Opinion of the

SSC

on a method to assess

the Geographical BSE-Risk (GBR)

of Countries or Regions

adopted on 18 February 1999

revised on 23 April 1999

in the light of the experience gained during the first risk assessment exercise carried out in March 1999

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 Specified Risk Materials (SRM) of 9/12/97 the SSC stated that the SRM-lists could 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 12 Member States and 11 Third Countries have provided[1] 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, in view of measures taken to manage the risk and in view of the BSE-incidence. 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. A discussion paper was adopted, annexed to the minutes of the SSC meeting in December 1998, and send to the the OIE for information and comments.

On 25/11/98 the Commission adopted a proposal for a revision of its decision 97/534 and a proposal for a regulation by the EP and the Council of the management of TSEs (100a-proposal). In these proposals the Commission suggested 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 the transformation of bovine materials

[1] As of 18.2.99

into bovine based products and by consumption patterns of these products. Imports and exports influence both risks.

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. In essence the geographical BSE-risk can be seen as indicator for the current and near-future risk that life animals could be infected with the BSE-agent when entering the food and/or feed chain.

Outline of the method for assessing the geographical BSE-risk

Preamble

The proposed method should allow identifying the level of geographical BSE-risk present in a country. However, any other geographical unit could also be taken as basis for assessment as long as the boundaries of the appropriate data can be clearly related to the geographical boundaries. As data boundaries are normally identical with administrative boundaries, countries will in most cases be 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. Given the unavoidable limitations of available data, in particular those for the past, the SSC came to the conclusion that a quantitative risk assessment is not yet possible.

Basic assumptions

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

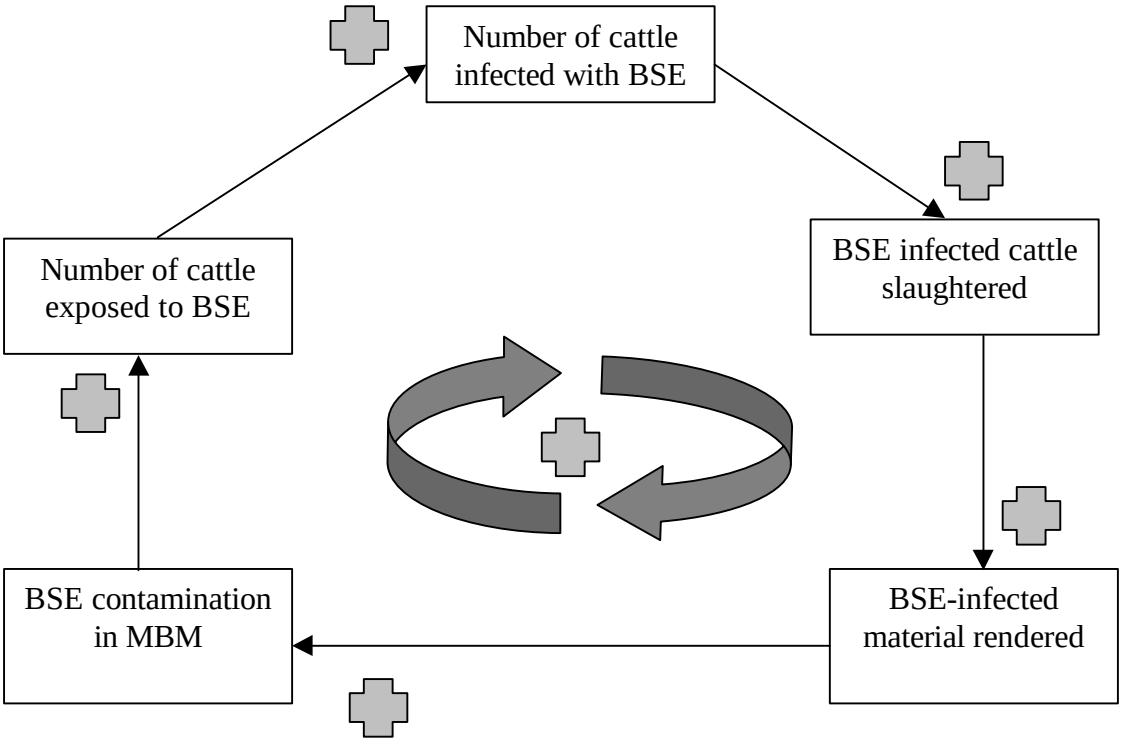
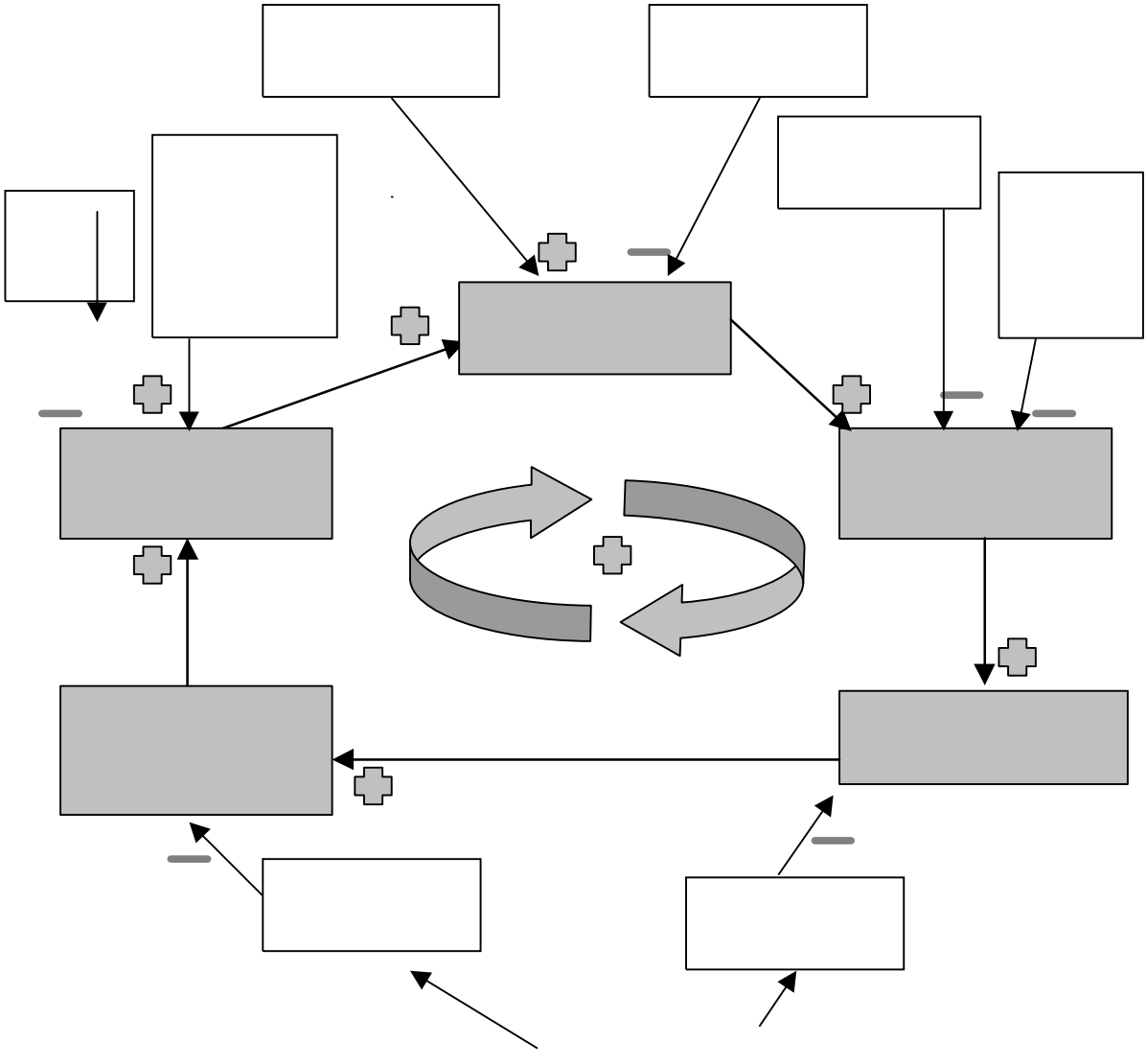


Figure 1: The basic BSE/Cattle system

The core is a positive feed-back loop which, if not counteracted, leads to a continuos increase of BSE infection in cattle until an epidemic outbreak becomes apparent 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 offal rendered. This will lead to more contaminated MBM and more exposed cattle, and so on.

The ability of the system to counteract this feed-back loop defines its stability. A stable system would be able to cope with BSE infectivity coming in (a "challenge" to the system) while the feed back loop in an un-stable system would not be counteracted and could finally lead to an epidemic.

Figure 3 shows the key factors controlling this feed-back-loop and their point of action:



* Points where the BSE-agent could be introduced into the system = potential "challenge" points.

Figure 2: Key-variables controlling the BSE-Cattle System

Two control factors are of major importance:

- The efficiency of the rendering system to reduce or (theoretically) eliminate any contamination of the MBM with the BSE-agent has the potential to interrupt[2] or limit the feed-back to build up.
- Not feeding MBM to cattle would be a second point at which the loop could, theoretically, be interrupted[3].

Combining efficient rendering with not feeding MBM will significantly increase the potential to interrupt the feed-back loop.

The following factors are able to modify the growth in numbers of BSE infected cattle, and hence of the geographical BSE-risk, which results 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.
- Import of BSE contaminated feed and feeding it to domestic cattle would also increase the number of infected cattle in the importing country while exports could, theoretically, reduce the risk in the exporting country.
- An ideal surveillance system would identify all infected animals showing any clinical sign, all suspect cases showing clinical signs compatible with BSE and all animals being at risk to be infected with BSE, either because of link to confirmed cases or because of other risk factors. If these were excluded, by an appropriate culling system, from processing (incl. rendering) the processing risk would be significantly reduced and, because a significant part of the infectivity would be taken out of the system, the resulting propagation risk would be reduced, too. This would reduce the growth in numbers of infected cattle.
- An ante- or post-mortem test able to identify all BSE carriers even at early stages of the incubation period, i.e. well before they show 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 reduction, however, could contribute to a reduction in the growth of the number of infected cattle

THE METHOD

Factors to be taken into account

Based on this model of the BSE/cattle system the SSC has identified 8 risk-factors[4] 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 hence would determine the overall BSE-risk in a given geographical area. Figure 4 shows the relationship of these risk factors to the BSE/cattle system.

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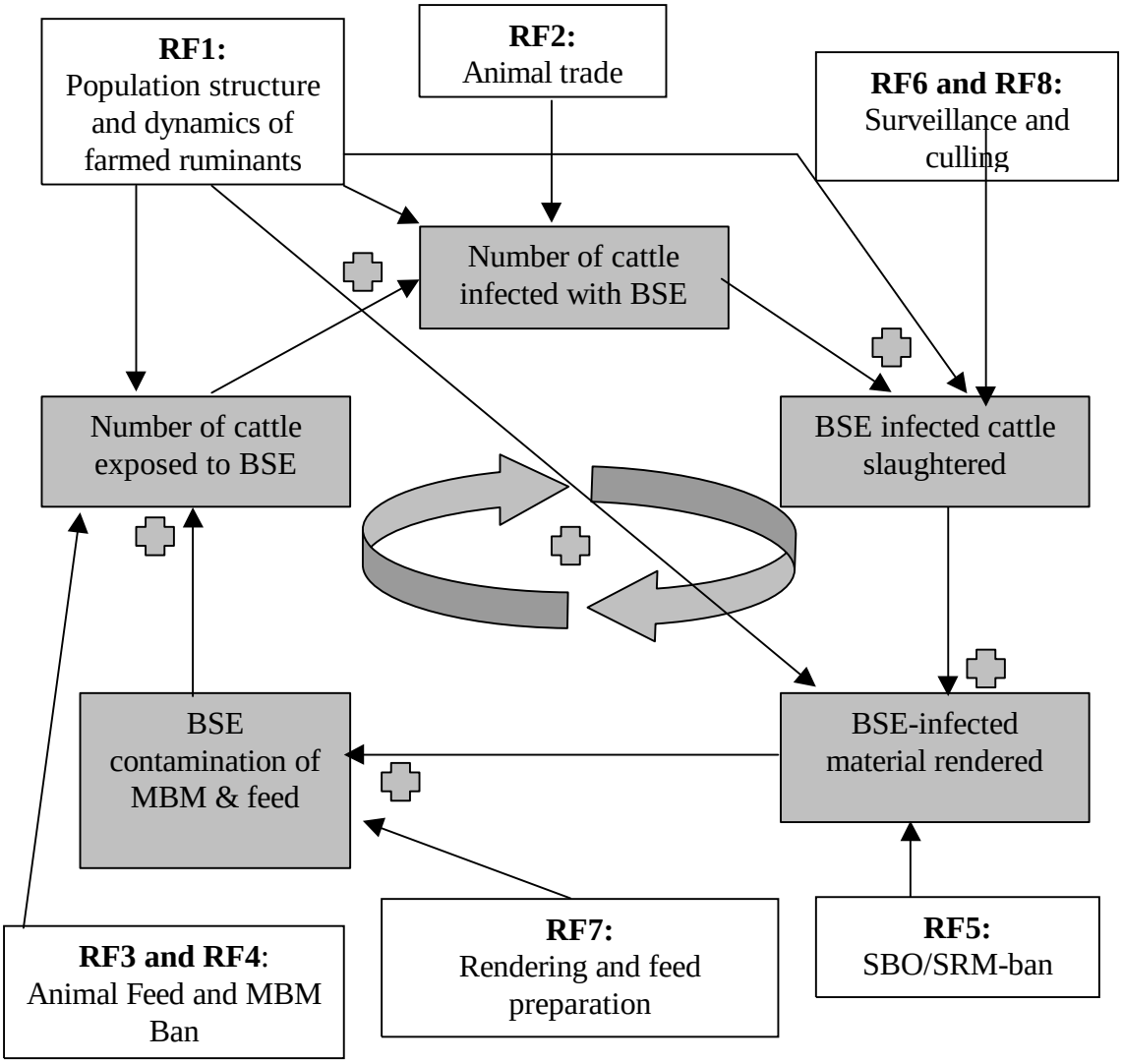
[2] It should be kept in mind that it is highly unlikely that in reality a perfect rendering system, able to interrupt the feed-back loop, could be realised

[3] Again it should be kept in mind that the risk of cross-contamination is difficult to be reduced to zero. It is therefore very difficult to fully guarantee that cattle is not exposed to MBM as long as supplementary feed is fed to cattle and feed for other animals is still allowed to contain mammalian protein.

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

- **Risk Factor 1:** A cattle population with a large fraction of high yielding dairy cows, managed intensively with significant amounts of supplementary feed, that could include mammalian proteins, would have a higher risk to be exposed to the BSE agent than an extensively ranched beef cattle population. The reason lies in the greater likelihood of including BSE-contaminated MBM in the dairy cow diets. As the infective load of an infected animal grows slowly over the incubation period, age at slaughter is important for the amount of BSE infected material entering the rendering system or the food chain (or, more precisely, the infective load of that input-material). Equally age at exposure is important because animals have to live long enough after exposure to develop the disease.



Note: If it would be assumed that BSE originates from scrapie, or that BSE has been re-transmitted to sheep and goats, these animals could be a source of BSE-contaminated raw-material for rendering. Other farmed ruminants (deer, buffalo) could theoretically pose a similar risk. As long as they are not a major part of the ruminant population and/or are not managed intensively, they are currently not taken into account. However, RF1 refers to farmed animals and not only to cattle.

Figure 3 The 8 SSC-Risk factors and the BSE/Cattle system

- **Risk factor 2:** The impact of import or export of infected cattle on the number of infected animals alive, and subsequently the number of infected animals at slaughter, is evident. Imports from BSE-affected countries must be seen as increasing the risk that BSE-infected cattle are arriving at processing.
- **Risk factor 3 and 4:** Information on cattle feed and on the control of feeding cattle with mammalian (potentially bovine) protein is essential in assessing the probability that the feed-back loop has been interrupted at this stage. An indication that cattle are being fed with MBM must be seen as significantly enhancing the propagation risk. Imports of MBM from BSE-affected countries are particularly relevant if feeding to cattle is likely.
- **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, however, not be able to reduce the propagation risk 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 for the processing risk.
- **Risk factor 7:** The efficiency of the rendering system to reduce the BSE infectivity of the rendered material, 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 materials, is therefore extremely important. The existence of ineffective rendering processes within a country is pointing to a significant enhancement of the propagation risk. A country with an ineffective rendering system has a weak point which would make avoiding any initial BSE-introduction the most critical measure. However, it should no be overlooked that according to the SSC opinion of 26-27.03.98 no rendering system is able to fully eliminate the BSE agent. Hence breaking the cycle, or avoiding propagation of an initially imported BSE-disease, with appropriate rendering alone can not be guaranteed.

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 aspects of the geographical BSE-risk: the **propagation risk** and the **processing (incident) risk**. The method for this risk assessment is qualitative in nature and based on expert judgement. Guidelines for the experts carrying out the assessment are provided in the "manual" in annex.

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

The **processing risk** is defined as the probability that, within a given time period, an infected 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.

The **Geographical BSE-risk (GBR)** is defined as the combined probability that

- the BSE-agent is currently and in the foreseeable future present in the native cattle herd, and
- currently and in the foreseeable future one or more BSE-infected native animals per year enter processing in that geographical area.

It is hence integrating the two risks mentioned beforehand.

These two risks are mainly referring to two parts of the above-described cattle/BSE – system.

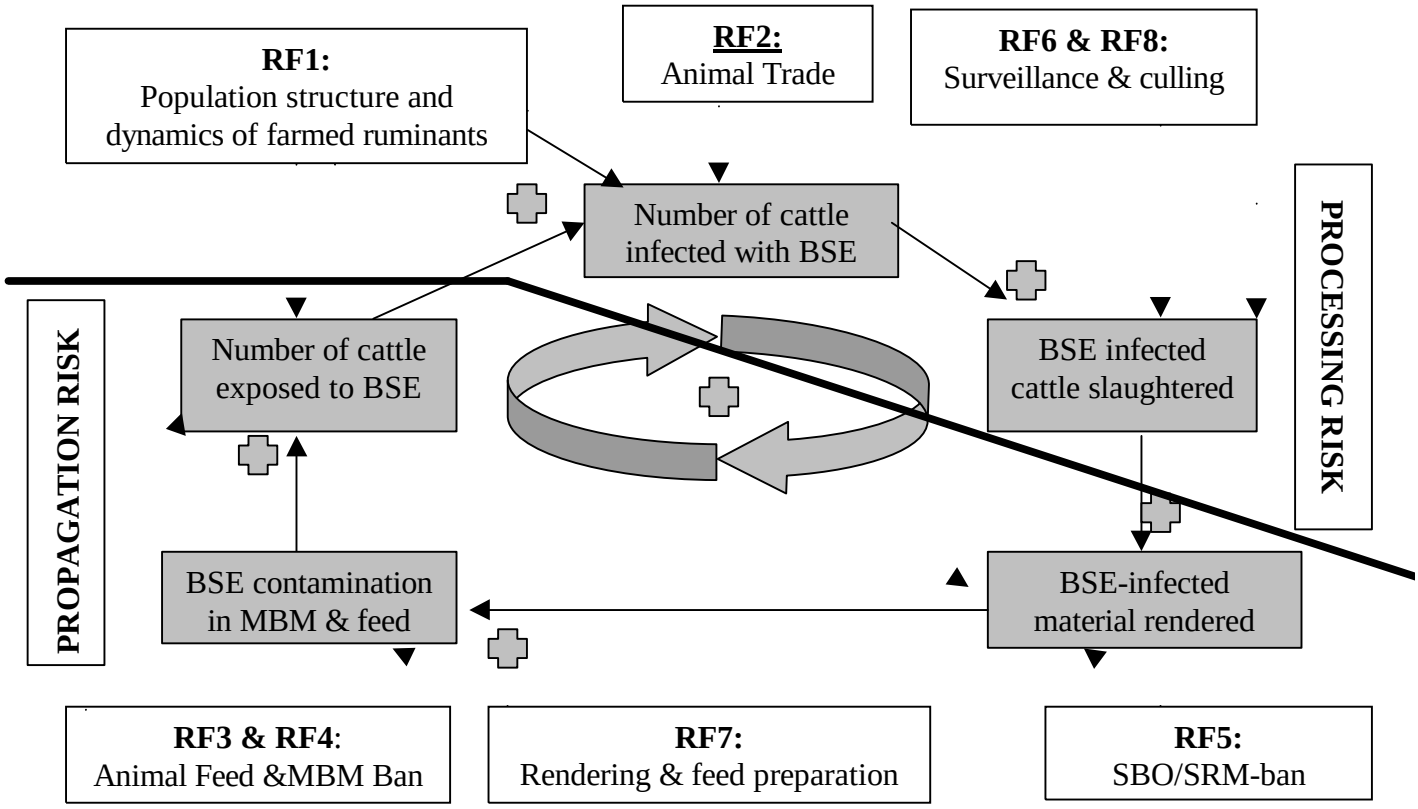


Figure 4 Relation of the 8 SSC-risk factors and the BSE-Cattle system with the propagation risk and the processing risk.

The **processing risk** is depending on the number of infected cattle alive at a given moment and the number of infected cattle slaughtered without being identified as infected. The higher the number of infected cattle the higher is the risk that infected cattle are slaughtered (or exported).

The **propagation risk** depends of the amount of infective material being recycled, the resulting BSE-contamination of the MBM and the number of cattle exposed to BSE via feed. More infective material recycled leads to a higher (potential) contamination of MBM, this could lead to a higher number of cattle exposed to the BSE-agent via feed and therefore to an increased risk of propagation of the disease.

Figure 4 visualises the relation between the two risks and the BSE-Cattle system. It also shows that the different risk factors, identified by the SSC, are mostly relevant for one of the two risks. Only the population structure (RF1) influences both risks.

The figure also shows the feed back between the two risks: a higher propagation risk will lead to a higher processing risk and vice versa. Hence measures influencing one of the two risks will always have an impact on the other one, too, although with some delay.

The result of the factor-by-factor assessment can be summarised in a graphic. Figure 6 shows a hypothetical development of the eight risk factors over time, using a scale from 1 to 5; 1 indicating a significant risk reducing impact, 3 indicates no impact and 5 indicating a significant risk-enhancing impact.

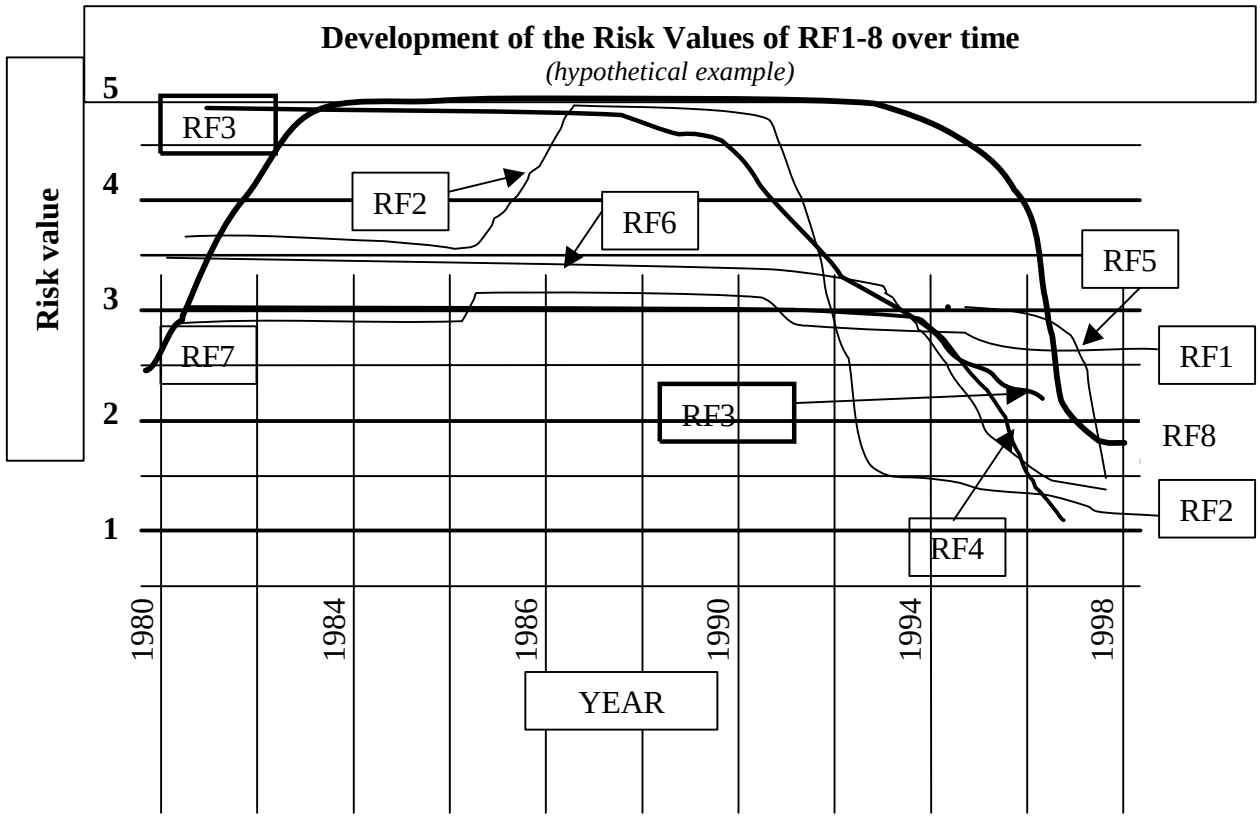


Figure 5: Hypothetical example of the development of risk Factors 1 to 8 over time.

This hypothetical example 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 rendering conditions). Around 1993 a slight improvement begun but only after 1996 the system really improved and after 1997 it is assumed that it became good enough for reducing the risk. The figure also shows the change in the animal feed risk-factor (RF3). In the past feeding mammalian, including ruminant, MBM to cattle was common practice in this hypothetical example. Only since the late 80^{s} has this changed and is now expected to have reached such low levels that it is in fact reducing the risk.

From the factor-by-factor analysis the experts are asked to judge the development of the propagation risk and the processing risk over time. Taking account of the assumed impact of each risk factor on one or both of these risks as well as the relative weight of the different factors, they should conclude on the risk on a year by year basis. However, no defined function is given and it is left to the experts' judgement to decide about the appropriate risk

level to be assumed[5]. A suggestion for illustrating the assessed risk levels is provided in the manual for the assessment of the geographical BSE-risk, attached to this opinion.

Note: When judging on the risk level of the processing risk and the propagation risk, their interaction has to be taken into account. Typically it can be assumed, for example, that the current processing risk is strongly influenced by the propagation risk in the past. Given the long incubation time, infected animals now being slaughtered and processed must have been exposed to the BSE agent two to eight years before. On the other hand a high processing risk has an immediate impact on the propagation risk if no measures are taken to avoid recycling of infective material (e.g. MBM- and/or SRM-ban). If incidence figures are available, these should be taken into account in the risk assessment in the context of the quality of the surveillance and as indicator for past problems.

Taking account of the historic trends of the two risk factors and their current level, as well as of incidences figures weighted in light of the assessed surveillance quality, the geographical BSE-Risk has to be assessed, being defined as the combined probability that

- the BSE-agent is currently and in the foreseeable future present in the native cattle herd, and
- currently and in the foreseeable future one or more BSE-infected native animals per year enter processing in that geographical area.

To derive an estimate of the geographical BSE-risk from the partial risks the following conditions should be used for a first approximation (PRR = Processing Risk, PRG = Propagation Risk, GBR = Geographical BSE-Risk):

- if PRR >= PGR then GBR = PRR
- if PRR < PGR then GBR = (PRR+PGR)/2

These conditions reflect the fact that the current geographical risk level can never be lower than the current processing risk level. It can, however, be higher if the propagation risk level is higher than the processing risk level. The reason lies in the different time dimension of the two risks: a change of the processing risk results in an immediate change of the risk for man. Its value therefore represents the present situation. The propagation risk of today, on the other hand, points into the future. A change of this risk will have an impact on the risk for man only with the delay of the incubation period of BSE. In cattle this seems to be between 2 and 8 year, with the large majority of cases in the range of 4 to 6 years.

The assessment process

In view of the importance of the data-quality for the quality of the risk assessment, the exercise will start with a preparatory phase in which the country dossiers are analysed. The dossiers available from a group of countries have undergone this process in January 1999 and a standardised set of the most relevant data was prepared. In future this process will be integrated into the risk assessment per see. In general, the assessment will be based on the data provided from the country under consideration. However, other information, such as those gathered in veterinary inspection missions of the Commission to the countries, or publicly available data, should also be used whenever deemed necessary.

[5] The discussion of the experts should particularly focus on this judgement and the applied weighting. The assessment report should clearly explain their basis.

This risk assessment itself will be carried out as follows[6]: Three independent experts will evaluate each country dossier. Each of the experts will first verify the available information in view of completeness and consistency. They will then carry out an as complete as possible evaluation without discussion with his/her fellow colleagues. Subsequently the three experts will meet, discuss their findings and produce a group report. The countries in question are invited to send a country expert who could help clarifying any aspect of the available data and to close gaps identified by the evaluators. They will not be involved in the drafting of the group report. This group report will be presented to the entire assessment panel, i.e. all experts who in parallel assessed dossiers of other countries. After a thorough discussion, all experts, i.e. those who worked through a country dossier and those who did other dossiers, will conjointly produce a consensus report that proposes a 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.

> *Note: Given the importance of expert-judgement for the outcome of the assessment, the discussion between the experts is felt to be of utmost importance. In this discussion, particular attention should be paid to the foundation of the judgement as well as to measures taken to close remaining gaps. It should also strive for an overall consistency of the risk assessments carried out by the different groups.*

Opinion:

The SSC is of the opinion that the attached "Manual for assessing the Geographical BSE-Risk", ***revision 1***, describes appropriately the ***revised*** approach to geographical BSE-Risk assessment that the SSC wants to apply. It provides guidelines for independent experts to estimate the geographical BSE-Risk on the basis of dossiers provided by countries. The described process corresponds well with the overall approach described above.

Being aware of the unavoidable shortcomings in the information on which the assessment of the geographical BSE-risk has to be based, and after having discussed in depth the use of other methods, the SSC came to the conclusion that a quantitative, or even semi-quantitative, risk assessment is not currently feasible. Appropriate approaches, such as mathematical models to calculate the R_0-factor as indicator of the propagation risk, are expected to appear in the future and should be used for improving the risk assessment.

It should, however, not be overlooked that the value of the currently proposed qualitative assessment is also critically dependent on the quality of the information provided. In this context it is felt that the inherent dependence of the method on expert-judgement is felt to be a strength of the process, because it allows to benefit from the experience of the experts, and their ability to integrate information from different sources, in addition to the written information. Together with the possibility to discuss with fellow evaluators and country experts this should help to come to reliable conclusions, even if the information base is less than optimal.

The SSC is aware that the dependence on expert judgement could also be seen as a weakness, because the inevitable biases of experts will influence their judgement. However, the SSC expects that the discussion between the evaluators will counterbalance this aspect. It invites the TSE/BSE ad-hoc group to nominate one of its members to chair the final discussions of

[6] See manual, for details

the assessment panel in order to ensure a high quality of that very important step in the process.

MANUAL

FOR THE ASSESSMENT

OF THE

GEOGRAPHICAL BSE-RISK

MAIN PART

REVISION 1

REVISED AFTER THE FIRST RISK ASSESSMENT EXERCISE

IMPORTANT NOTE

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

The first assessment of the geographical BSE-risk of countries or regions was carried out from 1-6 March. For 12 MS the risk was assessed in qualitative terms, taking account of the factors listed in the SSC opinion of January 1998, and following the method described in the opinion of the SSC of February 1999.

In the course of the exercise it became clear that clarifications of the method described in the opinion would be appropriate. These clarifications have been discussed by the TSE/BSE ad-hoc group and the SSC and are introduced into this version of the manual.

INTRODUCTION

The purpose of this "Manual" 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[7]. 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[8] (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 on 21/1/98 an opinion on "defining the BSE risk for specified **geographical areas**". In this opinion it identified two risks appearing to be of major importance:

Incident (or processing) 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.

Following the first risk assessment exercise the SSC felt the need to clarify that, in the context of BSE, and hence nvCJD, the infective agent causing these diseases is the hazard being considered in a comprehensive risk assessment.

Accordingly the ultimate exposure of relevance is the entry of the BSE-agent into the human food chain.

However, for the purpose of the geographical BSE-risk assessment, the exposure is defined as the entry of the BSE-agent into the processing chains, be it via slaughtering infected, but apparently healthy animals for food, or by rendering of fallen stock or condemned material for feed.

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

[8] 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.

Note: both product lines could function as "dead-ends": as long as the agent is not recycled to bovines (in particular cattle) the disease will not be propagated. However, the lines could cause an exposure risk for man and/or other species. The infectivity is currently not clear, except that there is evidence that humans, cats, etc. are susceptible.

Further on the SSC clarified that the Geographical BSE-risk (GBR) is defined as the combined probability that

- the BSE-agent is currently and in the foreseeable future present in the native cattle herd, and
- currently and in the foreseeable future one or more BSE-infected native animals per year enter processing in that geographical area.

These probabilities depend on the inherent ability of the BSE/Cattle system to eliminate BSE-infectivity as well as on the amount of infectivity being present. It is obvious that an initial infection ("challenge") is required before the BSE-agent can enter processing and/or can be propagated.

Assessing the geographical BSE-risk (GBR)

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 epidemiological TSE-status could be determined. On 22/7/98[9] the Commission invited Member States and third countries to provide information on these 8 factors and listed 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.

The concept

As already indicated above, the GBR depends on the one hand on the stability of the system, i.e. its ability to cope with an initial introduction of the BSE agent and, on the other hand, on the occurrence and strength of that initial introduction, i.e. the challenge it experienced.

To assess the current GBR both aspects have to be taken into account over a period of at least the past 10 years.

Step one: Stability characterisation

With regard to BSE the stability of the system is on the one hand characterised by its ability to identify and eliminate BSE infected animals before they enter processing. This ability is described by the risk factors relevant for the processing risk (RF1, RF6 and RF8). If they point to a potentially increased processing risk the probability is high that an infected animal is processed. If they point to a reduced processing risk, the probability that this happens is low.

The system's stability is also characterised by its ability to avoid propagating BSE-infectivity. This ability is described by the risk factors relevant for the propagation risk (RF1, RF3, RF4, RF5, and RF7). If they indicate an increased propagation risk, they indicate that it is likely

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

that infectivity entering the feed cycle would be fed to cattle (or ruminants). If the risk factors point towards a reduced propagation risk, it would be unlikely that infectivity entering the feed cycle would be fed to cattle (or ruminants).

Together these risk factors allow assessing the inherent stability of the BSE/cattle system of a country or geographical area with regard to BSE. A stable system will cope with an initial infection by excluding potential carriers from processing and/or by preventing the BSE-agent from being re-cycled to cattle (ruminants). An unstable system could not exclude infected animals from processing and/or could not prevent the BSE-agent from being re-cycled to cattle (ruminants).

As the risk factors change over time, the stability of the system will also change over time. It is therefore necessary to assess the stability over time, as far as possible on an annual basis.

In this first step of the risk characterisation it should be assessed whether, in a given year, the system could cope with a BSE-challenge - should it occur – or not.

Step two – Challenge assessment

In a second step, the probability of an initial introduction of the BSE-agent (the "challenge" to the BSE/cattle system of a country or geographical area) should be assessed. The route, intensity and time of the BSE-introduction has to be defined as well as possible:

The routes to be considered are:

- An existing BSE-prevalence at the beginning of the reference period (incidence).
- Import of BSE-infected animals, semen or embryos (RF2).
- Import of BSE-contaminated feed (MBM as such or composite feed including contaminated MBM, second sub-factor of RF3).
- Other sources, such as other animal species infected with other TSEs than BSE. These might also be considered as potential risks.

The intensity:

- An initial prevalence has to be estimated on the basis of the available TSE-incidence figures and other sources.
- The number of imported animals, semen or embryos from a potentially BSE-affected region and the BSE-prevalence in that region determines the amount of infectivity entering the system by this route. This amount is also influenced by the age of the animals at import. (RF2).
- MBM-imports from areas affected by BSE also enhance the intensity of the challenge. (Second sub-factor of RF3).
- Other sources might be considered but require a clear justification of their relative importance.

Time:

- The period over which BSE was introduced into the system has to be determined.

Step three - The characterisation of the geographical BSE-risk

To assess the GBR it is important to take account of the stability of the BSE/cattle system and its development over time as well as of the challenges to the system. Assessing how the system coped with identified challenges is essential.

- If BSE were introduced in a period where the system was stable the resulting GBR would be low. Infected animals would be excluded from processing (low processing risk) and, if any infective material would nevertheless slip through it's infectivity would be significantly reduced and/or prevented from reaching cattle (ruminants) (low propagation risk). Hence it would be unlikely that BSE exists in the domestic herd and that domestic BSE-infected animals would be processed now or in the foreseeable future.
- If BSE were introduced in a period where the system was not stable, the resulting GBR would be high. It has to be assumed that infected animals were processed (high processing risk) and that the initial infectivity was propagated (high propagation risk). The latter would have lead to newly infected animals shortly after the initial BSE-introduction. If the system's stability did not increase, these animals would have entered processing at different stages of their incubation period and would be propagated again. An initial infection occurring one or two incubation periods ago could, theoretically, be responsible for the current numbers of living but infected cattle. Hence the likelihood that BSE-infected animals are alive in a country and would be processed now or in the foreseeable future would be high.

In general terms it has to be seen that an in-stable, but never challenged system could have a low GBR while a stable, but severely challenged system, might carry a high GBR.

If the processing and the propagation risk are related to the stability of the system and the respective challenges the geographical BSE-risk depends of the processing risk and the propagation risk. The general approach to assessing the GBR is therefore to first assess the development of the propagation and processing risk over a relevant period of time and second to conclude from these two partial risks on the geographical BSE-risk.

Estimating the propagation risk.

The **propagation risk** is, stricto senso, 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 purposes of the GBR-assessment it should also take account of new infections resulting from imported feed stuff. In this context the propagation risk provides a measure for the number of newly infected cattle or the probability that at least one new case occurs.

For the propagation risk, the most important factor is the exposure of ruminants to the BSE-agent via contaminated feed (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. Current estimates assume about 5-10% of the offspring of dams who developed BSE-symptoms within 6 months before or after birth might be affected. 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.

The exposure of cattle to the BSE-agent could result from feeding domestically produced feed stuffs or from feeding imported feed stuffs.

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. These are addressed by the Risk-Factors RF1 (population structure), RF3 and 4 (feeding practice, feed imports and feed bans), RF5 (SRM-bans) and RF7 (rendering and feed production).

Estimating the processing risk

The processing risk is 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*: 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) was only found 32 months after challenge. The infectivity in the CNS is assumed to be significantly 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.

If no measures are taken, the current processing risk would depend only on the relative number of infected cattle alive at a given moment. This number depends on the past exposure of cattle to the BSE-agent and the resulting new infection. The propagation risk is an indicator for the probability that this happened and for its extent. Because of the long incubation period of BSE, which may increase with lower doses of exposure, it is important for the assessment of the current processing risk, and for forecasting the future processing risk, to take account of the propagation risk in the preceding 8 to 10 years.

In addition to exposure of domestic cattle to the BSE-agent, importing infected animals could also increase the number of infected cattle alive. The probability that infected animals are imported increases with the number of cattle imported from BSE-affected countries and the assumed prevalence of BSE in these countries. Even if it is not certain, embryos from infected dams may pose a risk of being infected and could hence be a route of importing BSE. For the time being, however, that risk is assumed to be negligibly low.

In reality measures will be in place to monitor and control diseases, including BSE. Depending on their efficiency these measures will reduce the processing risk by identifying not only all animals showing clinical signs of BSE but also those animals at risk because they where raised together with BSE-cases or because of maternal transmission. If these animals at risk are efficiently excluded from processing, the processing risk is lower than it could theoretically be.

The processing risk therefore depends on the theoretically possible number of infected cattle being alive and the measures in place to effectively exclude these animals from processing.

- The propagation risk in the past 10 years allows estimating the risk that cattle have been exposed to and hence infected by the BSE agent.
- Together with the imports of live animals and embryos from BSE-risk countries, and the number of imported animals still being alive (see risk factor 2), this allows estimating the maximum processing risk.

- Risk factors 6 (surveillance) and 8 (culling) address the measures in place to control the disease. Their efficiency determines the degree to which the actual processing risk is below the theoretical maximum. A new annex 3a provides guidance on this aspect.
- As the infective load of an infected animal increases with time since infection, the age at slaughter (see RF1) is an important parameter for the amount of BSE infectivity being processed if an infected animal is slaughtered or rendered. Measures reducing the age at slaughter or excluding older animals from normal processing would hence reduce the processing risk, too.

Methods for assessing the propagation and the processing risk

To assess the propagation and the processing risk three different approaches have been discussed by the SSC. A semi-quantitative approach and a mathematical approach have finally been rejected. The former because of its dependence on data quality and completeness and the latter in addition to these aspects because it was not yet published in peer reviewed journals. However, work on these approaches continues and might lead to further improvements in the future.

For the time being the SSC has decided to remain with a qualitative risk assessment approach which will allow estimating the order of magnitude of the geographical BSE-risk in qualitative terms but not to assess it quantitatively

Qualitative assessment

Based on the eight factors identified by the SSC as key-factors for the geographical risk (see annex 01) a qualitative assessment of the propagation risk and the processing risk is possible.

The impact of each risk factor on the processing risk or the propagation risk or both should be assessed, if possible year by year for at least the last 10 years.

This impact could be

- very positive/positive, triggering a significant/some reduction of the risk;
- neutral, or
- negative/very negative, triggering an increase/ a significant increase of the risk..

On the basis of the factor by factor analysis it is then possible to estimate, in qualitative terms, if possible on an annual basis for the last 10 years, the processing and the propagation risk and to conclude from these risks on the geographical BSE-risk.

Annex 3 to this manual provides details on this qualitative factor-by-factor assessment and contains forms for noting down the findings and conclusions, inter alia in form of graphs. Annex 3a provides guidance for assessing the quality of a TSE-surveillance system with regard to its potential impact on the processing risk.

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

From the factor-by-factor analysis the experts are asked to judge the development of the two partial risks, the **propagation risk** and the **processing risk**, over time. Taking account of the impact of each risk factor on one or both risks as well as the relative weight of the different

factors, they should conclude on the propagation and processing risk on a year by year basis.[10] However, no defined function is given and it is left to the experts' judgement to decide about the appropriate risk level to be assumed.

As a means to illustrate the assessed risk, the experts should use a scale with logarithmic intervals where 0 indicates a zero probability that at least one BSE-incubating animal would be processed per year and per million adult cattle alive in the country or be newly infected with the BSE agent. "1" would accordingly indicate a probability of 100% that at least one animal per million adult cattle alive in the country is annually processed while incubating BSE or is newly infected. Values above 1 would then indicate the order of magnitude of animals per million adult cattle alive in the country being newly infected with BSE or processed while incubating BSE per year. The logarithmic intervals allow indicating if this order of magnitude is between 1 and 10, 10 and 100, 100 and 1000, or above.

On this scale, the assessed risk should be noted. It should be understood that the scale is a continuous one and should allow comparing different risk situations relative to each other. The risk should be indicated as a range within which the true risk is assumed to be. This range should be as narrow as scientifically justifiable in order to provide appropriate differentiation.

A similar scale should also be used for the GBR (Geographical BSE-Risk).

When estimating the GBR from the PRR and the PGR it should be taken into account that the geographical risk can never be below the processing risk. It can, however, be higher if the propagation risk is higher than the processing risk.

The reason lies in the different time dimension of the two risks: the processing risk influences immediately the risk that the ultimate hazard, the human exposure to the BSE-agent, occurs. The propagation risk of today, on the other hand, points, with regard to human exposure, into the future. The current propagation risk could have an impact on the human exposure risk only one incubation period of BSE in cattle, i.e. between 2 and 8 or more years, later, because it largely determines the future processing risk.

For orientation purposes the following conditions should be applied for deriving an indicator for the Geographical BSE-risk (GBR) from PRR (Processing Risk) and PGR (Propagation risk):

- if PRR >= PGR then GBR = PRR
- if PRR < PGR then GBR = (PRR+PGR)/2

Reporting on the geographical BSE-risk assessment

Finally it is necessary to prepare a report on the qualitative risk assessment which consists of:

- an executive summary which gives an overall assessment in qualitative terms and summarises the main points of justification for this assessment;
- a detailed report which repeats the overall assessment and provides a detailed justification of it. To this point it should discuss the following issues:
  - Quality of the information on which the assessment is based;

[10] The discussion of the experts should particularly focus on this judgement and the applied weighting. The assessment report should clearly explain their basis.

- Risk factors determining the ability of the BSE/cattle system to identify and eliminate BSE-infected animals before they are processed;
- Risk factors determining the ability of the BSE/cattle system to avoid recycling of BSE-infectivity via the feed chain;
- Risk factors representing challenges to the BSE/cattle system such as imports of potentially infected live animals, semen or embryos or imports of potentially BSE-contaminated MBM or feed preparations.
- The resulting processing and propagation risk, if possible on a year by year basis for at least the last ten years;
- The resulting GBR in each of the last ten years.

An outline of the assessment report is contained in annex 4 to this manual and a form to be used by the experts when preparing their report.

The assessment report will serve as the basis for the opinion of the SSC on the geographical BSE-risk. It is therefore essential that the report is exhaustive and complete.

Organisational aspects of the risk assessment procedure

Overview

- **Preparation**

1. With the help of external experts the Commission has analysed the dossiers provided by country before 11.1.1999. Standardised data sets (SDS, see annex 2) where established. Gaps in the documentation were closed by information readily available to the Commission or the experts. Whenever this was not possible worst case (but realistic) assumptions were used for establishing the SDS. Member States nominated experts who assisted in the preparation of the standardised data set. As far as possible they provided additional information on the spot or shortly after the exercise.
2. 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.
3. Third countries receive, together with the invitation to nominate a country expert to assist during the risk assessment, information on gaps in their dossiers which should be closed.
4. Independent experts are selected by the Commission in co-operation with the SSC or the TSE/BSE ad-hoc group from a list of suitable experts established by the SSC and taking account of pre-defined selection criteria. They are invited to participate in a risk-assessment exercise on a strictly personal basis, not as representatives of any country, organisation or institution.

- **The risk assessment procedure**

1. The independent experts will receive copies of this manual and of the dossiers they are going to evaluate in order to prepare their individual assessment before coming to the risk assessment exercise. Three independent external experts will assess each dossier.
2. The "assessment panel", i.e. all independent external experts participating in the risk assessment exercise, will be briefed on their task at the beginning of the risk assessment exercise. This briefing should ensure that the same approach is applied to each country dossier.
3. The experts who assessed the same dossier will discuss their findings with the aim to draft a consensus report summarising the analysis and conclusion of the group:

- Throughout step 3 Commission experts and Country experts will be available to support the evaluators upon request.
- Access to special expertise in TSE will be provided upon request.
- As a matter of principle none of the independent external experts analysing a file 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 discussion of the entire "assessment panel". Each group presents briefly their consensus reports (and, if necessary, the minority position) and defends their conclusion. The assessment panel will discuss each assessment. This discussion should lead to finalised assessment reports for each country, which normally should represent the

consensus of the entire assessment panel. By means of this general discussion of all reports it should be ensured that the assessments are consistent

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.

5. The countries will receive copies of their reports with the invitation to comment.

6. A re-assessment will be carried out if necessary.

NOTE ON BSE-STATUS DEFINITION

This method is only be used for assessing the geographical BSE-risk.
A method for the definition of the epidemiological BSE-Status has still to be defined.
The SSC continues its discussion on this issue.

Detailed description of the different steps of the risk assessment

Step 1 - Data analysis exercise

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 **and/**or in the public domain.

Participants, input, tools, output:
- External experts, Commission experts and Country-experts.
- Country dossier, mission reports from FVO, other publicly available data sources as far as feasible.
- Use forms in annex 1 and 2
- Output: Standardised data-set and information on completeness and consistency of the data.

This step was carried out separately once, for those countries which had provided a dossier at that moment. For other countries it will be integrated into the risk assessment exercise.

Step 2: Risk Assessment – Individual assessment.

Task: Establishing an individual first appraisal of the risk as basis for the group work.

Participants, input, tools, output:
- Independent external experts work separately from each other on the basis of the country dossiers and prior to the risk assessment exercise.
- Commission and country experts not involved.
- Input: Country dossier, output from step 1, if available, other documents if available.
- Use forms in annex 3.
- Output (as basis for group work):
  - Assessment of the impact of each risk factor on the propagation and the processing risk over the period 1980 (1985) to 1998 (2003), table and plots;
  - Assessment of the development of the propagation and processing risk over the same period, plots;
  - Assessment of the development of the GBR over the same period, plot;
  - Draft assessment report.

Step 3: Risk assessment – Group assessment.

Task: Preparing a fully documented group assessment report as basis for the panel discussion.

Participants, input, tools, output:
- All independent external experts who read the same dossier work together in groups of three.
- Commission and country expert involved upon request.
- Output of step 2, country report, standardised data set, other background documentation.
- Use guidelines in manual, annex 3 and annex 4.
- Output:
  - Group assessment of the impact of each risk factor on the propagation and the processing risk over the period 1980 (1985) to 1998 (2003), **table and plots**;

- Group assessment of the development of the propagation and processing risk over the same period, **plots**;
- Group assessment of the development of the GBR over the same period, **plot**;
- Draft group assessment report.

It is recommended to focus the discussion on points of difference in order to establish a common position. Particular attention should be paid to the experts' judgement and their respective reasoning. Ideally the group assessment report, to be drafted by one of the members of the group and signed by all members, should present the consensus of all members of the group. If no consensus can be reached, the minority position has to be spelled out clearly, together with the argumentation. The minority expert must sign it.

The group assessment report has to be fully documented with plots for the propagation risk, processing risk and geographical BSE-risk over time as well as with complete textual justification for these plots.

Step 4: Risk assessment –Panel assessment

Task: Preparation of the draft panel assessment report.

Participants, input, tools, output:

- All independent external experts (the "panel"), under the chairmanship of a member of TSE/BSE ad-hoc group.
- Commission and country expert not involved.
- Output of step 3, if necessary country dossiers and other background documentation.
- Use guidelines in annex 4.
- Output: Final assessment report, if required including minority opinion(s).

The entire assessment panel, i.e. all independent experts, meet under the chairmanship of a member of the TSE/BSE ad-hoc group. Each group 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 and their reasoning.

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

The final assessment reports should not contain index numbers or figures because these would seem to indicate a level of precision that is not justified. It will be drafted by members of the assessment panel and signed by the chairman.

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

Step 5: Preparation of comments on the draft reports by the concerned Countries

Task: Verification of the statements and arguments provided in the risk assessment report and preparation of comments, substantiated by appropriate additional information.

Participants, input, output:

- Responsible country administrations.
- Output of step 4.

- Comments on the draft assessment report, substantiated by appropriate additional information.

Step 6: Re-assessment, if necessary

Task: Verification if the comments provided by a country are sufficiently substantiated by appropriate additional information and justify a re-assessment.

Participants, input, output:
- TSE/BSE ad-hoc group of the SSC; SSC.
- Output of step 5.
- Decision of the SSC if a re-assessment is justified and necessary or final adoption of the assessment report.

Annexes to this manual

Annex 01: Recommendation of the Commission

Annex 1: Completeness checklist

Annex 2: Standardised data set (SDS)

Annex 3: Guidelines for the qualitative factor-by factor assessment

Annex 3a: Guidelines for assessing the quality of a TSE-surveillance.

Annex 4: Guidelines for the assessment report

Annex 4a: Assessment report form

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ANNEX 01

Recommendation of the Commission

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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				

Risk-Factor	Species	Complete	Interpolation possible	Add. Data needed	Comment
	other				
(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

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Standardised Data Set:

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 % of 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.)													

The following classes of animals, used in the national statistics, have been included in the different Beef and Dairy categories mentioned above:

In order to do so the following assumptions have been made :

Other 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 **[ ],** % of all Animals **[ ]**

Year	Beef cattle [mio **[ ]** or [% **[ ]** of cattle]				Dairy cattle [mio **[ ]** or [% **[ ]** of all cattle]				All cattle	Sheep 1000 [ ] or % of 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.)													

In order to complete this table the following assumptions have been made:

Comments:

Table 3 Fraction of class of ruminants which received additional feed

Country Code: _____

Coding used:

[**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.

In order to complete the table the following assumptions have been made:

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%

Assumptions made:

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Annex 3:

Qualitative

Factor – by – Factor Assessment

Revision 1

Revised after the first risk assessment exercise

Qualitative Factor by Factor Assessment

Introduction

This part of the manual describes in detail the qualitative factor by factor assessment and provides forms to guide the assessing experts through the process. These forms are divided into three parts. Part one lists the risk factors, part two provides tables to note the annual values for the risk factors and part three provides pre-formatted graphs for a graphical display of the development of the risk factors and the corresponding risks over time.

Part one : Factor by factor assessment - Risk factors

Part one contains a list of 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 could increase significantly/strongly the risk, assign the risk-value **5**

If a factor could increase 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 could reduce the risk slightly, assign the risk-value **2**

If a factor could reduce significantly/strongly the risk, assign the risk-value **1**

The different risk factors are directly relevant for either the processing or the propagation risk. They also may indicate a potential challenge in terms of BSE-infectivity entering the BSE/Cattle system of the country/area during the period under consideration. The actual risks can then be estimated taking account of the risk factors and challenges of the preceding years. The following text explains this.

Risk factors, directly relevant for the processing risk and the propagation risk.

Only risk factor 1, relating to the structure of the cattle, ovine and caprine population, is directly relevant for both risks, the propagation risk and the processing risk.

The population structure may indicate, for example, that cattle are likely to be supplied with additional feed other than from local grassland etc. This additional feeding could, if it can not be ensured that it is free of MBM, potentially increase the propagation risk.

The information that is provided under this factor also allows estimating the age at slaughter of cattle. If significant parts of the cattle population are slaughtered at a higher age (e.g. above 5 years) the processing risk could grow; not necessarily because of the number of infected animals that are processed but because the infective load per infected animal that is processed would be several orders of magnitude higher.

Risk factors, directly relevant for the processing risk.

Risk factors 6 (surveillance) and 8 (culling) are directly relevant for the processing risk. A good surveillance (RF6) would identify all BSE cases, even if they are very infrequent, and would also allow identification of animals being at risk, be it because they have been raised together with the cases (cohorts) or because of maternal transmission or because of other factors pointing to an enhanced risk of being infected with BSE. An appropriate culling strategy (RF8) would increase the likelihood that these "risk-animals" would be excluded from entering the processing chains. Together the two risk factors determine the capacity of the system to avoid that an infected animal, should it be present, would be processed.

Note:

- The quality of a TSE-surveillance system should be assessed against the criteria given in annex 3a.
- Incidence is addressed under RF6. In this context it should be used as an indicator for the quality of the surveillance system but not directly as a risk-enhancing factor. (See below).

Risk factors, directly relevant for the propagation risk.

Risk factors 3 (feed), 4 (MBM-ban), 5 (SSRM-ban) and 7 (rendering and feed processing) are directly relevant for the propagation risk.

RF3 and 4 indicate the likelihood that potentially contaminated MBM would be fed to cattle.

RF5 indicates if a potential control measure that could exclude infectivity from processing into feed is effectively in place. It indicates the potential to reduce the infectivity of the final feed product through reducing the infectivity input into the process.

RF7 indicates the ability of the rendering system to reduce any infectivity entering the feed production process. Together with RF5 it determines the theoretically possible level of infectivity in the feed that could result from a given number of processed infective animals.

Together these four risk factors determine the ability of the feed chain to avoid recycling of infectivity, either by reducing the infectivity before (SRM-ban) or at the rendering stage and/or by avoiding feeding MBM to cattle.

Given the fact that non of these potential controls is likely to be waterproof, all four risk indicators should show a potential to reduce the propagation risk before it could be assumed that recycling of BSE is prevented.

Note: Importing potentially contaminated MBM increases the risk to create new BSE-cases but not, stricto-senso, the risk to propagate an already existing infectivity. It is a challenge to the system – see next paragraph.

Risk factors indicating a challenge to the system

A part of risk factor 3 (imports of potentially contaminated MBM) and the entire risk factor 2 (import of potentially infected life animals, semen or embryos) are indicating the possibility that infectivity could be imported into the BSE/Cattle system. These imports are hence challenging the ability of the system to eliminate either infective animals or infective feed from the BSE/cattle system.

The presence of BSE-infectivity in the system (prevalence of BSE) at the beginning of the period under consideration, e.g. indicated by a given BSE-incidence, would hence be an initial challenge to the system.

The presence of TSEs in other animals could also be seen as a potential source of infectivity and therefore as a potential initial challenge. It would become a challenge to the system if (a) the TSE could enter the cattle feed chain and (b) could infect cattle with BSE. However, even if one of the theories concerning the origin of BSE is that it came from scrapie, the latter has not yet been proven but it has also not been thoroughly enough tested to allow excluding this possibility. The presence of a large sheep population in comparison to the cattle population (see RF1) may therefore increase the propagation risk, in particular if scrapie exists and scrapie infected animals are processed into animal feed.

Part two: Notation sheets

Part two contains a set of tables for noting down the appropriate risk value for each factor, as far as possible on a year by year basis. Risk values above three indicate that, in the respective year, the risk factor could enhance the risk under consideration. Values below 3 indicate that it could reduce the risk.

Part three: Graphical sheets

Part three provides a set of empty graphs that should be used by the assessors to present the development of the risk values and the resulting risks over time.

The graphs for the risk values are only meant to visualise the same information as contained in the tables provided in part two above.

Graphical presentation of the risk-factors

For each of the 7 risk factors which have an impact on the propagation and/or the processing risk; the development of their impact on the propagation and/or processing risk should be indicated by plotting the overall risk-values over time. It is important to be aware that these graphs are NOT presenting the risk but only the potential impact of the respective factor on the risk.

Graphical presentation of the risk-levels

To plot the risk levels over time requires reflecting on the state of the cattle/BSE system as indicated by the risk factors and its likely challenges in the past. It requires processing of the information provided by the risk values.

Estimating the current risks from the risk factors and challenges of the past.

Together the risk factors indicate if the system could cope with a "BSE-challenge" or not and if such challenges have taken place. The ability to eliminate BSE-infectivity from the system can be seen as its robustness with regard to BSE. A robust system would reduce and finally eliminate incoming infectivity while a less robust system would amplify it.

Estimating the processing risk

The processing risk is determined by the ability of the system to identify and eliminate infected animals before they are processed and the number of potentially infected cattle being present at a given point in time. This number is depending on the number of cattle exposed to, and subsequently infected by, the BSE agent in the preceding years. Past and present imports of animals or embryos from BSE-affected regions could increase the number of infected animals being alive and hence increase the processing risk. Imports over the past 8 years should be taken into account as long as animals are still alive. Because of the long incubation period of BSE they could, theoretically, still pose a risk. The fate of imported animals and embryos is an important aspect.

Incidence is a good indicator for the prevalence of BSE. Even if a fixed ratio of prevalence to incidence is not known, it has to be assumed that for each confirmed BSE case a certain number of pre-clinical (hence invisible) incubating animals are present in the cattle population. Estimations from the UK indicated a ration of 1 to 5 around the peak of the epidemic. Clearly this ratio depends on the likelihood of new infections occurring during the incubation time of the confirmed cases.

Estimating the propagation risk

The propagation risk is an indicator of the likelihood that, in a given year, cattle could be exposed to the BSE-agent. It depends on the amount of infectivity that could enter the rendering system, the ability of the rendering system to reduce, if not eliminate any incoming BSE-infectivity and the likelihood that cattle could be fed with MBM. The latter could be increased through imports of MBM-containing feed stuffs from BSE-affected regions, a challenge that could only be met by appropriate safeguards preventing that such feed stuffs would reach cattle.

In this context incidence can be used as an indicator for exposure that took place in the past and hence the propagation risk in the past.

Interaction of the two risks

The processing risk of today depends from the number of infected cattle being alive at a given point in time. This number depends largely from the exposure of cattle to the BSE-agent in the past years. As the propagation risk is an indicator for the likelihood that exposure takes place, the current processing risk depends on the past propagation risk. It therefore can be concluded that the processing risk follows the propagation risk with a certain delay. This delay depends on the incubation period of cattle, which lies between 2 (very seldom) and 8 or more years (also seldom) with the highest likelihood around 5 years. It is also influenced by the age at which cattle are slaughtered because slaughtering infected animals at young age would on the one hand reduce significantly the amount of infectivity entering processing but would inject this infectivity into the feed chain at an earlier stage.

The propagation risk, as indicator for the likelihood that in a given year exposure of cattle to the BSE-agent takes place, is largely depending of the BSE-infectivity entering the feed chain. The processing risk of the same year is an indicator for this. Hence the propagation risk of a given year is directly influenced by the processing risk of the same year. The reason lies in the short period which normally lies between production and use of MBM for feed.

Note: It can be assumed that animals below 2 years of age could not harbour significant amounts of BSE-infectivity and would hence not pose a risk of propagating the agent.

Graphical presentation of the propagation and processing risk

To plot the risk over time requires reflecting on the state of the cattle/BSE system and its likely challenges in the past, as already shown before.

To illustrate the risk a continuous scale is suggested. 0 indicates a (theoretically impossible) zero-risk and 1 indicating 100% probability that the hazard, to which the risk relates, occurs.

- A processing risk of "1" should be assigned if it is assessed to be certain that per million adult cattle alive in that country at least one infected animal per year will be processed. This may happen because of a lacking ability of the system to identify and eliminate that animal, not necessarily showing clinical symptoms of BSE, it in advance.
- A propagation risk of "1" is appropriate if it is assessed to be certain that per million adult cattle alive in the country one newly infected BSE-case will occur per year. This may be so because a processing risk of "1" is assumed and the recycling of the BSE agent is regarded to be likely. The resulting potential exposure might be seen to be sufficient to create at least on new infection. A propagation risk "1" may also result from importing potentially BSE-contaminated MBM and feeding this to domestic cattle.

If it is regarded to be likely that more than one infective animal would be processed or more than one new infection would occur, it is proposed to use numbers above 1 to illustrate the order of magnitude regarded to be likely. The logarithmic intervals in the chart on page 23 of this annex allow indicating if this order of magnitude is between 1 and 10, 10 and 100, 100 and 1000, or above.

The risk should be indicated as a range within which the true risk is assumed to be. This range should be as narrow as scientifically justifiable in order to provide appropriate differentiation.

Note: Risk management measures such as an MBM-ban or an SRM-ban or improved surveillance and culling schemes, have a more or less immediate impact on the risks. Also the introduction of optimal rendering standards would immediately reduce the propagation risk significantly. The plotted graphs may therefore not be smooth curves but could show abrupt changes.

Guidelines for estimating the processing risk: If the risk factors 1, 6 and 8 indicated little or no capacity to avoid infected animals from being processed the processing risk could be high. Its level would thus depend on the theoretically possible number of

infected animals being alive in the country. Imports of life animals or embryos from countries likely to be hit by BSE and exposure of domestic cattle to the BSE-agent in the past determine this number. If the risk factors indicate a good ability to identify and eliminate risk animals, the processing risk might be lower than the theoretically possible number of infected animals being alive would require.

Guidelines for estimating the propagation risk:

If risk factors 3 and 4 (feeding, feed ban), 5 (SRM ban), and 7 (rendering and feed processing) indicate that the infectivity harboured by infected cattle which were processed could reach cattle the risk level could be high. The level depends, however, on

- the amount of infectivity which could have entered the feed chain (as indicated by the propagation risk),
- the ability of the rendering system to reduce or eliminate that infectivity,
- the likelihood that the resulting potentially contaminated domestic MBM has reached cattle
- the likelihood that potentially contaminated MBM/feed stuff containing MBM was imported from BSE-affected countries and that cattle has been exposed to it.

Guidelines for estimating the GBR

Having assessed the two partial risks, the GBR-level has to be estimated. At this stage the incidence, calculated as confirmed cases per million cattle over 2 years of age, has to be taken into account.

- On the one hand incidence should be taken as indicator for the quality of the surveillance system: if all risk indicators point to an enhanced probability that BSE-cases should appear or should have appeared in the past but no incidence is known, the surveillance system needs careful checking. At the same time an incidence in line with the expectations resulting from the risk factor analysis would indicate a well functioning surveillance system.
- Incidence is also an indicator for past problems. Tracing of the BSE-cases is essential to decide if they where imported or not. If they where not imported or lived long enough in the country, domestic infection can not be excluded. The risk, that domestic infection happened should have appeared in the respective risk factors. If this is not the case, the relevant risk factors should be re-assessed.
- Finally incidence is also pointing towards the future processing risk and hence the GBR. Current cases have been un-identified alive the preceding years. If not very strong indications are given that the reason for the current cases, which lies 2,3, 4, 5 or more years back, has not been eliminated, it has to be assumed that infected animals are currently alive and pose a potential risk.

To plot the GBR over time the following has to be taken into account:

- The GBR indicates the current and future likelihood that infected animals could enter the food or feed processing chain. It therefore depends on the current processing risk and its assumed development in the foreseeable future.

- The current and future processing risk depends on the propagation risk in the past eight or ten years (see above). Both risks take account of the challenges that had to be faced by the system.
- When illustrating the development of the GBR over time at the same scale as the other two risks, the GBR should by definition never be lower than the processing risk. It may be higher than the processing risk if the propagation risk is higher than the processing risk because this would point towards an increasing processing risk in the future. Therefore the GBR should first be calculated according to the following rule:

  IF PRR>PGR then GBR=PRR

  IF PRR<PGR then GBR=PRR+(PGR-PRR)/2
- After having assessed the GBR in this more or less automatic way, it is important to verify if reasons exist for deviating from this result.
- When finally assigning a current GBR, it is, for example, necessary to take account of the development of the risks over the recent past, i.e. their trend. A decreasing processing risk, in particular in connection to a low propagation risk, would allow assigning a risk level below that one indicated by the formula above. At the contrary an increasing processing risk would justify, in particular in combination with high levels of propagation risk, to assign a GBR level above the one indicated by the formula. This “trend-aspect” should be discussed in the assessment report.
- Another aspect, which might require modifying the GBR, could be the BSE incidence (n° of confirmed BSE-cases per year and per million adult cattle alive in the country), and in particular its trend. Increasing incidence figures should be reflected in the increasing processing risk. However, if this is not the case, the incidence figures could indicate a need to correct this here.

Risk-Factor	Factors influencing the risk impact	Risk value[11]		Comment
1. Structure and dynamics of the bovine, ovine and caprine animal populations (relevant for propagation and processing risk)				
(a) absolute numbers of animals per species and breed, alive and at time of slaughter;	A high sheep/cattle ratio could indicate higher potential for BSE, in particular if fallen sheep are rendered. If ratio is > 1, assume risk increased to some extent (RF = 4). Population density could be an indicator of intensity of husbandry practices. Intensive husbandry would imply need to use concentrates due to shortage of grazing. Extensive husbandry would reduce need to use concentrates.	PGR 2 3 4	PRR 2 3 4	
(b) age distributions of animals per species and breed, sex and type;	A high average age could indicate a high average age at slaughter (see 1c) and hence point to a higher PRR but also higher infective load of rendered material; hence higher PGR..	2 3 4	2 3 4	
(c) age distribution of animals per species and breed, sex and type at time of slaughter;	The likelihood of infectivity entering the food/feed chain increases with higher average age at slaughter: age<2: RV=1, age=2: RV=2; age=3: RV=3; age=4: RV=4, age>4: RV=5.	1 2 3 4 5	1 2 3 4 5	
(d) geographical distribution of the animals by species and breeds;	High concentration points to higher exposure (PGR) leading to more infected cattle (PRR). Joint raising of pig and cattle points to a risk of cross-contaminating cattle feed with pig feed (PGR).	2 3 4	2 3 4	
(e) geographical distribution of the animals by husbandry system, herd size & production-purpose*;	PGR increases if husbandry system and/or production purpose require additional protein supply (for specific periods or permanent). Herd-size could provide hint on management intensity if seen in relation to available grazing area.		2 3 4	
(f) system of identification and capacities for tracing of animals.	A good identification system could help eliminating BSE-cases and BSE-suspect and reduce processing risk.	2 3		
Overall Risk Factor	Note: This should NOT be an arithmetic average of the component factors.			

Notes: * Cattle used for milk and meet production should for the purpose of the risk assessment be regarded as dairy. They will live as long, or even longer than dairy cattle and will have a similar possibility to live longer than the BSE incubation period.

[11] Risk value refers to Propagation Risk (PGR) for RF1, 3,4,5, and 7; or Processing risk (PRR) for RF1,2,6, and 8.

Risk-Factor	Factors influencing the risk impact	**Risk value**	Comment
2. Animal trade (Potential challenge: relevant for processing risk)			
(a) imports and exports;	Imports of live animals from any country with BSE would indicate a certain risk that infective but clinically healthy animals are processed. Significance of imports may depend on specific regions of countries of origin. Relevance for PRR (and subsequently PGR) at time of slaughter (not time of import) of imported animals increases with number of imported animals and BSE-prevalence in the country of origin.	3 4 5	
(b) trade within the geographical area;	Only relevant if one assumes sub-regions with remarkably different BSE-risk.	3 4	
(c) imports of embryos and semen;	Imports from any country with confirmed BSE prevalence could point to a remote risk to import BSE. If existing, it would influence the processing risk at the end of the life of the resulting animals.	3 4	
(d) use made of imported animals, embryos or semen;	Slaughtering imported animals at young age would reduce the PRR because their infective load could not be very high (RV=2). If animals kept alive for long (breeding cows, dairy) their BSE-load could be much higher (RV=4). As these animals are likely to be for breeding purposes, the PRG could increase because of vertical transmission.	2 3 4	
(e) mechanisms used by slaughterhouses to identify animals and their origins, as well as data from these procedures.	Relevant for surveillance and monitoring effectiveness. BSE cases may be identified at slaughterhouses if clinical condition brought on by stress of travel etc. See also 1 (f). Good back-tracing would allow eliminating animals exposed to similar conditions as the cases and hence to reduce the processing risk. Sourcing from BSE-free areas reduces the PRR, too.	2 3	
Overall Risk Factor	Note: This should NOT be an arithmetic average of the component factors.	1 2 3 4 5	

Risk-Factor	Factors influencing the risk impact	Risk value	Comment
3. Animal feed (relevant for the propagation risk, to be assessed in conjunction with RF4)			
(a) domestic production of Meat and Bone Meal (MBM), and its use per species and husbandry system (in particularly the proportion of the domestically produced MBM fed to bovine, ovine and caprine animals).	If MBM (which normally contains ruminant proteins) is used to supplement ruminant feeds to any extent: **RV = 5**. If (ruminant) MBM is used for any feed (e.g. pig and poultry): **RV=4**, because of potential cross contamination. If MBM is not used for any feed by controls are insufficient, assume **RV=3**. If MBM is not used in any feed and controls are good but not fully satisfactory: **RV=2** with fully satisfactory controls: **RV=1.**	1 2 3 4 5	
(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);.	*Note: This is a **challenge** to the system because it indicates a potential source of the BSE-agent. I has to be taken into account when estimating the propagation risk level in a given year. MBM imports from any country with confirmed BSE prevalence would increase the risk if feeding those imports to bovines could not be excluded.*	*3 4 5*	*This value indicates the strength of the challenge.*
(c) exported MBM, specifying country of destination.	Exporting large proportions of domestic MBM might reduce the risk but could increase it in the receiving country (in particular if ruminant based MBM is exported or if MBM made from high-risk material is imported). **Ensure information is passed to file of receiving country.**	2 3	
Overall Risk Factor	Note: This should NOT be an arithmetic average of the component factors.	1 2 3 4 5	

Risk-Factor	Factors influencing the risk impact	**Risk value**	Comment
4. Meat and bone meal (MBM) bans (risk management measure, relevant for propagation risk, to be assessed in conjunction with RF3)			
(a) complete description;	A convincing MBM-ban reduces significantly the PGR (**RV=1**). The structure of the ban is important in this context: a well-constructed ban has a higher likelihood of effective implementation and would hence reduce the risk, and vice-versa. No ban increases the risk that MBM is fed to cattle. Driving factors are technological appropriateness and relative price in comparison to vegetable protein.	1 2 3 4 5	
(b) dates of introduction;	An MBM-ban for bovines will quickly reduce the PGR to some degree but it will take about two years (or more) until it is fully effective. Assess impact on PGR in relation to period since implementation: 8 years ago: **RV = 1**, 4 years ago: **RV = 2**, 2 years ago: **RV = 3** If MBM is still allowed for non-ruminants or the implementation of a ban dates from less than 2 years, set **RV=4**.	1 2 3 4	
(c) actual implementation, policing and compliance figures;	Good, convincing implementation reduces the risk (**RV=2**). Need to demonstrate firm evidence of efficient implementation, with good controls. In-efficient implementation counteracts the risk reduction potential of the ban: **RV=4**.	2 3 4	
(d) possibilities of cross-contamination with other feed.	Cross-contamination (cc) increases PGR. Check potential for cc during production, transport and distribution. Cc is more likely if feed mills produce pig & poultry feeds that may contain MBM and ruminant feed, in particular if the same lines are used. Significant risk enhancement is likely as long as cc is technically not minimised and wellcontroled.	2 3 4 5	
Overall Risk Factor	Note: This should NOT be an arithmetic average of the component factors.	1 2 3 4 5	

Risk-Factor	Factors influencing the risk impact	**Risk value**	Comment
5. Specified bovine offal (SBO) & SRM-bans (risk management measure, relevant for propagation risk)			
(a) complete description;	The BSE-load possibly entering the food and feed chain decreases if more SRM/SBO are excluded. Note: The CNS alone contains about 90% of the infective load of a clinical BSE-case. Banning CNS from food but allowing it to be rendered for feed would **not** reduce the PGR, it would only have an effect on the Human Exposure Risk, which is not assessed here. No ban: **RV=4**; only brain banned: **RV = 2**, all CNS banned: **RV= 1**.	1 2 3 4	
(b) dates of introduction;	Because of assumed delay between introduction and effective implementation, set RV in relation to period since introduction: Less than 2 years ago : **RV=3 to 4**, 2 to 3 years ago: **RV = 2 to 3**, more than 3 years ago: **RV=1 or 2**	1 2 3 4	
(c) actual implementation, policing and compliance figures.	Good, convincing implementation reduces PGR. Need to demonstrate firm evidence that the ban has been implemented effectively, with good controls. An in-efficient implementation counteracts the risk reduction potential of the ban: RF=4, good implementation counteracts other weaknesses.	2 3 4	
Overall Risk Factor	Note: This should NOT be an arithmetic average of the component factors.	1 2 3 4 5	

Risk-Factor	Factors influencing the risk impact	**Risk-value**	Comment
6. Surveillance of TSE, with particular reference to BSE andscrapie (risk management measure, relevant for the processing risk, use annex 3a for assessing the impact of the surveillance system on PRR)			
(a) methods & programmes of surveillance & recording of clinical cases of BSE and scrapie, awareness training for farmers, vet., supervisory bodies & authorities;	The surveillance as such can not increase the risk of infected animals being slaughtered/processed but is essential for controlling this risk. The impact on the risk could therefore be neutral, (**RV=3**) or reducing it by identifying not only all cases but all "risk-animals", i.e. those raised together with cases or linked to them via vertical transmission (**RV=2 or 1**).	1 2 3	
(b) incidence of neurological disorders in which TSE could not be excluded on clinical grounds in any animal species;	The number & type of brains analysed in appropriate laboratories has been used as indicator for the capacity of a system to identify BSE. Ideally all brains from animals that died because of a CNS-disease and where BSE could not be clearly excluded should be tested. Experience indicates that a certain number of such brains is normal (e.g. 100/million). OIE & EU have recommended min.N° of brains to be tested annually. However, these figures are not fully supported by scientific evidence.	2 3 4	
(c) incidence of labconf. cases of BSE and scrapie;	Incidence figures should be discussed in the context of the assessed quality of the surveillance. They might be used as indicator for this quality.		Note incidence figures for 5 y.
(d) distribution by age &, place, and countries of origin of cases;	Cases born after the ban point to persisting implementation problems, age of cases <4 hints to high exposure. Incidence of imported animals is irrelevant for the domestic risk. Clustered native cases point towards geographical risk variation.		Take into account later
(e) incentives for reporting cases, compensation and reward schemes;	Reporting of suspect cases is less likely if compensation is below market value: **RV=3**. Effective compensation, covering loss of income & value of animals, enhances the likelihood of reporting: **RV=2**. No compensation: **RV=4**	2 3 4	
(f) Method of lab. Confirmation & recording of suspect cases of BSE and scrapie;	Better methodologies -> better surveillance. Good laboratory practices (**RV=2**) would combine other methods with histopathological verification (in one country it was found that histopathology alone could miss about 15-20% of cases). If methods are combined, sensitivity is increased if one confirmation is sufficient (**RV=2**). It decreases (**RV=4**), if both methods must confirm a case.	2 3 4	
(g) BSE and scrapie strains	Relevance ?	3	
(h) existing systems or current plans for targeted active surveillance.	Active surveillance would increase the value of incidence figures and support BSE-freeness. (See annex 3a). (RV=1 would require an adequate culling system – see RF8)	1 2 3	
Overall Risk Factor	This should NOT be an arithmetic average of the component factors.	1 2 3 4 5	

Risk-Factor	Factors influencing the risk impact	**Risk value**	Comment
7. Rendering and feed processing (relevant for propagation risk)			
(a) all rendering and feed processing systems used;	Only batch (133/20/3 or better); RV = 2; Mixture of batch (133/20/3) and Continuos; RV= 3 - 4, depending of relative weight of each type; only reliable continuos systems (133/20/3 or equivalent): RV = 4; other systems not in compliance with (133/20/3) or no reliable information; RV = 5	1 2 3 4 5	
(b) nature of the records of rendering and processing plants;	Important for the reliability of the information under 7a. Unreliable records increase the RV of 7a by 1 (if possible).	2 3 4	
(c) quantitative and qualitative parameters of MBM and tallow production by each of the processing systems;	Same considerations as for 7(a). Data should allow quantitative and qualitative verification. The relation of outputs from the different systems is important for the risk value.	1 2 3 4 5	
(d) the geographical areas from which the rendered materials originate;	Raw material from BSE-risk area: RV=4; Large proportion of raw material from BSE-free areas could reduce the: RV=2. Note that imported carcasses will carry the BSE-risk of their origin.	2 3 4	
(e) the type of raw material used;	SRMs, suspect TSEs (incl. SCRAPIE) and fallen stock excluded: RV=2; SRM etc. rendered at 133/20/3: RV=4; SRM rendered but not at 133/20/3: RF=5. Fallen stock used: RV+1, in particular if SRM are not excluded.	2 3 4 5	
(f) parameters on separate processing lines for materials from healthy and suspected animals;	No separate processing lines: RV=5, separate processing lines but within the same premises: RV=4; separate processing lines in different premises: RF=3. Only relevant if batches including MBM (e. g. pig feed) and MBM free batches are produced.	2 3 4 5	
(g) transport and storage systems for MBM or feed containing MBM.	Cross contamination may also result from inadequate (bulk) transport and storage systems.	2 3 4	
Overall Risk Factor	Note: This should NOT be an arithmetic average of the component factors.	1 2 3 4 5	

Risk-Factor	Factors influencing the risk impact	**Risk value**	Comment
8. BSE or scrapie related culling (risk management measure, relevant for processing risk, to be assessed in conjunction with RF6)			
(a) culling criteria;	Complete culling of case-herds/flocks including all offspring, cohorts and "in-contacts": RV=2. Less complete: RV=3 for BSE.	2 3	
(b) date of introduction of the culling scheme and of any subsequent modification;	The culling of the case-herds/-flocks would reduce the PRR in the subsequent years, when the animals normally would be slaughtered. For BSE the likelihood for multiple infection within herds seems to be small, therefore the impact of culling of herds on risk is not very substantial. Culling of cohorts might have a more significant effect. For SCRAPIE multiple infection of herds is normally the case and complete culling will have rather stronger impact on PRR.	2 3 4	
(c) animals culled (details as specified in point 1);		-	
(d) sizes of herds in which animals were culled.		-	
Overall Risk Factor	Note: This should NOT be an arithmetic average of the component factors.	1 2 3 4 5	

PART TWO: Risk-Tables

	Risk Factor	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	00	01	02
Population Structure (PGR & PRR)	1a PGR																							
	1a PRR																							
	1b PGR																							
	1b PRR																							
	1c PGR																							
	1c PRR																							
	1d PGR																							
	1d PRR																							
	1e PGR																							
	1e PRR																							
	1f PGR																							
	1f PRR																							
	ONE PGR																							
	ONE PRR																							

	Risk Factor	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	00	01	02
Trade	2a																							
	2b																							
	2c																							
	2d																							
	2e																							
	TWO																							
Animal feed	3a																							
	3b challen -ge																							
	3c																							
	Three																							
MBM Ban	4a																							
	4b																							
	4c																							
	4d																							

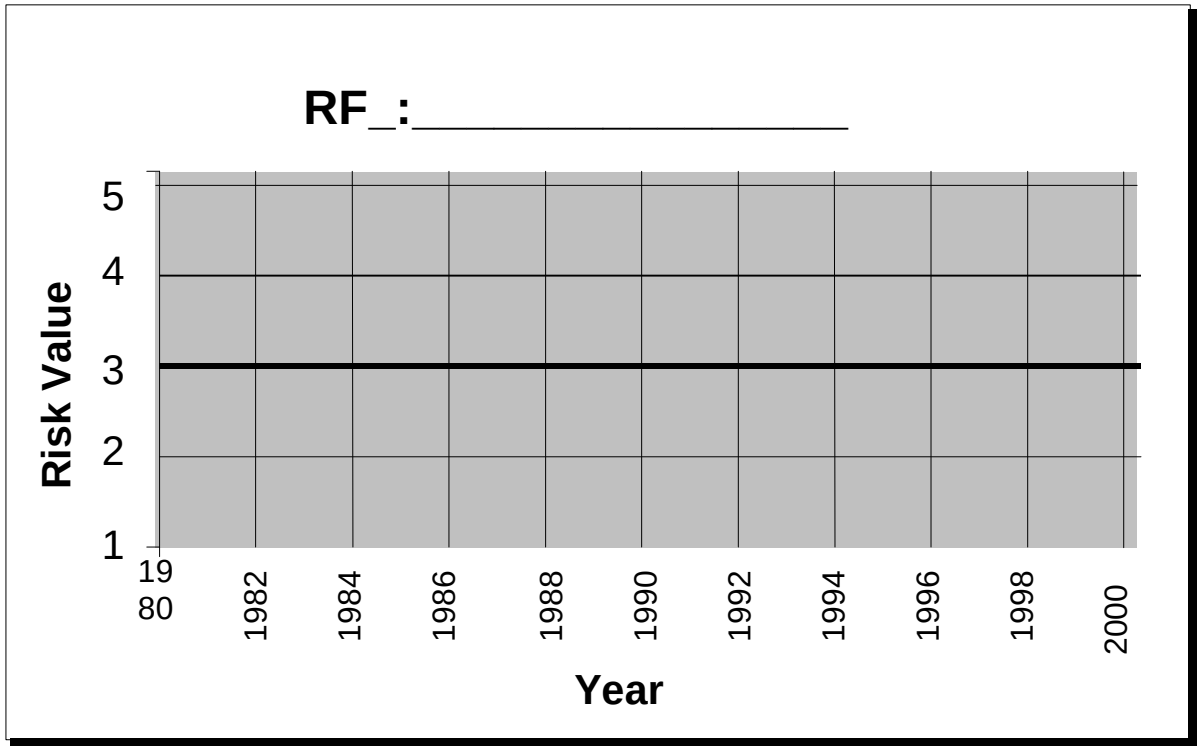
	Risk Factor	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	00	01	02
	FOUR																							
SRM-Ban	**5a**																							
	5b																							
	5c																							
	FIVE																							
Surveillance	**6a**																							
	6b																							
	6c																							
	6d																							
	6e																							
	6f																							
	6g																							
	6h																							
	SIX																							

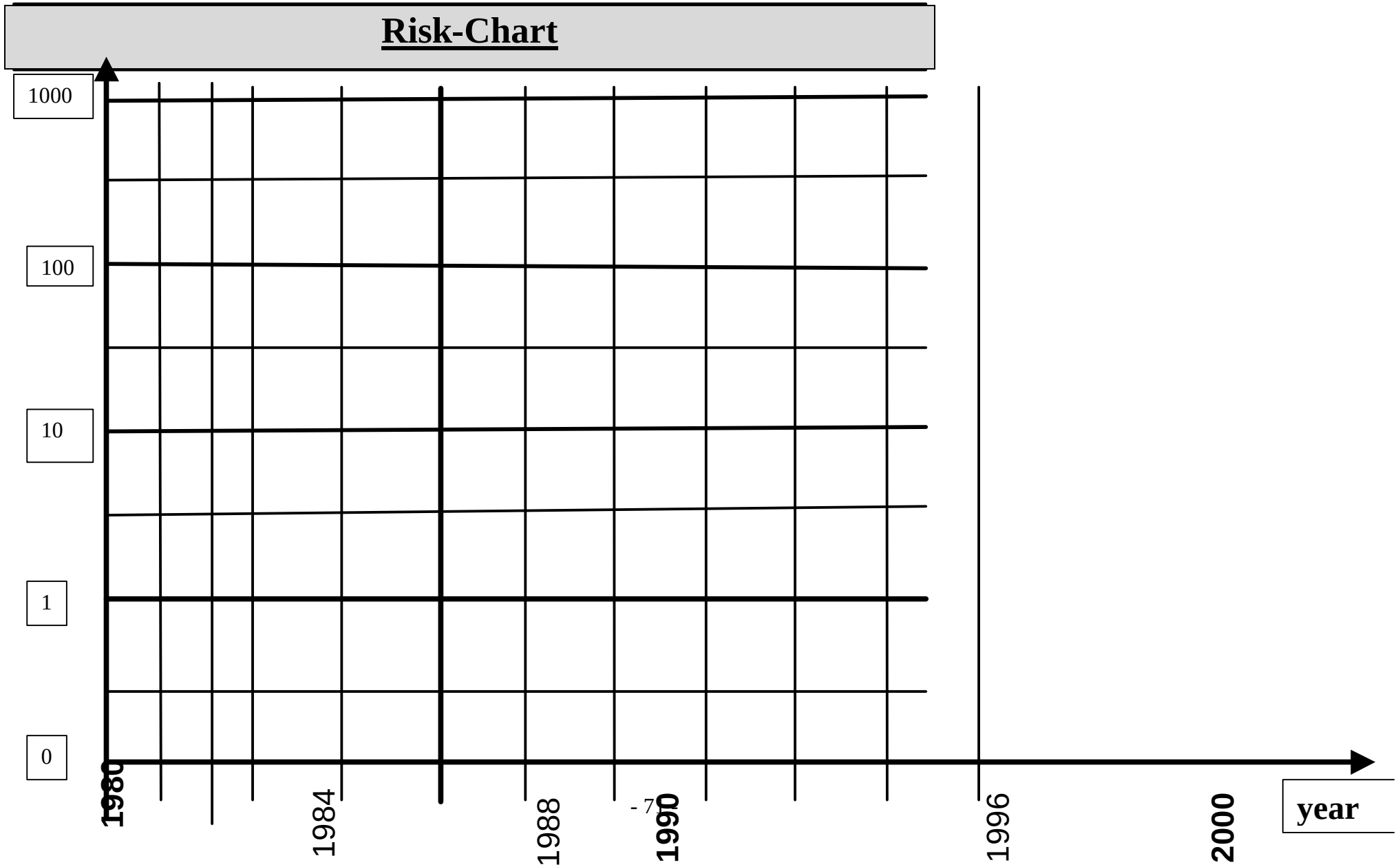
	Risk Factor	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	00	01	02
Rendering	7a																							
	7b																							
	7c																							
	7d																							
	7e																							
	7f																							
	7g																							
	Seven																							
Culling	8a																							
	8b																							
	8c																							
	8d																							
	Eight																							
Total Risk:	PGR																							
	PRR																							

"CHALLENGES"

Major potential imports of BSE into the BSE/Cattle system of Country by different routes:

Year	Type of challenge				Size of challenge	Comment
	Import of live animals	Import of embryos	Import of MBM or feed	Other	Indicate volume of import in terms of n° of animals or embryos or in ton per year.	Discuss importance of challenge in relation to domestic population and/or domestic production


RF_:_____
Risk Value
5
4
3
2
1
1980
1982
1984
1986
1988
1990
1992
1994
1996
1998
2000
Year


Risk-Chart
1000
100
10
1
0
1980
1984
1988
1990
1996
2000
year

Manual for the assessment of the geographical BSE-risk

Annex 3a

Indicative criteria for assessing the Quality of an Animal TSE-Surveillance System

Introduction

Based on an outline of the requirements for an theoretical standard for a TSE-surveillance system aiming to identify all BSE-cases, as well as all animals being suspected to be infected with BSE or simply seen to be at risk of having been infected, four quality-levels of surveillance are defined with regard to their capacity to reduce the processing risk or not.

Outline of an ideal TSE-surveillance system

Note to the reader: It is understood that the surveillance described hereunder is rather theoretical and over ambitious. However, the closer a real surveillance system comes to this standard, the higher is its capacity to contribute to a reduced processing risk through identifying incubating animals before they show clinical signs and allowing to eliminate them before they are processed.

Definitions

1. Surveillance system: System of measures/actions for the identification of clinically TSE-affected, incubating and/or exposed animals.
   1.1 Passive surveillance : based on reported cases
   1.2 Active surveillance : based, in addition to reported cases, on other risk parameters.
2. Exposed animals: exposed to the agent, in case of BSE mainly via feed.
3. Infected animals: Exposed animals where the agent replicated without finally leading to clinical outbreak.
4. Incubating animals: Infected animals where the BSE-agent replicates in such a way that it would finally lead to clinical outbreak, if the animal lives long enough.
5. Clinical BSE-case: Animal showing clinical symptoms compatible with BSE where BSE was confirmed by (post mortem) laboratory analysis.
6. Suspect clinical BSE-case: Animal, showing clinical symptoms compatible with BSE before (post mortem) confirmation. Also all animals with progressing diseases.
   - *Note: With regard to BSE it is currently not possible to differentiate between infected and incubating animals.*
   - *Note: With regard to BSE suspect clinical BSE-cases would normally not be less than 2 years old.*
7. Risk animals:
   7.1 Imported or native animals likely to have been exposed to the same feed as clinical BSE-cases.
   7.2 Imported or native animals being offspring from clinical BSE cases.
   7.3 Fallen stock whenever it can not positively be excluded that it was incubating BSE.
8. An ideal epidemio surveillance system should be able to detect all clinically TSE affected animals, all animals exposed to the BSE-agent and all animals incubating the BSE-disease. To this end it would combine an efficient passive surveillance of clinical cases (A) with an active surveillance targeting exposed animals around clinical BSE-cases (B1) and an active surveillance targeting risk populations defined by other parameters than incidence (e.g. fallen stock) (B2).

I. General requirements for an Animal TSE-Surveillance System

THE FOLLOWING REQUIREMENTS MUST BE FULFILLED BY ANY TSE-SURVEILLANCE SYSTEM FOR ANIMALS:

1. Suspected and confirmed TSE diagnosis in animals must be mandatorynotifiable, in particular with regard to BSE and scrapie.
2. Appropriate compensation for all animals slaughtered in the frame of TSE-surveillance and TSE-control measures (suspected, affected, farm culling).

II. SPECIAL REQUIREMENTS

II.A. Passive surveillance, targeting clinically affected animals

To guarantee that all clinically affected animals are identified, a surveillance system would have to fulfil the following conditions:

1. Continuous recognition of clinical signs of TSEs in ruminants, through continuous education, training and awareness raising for farmers, veterinarians and other concerned persons..
2. Guarantee that suspect animals, i.e. animals showing clinical signs of neurological disorders for which TSE can not be excluded, can in no way disappear without efficient clinical examination via slaughterhouses (especially emergency slaughter); rendering plants; burial; or slaughter at home.
3. Regular (at least 2 times a year) BSE-oriented inspections of all animals of a herd/flock by the official veterinary officer or practitioner and pre-slaughter inspection with a view to support points 1 and 2 above.
4. Specific BSE-oriented pre-slaughter inspection for allemergency slaughter.
5. To all suspect cases a quality assured test system is applied in national reference laboratory for TSE including
   - 5.1 histopathology on three sections of the brain stem (obex, medulla, mid-brain) following text book methodology; and
   - 5.2 immuno histochemistry on a brain stem section using appropriate anti-bodies or Western blot;
   - 5.3 For autolysed material western blot should be used and, if available, SAF.
   - 5.4 Differential diagnosis is carried out in addition to BSE testing using appropriately prepared and stored samples.
6. Testing of all suspected animals with tests mentioned under A4.
7. If epidemiological data on the "real" incidence of all suspect cases, i.e. neurological disorders in animals for which TSE can not be excluded, would be available for a given MS or region, it would be possible to estimate the expected number of suspect cases in that cattle population in order to verify, with a pre-defined level of confidence, that the number of actually examined brains from suspect cases is not significantly lower that the expected number of suspect cases

   Note: The normal incidence of neurological disorders compatible with TSEs in a given country or geographical area should be defined on the basis of:
   - *historical data such as autopsy reports in veterinary faculties, official laboratories etc., concerning at least the foregoing ten years with data on symptomatology, age and laboratory results; and*
   - *a field inquiry including a statistical valid proportion of cattle and sheep herds and flocks.*
   - *In defining this normal incidence animals for which a TSE could be excluded on the basis of age, incubation period or symptoms should not be taken into account. Particular, epidemic or accidental cases should also be excluded (e.g. if a high incidence of rabies is known to exist locally, or if poisoning plants or industry related environmental intoxication constitute a particular local risk, …).*
   - *To the knowledge of the WG no general "normal" level of TSE-compatible CNS-incidence is known. However, unpublished results from BE and some preliminary indication from CH allow to expect that, the order of magnitude which could be expected is about 100 cases of CNS-disorder compatible with BSE per one million of cattle over 2 years of age per year.*

- *It is recommended to verify the reason for any deviation from this rough orienting figure when assessing the quality of a TSE-(BSE-) surveillance system for animals from a given country.*
- *However, the scientific basis for this figure of 100/million is so small that the number of annually examined brains should not be used as the most significant indicator for the quality of a given TSE-surveillance system.*
- *Apparently there only exists a limited empirical basis for the estimated number of expected cases applied in the initial steps of the methodology behind the table proposed by the OIE, and used in the Commission Decision 98/272 of April 1998 on TSE-surveillance.*
- *It is also important to realise, that the subsequent step in the OIE Guidelines as also implemented in Decision 98/272 of April 1998 on TSE-surveillance, i.e. to reduce those numbers of expected cases to a level, which is sufficient to document an incidence of BSE below a certain threshold, should not be applied, since it counteracts the intentions to examine <u>all</u> suspect cases and since it would only be a meaningful procedure for those countries where BSE a priori is not expected to be present. In the current context such a procedure is therefore counterproductive and should not be used.*

<u>II.B. Active surveillance</u>

<u>II.B1. Active surveillance targeting exposed animals around clinical BSE-cases.</u>

For an effective active surveillance, able to identify the exposed animals around clinical BSE-cases, the following conditions should be met:

1. Identification and registration of all susceptible animals kept under controlled conditions, in particular farmed ruminants by
   1.1 individual identification (ear tags, chips)
   1.2 centralised data bases including or allowing to establish movement records
   1.3 It would be an advantage if herd and/or animal history records would be kept – on farm or centralised, which would include, for example, information on feeding, treatments, and clinical examination results.
2. Once they become available the following should be applied :
   2.1 <u>Fast post-mortem testing:</u> Individual testing (ELISA, Western Blot etc.) of CNS tissue of <u>slaughtered or dead</u> animals with the aim to identify infectious animals before appearance of clinical symptoms.
   2.2 <u>Ante-mortem testing:</u> Individual testing of other tissues (cerebro spinal fluid, peripheral nervous tissues, white blood cells, etc.) on all living animals with the aim to identify incubating animals before appearance of clinical symptoms.
3. Identification and testing (if available with the help of tests mentioned under point B1.2) of:
   3.1 all offspring and cohort animals of a TSE case; and
   3.2 all animals of the affected herd with test 2.2 (if available); or, if ante mortem tests are not available
   3.3 all sheep and goat above 6 months of the affected herd with post mortem tests as described above (2.1) and under A5, and
   3.4 all cattle above 20 months of affected herd with post mortem tests as described above (2.1) and under A4.

<u>II.B2. Active surveillance, targeting risk populations defined by other parameters than incidence, e.g. fallen stock</u>

Efforts have to been made to define, identify and monitor potentially exposed animals or animals being at risk to be infected by the BSE-agent independent of the appearance of clinical BSE-cases. For this purpose a surveillance system should fulfil the following conditions:

1. Records on production systems of MBM are available which allow assessing its ability to reduce/eliminate BSE-infectivity during the last 10 years.
2. Information on feeding practices is available, including historical data on feeding of MBM to ruminants, covering at least the last 10 years.
3. Full records of trade flows of life animals, embryos and semen as well as MBM and feed stuffs containing MBM are available, allowing estimating the origin of these imports for at least the last 10 years.
4. A control of feed stuffs with regard to MBM in concentrates is in place since at least 5 years with a sufficient number of samples examined annually. Appropriate control methods are used (ELISA, PCR, microscopic examination).
5. Active efforts are made to identify historically (at least during the last 8 years) exposed populations/individual animals.
6. All exposed animals are monitored by clinical examination at regular intervals (at least 2 times a year) by the official veterinary.
7. A control, BSE-free, population is surveyed.
8. Survey of other potentially high-risk populations, e.g. fallen stock, animals imported from BSE affected countries/regions, etc.

INDICATIVE CLASSIFICATION OF 4 QUALITY LEVELS OF TSE-SURVEILLANCE SYSTEMS

1.

The system is able to provide a complete image of the epidemiological TSE-situation of the country and can significantly reduce the processing risk (RV=1).

- The system meets **all** requirements listed under I and II A and B1 and B2 with the exception of the application of fast post-mortem tests and/or ante mortem BSE-tests as long as no approved tests are available.

2.

The system is able to provide an appropriate but not fully complete image of the epidemiological TSE-situation of the country and can reduce the processing risk to some extent (RV=2).

- The system meets the requirements listed under I, and II.A and II.B1

3.

The system would not be able to provide and appropriate image of the epidemiological TSE-situation of the country and could not reduce the processing risk (RV=3).

- The system meets only the requirements of I and II.A

4.

The system could provide a wrong image of the epidemiological TSE-situation of the country and could even increase the processing risk by creating a wrong impression of safety (RV=4).

- The system does not fulfil the conditions under I. and only partly the conditions listed under A.

Checklist

I. GENERAL REQUIREMENTS FOR AN ANIMAL TSE-SURVEILLANCE SYSTEM	**YES**	**NO**	**PERIOD**	**COMMENT**
1. Mandatory notifiable				
2. Appropriate compensation				
BASIC CONDITIONS OK				
II. SPECIAL REQUIREMENTS				
II.A. Passive surveillance, targeting clinically affected animals				
1. Education etc.				
2. Guaranteed examination				
3. (a) BSE-oriented inspections of herds/flocks				
3. (b) general pre-slaughter inspection				
4. pre-slaughter inspection for all emergency slaughter.				
5. **All** suspect cases are lab-tested				
5.1 histopathology; and				
5.2 immuno histochemistry;				
5.3 autolysed material: western blot and, if available, SAF.				
5.4 Differential diagnosis is carried out in addition to BSE testing using appropriately prepared and stored samples.				
PASSIVE SURVEILLANCE OK				
II.B. Active surveillance				
II.B1. Basic active surveillance (linked to clinical BSE-cases).				
1. all susceptible farmed animals				
1.1 individual identification				
1.2 centralised data bases				
1.3 if possible: herd and/or animal history records				
2. If available application of				
2.1 Fast post-mortem testing				
2.2 Ante-mortem testing				
3. Identification and testing of:				
3.1 all offspring and cohort animals of a TSE case; and				
3.2 all animals of the affected herd with ante mortem test or, if not available,				
3.12 all sheep and goat above 6 months of the affected herd with *post mortem tests &* lab test (II.A5), and				

3.22 all cattle above 20 months of affected herd with *post mortem tests* & lab test (II.A.5).				
BASIC ACTIVE SURVEILLANCE OK				
II.B2. Advanced active surveillance (targeting risk populations)				
Efforts have to been made to define, identify and monitor potentially exposed animals or animals being at risk to be infected by the BSE-agent independent of the appearance of clinical BSE-cases.				
1. Records on production systems of MBM				
2. Information on feeding practices				
3. Full records of trade flows of life animals, embryos and semen as well as MBM and feed stuffs containing MBM are available				
4. A control of feed stuffs with regard to MBM in concentrates is in place				
4.1 since at least 5 years				
4.2 with a sufficient number of samples examined annually				
4.3 with appropriate control methods				
5. Efforts to identify exposed populations or individual animals.				
6. All exposed animals are monitored				
7. A control, BSE-free, population is surveyed.				
8. Survey of other potentially high-risk populations				
ADVANCED ACTIVE SURVEILLANCE OK				

MANUAL

FOR THE ASSESSMENT OF

THE GEOGRAPHICAL BSE-RISK

ANNEX 4

Guidelines

for a Report on

the Assessment of

the Geographical BSE-Risk

Revision 1

Revised in the light of the first risk assessment exercise

Country: _____

Executive summary

On one page max. the summary should give an overall assessment in qualitative terms and summarises the main points of justification for this assessment. Details may be left to the full report.

Overall assessment

In general terms the geographical BSE-risk should be characterised. It may be illustrated by a risk-indicator.

Main points of justification

The most important factors that determine in the view of the expert the GBR should be listed and their impact on the risk should be explained by summarising the details given in the detailed report. The justification should follow the same structure as the detailed report, namely:

- Quality of the information on which the assessment is based.
- Ability in the last 10 years of the BSE/cattle system to identify and eliminate BSE-infected animals before they are processed. Incidence figures should be discussed in light of the assumes surveillance quality.
- Ability of the BSE/cattle system to avoid, in the last 10 years, recycling of BSE-infectivity via the feed chain. Incidence figures should be discussed as indicator of past problems.
- Challenges to the BSE/cattle system such as imports of potentially infected live animals, semen or embryos or imports of potentially BSE-contaminated MBM or feed preparations. Incidence should be discussed as indicator of prevalence and (b) as indicator of cattle exposure to the BSE agent in the past.
- The resulting processing and propagation risk over the last ten years.
- The GBR over the last ten years.

Full Assessment report

Overall assessment

In general terms the geographical BSE-risk should be characterised. It may be illustrated by a risk-indicator.

Detailed Justification

The overall assessment should be justified by discussing (a) the information on which the assessment is based and (b) the results of the RA.

Information on which the assessment is based

Discuss not only the completeness and consistency of the information available (see annex 1 and 2 to the manual) but also any doubt as to the reliability. Critical remarks, in particular those on the reliability have to be substantiated. Lacking information

should be identified as precise as possible in order to give the country an opportunity to close the gaps if possible.

Describe how the identified gaps were taken into account and dealt with when making the risk assessment, e.g. by interpolation, (worst case) assumptions, etc.
If interpolations have been made and/or (worst-case) assumptions were used, they have to be summarised under this heading but details should be given under the corresponding headings below.
Additional sources of information used have to be mentioned in this chapter.
Summarise if and how the basis for an assessment of the geographical BSE-risk (not necessarily the result) could be further improved.

Assessment of the Processing Risk

Ability of the BSE/cattle system to identify and eliminate BSE-infected animals before they are processed during the last ten years (1988-1998).

Discuss risk factors 6 (Surveillance) and 8 (Culling) on an annual basis.

Describe the surveillance system and discuss its quality in terms of TSE-surveillance by using the criteria given in annex 3a to the manual. Incidence figures should be discussed in view of the assumed quality of the surveillance system. Describe the culling system, even if only existing as plan, and discuss the assumed capacity of the culling system to eliminate, based on a good surveillance, potential BSE-carriers (animals at risk to carry the BSE-agent).

Give an overall assessment of the ability of the system during the last ten years (1988-1998) to identify and eliminate BSE-infected animals before they are processed. (Note: a good surveillance has no effect on the processing risk if it is not combined with an adequate culling system, and vice versa.)

Challenges of the ability of the BSE/cattle system to identify and eliminate BSE-infected animals before they are processed during the last 10 years (1988-1998).

Discuss risk factor 2 (trade with animals, semen and embryos) on an annual basis and in view of the risk that BSE-infected animals, semen or embryos have been imported.

- According to the recent opinion of the SSC the risk from semen is minor and may be neglected while the risk of embryos could be more relevant if its possible that embryos were gained from BSE-infected dams close to clinical outbreak of the disease.
- The major risk remains with import of live animals from BSE affected countries, in particular the UK in the early years of the epidemic (1985-1990). However, in addition of the assumed prevalence of BSE in the country/herd of origin, the use made of these animals in the importing countries is essential for the impact of these imports on the processing risk. Animals imported from an BSE-affected country at young age and slaughtered before reaching an age of 2 years or even 30 months will normally not pose a significant risk. Even if they happened to be infected in their country of origin, they would hardly harbour high amounts of the BSEE-agent at the moment of slaughter.

Give an overall assessment of the combined impact of the potential imports of BSE into the system, defined in terms of period and size.

Discuss, on an annual basis, the propagation risk of the past as an indicator for a possible internal challenge. It indicates a risk that cattle would have been exposed and subsequently be newly infected[12] with BSE and hence of the theoretically possible maximum current prevalence of BSE.

Give an overall assessment of the resulting challenges to the life-animal part of the BSE/cattle system during the past 10 years (1988-1998).

The development of the resulting processing risk over the last 10 years (1988-1998).

Discuss the interaction of the ability of the BSE/cattle system to identify and eliminate BSE-infected animals and the challenges to the system and describe the resulting processing risk

- either in terms of the probability that one infected cattle would be processed for feed or food, or, if this probability is regarded to be 1,
- in terms of the order of magnitude of the number of infected animals which could enter processing for feed or food.

The maximum processing risk results from the combined impact of imports of BSE-infected animals (or embryos) and newly infected domestic cattle. The processing risk can be reduced below this theoretical maximum by an effective surveillance in combination with an effective culling system.

- When discussing the maximum processing risk it has to be taken into account that the risk of a slaughtered animal being infected with BSE depends on the propagation risk it was exposed to during its lifetime. However, due to the long incubation time, this is only relevant for animals older than 2 years at slaughter. Animals, which could have been exposed to the BSE-agent 4 or more years before slaughter, carry the highest probability to harbour significant amounts of the BSE-agent, i.e. high titres in the CNS.
- Imports could have an immediate impact on the processing risk if old animals are imported from BSE-affected countries for slaughter. They will have a delayed impact if the imported animals are kept alive for some years before slaughtered. If embryos are imported the delay is longer, depending on the assumed incubation period.

Note:

- *Incidence figures should be taken into account when discussing the processing risk.*
- *The graphical presentation of the development of the processing risk over time should be added to the report.*

[12] The dose of BSE-contaminated MBM necessary to orally infect cattle is not known. It has to be assumed that any exposure poses a risk of infection.

Ability of the BSE/cattle system to avoid recycling of BSE-infectivity via the feed chain during the last ten years (1988-1998).

Discuss **risk factors 3 and 4** (Feed and feed bans) in view of the likelihood that cattle could have been exposed to MBM. The higher this likelihood the worse is the ability of the BSE/cattle system to avoid recycling of the BSE-agent, should it be present in the feed.

Discuss **risk factor 7** (rendering and feed processing) in view of

- the ability of the rendering system to reduce any potential BSE-infectivity of the raw material being processed. The better the rendering processes, the higher the reduction potential.
- the likelihood that cross contamination of MBM-free cattle feed with MBM-containing feed for other species occurs in rendering plants, in feed mills, during transport, or on-farm, or elsewhere.

Discuss **risk factor 5** (SRM-bans) in view of the reduction of any BSE-infectivity which could enter the feed production process.

Give an overall appreciation of the development of the ability of the system to avoid recycling of the BSE-agent during the last 10 years (1988-1998). Include incidence figures into this discussion because they indicate past problems.

Challenges of the ability of the BSE/cattle system to avoid recycling of BSE-infectivity via the feed chain during the last ten years (1988-1998).

Two types of challenges should be discussed:

- an internal challenge resulting from BSE-infected animals being processed and BSE-infected material being used for feed production. The internal challenge in a given year is proportional to the processing risk in that year.
- an external challenge resulting from importing potentially BSE-contaminated feed (MBM or MBM containing composite feed). The external challenge is proportional to the amount of imports from BSE-affected countries and, as far as this can be taken into account, the likelihood that the feed stuffs produced in that country could be BSE-contaminated.

Give an overall assessment of the internal and external challenges for the last 10 years (1988-1998) in terms of period and intensity.

The development of the resulting propagation risk over the last 10 years (1988-1998).

Discuss the interaction of the ability of the BSE/cattle system avoid recycling of BSE-infectivity and the challenges to this part of the BSE/cattle system and describe the resulting propagation risk

- in terms of the probability that at least one cattle would be newly infected with BSE, or, if this probability is regarded to be 1,
- in terms of the orders of magnitude of the number of animals which could be newly infected.

Note:

- *Incidence figures should be discussed as indicator of past problems in this part of the system.*
- *The graphical presentation of the development of the propagation risk over time should be added to the report.*

Deriving the geographical BSE-risk from the propagation and the processing risk

Show the development of the GBR over the last 10 years (1988-1998) that would result from the processing and the propagation risk when applying the following conversion rule: if PRR ≥ PGR : GBR = PRR; if PRR < PGR : GBR = (PRR+PGR)/2.

Discuss if this development needs to be adjusted and explain any assumed deviation.

Discuss the development of the GBR in the forthcoming years, taking due account of recent measures taken to manage the risk and of trends of most important risk factors. The propagation risk of the last 5 years is very important for this discussion, as are incidence figures. If the latter are available their trend has to be taken into account, too.

Manual
for the assessment
of the
geographical BSE-risk

Annex 4a

Form to be used by

the assessors to prepare their report on the

geographical BSE-risk assessment of a

country.

Revised after the first risk assessment

exercise March, 1999

Report on

the Assessment of

the Geographical BSE-Risk

COUNTRY: _____

Country: _____

Executive summary

Overall assessment

Main points of justification

- Quality of the information on which the assessment is based.

- Ability, in the last 10 years, of the BSE/cattle system to identify and eliminate BSE-infected animals before they are processed. (Discuss incidence in light of this ability).

- Ability, in the last 10 years, of the BSE/cattle system to avoid recycling of BSE-infectivity via the feed chain. (Refer to incidence as indicator for past problems)

- Challenges, in the last 10 years, to the BSE/cattle system such as imports of potentially infected live animals or embryos or imports of potentially BSE-contaminated MBM or feed preparations.

- The resulting processing and propagation risk over the last ten years. Take account of incidence if appropriate.

- The GBR over the last ten years. Take into account incidence and its trend in the recent years.

Full Assessment report

Overall assessment

Detailed Justification

Information on which the assessment is based

Completeness and treatment of gaps

The information available is	complete	[ ]
	largely complete	[ ]
	incomplete	[ ]

Information on the following Risk Factors was lacking or was incomplete (details given thereunder):

RF1 [ ],	RF2 [ ],	RF3 [ ],	RF4 [ ],
RF5 [ ],	RF6 [ ],	RF7 [ ],	RF8 [ ]

The identified gaps were dealt with by

interpolation [ ]	(worst case) assumptions [ ]	other[ ]

General description of the gaps and how they were taken account of in the risk assessment (details under the related risk factor):

Consistency of the information available (identify inconsistencies as precise as possible).

Reliability:

Additional sources of information:

Summary of recommendations how the basis for an assessment of the geographical BSE-risk (not necessarily the result) could be further improved

(detailed requests for additional information needed for a better assessment are to be provided under the appropriate headings)**:**

Assessment of the Processing Risk

Ability of the BSE/cattle system to identify and eliminate BSE-infected animals before they are processed during the last ten years (1988-1998).

Risk factor 1 (population structure):

Total size of the cattle herd; relative share of dairy, beef, and dual use cattle; ratio cattle/sheep (development over the last 10 years):

Age distribution of cattle, alive and at slaughter:

Most relevant types of cattle husbandry systems (extensive beef, intensive dairy, dual purpose, …) and their relative share:

Characterisation of the cattle identification and monitoring system:

Additional information needed for a better assessment of the impact of the population structure on the processing risk:

Risk factor 6 (Surveillance):

Summary description of the surveillance system and its development over time.

Quality of the surveillance system in view of the criteria given in annex 3a to the manual and its development over time.

Additional information needed for a better assessment of the quality of the surveillance system:

Incidence figures in the light of the assumed quality of the surveillance system.

Risk factor 8 (Culling)

A culling system exists in the national legislation [ ],
and has been applied in the past [ ]
and has not yet been applied [ ]

Description of the culling system

Assumed capacity of the culling system to eliminate, together with the surveillance, potential BSE-carriers (animals at risk to carry the BSE-agent):

Additional information needed for a better assessment of the efficiency of the culling system in view of eliminating animals at risk to be infected with BSE:

Overall assessment of the ability of the system to identify and eliminate BSE-infected animals before they are processed during the last ten years (1988-1998):

Challenges of the ability of the BSE/cattle system to identify and eliminate BSE-infected animals before they are processed during the last 10 years (1988-1998).

Risk factor 2 (trade with animals, semen and embryos)

Import of life animals, semen or embryos from countries at risk to be affected by BSE

Overall assessment of the likelihood that the BSE agent was imported (period & size).

Additional information needed for a better assessment of the risk that BSE-infected animals or embryos could have been imported:

The past propagation risk as indicator for a domestic prevalence of BSE:

Overall assessment of the resulting challenges to the life-animal part of the BSE/cattle system during the past 10 years (1988-1998):

Additional information needed for a better assessment of the past challenges through imports of life animals or domestic prevalence:

The development of the resulting processing risk over the last 10 years (1988-1998).

Interaction of the ability of the BSE/cattle system to identify and eliminate BSE-infected animals and the challenges to the system:

The resulting processing risk over time. (Take account of incidence figures if available).

The maximum processing risk

Factors reducing the processing risk below the theoretical maximum:

Development of the processing risk over time:

Note:

- *Take account of incidence figures, if available.*
- *The graphical presentation of the development of the processing risk over time should be added to the report.*

Additional information needed for a better assessment of the processing risk, as far as not mentioned above:

Ability of the BSE/cattle system to avoid recycling of BSE-infectivity via the feed chain during the last ten years (1988-1998).

Risk factor 3 and 4 (feed and feed bans)

Domestic MBM production (tons per year):

Use of (domestic or imported) MBM:

Feeding animal protein

- is/was normal practice for calves [ ], adult dairy cows [ ], beef cattle [ ], other cattle [ ] _____, other ruminants [ ] _____
- is/was sometimes, not regularly done for calves [ ], adult dairy cows [ ], beef cattle [ ], other cattle [ ] _____, other ruminants [ ] _____
- is/was never done [ ]

Reason for this assumption (including information given under RF1):

A feed-ban exists	no [ ]		
	yes [ ],		
Type of ban:	RMBM to cattle	[ ],	period: _____
	RMBM to ruminants	[ ],	period: _____
	MBM to cattle	[ ],	period: _____
	MBM to ruminants	[ ],	period: _____
	RMBM to farmed animals	[ ],	period: _____

Compliance: the assumed compliance is/was in the following range

very good (>90%)	[ ], period: _____
good (>70%, ≤90%)	[ ], period: _____
average (>30%, ≤70%)	[ ], period: _____
low (≤30%)	[ ], period: _____

The overall efficiency of the feeding practice and the feed ban in reducing the risk that cattle of different age are exposed to MBM containing feed over time:

Additional information needed for a better assessment of the likelihood that different age classes and types of cattle were/are exposed to MBM:

Risk factor 7 (rendering and feed processing)

Ability of the rendering system to reduce any potential BSE-infectivity of the raw material being processed.

Processes (batch/continuous; time/temp/pressure) used and their relative share on the domestic production during the last ten years:

Potential for cross contamination of MBM-free cattle feed with MBM-containing feed for other species or of other types of cross contamination:

Overall assessment of the ability of the rendering system to reduce any potential BSE-infectivity of the raw material being processed:

Additional information needed for a better assessment of the capacity of the rendering system to reduce any potential BSE-infectivity of the raw material being processed.

Risk factor 5 (SRM-bans)

Description of the SRM ban(s)

An SRM-ban exists no [ ] yes [ ]

Dates of introduction:
List and treatment of SRMs:

Assumed compliance and its development over time:

Reasons for this assumption:

Overall assessment of the efficiency of the SRM-ban(s) in reducing any BSE-infectivity which could otherwise enter the feed production:

Additional information needed for a better assessment of the SRM-ban's efficiency:

Overall appreciation of the development of the ability, during the last 10 years (1988-1998), of the system to avoid recycling of the BSE-agent, taking due account of the feeding practices, the rendering system and the efficiency of eventually existing SRM-ban(s). (Note: this ability should be assessed independent from the question if it was challenged)**:**

Challenges of the ability of the BSE/cattle system to avoid recycling of BSE-infectivity via the feed chain during the last ten years (1988-1998).

Internal challenge resulting from BSE-infected material entering feed production because BSE-infected animals being processed (see processing risk):

External challenge resulting from importing potentially BSE-contaminated feed (MBM or MBM containing composite feed coming from countries where the contamination of these feed stuffs with the BSE agent can not be excluded). (Note**:** External challenges might include other imports, such as, for example, importing animal raw material for feed production from potentially BSE-affected countries.):

Overall assessment of the combined internal and external challenges for the last 10 years (1988-1998) in terms of period and intensity:

Additional information needed for a better assessment of the internal and external challenges of the BSE/cattle system:

The development of the resulting propagation risk over the last 10 years (1988-1998).

Interaction of the ability of the BSE/cattle system to avoid recycling of BSE-infectivity and the challenges to this part of the BSE/cattle system:

The resulting propagation risk over time (1988-1998):

Note:

- *Take account of available incidence figures because they indicate past problems.*
- *The graphical presentation of the development of the propagation risk over time should be added to the report.*

Deriving the geographical BSE-risk from the propagation and the processing risk

Development of the GBR over the last 10 years (1988-1998) that would result from the PRR and the PGR when applying the conversion rule (if PRR ^{3} PGR : GBR = PRR; if PRR < PGR : GBR = (PRR+PGR)/2).

Adjustment needed (e.g. because of incidence figures):

Development of the GBR in the forthcoming years (take account of the trend of the incidence figures in the last years) :

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Note: The graphical presentation of the development of the geographical BSE risk over time should be added to the report.