Preliminary-opinion of the SSC

on

A method to assess the geographical BSE-Risk

of Countries or Regions

adopted on 10 December 1998

open for comments until

15 January 1999

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Preliminary opinion of the SSC on a method to assess the geographical BSE-Risk of countries or regions.

The Question:

"How could the geographical BSE-risk, as defined by the SSC in its opinion of 23 January 1998, be assessed, assuming that the information listed in the said opinion would be provided by the country/region under consideration?"

The background:

In its opinion on SRMs of 9/12/97 the SSC stated that the SRM-lists should be modulated in the light of the geographical origin of the animals and the final use.

In response to this the SSC was asked to elaborate an opinion on the safety aspects of the geographical origin of animals.

In its opinions of 23/1/98 and 19/2/98 the SSC specified its thought on the BSE-Status of countries or geographical areas and listed the information its ideally would base an opinion as to the BSE-Status on.

On 22/7/98 the Commission issued a recommendation "concerning information necessary to support applications for the evaluation of the epidemiological status of countries with respect to transmissible spongiform encephalopathies."

Following this recommendation 11 Member States and 11 Third Countries have provided dossiers for supporting their application for an evaluation of their epidemiological status as regards BSE/TSEs.

In May 1998 the OIE adopted a draft BSE-code and invited a working group to clarify certain points. In October 1998 the OIE adopted a draft proposal for a new BSE-code which integrated the work of that working-group. In this proposal the OIE proposes to determine the BSE-Status of a country on the basis of a risk assessment and in view of the measures taken to manage the risk. Depending on the status of a country, different requirements where defined for allowing export or use of bovine based material.

The secretariat of the SSC prepared a comparison of the current OIE-proposal with existing SSC-opinions. The SSC discussed this comparison on its meetings in October and December 1998 and came to the conclusion that the positions taken are largely compatible. An opinion on the remaining differences and the approach of the SSC to deal with them is forthcoming. A discussion paper was adopted and the SSC proposed to send it to the secretariat of the OIE for information and comments.

On 25/11/98 the Commission adopted a proposal for a revision of the 97/534 proposal (SRM decision) and a proposal for a regulation by the EP and the Council of the management of TSEs (100a-proposal). In these proposals the Commission proposed to determine the BSE-Status of a country on the basis of the propagation risk, the processing (or incident) risk and the human exposure risk, also taking account of the recommendations of the OIE.

While the geographical BSE-risk, as defined by the SSC, integrates the propagation and incident risk, the human exposure risk is influenced by im-and export of bovine based products and by consumption patterns of potentially contaminated food and other products.

Scope of this opinion:

This opinion only concerns a method to assess the geographical BSE-Risk on the basis of the propagation and the processing risk, resulting from the situation in a country or region.

The procedure to establish a BSE-Status taking due account of the geographical BSE-Risk, the Human Exposure Risk and the recommendations of OIE, will be subject of a separate opinion.

The overall process from assessment of the geographical BSE-risk to the identification of the epidemiological status of a country is summarised in figure 1.

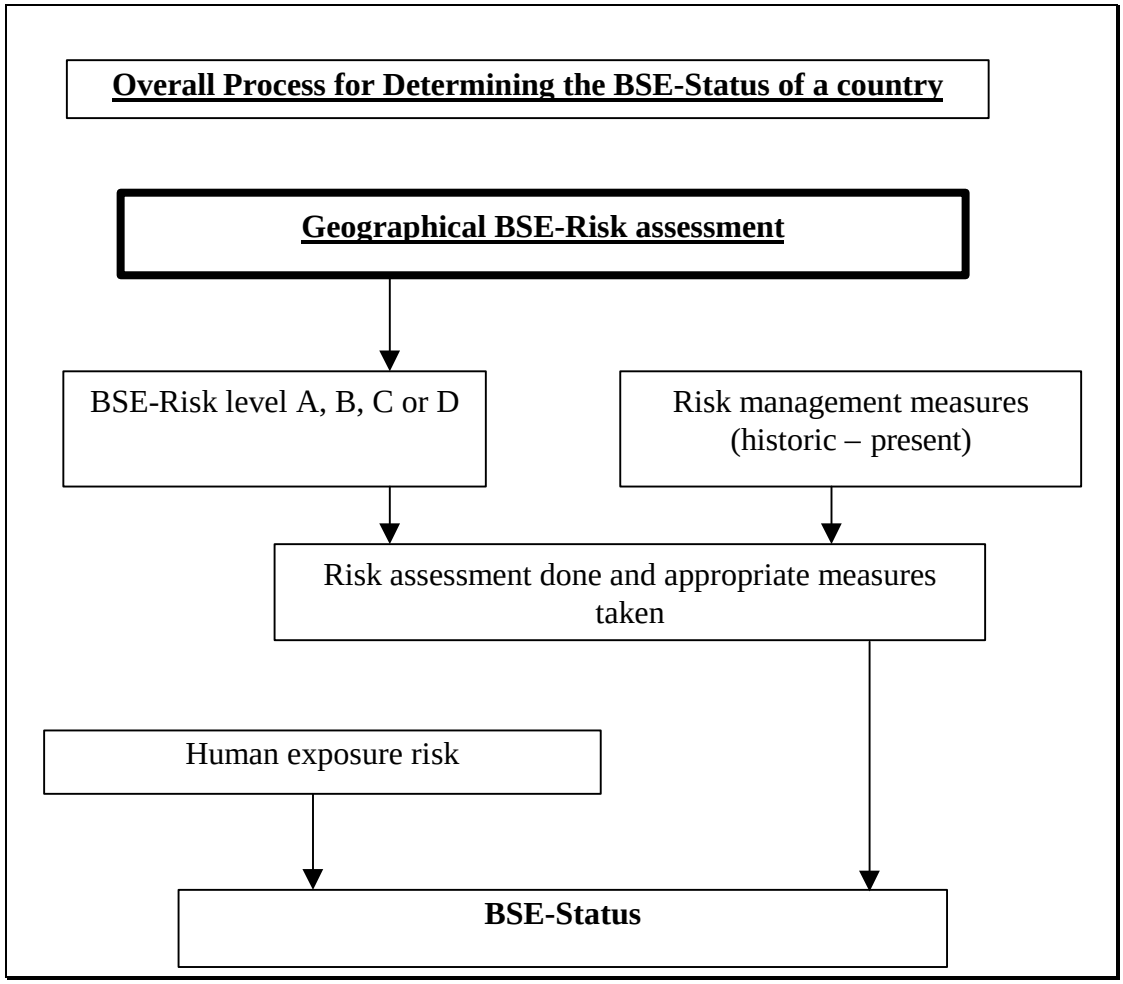

Figure 1: Overall process to determine the BSE-Status of a country or geographical area. This opinion only refers to the first step, the assessment of the geographical BSE-Risk.

Outline of the method for assessing the geographical BSE-risk

Preamble

The proposed method should allow to identify the level of geographical BSE-risk present in a country. However, any other geographical unit could also be taken as basis as long as the boundaries of the appropriate data are clearly related to the geographical boundaries. As data boundaries are normally identical with administrative boundaries, countries will be in most cases the geographical unit for which consistent data are available.

The SSC would also like to underline that it is well aware of the critical importance of data quality. Without reliable information no assessment can be made.

Basic assumptions

The method for the risk assessment is based on the general model of the BSE/cattle system described in figure 2.

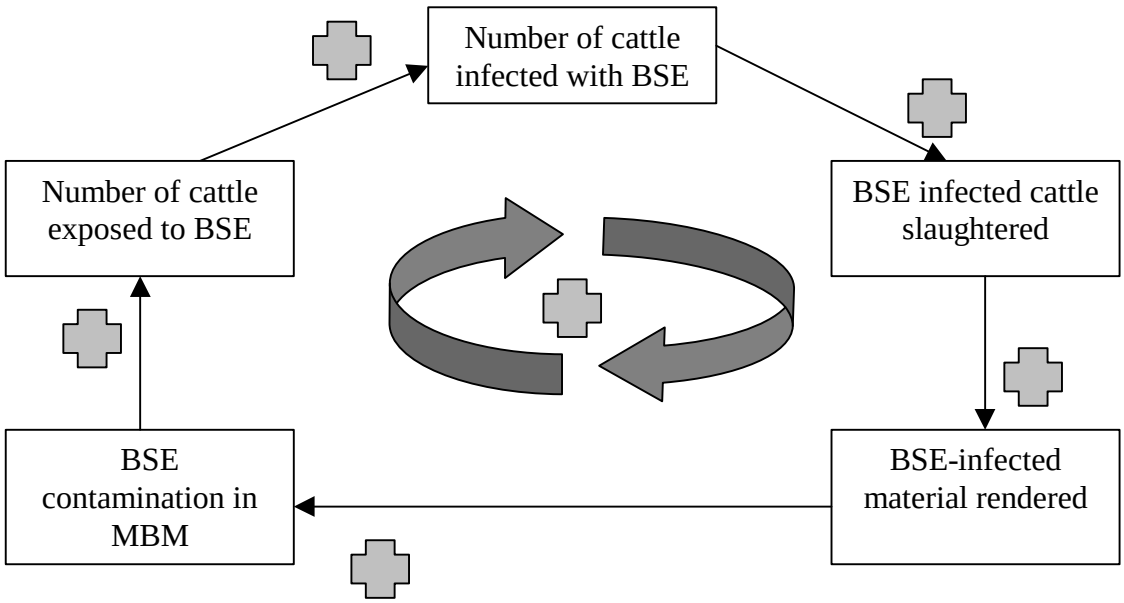

Figure 2: The basic BSE/Cattle system

The core is a positive feed-back loop which, if not counteracted, lead to a continuos increase of BSE infection in cattle until an epidemic outbreak The system is assumed to function as follows: BSE-infected material is rendered and contaminates MBM. Cattle are feed with MBM and thereby exposed to BSE. If more cattle are exposed, more cattle are infected. If more infected cattle are around, more infected cattle are slaughtered and the infected offals rendered. This will lead to more contaminated MBM and more exposed cattle, and so on.

Fortunately this potential positive feed-back loop is normally controlled and controllable at several points. Figure 3 shows the key factors controlling this feed-back-loop and their point of action:

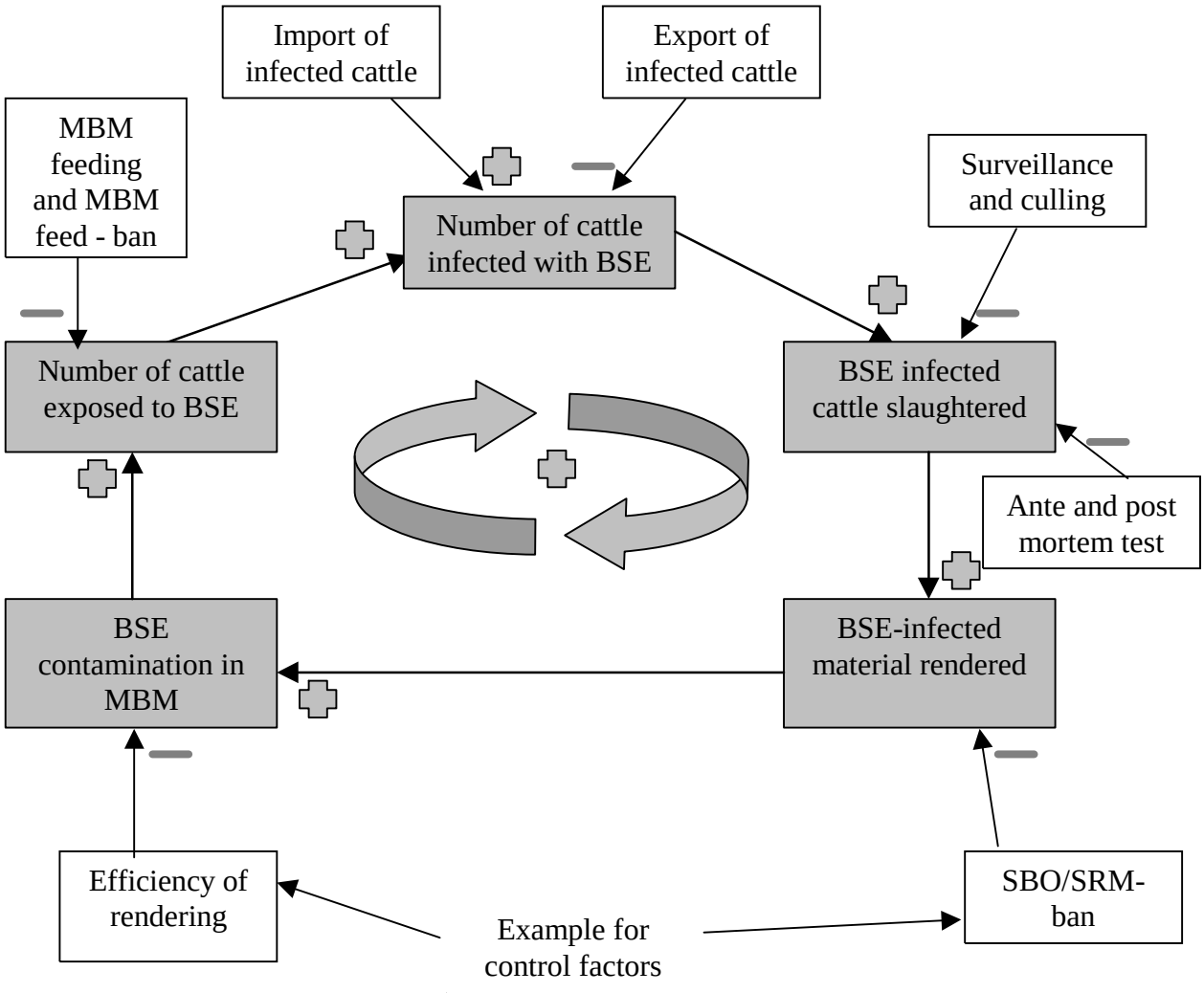

Figure 3: Key-variables controlling the BSE-Cattle System

- The efficiency of the rendering to eliminate or reduce any contamination of the MBM with the BSE-agent has the potential to interrupt or prevent the feed-back to build up.
- Not feeding MBM to cattle would be a second point at which the loop could be interrupted.

The following control factors are able to reduce the growth resulting from the positive feed-back-loop but are not able to fully interrupt it:

- Import of infected cattle would increase the number of infected cattle in the country while export would reduce it.
- A good surveillance system would identify all infected animals showing any clinical signs and suspect cases. If these would be excluded from further processing (also from rendering) a significant part of the infectivity would be taken out of the system. This effect would be enhanced by an appropriate culling system which includes all cattle likely to have been exposed to the same source of the BSE-agent as the identified case because such a culling would probably eliminate infected animals which are showing no clinical signs yet.
- An ante- or post-mortem test able to identify all BSE carriers even at early stages of the incubation period, i.e. not showing clinical signs of BSE, would have the theoretical potential to interrupt the feed-back loop but currently no such test exists.
- Eliminating SRMs (the specified risk materials) from rendering would reduce the infectivity entering the rendering process but would not be able to reduce it to zero.

The method

Factors to be taken into account

Based on this model of the BSE/cattle system the SSC has identified 8 risk-factors[1] on which it would need information to assess the geographical BSE-risk. These risk factors are significant for the efficiency of the control-factors shown in figure 3 and would hence determine the overall BSE-risk in a given geographical area. Figure 4 shows the relationship of these risk factors and the BSE/cattle system.

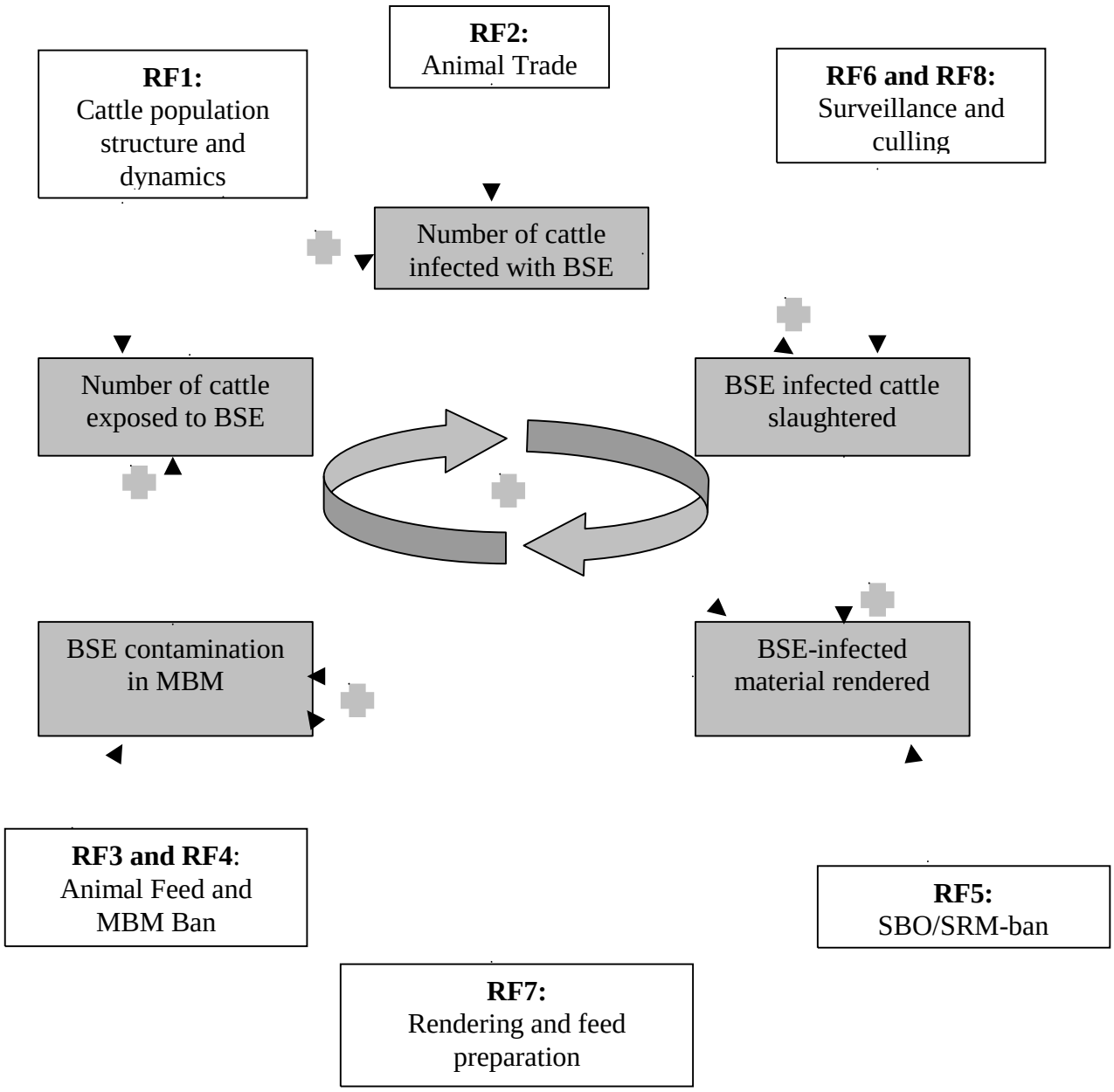

Figure 4 The 8 SSC-Risk factors and the BSE-Cattle system

[1] SSC-opinion on the geographical BSE-risk, 22 January 1998

- **Risk Factor 1:** A cattle population with a large fraction of high yielding dairy cattle, managed intensively with significant amounts of supplementary feed, would have a higher exposure risk than an extensively ranched cattle population. The reason lies in the potential inclusion of MBM in the cattle diet, MBM that could theoretically be contaminated with BSE. As the infective load of an infected cattle grows slowly over the incubation period, age at slaughter is important for the amount of BSE infected material entering the rendering (or, more precisely, the infective load of that material).
- **Risk factor 2:** The impact of im- or export of infected cattle on the number of infected animals alive is evident.
- **Risk factor 3 and 4:** Information on cattle feed and on the control of feeding cattle with mammalian (potentially bovine) protein is essential to assess the probability that the feed-back loop has been interrupted at this stage. Indication of feeding cattle with MBM must be seen as significantly risk enhancing.
- **Risk factor 5:** A well-implemented SRM-ban would reduce the amount of BSE-infectivity rendered and hence reduce the contamination of MBM with the BSE-agent. It would not be able to reduce it to zero.
- **Risk factor 6 and 8:** As described above an efficient surveillance and culling system would reduce the number of infected (and infective) cattle being slaughtered and has hence a risk reduction effect.
- **Risk factor 7:** The efficiency of the rendering system to eliminate the BSE-agent from the rendered material, or at least to reduce the BSE infectivity, is critical for the control of the BSE/cattle system. Information on the rendering processes applied and the compliance with rendering requirements able to at least reduce the BSE-load of MBM produced from contaminated raw material, is therefore highly important. The existence of insufficient rendering processes in a country is pointing towards a significant risk enhancement while a perfect rendering system would provide a good safeguard.

Risk assessment

The SSC-method for the assessment of the geographical risk is based on a qualitative factor-by-factor analysis to be carried out by independent experts. For each factor the experts will be asked to estimate for a given year its impact on the two most significant aspects of the BSE-risk: the propagation risk and the processing (incident) risk.
This method is qualitative in nature and based on expert judgement. Guidelines for the experts carrying out the assessment are provided in the "handbook" in annex.

The SSC has also developed a semi-quantitative methodology for assessing the processing risk. This method is described in annex 5 to the "handbook" and summarised in figure 5. It shall only be applied if sufficient data are available. If it can be applied it provides the expert with an additional input for his judgement.

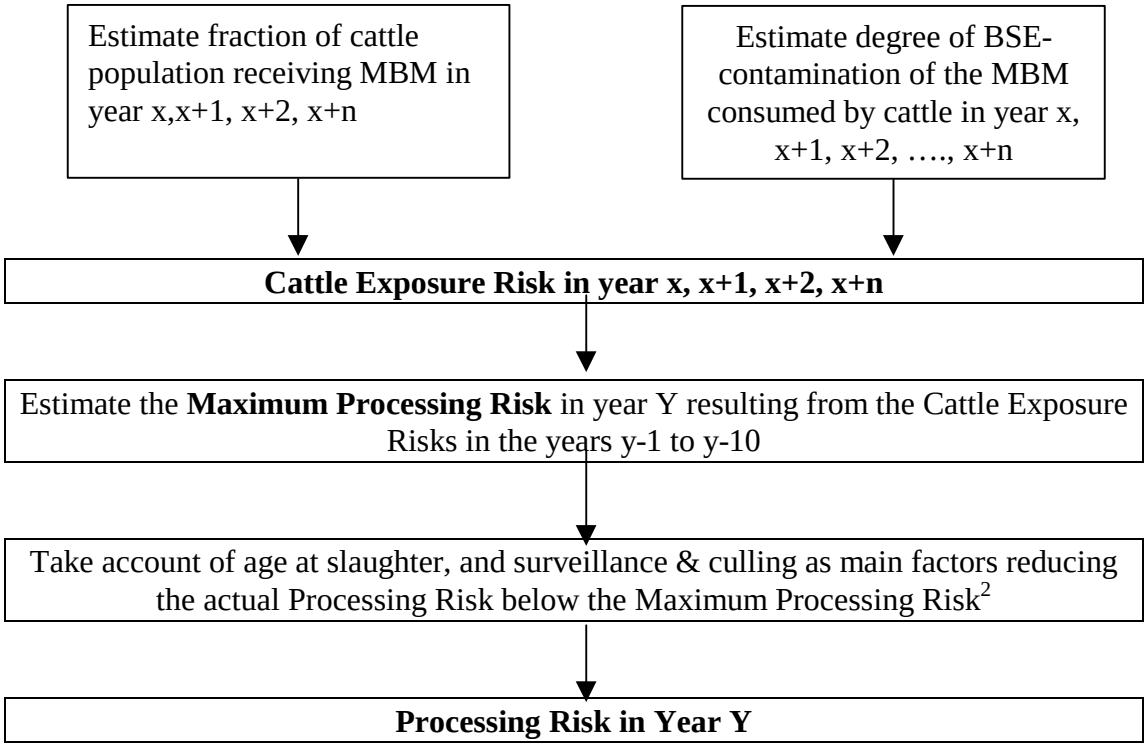

Figure 5 Semi-quantitative estimation of the Processing risk

Note: *The semi quantitative assessment is depending on appropriate quantitative data. It will only be used if the data-analysis has shown that the necessary, reliable data are available.*

[2] If a test able to detect BSE-infectivity before clinical symptoms would exist, its application could reduce the processing risk significantly.

The result of the factor-by-factor assessment can be converted into a graphic as shown in figure 6. If a semi-quantitative estimation of the processing risk was carried out, the result could be included into this graph, too.

Change of Risk indicators for the 8 SSC-Risk-Factors over time (here: impact on geo-BSE risk in general, integrating impact on propagation and processing risk)

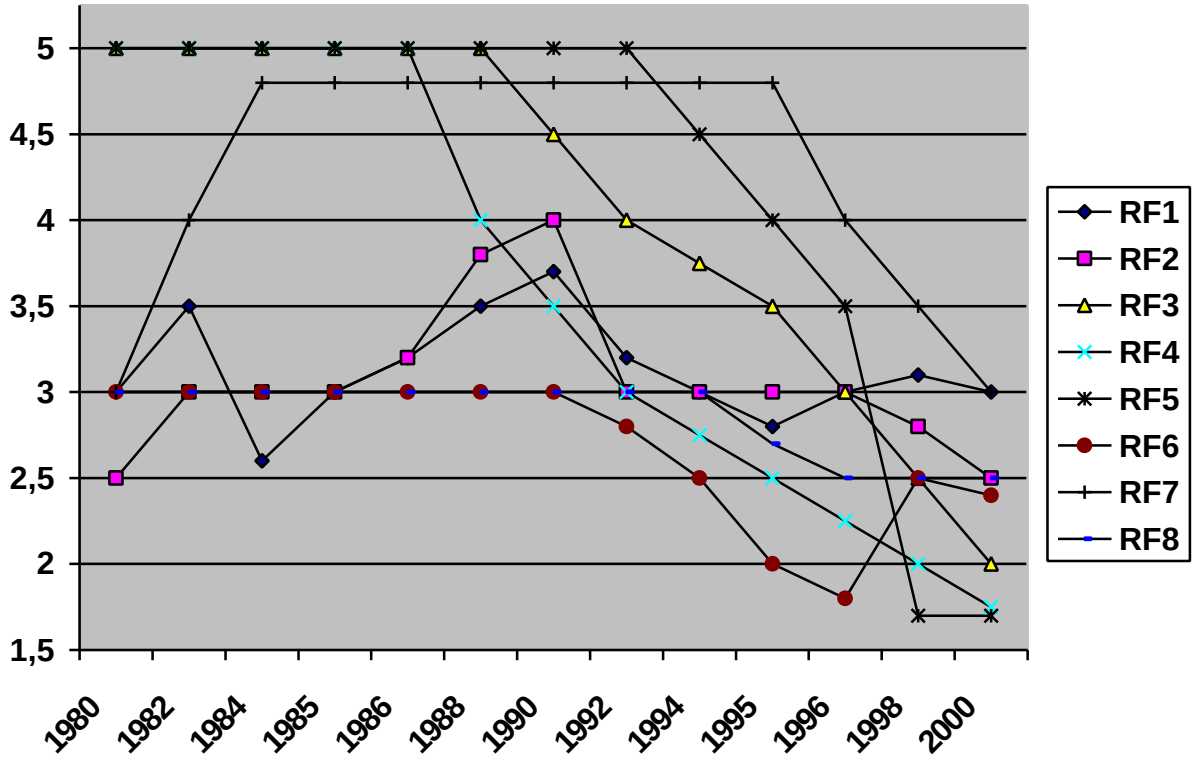

Figure 6: Hypothetical example of the development of risk Factors 1 to 8 over time.

The hypothetical example given in figure 6 shows that the rendering system (RF7) was first not enhancing the risk but then did so for a long period. The reason could be a shift to a system with lower BSE-reduction capacity (e.g. more gentle conditions than 133°C for 20 min and at 3 Bar). Around 1990 a slight improvement occurred but only after 2000 the system is expected to become satisfactory again. The figure also shows the animal feed factor (RF3). In the past feeding mammalian, including ruminant, MBM to cattle was common practice in this hypothetical example. Only since the late 80th this has changed and is now expected to have reached such low levels that it is in fact reducing the risk. It is also expected that this trend continue.

Based on the result of the factor-of-factor analysis (and the semi-quantitative processing risk estimation, if appropriate) the geographical BSE-risk has to be determined. Taking account of the historical trends of the risk factors and extrapolating their trends into the near future, the risk level has to be chosen. The SSC currently proposes four risk levels: A to D, A being the lowest, D the highest level of the geographical BSE-risk. Guidelines for estimating the risk level from the factor-by-factor assessment are still to be finalised but a first approach, leaving a large degree of freedom to the expert judgement, is described in the handbook.

The assessment process

In view of the importance of the data for the quality of the risk assessment, the exercise will start with a preparatory phase in which the country dossiers will be analysed and a standardised set of the most relevant data be prepared. For this phase the countries under question are invited to send informed representants who could clarify any aspect of the provided data. The Commission will also use own information, such as those gathered in missions to the countries by the FVO, to verify the information received. The result of this data analysis will be communicated to the experts who will carry out the assessment, and the countries concerned.

This risk assessment itself will be carried out as follows[3]: Three independent experts will evaluate each country dossier. Each of the experts will first carry out a complete evaluation without discussing with his fellow colleagues. Subsequently the three experts will meet, discuss their findings and produce a group report. This group report will be presented to the experts who in parallel assessed dossiers of other countries. After a thorough discussion, all experts together, i.e. those who worked through a country dossier and those who did other dossiers, will produce a consensus report which proposes a level for the geographical BSE-risk. During this discussion a member of the TSE/BSE ad-hoc group, a sub-structure of the SSC, will chair the assessment panel.

Current state and planning

The European Commission has recommended to member states and third countries to provide information on each of the eight risk factors identified by the SSC. Based on the information provided the epidemiological status with regard to TSEs could be evaluated: It has asked the SSC to provide an opinion on the BSE-status of countries that respond to the recommendation. At the moment of adoption of this opinion, 11 Member States have send in their dossiers, and 11 third countries as well.

As soon as its method for the assessment of the geographical BSE-risk is finalised, the SSC will start the evaluation of the epidemiological status of Member States and third countries by assessing their geographical BSE-risk, focussing on cattle. After this step it will try to prepare an opinion on the BSE-Status of these countries, taking into account the human exposure risk as well as risk management aspects, as proposed by the OIE. An opinion on the appropriate approach is in preparation.

Opinion:

The SSC is of the opinion that the attached "Handbook for assessing the Geographical BSE-Risk" describes appropriately the approach to geographical BSE-Risk assessment and provides guidelines for independent experts to estimate the geographical BSE-Risk on the basis of dossiers provided by the countries. It also appropriately describes the overall process.

Being aware of the importance of the matter, the SSC invites all interested parties to comment on the "Handbook" before 15 January 1999 in order to allow the SSC to adopt a final opinion on a method for assessing the geographical BSE-Risk at its meeting on 21/22 January 1999.

[3] See Handbook, p. 10-16, for details

HANDBOOK

FOR THE ASSESSMENT

OF THE

GEOGRAPHICAL BSE-RISK

VERSION 14

FINALISED: 18/12/98

IMPORTANT NOTE

This handbook describes only a method for the assessment of the geographical BSE-risk.

The method to be used for the BSE-Status definition will be defined in a separate document and adopted by the SSC as a separate opinion. In addition to the geographical BSE-risk it will take account of the Human Exposure Risk and of risk management measures and their implementation.

INTRODUCTION

The purpose of this "Handbook" is to describe the method that the SSC uses for assessing the geographical BSE-risk and to provide guidelines for the independent experts that will be asked to carry out that assessment.

The intention is, on the one hand, to make the method transparent to interested parties, and, on the other hand, to ensure that all assessments are carried out in a consistent way and their results are comparable.

For the time being the method only addresses the BSE-risk in cattle[4]. It is also based on the assumption that the country or region in question will provide information in accordance with the recommendation of the Commission of 22/7/1998[5] (see annex 01).

Foreword

In an attempt to manage the BSE risk, the European Commission has invited Member States and third Countries to provide information that would allow appraisal of their epidemiological status with regard to TSEs.

The SSC, advising the Commission on assessing the **geographical BSE-risk,** has delivered an opinion on "defining the BSE risk for specified geographical areas". In this opinion it identified three interlinked risks appearing to be of major importance:

Incident risk, defined as the probability that, within a given time period, an infectious animal (or material thereof) enters the food and/or feed chain, e.g. is processed either in a slaughterhouse or directly in a rendering plant with a view to be used as food or feed.

Note: The incident risk should not be confused with incidence. In order to avoid confusion with the commonly used definition of "incidence" (rate of occurrence of confirmed cases over a defined time), the term "incident risk" is replaced hereunder by "**processing risk**".

Propagation risk, defined as the probability that an initial infection is propagated within the animal population of a given region and within a given time period.

Human exposure risk, defined as the probability that a human being is exposed to an infective dose of the BSE agent, within a given time period. It is worth noting that the **human exposure risk** within a geographical area is strongly influenced by the processing and propagation risks in that area but also by other factors which are not confined to the limits of that specific geographical area. The human exposure risk is not further discussed in this handbook.

The SSC further defines the "**geographical risk**" as integrating the **processing risk** and the **propagation risk** in a given geographical area. A geographical BSE-risk

[4] If BSE would be confirmed in small ruminants (sheep and goats), a similar approach should be developed for assessing that risk. That approach would have to take into account the particularities of each species.

[5] Incomplete or insufficient information will be completed by information from other sources and/or, for the purpose of this risk assessment, worst case assumptions. As far as possible the information provided will be verified.

which is higher than negligible would indicate a higher than negligible probability that now, or in the near future, BSE-infective cattle would be slaughtered and "normally" processed.

> *Note:* The resulting exposure of consumers to the BSE-agent can currently not be quantified, nor is it possible to assess the relevance of this exposure in terms of infection. However, it seems to be appropriate to propose that measures to reduce the human exposure risk should be taken.

In its opinion on defining the BSE risk (23/01/98) the SSC established a list of factors contributing to the incident and propagation risk in geographical areas. In its opinion on the contents of a "complete dossier of the epidemiological status with respect to TSEs" (20/2/98), the SSC has identified the "ideal set of information" relating to eight factors and 38 sub-factors on which basis the TSE-status could be determined. On 22/7/98[6] the Commission invited Member States and third countries to provide information on these 8 factors and 40 sub-factors. The Commission now receives country dossiers and the SSC is asked to carry out an assessment of the geographical BSE-risk of these countries as a basis for defining the epidemiological status of a country or region with regard to BSE.

Assessing the geographical BSE-risk

On the basis of available information it is impossible to exactly quantify the probability of BSE-infective cattle entering the food (and feed) chain in a given country and at a given time.

It will, however, be possible to estimate the order of magnitude of that geographical BSE-risk. The SSC therefore proposes to estimate a "**geographical risk indicator**" which points to the current and future probability of BSE-infective cattle entering the food (and feed) chain in a given country.

> *Note:* In this context it is essential to realise that the **geographical risk indicator** does not directly represent the BSE-Status of a geographical area. That BSE-Status depends also of the risk management measures in force.

The geographical BSE-risk indicator depends of the processing risk and the propagation risk (see definition above). The general approach is therefore to assess the development of the propagation and processing risk over a relevant period of time and to conclude from that on the geographical BSE-risk.

Estimating the propagation risk.

The **propagation risk** is defined as the probability that an initial infection is propagated within the concerned animal population of a given region and within a given time period.

For the propagation risk, the most important factor is the exposure of ruminants to the BSE-agent via contaminated MBM, because this is regarded to be the by-far most significant transfer-vector.

> *Note:* Currently only one other transfer vector is regarded to be likely, the maternal transmission. However, this event is felt to be rather exceptional and may, in a first instance be ignored as long as no incidence of BSE is found. Once this is the case,

[6] OJ L 212 of 30.07.98, p.58ff, (doc. N° C(1998) 2268)

maternal transmission becomes an issue, mainly for offspring of dams who developed BSE-symptoms within 6 months after birth. A good surveillance and monitoring system should hence be able to trace offspring of BSE cases. Other postulated transfer vectors, such as bovine-derived vaccines, or horizontal transmission, are felt to be speculative and rather insignificant.

Given that the main propagation route is the exposure of cattle to BSE-contaminated MBM, the probability, that such an exposure took place, the cattle exposure risk (CER), can be used as an indicator for the propagation risk.

To assess the propagation risk in a given year the following question has to be answered:

What was the probability that cattle have been exposed to BSE through feed (MBM)?

This requires answering many sub-questions, including:

Did cattle receive feed containing MBM? Which type of cattle received how much of it? At which age? How long before slaughter? If MBM was fed to cattle, how likely was it that that MBM was prepared from ruminants? How likely was it that that MBM was contaminated with BSE? Which potential sources can be identified? If home made MBM from ruminants was fed to ruminants, how good was the capacity of the rendering system to reduce BSE-infectivity? If imported MBM was fed to ruminants, how safe were the sources? Etc.

Method for assessing the propagation risk

To assess the propagation risk three different approaches have been discussed by the SSC.

(a) Quantitative assessment

In epidemiology R_0 is defined as the propagation ratio, i.e. the number of cases that could result from one case of a disease. In the case of BSE, R_0 can be regarded as an indicator of the inherent capability of the cattle/BSE-system of a country or region to either eliminate any BSE-infectivity entering it or to amplify an initial infection. A system with the latter characteristics would hence be vulnerable to any source of BSE, be it in internal or imported.

A mathematical model has been developed for the calculation of R_0 of BSE. It is, however, not yet published in a peer reviewed scientific journal and can therefore not be used for estimating R_0 for countries applying for a BSE-Status. A stochastic simulation model, applying the same approach, is also under development but not yet fully operational.

Independent from the current usability of the model it has to be underlined that such an approach would allow a certain quantification of the propagation risk which would at least be helpful for comparing the situation in different countries. Because of the ability of such kind of models to handle rather complex interaction they could become very useful tools. Work on the models continues and they may be integrated into the risk assessment at a later stage.

(b) Semi-quantitative assessment of the cattle exposure risk as indicator for the propagation risk.

The cattle exposure risk (CER) is defined as the probability that cattle are exposed to infective doses of the BSE agent, within a given time period.

Currently the infective dose of BSE for cattle is not known, the effect of cumulative small doses is not clear and the infective load of potentially contaminated cattle feed is not understood. It is therefore necessary to define the cattle exposure risk as the probability that an exposure of cattle to any amount of the BSE-agent took place. This risk increases if more cattle are exposed to MBM and if the contamination of that MBM with BSE increases.

For the purpose of assessing the cattle exposure risk it is therefore necessary to estimate the fraction of the cattle population which, in a given period, has been exposed to potentially BSE-contaminated feed and to estimate the degree of contamination of this feed. From these two parameters an indicator for the CER is derived which is "0" if the risk is negligible and 10 if the risk is highest. As far as possible this indicator should be estimated on an annual basis. It is also appropriate to estimate this value for three cattle sub-population: beef-cattle (normally slaughtered with less than 30 months), young dairy cattle (up to 24 months old and normally kept alive until 5 or more years of age), adult dairy cattle (>24 months old).

The SSC proposes that, if the data provided by the applying country permit, the Cattle Exposure Risk (CER) would be estimated for each year since 1985. A detailed description of the assessment methodology is given in annex 4 to this handbook.

c) Qualitative assessment

Based on the eight factors identified by the SSC as key-factors for the geographical risk (i.e. the processing and the propagation risk) a qualitative assessment of the propagation risk is possible. Independent experts should be asked to assess for each of the 8 factors (40 sub-factors) if, in a given year, that factor increases of decreases the propagation risk, or has no influence. (The latter is possible because some factors/sub-factors are only relevant for the processing risk.)

A numeric scale from 1 to 5 should be used as indicator of the impact:

- 1 = very positive impact which could trigger a significant reduction of the risk;
- 2 = positive impact which could trigger some reduction of the risk;
- 3 = no impact on the risk;
- 4 = negative impact which could trigger some increase of the risk;
- 5 = very negative impact which could trigger a strong increase of the risk.

In the view of the SSC this is the backbone of the risk assessment because the data for a detailed quantitative (or semi-quantitative) risk assessment are still to scattered and incomplete, as is the understanding of the factors driving the propagation of the disease.

A description of the qualitative risk assessment is given in annex 3 to this handbook.

Estimating the processing risk

The processing risk is defined as the probability that in a given year an animal, which is carrying significant amounts of the BSE-agent, is processed (slaughtering for human consumption or rendering for feed production).

> *Note*: A precise definition of a significant amount of BSE is currently not possible. But, for the purposes of this risk assessment, it is assumed that the infective load of an infected animal increases with time after initial infection and that this increase follows an exponential curve. From the pathogenesis experiments in the UK it is known that 4 months after oral challenge infectivity was only found in the distal ileum. Infectivity in other organs (CNS and DRG) where only found 32 months after challenge. The infective titter in the CNS where significant higher than in the distal ileum. This allows assuming that only animals living long enough after initial infection will reach "significant" levels of BSE-load. As a conservative orientation one might assume that a "significant" level of BSE infectivity is not reached before two years after initial infection.

The current processing risk is a function of the past exposure of cattle to the BSE-agent. Assuming that each cattle that was exposed to the BSE-agent will sooner or later develop BSE[7], the current processing risk will be proportional to the cattle exposure risk in the past. Because of the long incubation period of BSE it is important for the assessment of the current processing risk, and for forecasting the future processing risk, to take account of the cattle exposure risk for the last 8 to 10 years.

For assessing the processing risk in a given year the following question has to be answered:

> ***How likely is it that in a given year BSE-infected cattle are slaughtered or rendered*?**

This requires responding to many sub-questions, including

> **What was the cattle exposure risk in the last 10 years? How high is the resulting maximum possible processing risk? Is it likely that the processing risk was reduced below that theoretically possible maximum, e.g. because many exposed animals have been slaughtered before building up any "significant" BSE-load? Etc.**

Method for assessing the processing risk

To assess the processing risk two different approaches have been discussed by the SSC:

a) A semi-quantitative approach

The semi-quantitative approach to assessing the processing risk is based on the following assumptions:

- The probability of an infective cattle being processed is proportional to the exposure of cattle to the BSE-agent in the past.
- Hence the processing risk is proportional to the cattle exposure risk (see above) in the past.

[7] It is understood that this is a conservative assumption. It is justified by the lack of confirmed information of the infectivity of (repeated) small doses of BSE-contaminated material.

- For estimating the processing risk it is assumed that a given CER would result in a maximum processing risk (MPR) five years later, because five years is the mean incubation period.
- For illustrating the proportionality it is proposed to assume that the value used to indicate MPR five years after exposure is equal to the value used to indicate the CER five years before.
- Given the variation of the incubation period around 5 years, the MPR will vary in a similar way, i.e. being smaller before and after the 5 years peak.
- By summing-up the MPR resulting from the CER in the preceding " 3 to 10 years an indicator for the MPR can be established.
- The indicator for the CER varies between 0 (no risk) an 10 (highest risk)
- The MPR, therefore, varies between 0 (no risk) and 30 (highest risk).

This MPR is a theoretical upper limit. The real processing risk (PR) will normally be below this. Reasons for that difference include:

- slaughtering of potentially infected animals before they could carry a "significant" infective load (e.g. younger than 2 years),
- good surveillance (including compulsory notification and appropriate compensation/penalty schemes) in combination with destruction of suspect cases and appropriate culling of related animals (herd and/or cohort).

In annex 4 to this handbook the method for estimating the CER and the MPR is described. The method includes guidelines for taking account of parameters likely to reduce PR below the MPR. However, the semi-quantitative assessment of the processing risk depends on the data availability and shall only be used additionally to the qualitative approach, described hereunder. In any case it will only provide an additional risk-indicator, not a quantitative measure for the processing risk.

b) A qualitative approach.

Based on the eight factors identified by the SSC as key-factors for the geographical risk (i.e. the processing and the propagation risk) a qualitative assessment of the processing risk is possible. Experts can assess for each factor (and sub-factor) its impact on the processing risk in a given country and at a given time.

A numeric scale from 1 to 5 should be used as indicator of the impact:

- 1 = very positive impact which could trigger a significant reduction of the risk;
- 2 = positive impact which could trigger some reduction of the risk;
- 3 = no impact on the risk;
- 4 = negative impact which could trigger some increase of the risk;
- 5 = very negative impact which could trigger a strong increase of the risk.

In the view of the SSC this is the backbone of the risk assessment because the data for a detailed quantitative or semi-quantitative risk assessment are still to scattered and incomplete.

A description of the qualitative risk assessment is given in annex 3 to this handbook.

Estimating the level of the geographical BSE-risk on the basis of the propagation and processing risk.

The geographical BSE-risk level has to be estimated on the basis of the propagation risk and the processing risk. In order to take account of the development of these risks over time the evaluators will plot an indicator for each of these risks over time, covering the period since 1985 and extrapolating until 2003. This indicator may vary between 0 (no risk of propagation the disease/of processing BSE-infected material) and 10 (maximum risk). The relative value has to be determined for each year on the basis of the risk-impact assumed for the 8 risk factors in the given year.

If a semi-quantitative estimation was possible, the results should also be plotted. Normally, the risk pattern should be similar to the pattern derived from the qualitative factor-by-factor assessment. If this is not the case the evaluators should identify the reason for the deviation and decide which pattern should finally be assumed.

Taking into account the overall pattern of the propagation and processing risk for the last 10 years as well as their forecasted development in the next years, the evaluators are requested to decide if they regard the Geographical BSE-Risk level to be at level A, B, C, or D, A being the lowest possible risk, D the highest.

For doing so the following definitions of the geographical BSE-risk levels are given:

Level of GBR	Definition (open for comments)
A	The probability that at present an animal is processed which harbours a "significant" load of BSE is regarded to be close to zero. Assuming that external factors do not prevent this and that the current parameters remain stable, the same is forecasted for the near future. If either the processing or the propagation risk indicator point towards a low risk, appropriate measures must be in place to set the GRI to "negligible".
B	The probability that at present an animal is processed which harbours a "significant" load of BSE is regarded to be larger than zero but still low. Assuming that external factors do not prevent this and that the current parameters remain stable, the same is forecasted for the near future. If either the processing or the propagation risk indicator point towards a medium risk, appropriate measures must be in place to set the GRI to low. The GIR might be set to low if one of the risk factors is negligible but showing trend towards an increasing risk.
C	The probability that at present an animal is processed which harbours a "significant" load of BSE is regarded to be larger than low but not high. Assuming that external factors do not prevent this and that the current parameters remain stable, the same is forecasted for the near future. If either the processing or the propagation risk indicator point towards a high risk, appropriate measures must be in place to set the GRI to medium. The GRI might be set to medium if one of the risk factors is low but showing a trend towards an increasing risk.
D	The probability that at present an animal is processed which harbours a "significant" load of BSE is regarded to be high. Assuming that external factors do not change this and that the current parameters remain stable, the same is forecasted for the near future. If either the processing or the propagation risk indicator points towards a medium risk and appropriate measures are not in place, the GRI might be set to high. This might also be the case if one of the risk factors is medium but showing a trend towards a higher risk.

Finally the experts are asked to justify their opinion in an assessment report, by discussing briefly each of the 8 risk factors. Annex 4 contains an example for such an assessment report and provides an outline of its structure.

Organisational aspects of the risk assessment procedure

Overview

- **Preparation**

1. With the help of external experts the Commission will analyse the dossiers provided by the country and establish a standardised data set for each country (see annex 2). Gaps in the documentation will be closed by information readily available to the Commission or the experts. Whenever this is not possible worst case (but realistic) assumptions will be used. The countries will be invited to nominate an expert to assist in the preparation of the standardised data set. If not otherwise possible, countries may be asked to provide additional information.

   Note: The first round of this preparation of standardised data sets is foreseen for the second week in January 1999.

2. The countries will receive a copy of their data set together with this handbook, prior to the risk assessment. They may comment and provide additional information as deemed appropriate.

   Note: After the first round of preparation of standardised data sets there will be about 7 weeks until the first risk-assessment exercise because the methodology will not be finalised before 19 February 1999.

3. Independent experts will be selected from a list established by the SSC and taking account of pre-defined selection criteria. They will be invited to participate in a risk-assessment exercise. All experts will be invited on a strictly personal basis, not as representants of any country, organisation or institution.

   Note: A list of experts is already existing, as well as criteria for selecting from this list. Additional names are still welcome but the invitations have to be sent out before the end of the year.

4. In parallel the countries, which are to be assessed, will be informed and invited to nominate a "country-expert". This country-expert will be invited to be available during the risk assessment in order to clarify points for the independent experts.

- **The risk assessment procedure**

  Note: The first risk assessment exercise is currently scheduled for as soon as possible after the SSC meeting on 18/19 February 1999, where the final opinion on the risk assessment method (the handbook) is planned to be adopted.

1. The "assessment panel", i.e. all independent external experts participating in the risk assessment exercise, will be briefed on their task. This briefing has the aim to ensure that the approach of all experts is as compatible as possible. This handbook forms the basis of the briefing.

2. The evaluators will receive copies of the country dossiers and the standardised data set. Working independently from each other they are asked to arrive at a conclusion as to the geographical BSE-risk level for each of the countries allocated to them. They are asked to summarise their assessment in an assessment report. Three independent external experts will assess each dossier.
3. The three experts who assessed the same dossier will meet as a group and discuss their findings with the aim to draft a consensus report summarising the analysis and conclusion of the group:

- Throughout step 1 to 3 Commission experts and an expert seconded by the country in question will be available to support the external experts upon request.
- Access to special expertise in TSE will be provided upon request.
- As a matter of principle none of the independent external experts will come from the country under assessment.
- If no consensus can be reached, the minority position (including detailed justification) will be transferred to the assessment panel together with the majority position.

4. Under the chairmanship of a member of the TSE/BSE ad-hoc group the risk assessment is concluded by a joint discussion of the entire "assessment panel". Each group presents briefly their consensus reports (and, if necessary their minority position) and defends their conclusion. The assessment panel will discuss each assessment with regard to the approach taken by the group or individual expert. This discussion should lead to finalised assessment reports for each country, which normally should represent the consensus of the entire assessment panel. These reports have to specify the level of the geographical BSE-risk which is assumed for a given country (or region) and a summary of the reasons for this. The report should not contain numerical indices in order to avoid misinterpretations. The report will serve as the basis for the definition of a BSE-status for a given country.

   Note:
   If the group or the assessment panel can reach no consensus, the minority opinion shall be recorded, including the arguments for it. In case of deadlock, the majority of the group of experts who read the dossier decides. The chairman may not vote. The TSE/BSE ad-hoc group (including the chairman of the assessment panel) will propose to the SSC which opinion should be followed.

Note on BSE-Status definition

The method to be used for the definition of the BSE-Status will be defined in a separate document and adopted by the SSC as a separate opinion. In addition to the geographical BSE-risk it will take account of the Human Exposure Risk and of risk management measures and their implementation, as proposed by the OIE..

Detailed description of the different steps of the risk assessment

Step 1 - Preparation

Task: Establishing a standardised data set on the basis of the dossier established by the country/region and other information sources available to the Commission or in the public domain.

Participants, input, tools, output:

- **External experts, Commission experts and Country-experts.**
- **Country dossier, mission reports from FVO, ather publicly available data sources.**
- **Use forms in annex 1 and 2**
- **Output: Standardised data-set and information on validity of data. Countries informed of the result and invited to comment before the appraisal.**

The experts shall verify if the information provided is complete. The completeness of the dossier is recorded by completing the table in annex 1.

The experts will then try to establish a standardised data set (annex 2) for each country.

By using other information sources being available to the Commission or in the public domain (e.g. FAO, EUROSTAT, OIE, etc.) gaps identified should be closed. If this is not possible reasoned interpolation should be used or realistic "worst-case" assumption have to be made.

Any information used in addition to the country dossier has to be documented and added to the original dossier for future reference. Any assumption or interpolation has to be explained and must be added to the evaluation dossier together with its explanation.

The country will receive a complete copy of the standardised data set together with the additional data used and the explanation for all assumptions and interpolations made. It may comment before the appraisal itself starts.

Step 2: Risk Assessment - Qualitative factor by factor assessment.

- **Independent external experts work separately from each other.**
- **Commission and country-expert may be requested to clarify points.**
- **Country dossier, output from step 1.**
- **Use forms in annex 3.**
- **Output: Development of the risk impact of each risk factor over the period 1985 to 2003, table and plot**

For each factor, which the SSC has identified as being relevant for the geographical risk, each individual evaluator has to assign a risk value representing the assumed overall contribution of this factor to the propagation risk on the one hand and the processing risk on the other. The estimation of the risk values is to be based on the country dossier and the standardised data set. A set of tables is provided which provides guidelines for assessing each factor. These guidelines are not meant as fixed rules but as orientations for the expert judgement. They shall ensure that all experts follow the same approach. As far as possible the experts should establish a risk factor

for each year but at least the following periods should be looked at separately: 1985-1989, 1990-1993, 1994-1995, 1996-1998.

For each of the eight major risk factors its contribution to the two risks (propagation and processing risk) shall be estimated and noted in the tables and plotted against time on the empty charts included in annex 3.

Based on the assumed impact of each of the eight risk factors on the propagation and/or processing risk the experts have to estimate the level of each of these two risks on an annual basis. The scale on which the estimated risk level is to be noted ranges between 0 (no risk) and 10 (highest possible risk).

Step 2a: Risk Assessment – semi-quantitative assessment of the cattle exposure risk (CER) and the resulting processing risk (PR)

- **ONLY IF THE AVAILABLE DATA PERMIT A SEMI-QUANTITATIVE APPROACH**
- **Independent external experts work separately from each other.**
- **Commission and country expert may be requested to clarify points.**
- **Country dossier, output from step 1.**
- **Use guidelines given in annex 5 and, if available, spreadsheet model for calculating MPR.**
- **Output: Estimation of Cattle Exposure Risk and Processing Risk on an annual basis from 1985 to 2003 (table, graphic)**

Starting from the standardised data set the experts will estimate the CER and calculate the related MPR (Maximum Processing Risk). They will estimate the impact of factors that would reduce the Processing Risk (PR) below the theoretical maximum. By this way they will determine for each year, or the periods mentioned above, the CER and the actual PR, which should be plotted against time as for the qualitative factor-by-factor assessment.

Annex 5 to this handbook contains guidelines for this process. For calculating the maximum processing risk a spreadsheet model may be developed.

Step 3: Risk assessment - Estimating the geographical BSE-risk level

- **Independent external experts work separately from each other.**
- **Commission and country expert not involved.**
- **Output from step 2a and, if available 2b.**
- **Use guidelines in annex 4 for drafting the assessment report.**
- **Output: Estimation by the individual experts of the level of the geographical BSE-Risk.**

Each expert has to estimate by himself, without prior discussion with the other members of his/her group, the **level of the geographical BSE-risk** of the country/region under consideration.

If available she/he uses, in addition to the results of the factor-by-factor assessment, the results from the semi-quantitative estimation of the CER and PR over the period 1985 to 2003. Based on these results he/she decides on the appropriate level of the

geographical BSE-risk. Her/his conclusion is described and justified in an assessment report, following the outline and example given in annex 4.

Note: it might be appropriate to provide stricter guidelines for the transition from propagation and processing risk to geographical BSE-risk. Comments on this are invited.

Step 6: Risk assessment - preparation of a group assessment report.

- **Independent external experts work together as group.**
- **Commission and country expert not involved.**
- **Output of step 3, if needed also country report and output of step 1.**
- **Use guidelines in annex 4.**
- **Output: Group assessment report, including, if necessary, a minority opinion.**

The experts who analysed the same dossier meet and establish jointly an assessment report (for the structure and presentation, see annex 4). The evaluators are asked to discuss the points of differences between them and to come to a common position. The report is drafted by one of the members of the group and signed by all members. If no consensus can be reached, the minority position has to be spelt out clearly, together with the argumentation. It must be signed by the minority expert.

Step 7: Risk assessment – preparation of the final assessment report

- **All independent external experts together under the chairmanship of a member of TSE/BSE ad-hoc group.**
- **Commission and country expert not involved.**
- **Output of step 6, if necessary country dossiers and output of step 1.**
- **Use guidelines in annex 4.**
- **Output: Final assessment report, if required including minority opinion(s).**

The entire assessment panel, i.e. all experts, meet under the chairmanship of a member of the TSE/BSE ad-hoc group. Each assessment report is presented and discussed with a view to ensure a common general approach throughout all assessments. Particular emphasis should be put on assumptions and judgements made. All deviations from the guidelines in the handbook and its annexes must be justified.

Once all assessment reports are discussed, and if necessary modified, the assessment panel will adopt the final assessment reports for all countries discussed.

These reports will be drafted by one member of the assessment panel and signed by all members of the assessment panel.

If no consensus can be reached, the minority opinion has to be spelt out clearly, together with the argumentation. The supporting experts shall sign it.

The final assessment report defines an appropriate geographical risk indicator but also provides a justification, based on a qualitative discussion of each of the eight risk factors defined by the SSC.

The adopted final assessment report is transferred to the TSE/BSE ad-hoc group for further consideration. It includes, if unavoidable, the minority position(s).

List of Annexes

Annex 01: Recommendation of the Commission

Annex 1: Completeness checklist.

The checklist provides an overview of the information provided by the country. It also helps identifying gaps in the information and allows noting down how they where closed. This information must be provided to the expert assessors and should be summarised in the final assessment report.

Annex 2: Standardised data set

This annex contains a set of tables that should be completed on the basis of the country dossier and additional sources, as needed. For guidance default values are given where possible. They should be used whenever the available data do not allow other assumptions. The standardised data set will be provided to the experts for assisting them in their qualitative assessment. If possible, the data set will provide the basis for the semi-quantitative and quantitative assessment. The standardised data set will be transferred to the country/region under consideration for eventual comments.

Annex 3 –Guidelines for the qualitative factor-by factor assessment of the propagation and processing risk.

The tables in annex 3 ensure that each factor is appropriately taken into account as far as its impact on the propagation and processing risk is concerned.

Guidelines are provided as orientation for the expert's estimation of the potential contribution of each factor to the risk. For ease of comparison a numeric scale is used from +5 (very significant risk enhancement) to 1 (very significant risk reduction), +3 being the neutral value. For each factor the range of possible values is given. In certain cases, where the impact could not be significant, the range may be limited. In other instances a factor may increase a given risk but can not decrease it, or vice-versa. In those cases the scale runs from 1 to 3 or 3 to 5 but does not allow inverse impacts.

For the qualitative risk assessment the impact of each factor on the respective risk is to be estimated, as far as possible on an annual basis. The resulting development of that impact over time should be plotted against time. This pattern will be an important input to the overall risk assessment.

The combined impact of all risk factors will lead to an assumed level of the propagation risk and the processing risk. Using a scale between 0 (no risk) and 10 (highest possible risk), that level can be plotted over time, if possible on an annual basis.

Annex 4 – Example of an assessment report for a hypothetical country.

This annex provides the expert with an example for an assessment report. Guidelines for the experts are given as well as examples for the kind of information expected under each point of the report.

The objective of this annex is to ensure that all reports follow the same structure and logic and provide the same information as basis for, and justification of, the level of the geographical BSE-risk finally assumed for a given country or region.

- The final assessment report has to be formulated in a qualitative way without using numeric indicators to describe the level of risk. This is requested in order to avoid miss using of indicator values for arithmetic calculations.
- It is essential that the report clearly states the level of geographical BSE-risk and the scientific justification of this statement.

Annex 5 – Guidelines for semi-quantitatively estimating the Cattle Exposure Risk (CER) and the Processing Risk (PR)

This annex describes the procedure for the semi-quantitative estimation of the CER and the PR. Fed with identical data it ideally should always produce largely the same result.

The cattle exposure risk shall be estimated from the consumption of MBM by cattle and the possible degree of contamination with BSE. Orientations are given as to how these parameters should be estimated and how a value for the CER can be derived from this estimation. Several, more or less arbitrary, relationships are defined in order to avoid strong variation of the expert opinions[8]. As far as possible these assumptions are based on current scientific knowledge.

The maximum processing risk (MPR) is depending on the accumulated cattle exposure risk during the last 10 years (twice the average incubation time for BSE in cattle). Measures taken to control BSE may reduce the actual PR below this maximum-PR. A correlation matrix is given which allows allocating an indicator-value for the MPR in a given year to the CER in one of the 1 to 10 years before. By simply adding up these $MPRs_{(1\text{-}10)}$ a value for the theoretically possible maximum PR is derived. By reducing this MPR-value in relation to risk management measures taken during the previous 10 years (or longer), an estimation is generated for the processing risk in a given year.

Note: It is important to understand that this value is not equivalent to the probability that in a given year one or several BSE-infected cattle would be slaughtered. PR is to be interpreted as an indicator, pointing to a certain risk level. To quantify the probability, e.g. in %, much more complicated calculations would be needed. It is highly unlikely that the necessary data are available and no consistent model of the multidimensional interaction of the various parameters is yet developed. The PR – value generated by the described semi-quantitative method will, however, allow to

[8] These assumed relationships could be modified if convincing arguments can be provided to do so. The basic methodology would not be changed by this. The current set of assumptions has been established on the basis of available scientific knowledge and with a view to remain practical in comparison to the provided data.

compare the risk situation in different years (and between different countries) and to verify its trend over time.

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ANNEX 01

Recommendation of the Commission

COMMISSION RECOMMENDATION
of 22 July 1998
concerning information necessary to support applications for the evaluation of the epidemiological status of countries with respect to transmissible spongiform encephalopathies.

(notified under document number C(1998) 2268)
(Text with EEA relevance)
(98/477/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 155 thereof,

1. Whereas new information has been published in the United Kingdom further supporting the hypothesis that exposure to the bovine spongiform encephalopathy (BSE) agent is linked to the new variant of Creutzfeldt Jacob disease in humans; whereas on 16 September 1997 the Spongiform Encephalopathy Advisory Committee of the United Kingdom concluded that recent research provided compelling new evidence that the agent which causes BSE is identical to the agent which causes the new variant of CJD in humans; whereas on 18 September 1997 the Advisory Committee on Dangerous Pathogens concluded that the BSE agent should now be classified as a human pathogen; whereas on 26 November 1997 the Commission adopted Directive 97/65/EC which classified the BSE and other animal TSE agents in the same group of risk as the human pathogen causing CJD;

2. Whereas the Council on 31 March 1998 invited the Commission to submit an appropriate proposal in the field of specified risk material after the conclusions of the World Organisation for Animal Health (OIE) session in May 1998; whereas the Commission reconfirmed its intention to elaborate a wider Community proposal on the basis of Article 100A, involving both the Council and the European Parliament; whereas Chapter 3.2.13 of the OIE code on BSE recommends to take account of the epidemiological status when importing from a country or a zone;

3. Whereas a risk assessment based on accepted scientific methodology may show that there is a significantly higher risk of exposure of animals or humans to transmissible spongiform encephalopathies (TSEs) in certain countries; whereas a thorough epidemiological evaluation conducted to common standards through a Community procedure will give the necessary information about the status of each country;

4. Whereas the Scientific Steering Committee (SSC), in its opinion of 23 January 1998, has established the list of factors determining the geographical risk in a given geographical zone; whereas the SSC, in its opinion of 19 and 20 February 1998, has established the contents of a complete dossier of epidemiological status with respect to TSEs;

5. Whereas the task of countries in preparing an application for recognition of the epidemiological status of countries with respect to TSEs will be facilitated when information is presented according to the above scientific opinion; whereas the evaluation of those applications will be facilitated when such data are presented according to the above scientific opinion;

6. Whereas the Commission will base its approach concerning the epidemiological status on the opinion of the SSC; whereas, therefore, the Commission encourages countries to submit a dossier according to this recommendation,

HEREBY RECOMMENDS THAT:

1. Member States are invited to submit as soon as possible, and preferably before 1 October 1998, an application for recognition of their epidemiological status with respect to TSEs, in at least one of the official languages of the Community.

2. Member States should ensure that supporting documents accompanying the application are prepared and presented in accordance with the recommendations set out in the Annex.

3. All the applications and requests for additional information should be addressed to:

European Commission
Directorate-General for Consumer Policy and Consumer Health Protection
DG XXIV/B.1,
Rue de la Loi/Wetstraat 200,
B-1049 Brussels.
Tel. (32-2)295 39 62, fax (32-2)299 63 01,
e-mail: tse-status@dg24.cec.be

4. The possibilities foreseen by this recommendation shall also be open to non-member countries.

5. The Commission services will ensure evaluation of the dossiers and will ask the Scientific Steering Committee to give an opinion on all applications.

For the Commission
Franz FISCHLER
Member of the Commission

ANNEX
Information to be submitted in support of an application for recognition of epidemiological status

All data must be provided on an annual basis and preferably from 1980 onwards, but at least from 1988.

Applicant States must make every effort to provide comprehensive and consistent information. Data, which are not provided or are regarded as incomplete or as unsatisfactory, may have to be replaced by worst-case assumption for the purposes of a risk assessment.

Information must be provided on:

1. Structure and dynamics of the bovine, ovine and caprine animal populations

(a) absolute numbers of animals per species and breed, alive and at time of slaughter
(b) age distributions of animals per species and breed, sex and type;
(c) age distribution of animals per species and breed, sex and type at time of slaughter;
(d) geographical distribution of the animals by species and breeds;
(e) geographical distribution of the animals by husbandry systems, herd sizes and production purposes;
(f) system of identification and capacities for tracing of animals.

2. Animal trade

(a) imports and exports;
(b) trade within the geographical area;
(c) imports of embryos and semen;
(d) use made of imported animals, embryos or semen;
(e) mechanisms used by slaughterhouses to identify animals and their origins, as well as data from these procedures.

3. Animal feed

(a) domestic production of meat and bone meal (MBM), and its use per species and husbandry system (in particular the proportion of the domestically produced MBM fed to bovine, ovine and caprine animals;
(b) imports of MBM, specifying country of origin, and its use per species and husbandry system (in particular the proportion of that MBM fed to bovine, ovine and caprine animals;;
(c) exported MBM, specifying country of destination.

4. Meat and bone meal (MBM) bans

(a) complete description;
(b) dates of introduction;
(c) actual implementation, policing and compliance figures;
(d) possibilities of cross-contamination with other feed.

5. Specified bovine offal (SBO) and specified risk materials (SRM) bans

(a) complete description;
(b) dates of introduction;
(c) actual implementation, policing and compliance figures.

6. Surveillance of TSE, with particular reference to BSE and scrapie

(a) incidence of laboratory confirmed cases of BSE and scrapie;
(b) age distribution, geographical distribution, and countries of origin of cases;
(c) incidence of neurological disorders in which TSE could not be excluded on clinical grounds in any animal species;
(d) methodologies and programmes of surveillance and recording of clinical cases of BSE and scrapie, including awareness training for farmers, veterinarians, supervisory bodies and authorities;
(e) incentives for reporting cases, compensation and reward schemes;
(f) methodologies of laboratory confirmation and recording of suspect cases of BSE and scrapie;
(g) strains of BSE and scrapie agents possibly involved;
(h) existing systems or current plans for targeted active surveillance.

7. Rendering and feed processing

(a) all rendering and feed processing systems used;
(b) nature of the records of rendering and processing plants;
(c) quantitative and qualitative parameters of MBM and tallow production by each of the processing systems;
(d) the geographical areas from which the rendered materials originate;
(e) the type of raw material used;
(f) parameters on separate processing lines for materials from healthy and suspected animals;
(g) transport and storage systems for MBM or feed containing MBM.

8. BSE or scrapie related culling

(a) culling criteria;
(b) date of introduction of the culling scheme and of any subsequent modification;
(c) animals culled (details as specified in point 1);
(d) sizes of herds in which animals were culled.

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Annex 1 :

Completeness of Data

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Risk-Factor	**Species**	Complete	Interpolation possible	Add. Data needed	Comment
1. Structure and dynamics of the animal population	**B**				
	O/C				
(a) absolute numbers per breed, alive and at time of slaughter;	**B**				
	O/C				
(b) age distributions of animals per breed, sex and type;	**B**				
	O/C				
(c) age distribution of animals per species and breed, sex and type at time of slaughter;	**B**				
	O/C				
(d) geographical distribution of the animals by breeds;	**B**				
	O/C				
(e) geographical distribution of the animals by husbandry systems, herd sizes and production purposes;	**B**				
	O/C				
(f) system of identification and capacities for tracing of animals.	**B**				
	O/C				
2. Animal trade	**B**				
	O/C				
(a) imports and exports;	**B**				
	O/C				
(b) trade within the geographical area;	**B**				
	O/C				
(c) imports of embryos and semen;	**B**				
	O/C				
(d) use made of imported animals, embryos or semen;	**B**				
	O/C				
(e) mechanisms used by slaughterhouses to identify animals and their origins, as well as data from these procedures.	**B**				
	O/C				

Risk-Factor	**Species**	Complete	Interpolation possible	Add. Data needed	Comment
3. Animal feed	**B**				
	O/C				
(a) domestic production of Meat and Bone Meal (MBM), and its use per husbandry system	**B**				
	O/C				
(b) imports of MBM, specifying country of origin, and its use per species and husbandry system (in particularly the proportion of that MBM fed to bovine, ovine and caprine animals);.	**B**				
	O/C				
(c) exported MBM, specifying country of destination.					
4. Meat and bone meal (MBM) bans	**B**				
	O/C				
(a) complete description;	**B**				
	O/C				
(b) dates of introduction;	**B**				
	O/C				
(c) actual implementation, policing and compliance figures;	**B**				
	O/C				
(d) possibilities of cross-contamination with other feed.	**B**				
	O/C				
5. Specified bovine offal (SBO) and specified risk materials (SRM) bans	**B**				
	O/C				
(a) complete description;	**B**				
	O/C				
(b) dates of introduction;	**B**				
	O/C				
(c) actual implementation, policing and compliance figures.	**B**				
	O/C				

Risk-Factor	**Species**	Complete	Interpolation possible	Add. Data needed	Comment
6. Surveillance of TSE, with particular reference to BSE and scrapie	**B**				
	O/C				
(a) incidence of lab. conf. cases of BSE and scrapie;	**B**				
	O/C				
(b) age & geographical distribution, and countries of origin of cases;	**B**				
	O/C				
(c) incidence of neurological disorders in which TSE could not be excluded on clinical grounds in any animal species;	**B**				
	O/C				
	other				
(d) methods & programmes of surveillance & recording of clinical cases of BSE and scrapie, awareness training for farmers, vets, supervisory bodies and authorities;	**B**				
	O/C				
(e) incentives for reporting cases, compensation and reward schemes;	**B**				
	O/C				
(f) method of lab. conf. & recording of suspect cases of BSE and scrapie;	**B**				
	O/C				
(g) strains of BSE and scrapie agents possibly involved;	**B**				
	O/C				
(h) existing systems or current plans for targeted active surveillance.	**B**				
	O/C				
7. Rendering and feed processing					
(a) all rendering and feed processing systems used;					
(b) nature of the records of rendering and processing plants;					
(c) quantitative and qualitative parameters of MBM and tallow production by rendering system;					
(d) geographical origin of rendered materials;					
(e) the type of raw material used;	**B**				
	O/C				
	other				

Risk-Factor	**Species**	Complete	Interpolation possible	Add. Data needed	Comment
(f) parameters on separate processing lines for materials from healthy and suspected animals;					
(g) transport and storage systems for MBM or feed containing MBM.					
8. BSE or scrapie related culling	**B**				
	O/C				
(a) culling criteria;	**B**				
	O/C				
(b) date of introduction of the culling scheme and of any subsequent modification;	**B**				
	O/C				
(c) animals culled (details as specified in point 1);	**B**				
	O/C				
(d) sizes of herds in which animals were culled.	**B**				
	O/C				

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ANNEX 2

Standardised Data Set:

Set of tables to be completed on the basis of the country dossiers and, whenever necessary and possible, data available to the Commission (FVO or DG VI) or data from the public domain.

Remaining gaps might be closed by assumptions. These have to be indicated and justified.

Interpolation or aggregation of data is permitted but has to be indicated and explained.

Table 1 Structure and dynamic of the animal population

Country Code: _____

Tick box as appropriate : Number of animals [ ] or % [ ]

Year	Beef cattle [mio [] or [% [] of cattle]				Dairy cattle [mio[] or [% []] of all cattle]				All cattle	Sheep [1000] or [% All]			Goats 1000
	0-1	>1-2	>2	All	0-1	>1-2	>2	All	[mio]	0-1	>1	All	All
1985													
1986													
1987													
1988													
1989													
1990													
1991													
1992													
1993													
1994													
1995													
1996													
1997													
1998													
1999 (estim.)													

Which classes of animal, used in the national statistics, have been included in the Beef and Dairy categories.:

Comments:

Table 2 Number or fraction of animals slaughtered in a given calendar-year, by type of animal and age.

Country Code: _____

Tick box as appropriate : Number of animals [ ], % [ ]

Year	Beef cattle [mio [] or [% [] of cattle]				Dairy cattle [mio[] or [% [] of all cattle]				All cattle	Sheep [1000] or [% All]			Goats 1000
	0-1	>1-2	>2	All	0-1	>1-2	>2	All	[mio]	0-1	>1	All	All
1985													
1986													
1987													
1988													
1989													
1990													
1991													
1992													
1993													
1994													
1995													
1996													
1997													
1998													
1999 (estim.)													

If a further breakdown is given for dairy cattle over 2 years of age please specify.

Comments:

Table 3 Fraction of class of ruminants which received additional feed

Country Code: _____

Put the following:

[**R**] if you regard it as possible that **ruminant-derived MBM [RMBM]** has been fed in a given year to the age-class and type of ruminant to which the box refers.

[**M**] if it can be confirmed that only **non-ruminant mammalian-MBM [MMBM]** was fed**,**

[**C**] if it is not possible to estimate the feeding of RMBM or MMBM but only the feeding of **Composite or Concentrate feed** as supplementary feed.

[**0**] if it is assumed that neither Concentrates, nor RMBM, or MMBM have been fed.

As far as possible give an estimation of the fraction [%] of the class receiving the indicated supplementary feed. If necessary, assumptions should be made and explained below.

Year	**Beef cattle**				**Dairy cattle**				**Cattle**	**Sheep**			**Goats**
	0-1	**>1-2**	**>2**	**All**	**0-1**	**>1-2**	**>2**	**All**	**ALL**	**0-1**	**>1**	**All**	**All**
19xx example	*0*	*0*	*0*	*0*	*R 80%*	*R 50%*	*R 90%*	*R 75%*	*R 40%*	*C 10%*	*C 80%*	*C 16%*	*O*
1985													
1986													
1987													
1988													
1989													
1990													
1991													
1992													
1993													
1994													
1995													
1996													
1997													
1998													
1999 (estim.)													

Assumptions made and their justification:

Table 4: Estimated content of MBM in composite or concentrate feed (CF), fed to ruminants

Country Code : _____

Year /period	**MBM content in % of total CF-weight per type of starting material**		
	ruminant	**other mammalian**	**Total MMBM**
1980			
1981			
1982			
1983			
1984			
1985			
1986			
1987			
1988			
1989			
1990			
1991			
1992			
1993			
1994			
1995			
1996			
1997			
1998			

Default values:
before 1990 : all CF contained about 6% of MBM, potentially from ruminants.
1990-1994 : all CF contained about 4% of MBM (potentially from ruminants).
Since 1994: all CF contains 1% of MBM (potentially from ruminants), due to cross contamination.

Comment:

Table 5: The rendering system

Reference year(s): _____ Country Code: _____

Raw material Source **[0] = material not used,** **[S]=material used but SRM/SBO excluded,** **[X]=material used incl. SRM/SBO** **In "other" indicate** **[F] for fallen stock, [E] for exotic animals, [L] for laboratory animals if such information is available.** **Otherwise us [X] as long as it is not explicit that no other animals are rendered and put [0] if it is.**							**Capacity per type of rendering system in % of total rendering capacity**					
Period	**Cattle < 2**	**Cattle >=2**	**Sheep & Goats**	**Pigs**	**Poultry**	**Other**	**Batch 133/20/3**	**Other batch**	**Con-tinouos, 133/20/3**	**Other cont.**	**Other**	**Total 100%**
1985												
1986												
1987												
1988												
1989												
1990												
1991												
1992												
1993												
1994												
1995												
1996												
1997												
1998												
1999(est.)												

Default values:

- 100% of the rendering capacity operates with processes with insufficient time-temperature combinations and hence a low capacity to reduce BSE (TSE) infectivity.
- SRM /SBO and fallen stock and exotic animals, etc. are all rendered in inappropriate facilities.

Comments:

Table 6: Existence of MBM and/or SRM ban and estimations for compliance

Year /period	MBM-feed ban		SRM-ban	
	existing	Compliance (%) and comment	existing	Compliance (%) and comment
Example	*X*	*50%* *ruminant to ruminant*	*X*	*60%* *only head of bovine >30 months*
1980				
1981				
1982				
1983				
1984				
1985				
1986				
1987				
1988				
1989				
1990				
1991				
1992				
1993				
1994				
1995				
1996				
1997				
1998				

Default values:
Compliance in first year of existence: <=60%, second year: <=70%; third year: <=80%; fourth year: <=90%; fifth year and later: <=95%

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Handbook

For The Assessment of
The geographical BSE-risk

Version 14,
Finalised: 18 December 1998

Annex 3:

Qualitative Factor – by – Factor Assessment

Qualitative Factor by Factor Assessment

Part one :List of risk factors

Part one contains a list of all risk factors of relevance for the propagation and processing risk, as identified by the SSC. For each factor short guidelines are given for estimating its impact on the propagation and/or processing risk. The following scale is proposed for indicating the relative importance/relevance of the factor for the risk.

Proposed scale for the risk-value

If a factor enhance significantly/strongly the risk, assign the risk-value	**5**
If a factor enhances the risk only to some extent, assign the risk-value	**4**
If a factor has NO influence on the risk, assign the risk-value	**3**
If a factor reduces the risk slightly, assign the risk-value	**2**
If a factor reduces significantly/strongly the risk, assign the risk-value	**1**

Part two: Notation sheets

Part two contains a set of table in which the experts should note the appropriate risk value for each factor and each year between 1985 and 1998.

Part three: Graphical sheets

Part three provides a set of empty graphs. For each of the 8 main risk factors its contribution to the propagation or processing risk should be plotted over time.