133/20/3 standard.

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

- At least until 1996, more than 50% of the Italian rendering system did not have the ability to considerably reduce potential BSE-infectivity in the processed raw materials.

- After 1997 improvements in the rendering industry, but also deficiencies, were reported. The ability to reduce incoming BSE-infectivity increased but remained sub-optimal.
- Since June 1999 all rendering plants are confirmed as operating according to standard. The rendering system should hence now have a close to optimal capacity to reduce BSE-infectivity should it be present in the raw material.

2.2.4. Cross contamination

2.2.4.1. Possible types of cross contamination

- Cattle feed is prepared using the same lines as for pig feed in domestic feed mills. This indicates a significant risk of in-mill cross-contamination. This has been confirmed by the result of a reliable and sensitive method used for feed control (detection limit 0.01%): 14.1% and 4.4% of all samples were positive in 1998 and 1999, respectively.
- Cross-contamination of cattle feed with MBM is also still possible during production (material from different species is rendered together), transport and storage of MBM or the feed designated for different species.
- As long as MBM is still included in feed preparations for pig and poultry, co-farming of pigs and cows (which is not frequent but occurs) presents a certain risk of on-farm cross contamination.

2.2.4.2. Measures undertaken to control cross-contamination

- Circulation of guidelines “Good manufacturing practices for ruminant feed stuff” and intensified control of feed for cross-contamination reduced the in-mill cross-contamination, as demonstrated by the decline in the proportion of positive feed samples from 1998 to 1999.

2.2.4.3. Assessment of the potential level of cross-contamination

- The significant number of cattle feed samples that were found to contain some MBM confirms that cross-contamination is/was rather frequent, even after the feed ban. However, the data from 1998 and 1999 show a remarkable decline in the number of positive samples.
- There is no information on controls of cross-contamination during transport or on-farm. As a realistic worst case scenario it has to be assumed to occur. As long as feeding MBM to non-ruminant farm animals is legally possible, cross-contamination of cattle feed with MBM will remain a problem.

2.2.5. Overall appreciation of the ability to avoid recycling BSE-infectivity should it enter processing

- Until 1994 BSE infectivity that would have entered the Italian BSE/cattle system would have been recycled and amplified, because rendering was not appropriate, SRM were not destroyed and feeding of MBM to cattle was possible.
- Also after the feed ban of 1994 BSE-infectivity could have been recycled, in particular because of cross-contamination.
- The improvements of the rendering system, that started in 1996 and the SRM-ban for imported animals of the same year, reduced the risk that BSE-infectivity would be recycled to some extend.

- Since mid 1999 recycling is much less likely but as long as domestic SRM are still rendered for feed production and cross-contamination remains possible, recycling will continue to occur. However, amplification is now regarded to be unlikely.

2.3. Overall assessment of the stability

- Until 1993, the Italian BSE/cattle system is assumed to have been very unstable. Although feeding MBM to cattle was not common, no formal feed ban existed, rendering was mostly inappropriate, and SRM were processed into feed.
- From 1994 to 1998 the system was unstable, even if the effect of the MBM ban of 1994 was reduced by cross-contamination. The removal of SRMs of imported cattle (since 1996) contributed to the stability, as did the improvements in the rendering system that began in 1996.
- Since mid 1999 the system is regarded to be neutrally stable, thanks to the confirmed compliance of all rendering facilities with the 133/20/3-standard and the apparent improvements in the MBM-ban implementation. It is not yet stable because domestic SRM are still rendered and included into animal feed while cross-contamination is apparently still non-negligible (in 1999 4.4% of all cattle-feed samples were found to include MBM).
- As long as domestic SRM are rendered and cross-contamination of cattle feed with MBM cannot be excluded, the system will not become stable.

3. Challenges to the BSE/cattle-system

3.1 External challenge

3.1.1. Factor 2: Import of live cattle

- Until 1995 large numbers of bovines have been imported from the UK, notably for fattening and slaughter before an age of 6 or 18 months. Total imports from UK in the period 1985 to 1995 = 20.023. (1985-87: 9683, 88-93: 5293, 94-96: 5047). Of the roughly 10.000 cattle imported from the UK until early 1990 about 10% were introduced into the national herd, of the UK imports after early 1990 this fraction is assumed to be zero because they had to be slaughtered before reaching an age of 6 months.
- The fate of the UK-imports included into the Italian herd is not known, neither the BSE-status of their herds of origin. However, in 1994 two cases of BSE were confirmed in cattle imported from the UK. Thus it can be regarded as proven that a definite challenge from imported livestock has occurred.
- In 1996, Italy banned all importation of livestock from the UK and Switzerland.
- Italy imports around 1 million bovines from France each year. According to the Country Expert, the vast majority is for immediate slaughter or fattening. Since 1996 the cattle imported from France must born after July 1991.
- There has also been a continuing importation from other countries (Member States and Third Countries) of approximately 1 million cattle per year, again mostly for fattening or immediate slaughter at very young age. The countries of origin include CH (until 1996), BE, and NL, known to be affected by BSE.

3.1.2. Factor 3: Import of MBM or feed containing MBM

- MBM has been imported from BSE affected countries. For example,

  - IRE: 2.400 tons in 1989 and 10.384 tons in 1997,
  - FR: 600 tons in 1990, 1.587 in 1992, 3.586 in 1997,
  - BE: 148 tons in 1991
  - UK: 750 kg in 1987.
- Since 1989 import of MBM from the UK is banned.
- According to the CEs the majority of MBM imports were used for pig and poultry feed.

3.2 Internal challenge

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

- It is regarded to be highly likely that the BSE agent was imported into Italy with UK livestock (in particular by the 1.000 UK-cattle that were introduced into the Italian herd before 1990) and cattle from other BSE-affected countries (until 1996 and later).
- The MBM-imports from the UK and other countries now known to be affected by BSE are seen as a second potential route by which the BSE-agent could have entered the Italian BSE/cattle system.
- The high external challenge that thus occurred in the 80s met a very unstable system. It therefore has to be assumed that the incoming BSE-infectivity was recycled and amplified, leading to an internal challenge.
- This internal challenge is assumed to have over-compensated the decrease in the external challenge that occurred after 1990, when imports from UK where limited to animals for slaughter before 6 months of age, and after 1996, when livestock imports from UK and Switzerland were banned and animals imported from France had to be born after June 1991.
- Hence a very unstable (until 1994) and unstable (until 1999) system has been exposed to high and very high challenges since the 80s.

3.2.2. Domestic prevalence

- The exposure of a very unstable (until 1994) and unstable (1994-1999) system to high and very high challenges make it most likely that the BSE agent entered the Italian BSE/cattle system and was recycled and amplified.
- It is therefore likely that a domestic prevalence has been build-up since the late 80s and continued to rise until 1999, when the system became finally neutrally stable.
- In the light of the passive nature of the surveillance system, the current zero-incidence of clinical cases in domestic cattle cannot be taken as a guarantee that BSE is absent from the Italian cattle population.

3.3 Overall assessment of challenges

- From 1980 to 1996 Italy had to face high external challenges due to importation of potentially BSE-infected animals and feed stuffs from the UK and other BSE-affected countries. The external challenge have probably reached very high levels in 1988-1990 and then returned to high levels.
- Given the limited stability of the system it is therefore likely that domestic cattle were exposed to and subsequently infected by BSE already in the late 80s/early 90s and an internal challenge gradually built up.

- This internal challenge grew fast enough to over-compensate the decrease in external challenge after 1990 and hence the combined challenge stayed at very high levels even after the external challenges were reduced.
- From 1994 to 1996, before the external challenge was largely reduced due to import restriction and better controlled due to the SRM-ban, the combined challenge even reached extremely high levels. It returned to high levels in 1997 when the external component became much smaller.

4. Conclusion on the resulting risks

4.1. Interaction of stability and the combined challenges

- Until 1993 a very unstable Italian BSE/cattle system had to face high challenges firstly resulting from imports of potentially BSE-infected animals and feed stuffs and later on also from an internal challenge.
- The gradual improvements of the stability of the system in 1994 (MBM-ban) was not enough to prevent the internal challenge growing and from 1994 to 1996 the overall challenge was extremely high, even if the stability of the system was regarded to be improved to "unstable".
- After 1997 the external component of the challenge decreases significantly and the challenge was returning to high, even if the unstable system would still have recycled and amplified the BSE-infectivity that was already circulating.
- As the system is now, since mid 1999, considered to be neutrally stable, the challenge will remain at this very high level, as long as the stablitity is not further increased and no new external challenges will introduce more BSE-infectivity into the system.

	Probable Challenge			**|**	**Definite Challenge**		
Stability	**Negligibe**	**Very low**	**low**	**moderate**	**high**	**Very high**	**Extremely high**
Optimally stable							
Very stable							
Stable						**?**	
Neutral						**1999**	
Unstable						**↑97-98**	**←94-96**
Very Unstable					**80-87→**	**88-93**	
Extremely Unstable							

Figure 1: Stability and challenge over time

4.2 Risk that BSE-infectivity enters processing

- The risk that BSE-infectivity enters processing (processing risk) was highest when the cattle imported from the UK in the 80s and introduced into the Italian cattle-herd were processed, probably in the late 80 or early 90s. The imports slaughtered at an age below 6 or 18 months are not considered as posing a significant processing risk.
- Assuming that BSE-infectivity was introduced to Italy in the late 80s and domestic cattle were infected at that period, a processing risk could have resulted when these domestic cases entered processing, be it as "healthy" (pre-clinical) animals at normal slaughter or in emergency slaughter or as fallen stock with or without diagnosis.
- Hence a certain processing risk existed since the late eighties, first due to import animals, later from domestic cattle.

4.3 Risk that BSE-infectivity is recycled and propagated

- Given the fact that BSE probably entered the Italian system in the late 80s and is present since, and given the low stability of the system, a high risk existed since then that BSE-infectivity was recycled and propagated.
- Since 1994, with the introduction of a feed ban, and since 1996/97 with an improvement of the rendering system, the propagation risk started to decline.
- Today, since mid 1999, the propagation risk is regarded to be small enough to assume that the amount of BSE-infectivity already circulating in the system will not be amplified. It is, however, still big enough to ensure that the circulating BSE-infectivity will remain fairly constant.

5. Conclusion on the geographical BSE-risk

5.1 The current GBR

- **The current geographical BSE-risk (GBR) level is III, i.e. it is likely that domestic cattle are infected with the BSE-agent but it is not confirmed.**

5.2 The expected development of the GBR

- Without further improvements of the stability of the Italian BSE/cattle system, the GBR will remain at its current level.

5.3 Recommendations for influencing the future GBR

- Incineration of the domestic SRMs and exclusion of fallen stock from rendering would significantly increase the stability and hence lead, over time, to a decrease of the GBR.
- In addition, expanding the surveillance system to target high risk populations such as adult fallen dairy stock and adult cattle presented for emergency slaughter will allow verification of this GBR assessment and its trend.