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**Draft opinion of the Scientific Panel on Biological Hazards**

3

**on the revision of the Geographical BSE risk**

4

**assessment (GBR) methodology**

5

**Approved for public consultation**

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**BIOHAZ Plenary of 8-9 November 2006**

7

**Question EFSA Q-2004-150**

8

**PANEL MEMBERS**

9 Olivier Andreoletti, Herbert Budka, Sava Buncic, Pierre Colin, John D Collins,  
10 Aline De Koeijer, John Griffin, Arie Havelaar, James Hope, Günter Klein, Hilde Kruse,  
11 Simone Magnino, Antonio Martínez López, James McLauchlin, Christophe Nguyen-The,  
12 Karsten Noeckler, Birgit Noerrung, Miguel Prieto Maradona, Terence Roberts,  
13 Ivar Vågsholm, Emmanuel Vanopdenbosch.

14

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18 Vittorio Silano, Ivar Vågsholm (Rapporteur), Emmanuel Vanopdenbosch (Chairman),  
19 John Wilesmith.

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**SUMMARY OF OPINION:**

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**Key Words**

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70 **1. INTRODUCTION**

71 The Geographical BSE-Risk assessment (GBR) is a qualitative indicator of the likelihood of  
72 the presence of one or more bovines being infected with Bovine Spongiform Encephalopathy  
73 (BSE), pre-clinically as well as clinically, at a given point in time, in a country. It is based on  
74 a qualitative analysis of:

75 (1) the likelihood that the BSE agent was introduced into a country and if so, when and to  
76 what extent

77 and

78 (2) the potential of it being recycled and potentially amplified or eliminated.

79 For ease of reference, the methodology as described hereunder and as developed and used by  
80 the previous Scientific Steering Committee (SSC) of the European Commission between 1998  
81 and 2003 is referred to as **SSC GBR** and outcome of these assessments can be found on the  
82 former SSC website<sup>1</sup>. As from 2003 the European Food Safety Authority (EFSA) took over  
83 this task and assessed a number of countries using this SSC GBR method. Further details on  
84 the countries assessed follow below. The updated methodology, described in this opinion,  
85 will be referred to as **EFSA GBR**.

86 The GBR methodology was first developed by the Scientific Steering Committee (SSC) of the  
87 European Commission (EC) in 1998 (SSC, 1998 with revisions in 1999, 2000 and 2002). The  
88 aim was to develop a transparent methodology to assess the BSE risk in the domestic cattle  
89 population of any given country at a given point in time. The Risk Assessment is based on  
90 data and information provided by the country. This methodology is limited to bovine and feed  
91 based transmission of BSE (*i.e.* it does not take into account any other initial sources of BSE  
92 than the import of potentially infected cattle or potentially contaminated feed). An important  
93 characteristic of the GBR methodology is that it did/does not depend on the confirmed  
94 incidence of clinical BSE, which is sometimes difficult to assess due to serious intrinsic  
95 limitations of the detection component of surveillance systems.

96 On the basis of the outcome of these SSC GBR assessments, all EU Member states were  
97 classified in GBR classes<sup>2</sup> I through IV, class I being the lowest, meaning that it is considered  
98 highly unlikely that one or more cattle are clinically or pre-clinically infected. However, a  
99 number of EU countries did not detect any case of BSE before 1 January 2001 despite their  
100 rather high GBR level. Therefore, and also to protect consumer health, the EC imposed the  
101 application of rapid BSE tests on all cattle when slaughtered for human consumption above 30  
102 months of age, and on risk populations such as emergency slaughtered animals and animals  
103 found dead on the farm, sent to the rendering plants (“active” surveillance).

104 By showing that many of the countries previously classified as Category III, did indeed have  
105 BSE present in their cattle populations; the results of the BSE testing confirmed the validity of

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<sup>1</sup> Relevant opinions of the Scientific Steering Committee (SSC) of the European Commission on Web Address: [http://europa.eu.int/comm/food/fs/sc/ssc/outcome\\_en.html](http://europa.eu.int/comm/food/fs/sc/ssc/outcome_en.html)

<sup>2</sup> **GBR level:** *Presence of one or more cattle clinically or pre-clinically infected with the BSE agent in a geographical region/country.* **GBR I** : Highly unlikely; **GBR II** :Unlikely but not excluded; **GBR III**: Likely but not confirmed or confirmed, at a lower level; **GBR IV**: Confirmed, at a higher level

106 the SSC GBR methodology. Germany, Italy, Spain, Poland, the Czech Republic and the  
107 Slovak Republic were all classified as GBR III before they detected their first case. The SSC  
108 GBR for Denmark was already at an advanced stage, pointing to GBR III, when the first case  
109 was confirmed. In addition, Japan and Greece have now confirmed the first domestic BSE  
110 cases. Also Austria, Finland and Slovenia, all three initially in GBR II, detected their first  
111 domestic case(s) of BSE and were therefore also classified in GBR III. In all cases, active  
112 surveillance detected BSE cases that would have remained undetected by the already existing  
113 passive surveillance, which was targeted at animals with neurological symptoms. In addition,  
114 Sweden which was classified as a GBR II country had a case during March 2006.

115 In 2003 responsibility for carrying out the GBR assessments was transferred from the SSC to  
116 EFSA. Two mandates were received (D (2003)/KVD/ip/420722 and D (2004)/KVDip/  
117 420863) in order to re-assess a total of 18 countries<sup>3</sup> and EFSA added one GBR assessment  
118 under a self-tasking mandate. EFSA used the SSC GBR to assess the given list of countries.  
119 The outcome of these assessments can be found on the EFSA website.<sup>4</sup>

120 The SSC GBR methodology was used up to now to assess the BSE risk in a given country.  
121 The model and its basic assumptions remained unchanged throughout the assessments carried  
122 out to date both by the SSC and the EFSA. Consistency of the past and future assessments  
123 was therefore ensured. However, over time the assessment of the external challenge was  
124 refined and the process was streamlined since the first assessments were completed in 2000.

125 Experience obtained by the EFSA experts while carrying out the most recent assessments of  
126 19 countries, indicated that the SSC GBR methodology needed to be reconsidered taking  
127 account of the newly obtained scientific knowledge on BSE and the availability of new data  
128 on the assessed countries. The SSC GBR method was geared to identify or predict a potential  
129 first case in a certain country but the EFSA GBR methodology should also allow the  
130 assessment of “an expected future development of the risk over time” *i.e.* be able to allow the  
131 expert group to declare a decrease of the risk in a certain country and when the risk has  
132 reached a negligible level.

133 The issues necessitating change include the following:

- 134 • The SSC GBR methodology works well for assessing the risk from cattle and MBM  
135 exports from Category III European countries. However, the risk from exports from  
136 countries with a low BSE prevalence and a large cattle population was overstated and  
137 needs to be corrected.
- 138 • The assessment of the stability needs to be more flexible allowing partial improvements in  
139 stability to be taken into account. For example, under the SSC GBR methodology, a  
140 rendering system could only be considered to be “OK” if it was operating at 133 ° Celsius  
141 and 3 bar for 20 minutes. While these are the recommended operating conditions, the  
142 assessment of the stability in the GBR methodology should allow the recognition that sub-  
143 optimal conditions such as a temperature of 120 ° Celsius, degrees are not “optimally OK”  
144 but would also lead to an improvement in stability.

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<sup>3</sup> Argentina, Australia, Botswana, Brazil, Canada, Chile, Costa Rica, El Salvador, Namibia, Nicaragua, Norway, Mexico, Panama, Paraguay, South Africa (EFSA self task), Swaziland, Sweden, United States of America, and Uruguay.

<sup>4</sup> [http://www.efsa.europa.eu/en/science/tse\\_assessments/gbr\\_assessments.html](http://www.efsa.europa.eu/en/science/tse_assessments/gbr_assessments.html)

- 145 • The SSC GBR method could not take account of surveillance data, since it was not part of  
146 the method and full sets of data were not yet available. The results of the epidemiological  
147 surveillance of BSE in cattle since 2001 are now available and the EFSA GBR should take  
148 account of these data which allow a better perspective of geographical risk.
- 149 • The BSE status of countries will change over time depending on their external challenge  
150 based on their imports of cattle and MBM and their internal stability. Therefore there is a  
151 need for an ongoing reassessment of the BSE status of individual countries.
- 152 • While the situation for the foreseeable future indicates that the BSE epidemic is declining  
153 within the EU and most other third countries, the challenge is now how to assess any  
154 continuing risk allowing a proportionate management of that risk.
- 155 • Moreover, the CVO/EU Parliament dialogue of September 2005 concluded that the BSE  
156 classification should be based on OIE guidelines wherever possible.
- 157 Given the above reasons, the Scientific Panel on Biological Hazards (BIOHAZ) was requested  
158 by EFSA in March 2005 under a self-task to update the SSC GBR methodology.

## 159 **2. TERMS OF REFERENCE**

160 The Scientific Panel on Biological Hazards is requested:

- 161 1. To review the SSC GBR methodology as currently described in the SSC opinions (SSC,  
162 February 1999; refined with SSC, 2000 and 2002) and to update the current method. In  
163 particular:
- 164 a. To identify parameters and assessment rules in the current methodology, that needs  
165 to be updated and analyse new information, which could allow their update.
- 166 b. To assess the various factors contributing to the assessment of BSE risk in a certain  
167 country and to attribute a more appropriate weight factor to these taking account of  
168 information now available.
- 169 c. To consider a change of the current “GBR” to another acronym to determine the  
170 BSE risk in a certain country.
- 171 d. The method should allow assessing an expected future development of the risk over  
172 time *i.e.* be able to allow declaring a decrease of the risk in a certain country.
- 173 e. Prepare a detailed questionnaire to go alongside the new method
- 174 2. To take account of Chapter 2.3.13 of the OIE terrestrial animal health code (the general  
175 and new BSE Surveillance Chapter of the OIE (May 2005)) and the appendix 3.8.5 to this  
176 chapter (Factors to consider in conducting the BSE RA recommended in chapter 2.3.13.).
- 177 3. To consider an updated risk assessment method (*e.g.* GBR) taking into account  
178 quantitative surveillance data and models (*e.g.* BSurVE).
- 179 4. To finalize a draft update after which the document can be opened for a public  
180 consultation.
- 181 5. To produce a final document taking account of the comments made during the  
182 consultation period.

### 183 3. APPROACH CHOSEN BY THE BIOHAZ PANEL

184 The Working Group (WG) under the EFSA BIOHAZ Panel proceeded by evaluating the SSC  
185 GBR method and based on this evaluation suggesting possible amendments and/or  
186 improvements. In interpreting and addressing the terms of reference (see also Annex I for  
187 more details), the BIOHAZ Panel considered experiences gained from previous assessments,  
188 new data and information, developments in EU policies as well as development in the OIE  
189 methodology (see also Annex II for comparison of the GBR method with OIE method).

190 The BIOHAZ Panel and its WG decided to produce a standalone document describing the  
191 EFSA GBR methodology. The main purpose of this document is to describe the basic  
192 methodology to carry out the risk assessment. Where necessary, the document provides the  
193 rationale and the scientific basis for specific parts of the methodology. This stand-alone  
194 document serves as the set of instructions that can be used by either the members of any  
195 international independent expert group responsible assessing a country as well as by the  
196 contact people in the countries being assessed.

197 As part of the terms of reference, the BIOHAZ Panel agreed on referring to SSC GBR as the  
198 old method and EFSA GBR as the updated method. In this way continuity is retained in  
199 referring to the well known acronym of GBR but differentiating between the previous and  
200 updated version (See also Annex III outlining changes from the SSC GBR).

201 A preliminary report was put on the EFSA web for public consultation on 17 November 2006.  
202 The methodology was revised following consideration of the comments and the results of test  
203 runs of the new method of a few country dossiers. (*The comments of the public consultation*  
204 *as well as the experience of the test runs will be reflected in the final report and opinion*).

### 205 4. THE EFSA GBR METHODOLOGY

#### 206 4.1 Definition of the Geographical BSE-risk in cattle

207 The Geographical BSE-Risk assessment (GBR) is a qualitative indicator of the likelihood of  
208 the presence of one or more bovines being infected with BSE, pre-clinically as well as  
209 clinically, at a given point in time, in a country.

210 Essentially, any GBR exercise attempts to answer two questions:

- 211 • Is it likely that the BSE-agent was imported into the country under consideration  
212 (**external challenge**)?
- 213 • If the BSE-agent was introduced into a country, is it likely that it would have been  
214 recycled and amplified or was the BSE/cattle system of that country able to eliminate  
215 the agent (*i.e.* internal **stability**)?

216 In addressing these issues, the following factors are taken into account:

- 217 • Structure and dynamics of the cattle population
- 218 • Animal trade
- 219 • Animal feed
- 220 • Meat and bone meal (MBM) bans
- 221 • Specified risk materials (SRM) bans
- 222 • Surveillance of BSE

223           • Rendering and feed processing

224 Following consideration of these issues, an assessment is made of the likelihood of one or  
225 more cattle in the native population being infected with BSE.

226 On the basis of this assessment, the country/region using the SSC GBR method was assigned  
227 a GBR category between I to IV (see footnote<sup>2</sup> for GBR levels).

228 Under the EFSA GBR these categories are changed to the following:

229           • **Unlikely** – cases of BSE are unlikely to be present in the evaluated cattle population

230           • **Likely - one or more cases of BSE are present in the evaluated cattle population.**

231 The category **likely** is split into two subcategories based on the assessment of the stability of  
232 the system:

233           • **Likely and decreasing**

234           **or**

235           • **Likely and increasing**

236 If the country assessed is categorised as likely and neutrally stable, it falls into the category of  
237 likely and increasing applying worst case assumptions.

#### 238 **4.2 Assumptions on transmission of BSE and origin of the BSE epidemic**

239 The methodology for the assessment of the GBR is based on the assumption that BSE arose in  
240 the United Kingdom (UK) from a still unknown initial source and was propagated through the  
241 recycling of contaminated bovine tissues into animal feed. Later, the export of infected  
242 animals and infected feed provided the means for the spread of the BSE-agent to other  
243 countries where it was again recycled and propagated via the feed chain. A simplified model  
244 of the assumed BSE/cattle system is described in Figure 1.

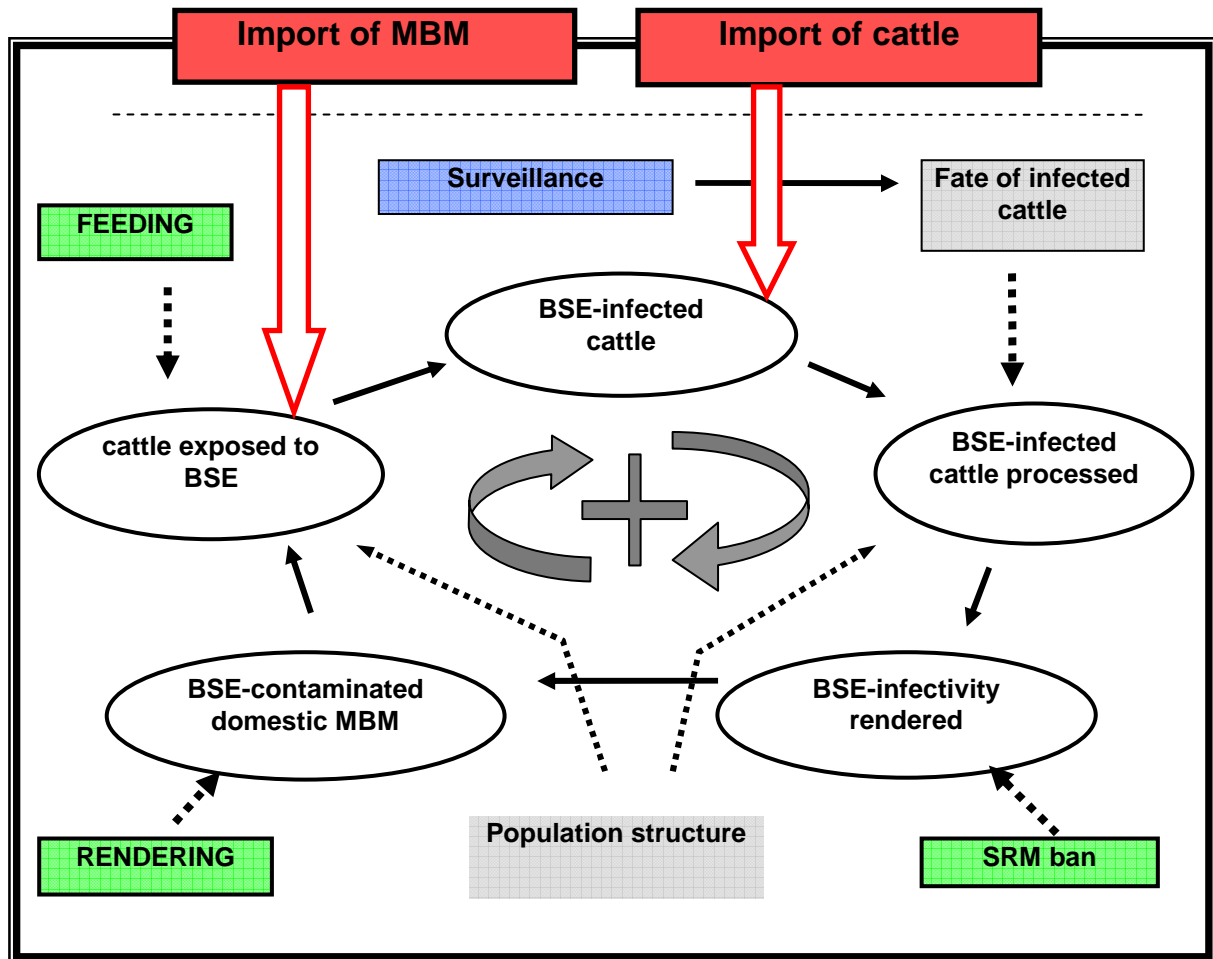


Figure 1: The model of the BSE/cattle system

245

246 For all countries other than the UK, import of contaminated feed or infected animals was the  
 247 only possible initial source of BSE that was taken into account. Other sources such as vertical  
 248 transmission, such as potential spontaneous occurrence of BSE at very low frequency, or the  
 249 transformation into BSE of another (animal) TSE (Transmissible Spongiform  
 250 Encephalopathy) (scrapie, CWD or Chronic Wasting Disease, TME or Transmissible Mink  
 251 Encephalopathy and FSE or Feline Spongiform Encephalopathy) being present in, or imported  
 252 into a country were not considered, as these putative sources were not scientifically  
 253 confirmed.

254 The only transmission vehicle considered in any GBR exercise is, was and continues to be  
 255 feed containing animal protein such as MBM. Blood, semen and embryos/ova are not seen as  
 256 effective transmission vectors and accordingly, blood-meal or embryos/ova and semen were  
 257 not taken into account. The recent results of large scale BSE-testing in combination with  
 258 reports on feed controls have further substantiated the opinion of the SSC that any cross-  
 259 contamination of cattle feed with bovine MBM, even below 0.5%, represents a risk of  
 260 transmitting the disease. However, the influence of potential cross-contamination on the GBR  
 261 had to be seen in the light of the risk that the animal protein under consideration could carry  
 262 BSE-infectivity.

263 Other transmission routes can be considered if the scientific evidence becomes available to  
 264 support, however, to-date no such evidence has been forthcoming that necessitates changes of  
 265 the GBR assumptions.



### 266 4.3 Geographical limitations, Compartments and Zones

267 So far, the SSC GBR risk assessments have only addressed entire countries and national  
268 herds. This was due to the limited availability of detailed, regionalized data. However the  
269 issue of regional differences, for example in the types of animal husbandry, *e.g.* dairy or beef,  
270 or with regard to feeding or to slaughtering ages are not discounted. If complete data sets are  
271 provided on a regional scale, *i.e.* clearly relating to a defined geographical area smaller than a  
272 country, these can be assessed in the same way as data referring to entire countries. This  
273 assessment applies to the BSE status of a country and does not necessarily apply to the trade  
274 of commodities as this is dealt with separately by EU legislation and the OIE terrestrial animal  
275 health code.

276 The OIE animal health code opens the possibility of defining health status for compartments<sup>5</sup>  
277 of animals – *i.e.*, a defined production system. This could be an important development to  
278 enable a production system to achieve recognition of its health status within its compartment  
279 in a situation where a separate definition of disease status may not be possible in the  
280 geographical area enveloping the compartment. Moreover, the GBR assessment of a country  
281 does not exclude the possibility that a GBR assessment of different compartments or zones  
282 within a country might give varying results. This possibility should be explored as a separate  
283 exercise.

284 An example of compartmentalisation within the EU is the provision specific to the UK  
285 (EFSA, 2004a) that bovine animals born in the UK after 1 August 1996 (the date that the  
286 animal protein feed ban entered into force) are considered to be at no higher risk of  
287 developing BSE than animals in other EU countries, thus these bovine animals, beef and  
288 products thereof, can be traded having regard to the same rules as for the rest of EU. Hence  
289 the UK is set on equal footing in terms of trade with the rest of EU for these animals. On the  
290 other hand, all bovine animals born before 1 August 1996 are permanently excluded from the  
291 food and feed chain. This means that at the end of their productive life (*e.g.* producing milk  
292 and calves), these animals must be destroyed.

### 293 4.4 External challenge

294 The term **external challenge** refers to both the likelihood and the amount of the BSE agent  
295 entering into a defined geographical area in a given time period through imported cattle or  
296 MBM. The assumed external challenge resulting from imports from the UK during the peak  
297 of the BSE epidemic in the UK is taken as the point of reference. The challenge resulting from  
298 imports during other periods and from other BSE-risk countries is assessed in relation to this  
299 baseline. A BSE-risk country is any country classified as “Likely” under the EFSA GBR  
300 methodology (under the SSC GBR this would relate to a GBR III or IV level).

301 Imports from countries that have not been assessed before but that might pose a risk due to  
302 imports from BSE risk countries can be taken into account as external challenge.

303 The only two possible routes of introduction of the BSE agent into a BSE/cattle system of a  
304 specific country are the imports of BSE-infected cattle or of BSE-contaminated processed

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<sup>5</sup> **Compartment** (OIE Terrestrial Animal Health Code, Chapter 1.1.1., General Definitions, Article 1.1.1.1.) means one or more [establishments](#) under a common biosecurity management system containing an animal [subpopulation](#) with a distinct health status with respect to a specific [disease](#) or specific [diseases](#) for which required surveillance, control and biosecurity measures have been applied for the purpose of [international trade](#).

305 proteins. In this document, all forms of processed protein are referred to as "MBM". This  
306 includes Meat and Bone Meal as such, Meat Meal, Bone Meal and Greaves made from meat  
307 and offal. It is synonymous to "flours, meal, pellets made from meat or offal; greaves" (*i.e.*  
308 EUROSTAT custom code 230110) in the import/export context. Available import/export  
309 statistics do not, in fact, allow differentiation of the various forms of processed animal  
310 proteins referred to; they also do not differentiate between the type of product or by species  
311 from which it is produced.

312 The external challenge is assessed in three steps:

313 *Step 1*           Acquisition of import data concerning live cattle and MBM from BSE-risk  
314 countries

315 *Step 2*           Determination of whether the imports entered the BSE/cattle system

316 *Step 3*           Estimation of the level of infectivity in the imported material using imports  
317 from the UK during the peak of the epidemic as the point of reference

318 The data for assessing the external challenge is compiled by the Competent Authority (CA) of  
319 the country being assessed using a specially designed questionnaire (see annex IV) and Excel  
320 spreadsheets ("GBR Template import table\_July06b").

#### 321 *4.4.1 Acquisition of import data from BSE-risk countries*

322 In the light of new scientific knowledge and data, it is necessary when assessing the external  
323 challenge to take account of imports from all countries found to have a BSE risk. The  
324 information is gathered for each BSE-risk country for each year in which imports from that  
325 country are considered to present a risk. This is determined when those countries are  
326 themselves being assessed and categorized under the GBR methodology.

327 In some cases, import data from a particular country may be available from a number of  
328 different sources. For example, the country being assessed will have its own import data, but  
329 such data may also be made available by EUROSTAT and/or other sources (*e.g.* export data  
330 from the exporting country). In case of discrepancies between the number of EUROSTAT  
331 and the number of the dossier, the higher figure will be taken into account as the worst case  
332 scenario. If the assessed country wishes to make the case that this figure is incorrect, this can  
333 be done in Step 2.

#### 334 *4.4.2 Determination of whether the imports entered the BSE/cattle system*

335 In order to assess the external challenge that has entered the BSE/cattle system in a country  
336 through imported cattle or MBM, the fate of the animals and MBM following importation  
337 should be considered. The key question is whether the BSE-infectivity that could have been  
338 carried by these imports did enter the country's BSE/cattle system or not. Based on the  
339 analysis of the information provided, the revised figures for the number of cattle and amount  
340 of MBM that enters the BSE/cattle system are placed in Table 2 of the Excel spreadsheet.

341 Only well-substantiated reasons are acceptable for excluding live animals or MBM imported  
342 from BSE risk countries, from the external challenge. Documentary evidence relating to the  
343 specific animals or MBM under consideration should be provided by the country being  
344 assessed to support the exclusions, if applicable. Other types of information such as common  
345 practices adopted in the country being assessed or recording systems may also be used to  
346 support the proposal. In cases where the available information indicates but does not

347 conclusively show that the animals/MBM did not enter the feed chain, only a proportion of  
348 the imports may be deducted depending on the quality of the provided data.

349 **A. Reasons accepted as basis to exclude certain live animals from the external**  
350 **challenge**

351 The basic assumption is that all animals imported have potentially been slaughtered, rendered  
352 and thus entered the feed chain and could have reached cattle. However, if evidence is  
353 provided, these animals can be excluded from the external challenge.

354 • ***Animals that are recorded as imports in error.***

355 To have these animals excluded, the importing country needs to provide an acceptable  
356 explanation as to why the animals were erroneously recorded in the export figures of the  
357 country of origin. To this end, the exporting country can be asked to check the data and  
358 provide documentary evidence of the exact figures through an official letter signed by the  
359 importing country's Competent Authority (CA).

360 • ***Age of animals at slaughter.***

361 Imported animals slaughtered young (*i.e.* below 30 months of age) can only carry a very  
362 small fraction of the infectivity found in a clinical case, even if infected prior to export.  
363 Imported calves that are immediately slaughtered or fattened and slaughtered before 2.5  
364 years of age can, therefore, be assumed to represent, as long as this can be assessed with a  
365 reasonable certainty, no external challenge.

366 • ***Dead animals which were disposed-of by burial or incineration.***

367 Infectivity imported via live cattle only enters the BSE/Cattle system of the importing  
368 country if these animals die or are slaughtered and rendered into MBM that could reach  
369 cattle via the feed-chain. If rendering of imported cattle is avoided through burial or  
370 incineration of the dead animals, there is no risk that domestic infections could result from  
371 imported infected cattle.

372 • ***To have these animals excluded, the following information must be provided:***

- 373 ○ Evidence to show that a system was in place in the country at the time of  
374 importation that allowed imported animals to be traced;
- 375 ○ Evidence to show that the particular animals were traced;
- 376 ○ Evidence to show, either directly or indirectly, that the animals were buried or  
377 incinerated.

378 The critical issue in such a case is the quality and effectiveness of the cattle tracing-back  
379 system that should be described and confirmed. Specific data concerning the identification  
380 of all the traced-back animals and the disposal of those animals by burial or incineration  
381 must be available.

382 • ***Animals that are still alive and are prohibited from entering the feed chain.***

383 Live animals do not obviously constitute a risk since these cannot have reached cattle via  
384 the feed-chain. To have these animals excluded, the following information must be  
385 provided:

- 386 ○ Evidence to show that a system is in place in the importing country that  
387 allows imported animals to be traced;

- 388           ○ Evidence to show that the particular animals have been traced;  
389           ○ Evidence to show that a system is in place to ensure that the imported animals  
390           will be excluded from the feed chain when they die or are slaughtered.

391 The critical issue in such a case is the quality and effectiveness of the cattle tracing-back  
392 system that should be described and confirmed.

- 393     • *Animals imported into a country that only has rendering plants that process animal*  
394     *by-products from export abattoirs and where the imported animals were excluded*  
395     *from going to slaughter at such abattoirs.*

396 To have these animals excluded, evidence must be provided of systems in place to ensure  
397 that imported animals are excluded from the slaughter at export plant.

- 398     • *Cattle which are re-exported.*

399 Live cattle imported into a country from a BSE-risk country and exported to another country  
400 obviously do not constitute a challenge for the importing country. In order to apply this  
401 criterion import/ export certificates or equivalent documentary evidence should be available  
402 with a clear identification of the involved animals.

403     **B. Reasons not accepted as basis to exclude certain live animals from the external**  
404     **challenge:**

- 405     • animals were older than 10 years of age at slaughter;  
406     • animals were slaughtered after a feed ban was put in place in the country of  
407     destination;  
408     • animals were born after a feed ban was put in place in the country of origin;  
409     • animals originated from herds that had no case of BSE.

410     **C. Reasons accepted as basis to exclude certain MBM from the external challenge**  
411     **listed in the export data from BSE-risk countries under custom code 230110:**

412 The basic assumption is that all MBM imported has potentially entered the feed chain and  
413 could thus have reached cattle. However, if evidence is provided, these animals can be  
414 excluded from the external challenge.

- 415     • *MBM recorded as imports in error.*

416 To have the MBM excluded, the importing country will need to provide documental  
417 evidence or an acceptable explanation as to why it was erroneously recorded in the export  
418 figures of the country of origin. The following would include some of the acceptable  
419 explanations:

- 420           ○ A selling price significantly lower than the average market price for MBM at  
421           the time of the import provides a strong indication that the import was not  
422           MBM but rather another less valuable material recorded under a wrong tariff  
423           number. Documentation must be available indicating the selling price of the  
424           import and on market average price of MBM at the relevant time.  
425           ○ No protocol is in existence for MBM exports between the exporting and  
426           importing countries and an official letter to the effect that no MBM was  
427           exported will be required from the country of origin.

428 ○ As the export of MBM has been prohibited from the UK since 1996, in case  
429 such a consignment appears in the export statistics from the UK or in the  
430 EUROSTAT statistics, it should be assumed to be an error.

431 ○ Importation is not consistent with legislative requirements of the importing  
432 country; this could be the case if a license has to be issued based on a risk  
433 analysis before importation may take place and no such a license is available.

434 • ***Imported MBM was only used as a feed for non-ruminant animals and was***  
435 ***processed in a manner that would have prevented cross-contamination of ruminant***  
436 ***feed.***

437 Infectivity imported via MBM enters the BSE/cattle system when it is integrated into feed  
438 that could reach cattle, be it deliberately or via cross-contamination during transport, in  
439 feed mills and on farms.

440 ○ If imported MBM is reliably only used for non-ruminants, *e.g.* poultry, pet  
441 food, fish or pigs, it would not represent an external challenge. In such a case,  
442 it would be necessary to trace back the importer for each MBM batch and  
443 acquire the documents confirming the specific end use of each batch.

444 ○ To have the material excluded from the external challenge, it would be  
445 necessary to provide documentary evidence to show that the MBM was only  
446 incorporated in non-ruminant feed and could not have given rise to cross-  
447 contamination.

448 ○ In cases where the available information indicates but does not conclusively  
449 show that MBM did not enter the feed chain, only a proportion of MBM  
450 imports may be deducted.

451 • ***Imported MBM is of non-bovine origin.***

452 If evidence can be provided that the MBM was obtained from animals other than cattle  
453 (*e.g.* dehydrated pork meal or fishmeal), obviously no challenge can be attributed to the  
454 MBM. In such a case, to have the material excluded from the external challenge it would  
455 be necessary to identify not only the importer, but also the manufacturer in the exporting  
456 country and documentation should be available to confirm the nature of the materials used  
457 to produce the MBM.

458 • ***Imported MBM is of bovine origin but from materials very unlikely to be***  
459 ***contaminated by BSE.***

460 If evidence can be provided that the MBM was obtained from bovine material very unlikely  
461 to be contaminated (*e.g.* gristle meal), it can be excluded from external challenge.

462 • ***MBM that is re-exported.***

463 MBM imported from a BSE-risk country and exported to another country without further  
464 handling that would allow cross-contamination obviously does not constitute a challenge for  
465 the importing country. In order to apply this criterion import/ export certificates or  
466 equivalent documentary evidence should be available with a clear identification of the  
467 involved MBM.

468 Please note: The international independent working group responsible for carrying out the  
469 assessment may consider these and other reasons for the inclusion or exclusion of live cattle  
470 and MBM on a case-by-case basis.

471 4.4.3 *Estimation of the level of infectivity in the imported material, using imports from the*  
472 *UK during the peak of the epidemic as the point of reference*

473 In order to correctly assess the external challenge, it is important not only to take into account  
474 the number of live cattle imported from BSE-risk countries but also the type of intervention  
475 measures that are taken by the exporting countries to prevent the spread of the agent to live  
476 animals and subsequently to the animal products. These measures are included in the stability  
477 assessment of the exporting countries. In addition, the following factors may considerably  
478 reduce the associated challenge, in particular:

479 It is clear that all imports of live animals and MBM from BSE-risk countries do not pose the  
480 same risk. Consequently, it is necessary to have a system for relative weighting of the  
481 different imports. This system is implemented using the specially designed Excel spreadsheet  
482 (see in annex ‘import tables’) and is based on the following assumptions:

- 483 • The external challenge is dependent on the size of the challenged BSE/cattle system and in  
484 particular the size and structure of the cattle population.
- 485 • The baseline of this assumed challenge results from imports from the UK during the peak  
486 of the BSE-epidemic in the UK.
- 487 • The challenge resulting from imports during other periods and from other BSE-affected  
488 countries is established in relation to this baseline.

489 The weighting is assigned when the exporting country is itself being assessed and categorised  
490 under the GBR methodology. The third refinement step deals with evaluating what proportion  
491 of the imported cattle and MBM, as estimated above, is likely to be infected by BSE.

492 The GBR has the task of combining the challenge from different countries, over different time  
493 periods, and different commodities (live cattle and MBM) into an overall measure of risk. To  
494 do so, it is assumed that 1 Ton (1000 kilo) of MBM is equivalent to 1 live animal (from the  
495 same year) and that the risk from animals are scaled relative to that posed by UK cattle from  
496 the reference period 1988 to 1993, *i.e.*, the UK BSE prevalence was thought to be 5%.

497 In the UK at the end of the 1980s, the size of a birth cohort is roughly 2 million cattle. The  
498 cohorts with the highest infection level showed cases in about 5% of the cohort (Schreuder *et*  
499 *al.*). Assuming that only 20% of the animals live long enough to become a case, this suggests  
500 that about 25% of the cohort had been infected, *i.e.* roughly 500 000 cattle in that year. Annual  
501 production of MBM in the UK is a bit less than 500 000 tonnes of MBM (including fish  
502 meal). Under “regular” feeding conditions, these 500 000 tonnes led to 500 000 infected  
503 cattle. Thus, we conclude that one live animal is comparable to one tonne of MBM. The  
504 numbers in this calculation are very rough, which suffices, since we are merely interested in  
505 the order of magnitude to compare live animals to MBM.

506 The comparison is valid for the UK in that period. We extrapolate this number to all other  
507 situations, using a worst case assumption for the risk level of MBM, assuming that in the  
508 observed case the feeding was similar to that applied in the UK during the 1980s.

509 In the **SSC GBR** methodology, the scaling of imports was achieved by the use of “*R*” values.  
510 These reflected the different magnitude and stage of a specific epidemic in relation to the UK  
511 highest risk period.

512 In the **EFSA GBR** methodology, although expanded here, exactly the same basic concept is  
513 applied. However, we have also taken this opportunity to clarify the method and the

514 introduction of new terminology. Hence we use external challenge “weighting factor” ( $w$ ) in  
515 place of the R1 and R2 values, which were previously found to be confusing.

516 **Determination of the weighting factors:**

517 • In the reference UK period, the prevalence of BSE was taken as 5%. For these animals we  
518 define  $w = 1$ , and one such animal (or Ton of MBM) is considered 1 “Risk Unit”. If the  
519 prevalence in a country at the time of export is known (see below) to be, for example 0.5%  
520 then such exports are weighted by a factor  $w = 0.1$ . *i.e.*,  $w$  is estimated by the prevalence in  
521 year of export /0.05. Ten such animals would therefore be equivalent to 1 Risk Unit (1  
522 animal from the UK during the reference period).

523 • If weighting factors are identified and applied to each year of export from each BSE risk  
524 country, then the resulting risk units can be combined between different countries and  
525 between different years. These are then used to obtain a final estimate of the risk that BSE  
526 could have been imported. Table 1 indicates that  $\geq 100$  live cattle from the UK reference  
527 period are a “High” external challenge (reflecting the high probability that the imports  
528 included infected animals). The weighting factor ensures that imports from other years or  
529 countries can be combined and converted to this standard scale.

530 • As an example, 50 live cattle from the UK in the reference period + 4000 live cattle  
531 having a weighting factor = 0.01 + 10000 Tons of MBM having a weighting factor 0.001  
532 would also constitute 100 Risk Units and a High challenge, in Table 1).

533 In practice, it is very difficult to estimate the yearly prevalence in the (exporting) BSE risk  
534 country and hence the weighting factor for a particular export. Here, two complementary  
535 methods are employed:

536 A) **Based on prevalence estimates** in the country using BSurVE (EFSA, 2004b) or another  
537 appropriate method. If yearly prevalence estimates are available for two or more years,  $w$   
538 is obtained directly using the upper 95% percentile estimate of prevalence divided by 0.05  
539 (which is the estimate used for the UK cattle BSE prevalence during the reference period  
540 1988 to 1993).

541 B) **Based on a rules system.** When reliable prevalence estimates are unavailable, a rules  
542 based approach is used. First it must be established when the exporting BSE risk country  
543 itself received its high external challenge and also its stability levels over time. These are  
544 used to approximate the course of the epidemic: its prevalence increasing over time while  
545 unstable, and decreasing when stable. The exports from the risk country are then weighted  
546 as follows:

547 **When no changes in stability in the exporting country appear, this will have the**  
548 **following effect:**

- 549 • No risk until the year a cumulative high challenge occurred in the exporting country.
- 550 • The weighting factor ( $w$ ) of the imports is 0.001 for the next 5 year period (very/extremely  
551 unstable) or 10 year (unstable), after which the  $w$  value increases to 0.01 *unless there are*  
552 *changes in stability*.

553 **When changes in stability in the exporting country appear, this will have the following**  
554 **effect:**

- 555 • If  $w = 0.01$ , a change to a stable system results in a reduction in  $w$  to 0.001 after a 5 year  
556 period.

557 **Note:**

- 558 • The **5-year period** is chosen to approximate the duration of BSE incubation time.
- 559 • The  $w$  values can be modified to reflect additional information of key importance. At  
560 present there are two examples in use. First, for non-UK EU (EU-15) MBM exports until  
561 1996, it is assumed that 0.1 Tons of MBM is equivalent to 1 live cattle. This was  
562 introduced because of the high risk of UK MBM being re-exported by other European  
563 countries. Second, for countries with very large cattle populations an adjustment may have  
564 to be made to reflect the fact that if the challenge is not “very high”, it will take a long  
565 time for the epidemic to reach appreciable prevalence. In these cases, no risk ( $w = 0$ ) is  
566 assumed until 5 years after the high challenge, and the progression from  $w = 0.001$  to 0.01  
567 is extended by 5 years.

568 **Table 1: Level of external challenge resulting from import of live cattle or MBM from**  
569 **UK or other BSE-risk countries**

Level of external challenge	Risk units resulting from imported live cattle and MBM Using weighting factors
Extremely high	$\geq 10,000$
Very high	1,000 - < 10,000
High	100 - < 1,000
Moderate	20 - < 100
Low	10 - < 20
Very low	5 - < 10
Extremely low	0 - < 5

570

#### 571 **4.5 Stability Assessment**

572 **Stability** is defined as: the ability of a BSE/cattle system (Figure 1) to prevent the  
573 introduction and to reduce the (amplification and) spread of the BSE agent within its borders.  
574 Stability relies on the avoidance of processing of infected cattle and the avoidance of recycling  
575 of the BSE agent via the feed chain. A “stable” system would eliminate BSE over time; an  
576 “unstable” system would amplify it.

577 Stability is linked to the basic Reproduction Ratio of the infection ( $R_0$ ).

- 578 • If  $R_0$  is bigger than one, the epidemic will grow, and the system is “unstable”.
- 579 • When this multiplication factor is close to 1, the infection level will remain constant and  
580 the system is called “neutrally stable”.
- 581 • When the multiplication factor is below one, the epidemic will decrease and the system is  
582 “stable”.

583 The most important stability factors are those to be able to prevent the building-up of BSE  
584 infectivity in the system and reduce the risk of recycling of the BSE agent within the cattle  
585 population, in particular SRM-removal, rendering and feeding.



586 *4.5.1 SRM-removal*

587 The infectivity that could enter the feed chain can be reduced by excluding from rendering  
588 those tissues (SRM) known to carry the bulk of the infectivity that can be harboured by pre-  
589 clinical BSE case. Information on the distribution of BSE tissue infectivity is provided by the  
590 updated SSC Opinion on TSE Infectivity distribution in ruminant tissues (SSC, 2002) and by  
591 Table 2 originating from the EFSA QRA Report (EFSA, 2004c).

592 Table 2: **Estimated tissue weights and infectivity levels from adult beef cattle, for an**  
593 **infectivity titre of 5 CoID<sub>50</sub> per gram in brain of a clinical case**

<b>Tissue</b>	<b>Total mass (g)</b>	<b>Titre: CoID<sub>50</sub>/g</b>	<b>Total infectious Load (%)</b>
Brain	500	5	2500 (60.1)
Trigeminal Nerve Ganglia (TRG)	20	5	100 (2.4)
Spinal cord	200	5	1000 (24.0)
Dorsal Root Ganglia (DRG)	30	5	150 (3.6)
Ileum	800**	0.5	400 (9.6)
Spleen*	800	0.0005	0.4 (0.01)
Rest of head, excl. skull and brain****	6,500		6.6 (0.16)
All bones, total:	58,000		
All bones, without skull	50,000		
Bones, excl. skull and vertebrae	37,000		
Bone marrow (10% ww)	2,900	0.0005	1.5 (0.04)
Bone adnexa (20% ww)	5,800	0.0005	2.9 (0.7)
Manure, gut content, ...	80,000		
Hooves, hide, horns, ...	50,000		
Other by-products / offals	129,450		
Consumed (excl. bones)	215,000		
<b>Totals</b>	<b>550,000***</b>		<b>~4160 CoID<sub>50</sub></b>

594 \* No BSE infectivity has so far been found in the spleen of bovines. As a prudent view, bovine spleen is considered to be  
595 possibly infectious, but the infectivity level attributed corresponds to the current limit of detection.

596 \*\* 800g may be excessive for the anatomical region strictly termed ileum (without content), which in an adult bovine  
597 represents about 1 meter of bowel.

598 \*\*\* It should be noted that, in practice, these weights would vary between different animals, depending on age and breed.  
599 Area dependent there can also be large differences. In the Netherlands for instance the average weight might be  
600 considerably lower because of the very large proportion of calves that are slaughtered there.

601 \*\*\*\* The rest of head is assumed to include the eyes (100g) and the tonsil (50g) both with an infectivity assumed to be 4  
602 logs less than brain from the result for tonsil (0.0005 CoID<sub>50</sub>/g) plus 1.3g of CNS contamination from captive bolt  
603 slaughter (Cooper & Bird 2002).

604 The removal involves SRM from all bovine animals that leave the population (healthy and  
605 casualty slaughtered animals, clinical suspect animals, fallen stock). For practical reasons the  
606 carcasses of fallen stock are most often entirely removed. Findings from the extensive active  
607 surveillance in Europe indicate that the frequency of pre-clinical infection in fallen stock and  
608 casualty slaughter cattle is significantly higher than in normal slaughtered cattle. This effect is  
609 further increased by the fact that fallen stock will normally be more advanced in the stage of  
610 the disease with significantly higher level of infectivity in the SRM than can be assumed for  
611 apparently healthy cattle that pass ante-mortem inspection despite that they are incubating  
612 BSE. These should normally be less advanced in the BSE incubation period (SSC, 1998).

613 4.5.2 *Rendering*

614 According to the SSC opinion on the safety of MBM (SSC, 1998), appropriate rendering  
615 methods reduce BSE-infectivity that enters the process via the raw material. The SSC  
616 assumes, for all practical purposes, a reduction factor of 1000 for a process known as “batch  
617 pressure cooking”, *i.e.* at 133°C during 20 minutes under a pressure of 3 bars. Rendering,  
618 however, can never be taken as a way to sterilize BSE contaminated material.

619 4.5.3 *Feeding*

620 The risk of new infections in the domestic cattle population would (under the basic  
621 assumptions made for the GBR) be nil if no feed that potentially carries the BSE-agent  
622 reaches bovines. However, experience from Europe has shown that traces of ruminant protein  
623 (other than milk) in feed are enough to infect cattle. These traces may result from cross-  
624 contamination of MBM-free cattle feed with MBM-contaminated pig or poultry feed, which  
625 may happen in feed mills that produce both types of feed in the same production lines.  
626 Apparently flushing batches, a method often used as a safeguard against such cross-  
627 contamination, is not sufficient. This conclusion from practical experience is supported by the  
628 oral exposure experiments in the UK that have shown that for 0.1g infective brain, 7 out of 15  
629 animals became positive, for 0.01 gram of infective brain, 1 out of 15 cattle became positive  
630 and for 0.001 gram infective brain, 1 out of 15 cattle became positive (Wells *et al.*, in press).

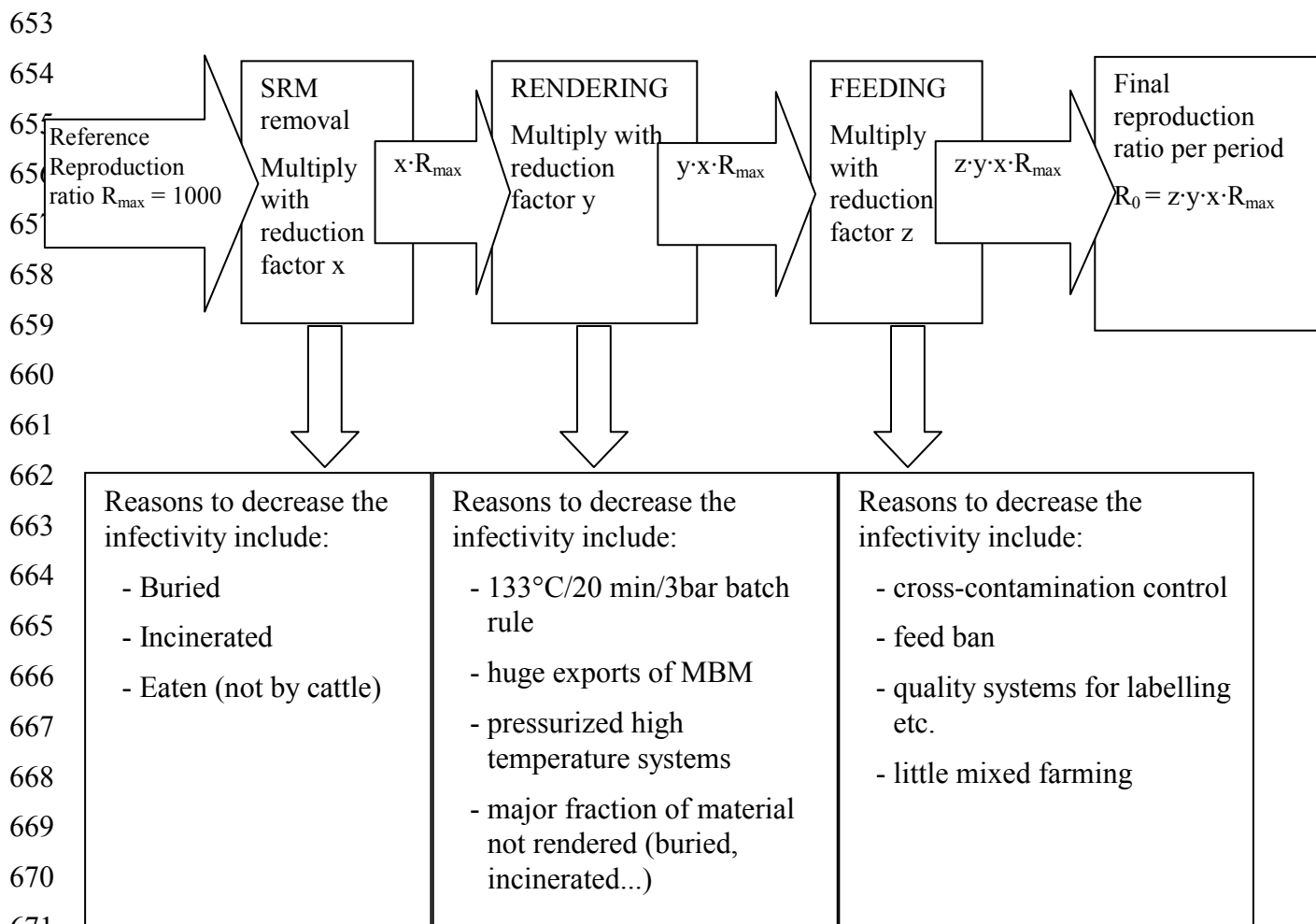
631 **4.6 Methodology for assessing stability**

632 The stability of the system is assessed for a particular period based on the set of stability  
633 factors existing at that time. The stability is assessed by estimating the level of propagation of  
634 the BSE agent for the set of factors using the reproduction ratio ( $R_0$ ). The  $R_0$  is initially set at  
635 a reference level based on minimum standards of stability. If the country being assessed has  
636 control measures in place to improve the stability,  $R_0$  is adjusted downward accordingly. A  
637 final  $R_0$  is obtained after the effect of all of the stability factors has been taken into account.

638 In setting the reference level, it is necessary to have information on the level of propagation of  
639 the BSE agent under minimum standards of stability. This is available for the UK during the  
640 pre-1986 period. During that time, it is estimated that the infection level multiplied by a factor  
641 of between 10 and 20 per generation (*i.e.* in about 5 years' time, the number of infections  
642 increases 10 to 20 times) (de Koeijer *et al.*, 2004; Ferguson 2003). The stability conditions  
643 that existed during that period were that no SRM was excluded from the feed chain, rendering  
644 was mainly carried out under atmospheric conditions (this led to a estimated reduction of the  
645 infectious load of 0.1) and approximately twenty percent of MBM was used for cattle feed.  
646 Assuming a linear relationship between  $R_0$  and the level of the risk factors, the upper value of  
647  $R_0$  ( $= R_{max}$ ) would have been 1000 if all of the MBM had been fed to cattle and if rendering  
648 had no effect whatsoever. This is taken as the reference level for  $R_0$ .

649 A schematic overview of the methodology for evaluating the stability is given in Figure 2.

650 This method uses the fact that the effect of control measures on the  $R_0$  is linear. Thus, by  
651 multiplying the reduction factor for each of the main control measures, we calculate the total  
652 effect of all the control measures together to give a final value for  $R_0$ .



672 **Figure 2. Schematic overview of the method to analyse stability. This scheme can be**  
 673 **worked out into a complete tree if required for more complicated systems.**

674

675 Example: If we find :

- 676
- 677
- 678
- 679
- 680
- $x = 0.7$  (some SRMs are used in food, a large part is rendered)
  - $y = 0.1$  (some reduction of infectious load in rendering)
  - $z = 0.2$  (about 20% of all MBM is fed to cattle)
  - setting  $R_{max} = 1000$
  - so we find that the final  $R_0 = 1000 * 0.7 * 0.1 * 0.2 = 14$

681 Further details on the adjustments that should be made to  $R_0$  to account for the various  
 682 measures in place to improve stability are given in the next section.

683 *4.6.1 Assessing the impact of SRM removal*

684 In this block the removal and fate of all the SRMs of all cattle slaughtered, culled or died of  
 685 other causes is assessed.

- 686 • The maximum reduction is proposed to be a factor of 0.001. Values between 1 and 0.001  
687 should therefore be applied depending on the nature of the SRM removal from the feed  
688 chain and the assessed efficacy of the system.
- 689 • If **no SRMs** are removed from the rendering to feed chain, this is valued as a factor of 1.
- 690 • If **all SRMs** are incinerated, buried or used in the human food chain, *i.e.* cannot go to the  
691 feed chain, it is optimal.
- 692 • If SRM removal is applied in full compliance with the list of SRM of OIE or EU, if fallen  
693 stock excluded, and implementation and control of measures guaranteed a maximum  
694 reduction factor of 0.001 can be theoretically achieved (SSC, 2002). However, this  
695 maximum indicated by the SSC document reflects an ideal situation that in practice hardly  
696 ever can be achieved, thus rather a maximum of 0.01 appears reasonable.
- 697 • If only fallen stock is excluded a reduction factor of 0.4 can be applied (removal of 60 %  
698 of infectious load).
- 699 • If SRM is usually eaten: when it can be assumed that all brain is eaten a reduction factor  
700 of 0.4 (removal of 60 % of infectious load) can be applied (EFSA, 2004c).
- 701 • If an official SRM ban is in place, but evidence for full compliance can not be provided  
702 (no or only limited control data provided), the reduction factor may vary.

#### 703 4.6.2 *Assessing the impact of Rendering*

704 In this block the effect of rendering is assessed.

- 705 • When an atmospheric pressure is applied in rendering, a reduction factor of 0.1 is  
706 considered. Improved systems will get a better reduction value. Systems according to  
707 133/20/3 are evaluated by a reduction factor of 0.001 if fully applied (Schreuder *et al.*,  
708 1998; Taylor and Woodgate, 2003). Other rendering systems or a combination of various  
709 systems can be evaluated between 1 and 0.001 depending on the information provided by  
710 the country.
- 711 • If no rendering exists a maximum reduction factor of 0.001 can be applied as no MBM is  
712 then produced.

#### 713 4.6.3 *Assessing the impact of Feeding*

714 In this block, the fraction of the MBM that may be fed to cattle is assessed.

- 715 • If all MBM of the national production is being fed to cattle this is valued by 1. In the UK  
716 prior to 1986 about 20% of the national MBM production (*i.e.* 20% of all rendered cattle  
717 protein) was used in cattle feed. This should be valued with a reduction factor of 0.2. An  
718 optimal feed ban supported by cross-contamination controls can be assessed with a  
719 reduction factor of 0.001.
- 720 • A well-implemented mammalian MBM feed ban to all farmed animals is considered the  
721 optimum (reduction factor of 0.001).
- 722 • For a well-implemented mammalian MBM feed ban to ruminants a reduction factor of  
723 0.01 can be applied.
- 724 • For a well-implemented ruminant MBM feed ban to ruminants a reduction factor of 0.1  
725 can be applied.

- 726 • If dedicated feed mills and/or rendering plants are used and data on the controls to exclude  
727 cross-contamination are provided a further reduction factor of 0.1 can be applied for the  
728 two later feed- bans.

729 *4.6.4 Evaluation of the overall stability of the system*

730 The different combinations of the three main stability factors accordingly result in different  
731 levels of stability, as shown in Table 3.

732 The overall stability is measured by the final value of  $R_0$  and this works as follows

- 733 • As long as the basic reproduction ratio is bigger than one, the epidemic will grow, and the  
734 system is “unstable”.
- 735 • When  $R_0$  is close to 1, the infection level will remain constant, and the system is called  
736 “neutrally stable”. In a neutrally stable system, the recycling rate of the BSE agent would  
737 just be high enough to maintain the total level of infectivity once introduced into the  
738 system. In other words, the number of new infections in the cattle population is more or  
739 less equal to the number of incubating cattle leaving the system.
- 740 • When  $R_0$  is below one, the epidemic will decrease, which makes the system “stable”.

741 It should also be understood that the table below is not intended to provide a semi-quantitative  
742 assessment of stability, but is rather designed as guidance for ensuring a consistent  
743 interpretation of comparable outputs. This should harmonize the assessment of different  
744 countries.

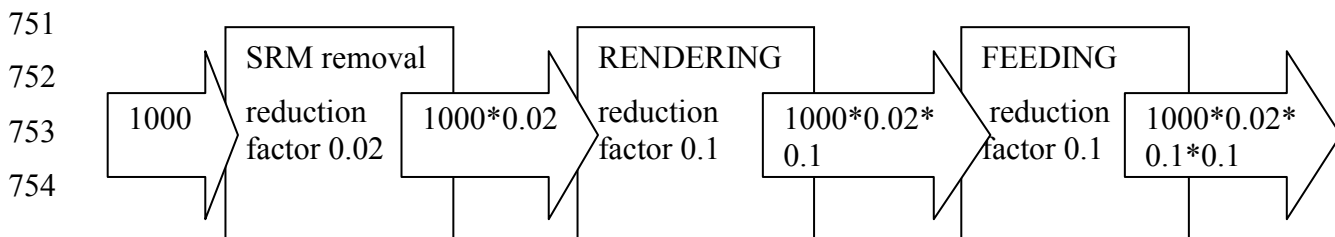
745 **Table 3: BSE stability levels and their interpretation with regard to Reproduction Ratio**  
746 **( $R_0$ ). Optimally stable should be understood as “as good as possible according to current**  
747 **knowledge”.**

STABILITY	Level	Effect on BSE prevalence	$R_0$
<b><u>Stable:</u></b>	Optimally stable	Very fast	0 to 0.05
The system will reduce BSE-infectivity	Very stable	Fast	0.05 to 0.2
	Stable	Slow	0.2 to 0.5
<b><u>Neutrally stable</u></b>		+ - constant	0.5 to 2
<b><u>Unstable :</u></b>	Unstable	Slow	2 to 5
The system will amplify BSE-infectivity	Very unstable	Fast	5 to 15
	Extremely unstable	Very fast	> 15

748

749

750 **Examples of stability assessment**



755

756 **Example:** if we find:

757 •  $x = 0.02$  (little SRMs are used in feed),

758 •  $y = 0.1$  (atmospheric rendering)

759 •  $z = 0.1$  (about 10% of all MBM is fed to cattle),

760 • using  $R_{\max} = 1000$  and we find that the final  $R_0 = 1000 * 0.02 * 0.1 * 0.1 = 0.2$

761 Further details on the adjustments that should be made to  $R_0$  to account for the various  
762 measures in place to improve stability are given in the next section.

## 763 4.7 Interaction of stability and challenge

### 764 4.7.1 General overview

765 The interaction between stability and challenge will determine how the GBR develops over  
766 time. Assuming that new challenges can be avoided, the current stability determines the slope  
767 of the GBR trend:

768 • A **stable** system will reduce the GBR level. In such a stable system, the rate of new  
769 infection is lower than the rate at which infected cattle leave the system. The risk is  
770 approaching zero once the last cattle born before achieving very stable levels of stability is  
771 slaughtered.

772 • An **unstable** system will amplify any BSE-infectivity that is already in the system and  
773 increase the GBR level.

774 As illustrated in Figure 3, four different basic combinations of stability and challenge can be  
775 foreseen during a particular period:

776 ○ A **stable** system that is not or only **slightly challenged**: this is the best  
777 situation.

778 ○ A **stable** system that is **highly challenged**: this situation is rather good since the  
779 system will be able to remove the BSE agent, over time.

780 ○ An **unstable** system that is not or only **slightly challenged**: as long as the BSE  
781 agent is not entering the system, the situation is good. However, the possibility  
782 of the BSE agent entering the system and being amplified can occur.

783 ○ An **unstable** system is **challenged**: this is an adverse situation, since the BSE-  
784 infectivity will be amplified over time and will lead to an epidemic.

785

786

		Overall Challenge						
		Negligible	Very low	Low	Moderate	High	Very high	Extremely high
Stability Amplification   Reduction	Optimally stable							
	Very stable	Best					Good	
	Stable							
	Neutral							
	Unstable				→			
	Very Unstable		X→	→				
	Extremely Unstable	Good						Worst

787

788 Figure 3: **Combinations of challenge and stability**

789

790 *4.7.2 Definitions of challenge*

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

793 The external and internal challenges are defined as follows:

- 794 • The external challenge (EC) is defined as both the likelihood and the amount of the BSE  
795 agent entering into a defined geographical area in a given time period through infected  
796 cattle and MBM, as defined in chapter 4.4 of this document.

797 A number of points need to be considered in relation to the external challenge:

- 798 ○ If BSE infected cattle are imported, they still need to be processed<sup>6</sup> before the  
799 agent can enter the domestic BSE/cattle system.
- 800 ○ Moreover, their BSE-load is regarded being significant, only if they are  
801 approaching the end of the incubation period when they are processed.
- 802 ○ Given that the average incubation period is 5 years and the import-age of breeding  
803 cows is normally around 2 years, the highest risk of introducing the BSE-agent due  
804 to cattle imports is about 3 years after the year of import of breeding stock. If the  
805 produced contaminated MBM is then fed to cattle, it will take a full incubation  
806 period, on average 5 years, before any clinical BSE case could appear as a result of  
807 this initial importation of infected cattle. It is therefore unrealistic to expect clinical  
808 BSE-cases resulting from cattle imports, before 8 years after the import, even if the  
809 importing system is very unstable.

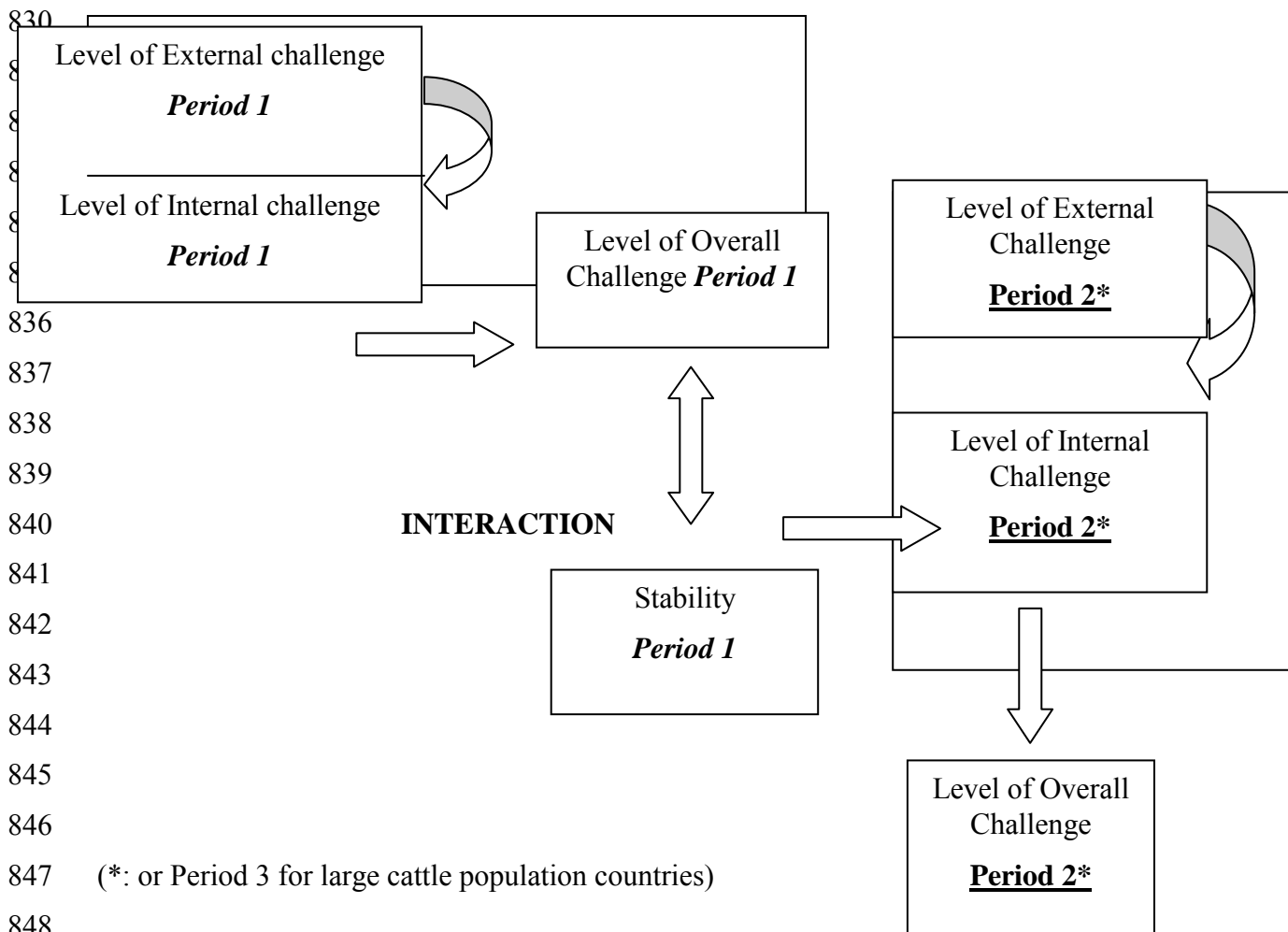
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<sup>6</sup> Processed: meaning cattle slaughtered and rendered for meat and bone meal so this can be fed to cattle.



- 810           ○ If cattle are imported for immediate slaughter, the challenge will depend on their  
811           age at import which is close to their age at slaughter. If they are young, the  
812           likelihood of them approaching the end of the incubation period and representing  
813           an external challenge is very low. If, however, older cows are imported and  
814           slaughtered, the risk that they introduce the BSE agent into the importing  
815           BSE/cattle system is at least as high as the GBR in the exporting country.
- 816           ○ If contaminated MBM is imported it is used for feed in the year of import. If it is  
817           fed to domestic cattle, these are likely to become infected. After approximately 5  
818           years (average incubation period) a certain number of them, which have survived  
819           until that age, could become clinical BSE cases.
- 820           ● The internal challenge (IC) is defined in the SSC opinion on the GBR (SSC, 2000) as the  
821           likelihood and the amount of the BSE-agent being present in the native domestic cattle  
822           population and circulating in a specific geographical area in a given time period. If  
823           present, the agent could be in infected domestic animals, where it would be replicated, in  
824           particular in SRMs, and in domestic MBM made from the infected domestic cattle. The  
825           internal challenge in a given time period is therefore a consequence of the interaction of  
826           the stability of the system and the past challenges (internal and external) to which it was  
827           exposed in a previous period (*i.e.* the overall challenge of the previous 5-year period). This  
828           concept is illustrated in Figure 4.

829   Figure 4: **Evolution of the overall challenge from one period to the next**



849 4.7.3 *Rules for assessing the interaction between challenge and stability*

850 The interaction between stability and challenge is assessed by a rules based approach. The  
851 main goal is to compute any challenge occurring at a period  $n$ , and to be able to infer, while  
852 using the stability level at period  $n$ , the internal challenge that will occur at period  $n+1$ .

853 Then it will be possible, at the period  $n+1$ , according to the internal and the external  
854 challenges, to evaluate the level of overall challenge for this particular period.

855 Expressed differently, this approach is using as inputs the external challenge and the stability  
856 of the cattle system of one 5-year period, to infer both the resulting internal challenge and the  
857 overall challenge of the following 5-year period.

858 The rules for assessing the interaction between challenge and stability are as follows:

859 a. An extremely to very unstable system will lead to an upgrade of one level of overall  
860 challenge (Table 4). This will occur in the next 5-year period for small cattle population  
861 countries ( $< 20$  million cattle) and in the second next 5-year period for large cattle  
862 population countries.

863 b. An unstable system, will lead to an upgrade by one level of the challenge. This will occur  
864 in the second next 5-year period for small cattle population countries ( $< 20$  million cattle),  
865 and in the fourth next 5-year period for large cattle population countries.

866 c. In a neutrally stable country, the overall challenge will stay at the same level from one  
867 period to the next.

868 d. A stable system, will lead to a downgrade by one level of challenge. This will occur in the  
869 second next 5-year period that the system is stable.

870 e. An extremely to very stable system will lead to a downgrade of one level of challenge.  
871 This will occur in the next 5-year period.

872 f. When both challenges are on the same level, for an unstable country, their effects add up  
873 and the overall challenge may therefore be one step higher in the second next 5-year  
874 periods. For a stable country, the overall challenge goes one step lower in the second next  
875 5-year periods.

876 g. It is assumed that the change in the overall challenge, over time, is on a logarithmic scale.  
877 Consequently, the highest level of one of the challenges (either external or internal) can be  
878 considered as equivalent to the level of the overall challenge at that particular time.

879 h. For the same reason, the level of the overall challenge will be equivalent to those of  
880 external and internal challenges, when they both share the same levels of challenge (*i.e.*  
881 their effect on the level of challenge is not additive).

882 The following table (Table 4) present the basic rules to use the interaction chart.

883

884

885

886

887

888

889

890 Table 4: **Diagrammatic representation of rules for assessing the interaction between**  
891 **challenge and stability**

<b>LEVEL OF CHALLENGES</b>							
<b>Extremely high</b>	Stay at the same level				One downgrade of level on the second next 5-year period*	One downgrade of level on the next 5-year period	
<b>Very high</b>	One level up on the next 5-year period*	One level up the second next 5-year period	Stay at the same level				
<b>High</b>							
<b>Moderate</b>							
<b>Low</b>							
<b>Very low</b>							
<b>Extremely low</b>				Stay at the same level			
<b>STABILITY LEVELS</b>	<b>Extremely unstable</b>	<b>Very unstable</b>	<b>Unstable</b>	<b>Neutrally stable</b>	<b>Stable</b>	<b>Very stable</b>	<b>Optimally stable</b>

892 (\*: for large cattle population countries, the level goes up or down on the second next 5-year period. The stability taken into account to  
893 assess the overall challenge is the one for the second next-5 year period).

894 *4.7.4 Example*

895 An example is worked out and presented in Annex V.

896

897 **4.8 Overall challenge and new EFSA GBR categorization**

898 Table 5 below gives the equivalence between the overall challenge and the new different GBR  
899 categorization.

900

901 Table 5: **Equivalence between the overall challenge and the new different GBR**  
902 **categorization**

Level of Overall Challenge	Estimated number of risk units	EFSA GBR categorization
Extremely high	$\geq 10,000$	
Very high	1,000 -<10,000	Likely
High	100 -<1,000	
Moderate	20 -<100	
Low	10 -<20	
Very low	5 -<10	Unlikely
Very Low	0 -<5*	

903 \* The risk unit as defined in this opinion is one cow with a 5 % probability of being infected.

904 The difference between likely and increasing, and likely and decreasing will be given  
905 according to the evolution of the stability of the country and the challenges occurring over  
906 time.

907 **4.9 Surveillance and its contribution**

908 *4.9.1 General comments*

909 In general, surveillance through its detection component is aimed at demonstrating the  
910 absence of disease or infection or determining the occurrence or distribution of disease or  
911 infection. The type of surveillance applied depends on the desired outputs needed to support  
912 decision-making.

913 Surveillance systems for BSE can have one or more goals, depending on the risk category of a  
914 country. These goals may include:

- 915 • to determine if BSE is present in the domestic cattle population
- 916 • to support a claimed BSE status or to (re)-gain a higher BSE status
- 917 • to monitor the level and evolution of the disease (when present), which will aid in  
918 assessing the effectiveness of control measures implemented.

919 In the SSC GBR method, surveillance data was taken into account, however, this factor had  
920 very little impact on the final assessment of the GBR in terms of preventing the introduction  
921 and spread of the BSE agent. In some cases it influenced, marginally, the assessment of the  
922 stability.

923 4.9.2 *Some points concerning surveillance data and their use in the EFSA GBR*  
924 *methodology*

- 925 • Relevant surveillance data can be taken into account for countries with overall challenge  
926 and stability resulting in an unclear outcome of the risk.
- 927 • The lack of surveillance data will not be used to change the final outcome of countries  
928 with a negligible external challenge and subsequently an unlikely BSE risk.
- 929 • Also surveillance data will not be used to change the final outcome of countries with a  
930 high external challenge combined with an (very/extremely) unstable system.

931 In general available surveillance data can be used to support the outcome of the assessment, in  
932 particular for confirming an increasing or decreasing trend of the BSE risk.

933 4.9.3 *Evaluation of surveillance systems capable of estimating the prevalence of BSE*  
934 *infection*

935 As indicated above, if yearly prevalence data are available then it is possible to estimate the  
936 weighting factor for a particular export of cattle from a country/region when exposure risks  
937 (external challenge) are being assessed.

938 An essential aspect of assessing the stability of a country or region is determining the  
939 effectiveness of the various controls instigated. One mean of achieving this is by auditing, *e.g.*  
940 determining if SRM are removed from carcasses and disposed of appropriately. The ultimate  
941 means of determining the effectiveness of controls is to estimate the prevalence of infection  
942 within birth cohorts before and after the introduction of the interventions. In the case of BSE  
943 this is only possible to determine some years after the initiation of controls, and this is a  
944 relatively expensive exercise. However, a number of countries notably of the EU have  
945 invested a great deal in extensive surveillance programmes. The BSurvE model does allow  
946 the synthesis of the results of the testing in the various surveillance streams in which cattle  
947 can be tested as they leave the population. One result of this synthesis is the provision of  
948 prevalence estimates in the birth cohorts for which sufficient test results are available. This  
949 therefore allows if applicable, a more definitive assessment of the stability within a country or  
950 region.

951 It is not possible to prove that a country is free of any disease by surveillance alone. To prove  
952 that a country is free of disease all animals must be tested with a test with perfect diagnostic  
953 sensitivity and yielding negative results, and there should be no entry of animals or animal  
954 products of unknown status that could transmit the infection thereafter. In addition, the  
955 uncertainty introduced by testing only a sample from the population with tests with a known  
956 (or not known) ability to classify correctly the animals tested make it impossible to prove true  
957 disease freedom of a population or a country.

958 For some countries/regions the risk assessment may have revealed some uncertainty in the  
959 exposure status and the stability following potential exposure. If there has been targeted  
960 surveillance, then analytical methods such as those provided by the BSurvE model allows the  
961 estimation of the prevalence of infection in the cattle population and more importantly the  
962 upper 95 % confidence interval. This is particularly important where the observed prevalence  
963 is zero.

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1 ANNEX I

2 INTERPRETATION OF THE TERMS OF REFERENCE

3 In deliberating the terms of reference the working group/Biological Hazards Panel noted the  
4 following points:

5 **A. Experience gained from previous GBR-assessments**

- 6 1. The GBR methodology as developed by the Scientific Steering Committee (SSC) and  
7 used up to now by the SSC GBR Peer group and the EFSA GBR expert group was  
8 found to be a helpful and evidence based assessment tool for assessing the BSE risk  
9 in cattle of a country.
- 10 2. The SSC GBR methodology worked well for assessing the risk from cattle and MBM  
11 exports from Category 3 European countries. However, the risk from exports from  
12 countries with a low BSE prevalence and large cattle populations was overstated and  
13 this needed to be corrected.
- 14 3. The assessment of the stability needed to be more flexible to allow for partial  
15 improvements in stability to be taken into account. For example, under the SSC GBR  
16 methodology, a rendering system was only considered to be ok if it was operating at  
17 133 degrees, 3 bar for 20 minutes. While these are the recommended operating  
18 conditions, it should be recognized in the assessment of the stability in the GBR  
19 methodology that conditions such as a temperature of 120 degrees at rendering will  
20 also lead to an improvement in stability.
- 21 4. The SSC GBR method was geared to identify or predict a potential first case in a  
22 certain country but the future GBR method should also allow the expert group to  
23 assess “an expected future development of the risk over time” *i.e.* be able to allow the  
24 expert group to declare a decrease of the risk in a certain country.
- 25 5. The SSC GBR method could benefit from an increased transparency, *i.e.* the tables in  
26 the report did not reflect the actual inputs as taken into account but were the *raw data*.  
27 The tables with the *final data* were not included in the report. However, an  
28 explanation was provided in the body of the report where an indication was given that  
29 certain animals or MBM imports were deducted from the risk factors. Adding a table  
30 with the final data of the imported commodities taken into account in the risk  
31 assessment may increase the transparency of the reports.
- 32 6. The GBR classification of countries will change over time depending on their imports  
33 of cattle and MBM and their stability. In turn, the risk posed by exports from those  
34 countries could have a domino effect on the GBR classification of their trading  
35 partners. The BSE-cases, confirmed in Austria, Finland, Sweden and Slovenia that  
36 were initially classified as GBR II, underlined the appropriateness of this statement.  
37 The explanation for these cases was that imports into these countries from GBR III  
38 countries were not regarded as external challenge when the GBR of these countries  
39 was assessed. Therefore there is a need for an ongoing reassessment of the GBR of  
40 individual countries.

41 It was concluded that for an update of the GBR methodology, the following points in  
42 particular would need to be clarified:

- 43
- 44 **a. General:**
- 45     • Type and quality of data that is needed from the country being assessed
- 46     • Assessment of the possible other transmission routes
- 47 **b. External challenge assessment**
- 48     • Indication of criteria for exclusion/inclusion of imports of animals and MBM
- 49     • Determination of the time when an internal challenge became possible (R1) or likely
- 50     (R2) in the exporting country
- 51     • Determination of the time when the internal challenge decreased from R2 to R1, and
- 52     the possible development of a newly defined risk period.
- 53     • The inclusion of a dilution factor for the more realistic evaluation of the risk due to
- 54     introduction of BSE infectivity in a large cattle population by using an extended R1.
- 55     • Surveillance systems of the exporting countries.
- 56     • Stability of the exporting countries e.g., determination whether a challenge
- 57     originating from a GBR category 3 country outside of Europe represents a similar
- 58     challenge as the challenge from a GBR category 3 country within Europe.
- 59     • Estimation of the risk from exporting countries when they are not yet formally
- 60     categorised
- 61 **c. Stability in the country being assessed**
- 62     • Overall appreciation of the ability to prevent recycling and entry, and overall
- 63     assessment of the stability; especially the effect of different control measures e.g.
- 64     MBM ban, SRM removal.
- 65 **d. Surveillance in the country being assessed**
- 66     • Assessment of the surveillance system of the country being assessed and its results
- 67 **e. GBR categorisation**
- 68     • Appropriateness to have 4 categories as defined in the current GBR methodology
- 69     • Criteria for improving the GBR classification over time
- 70     • Appropriateness to define BSE risk status for compartments of animals and its
- 71     relationship to the classification of a geographical area.
- 72 **B. New information and methods available – epidemiology and surveillance**
- 73 1. Since 2001 BSE surveillance has been intensified in many countries which give a better
- 74 perspective of geographical risk.
- 75 2. BSE surveillance software, BSURVE, has been developed to analyse the results from the
- 76 TSE surveillance in the EU and to design the most cost effective surveillance. The generic
- 77 idea is that all surveillance results are weighted in a points system and that the necessary
- 78 points can be achieved by surveillance in healthy cattle, fallen stock, emergency slaughter
- 79 and clinical suspects. This tool enables a better assessment of the surveillance and
- 80 planning of the most cost effective surveillance given a certain design prevalence, and also
- 81 to validate the results of the risk assessment, albeit retrospectively.

82 **3. Consideration of developments in EU policy and the OIE methodology**

83 1. The European Commission's TSE Roadmap published in July 2005 clarified the  
84 objectives of the EU for TSE control policies (EC, 2005). These include (a) a reduction in  
85 the number of tested bovines without sacrificing the epidemiological information to be  
86 gained, thus still continuing to measure the effectiveness of the measures in place and (b)  
87 better targeting of the surveillance activities. The Roadmap also includes the strategic goal  
88 for BSE Risk Assessment for different countries, namely, "Simplification of the  
89 categorisation criteria and conclusion of the categorisation of the countries before 1 July  
90 2007". The Roadmap notes that the objective of a categorisation system according to the  
91 BSE risk is to define trade rules that afford the necessary guarantees to protect animal and  
92 public health for the importing countries. The Roadmap further states that the conditions  
93 for such trade are already laid down in the current recommendations of the Terrestrial  
94 Animal Health Code ("Code") of the World Organisation for Animal Health (OIE).

95 2. The CVO/ EU Parliament dialogue September 2005 concluded that the BSE classification  
96 should be based on OIE guidelines wherever possible. In line with this conclusion, the  
97 EFSA considered that an updated GBR assessment method should as much as possible  
98 match the outline of the OIE already presented with the intention to harmonize with the  
99 existing method. However, it was noted that OIE takes both risk assessment and risk  
100 management parameters into account. The EFSA Biological hazards panel agreed that the  
101 EFSA GBR methodology would only deal with the risk assessment elements.

102 3. The approach of OIE is documented in Chapter 2.3.13 of the OIE terrestrial animal health  
103 code (the general and new BSE Surveillance Chapter of the OIE (OIE, 2005). At the OIE  
104 General Session in May 2006, an agreement was reached on the simplified categorisation  
105 procedure including the requirements on surveillance within the different categories. OIE  
106 Classifications will be based on a risk assessment, a functioning MBM ban to ruminants,  
107 the presence of indigenous cases and the quality of the surveillance. The categorisation  
108 procedure includes three categories:

109 Category 1: Countries with a **negligible BSE risk** and surveillance programme detecting a  
110 design prevalence of 1 per 50,000. The country must have had a functioning ruminant  
111 meat and bone meal ban for at least 8 years and no indigenous case of BSE born within the  
112 last 11 years.

113 Category 2: Countries with a **controlled BSE risk** and surveillance programme detecting  
114 a design prevalence of 1 per 100,000. The country must have a functioning ruminant meat  
115 and bone meal ban.

116 Category 3: Countries with an **undetermined BSE risk**.

117 Based on this new OIE standard the current provisions under the TSE Regulation will be  
118 amended. Following adoption of the new categorisation criteria, the countries will be  
119 categorised starting with the major trading partners. EC indicated (as mentioned in the TSE  
120 road map) that it considers OIE should play a major role in these re-assessments. Following  
121 this self-tasking mandate, EFSA received further input and clarification from the EC in a letter  
122 from DG Sanco (D(2005)/KVD/cin/42 1007, 20-10-2005) clarifying the EC's intention to ask  
123 the OIE to take the lead in this work. However, the letter further states that in the event that  
124 OIE fails to assess all countries or these assessments are significantly delayed, EFSA would  
125 be the most appropriate body to carry out these risk assessments.

1 ANNEX II

2 **COMPARISON OF GBR METHOD AND OIE METHOD ASSESSING GEOGRAPHICAL RISK FOR**  
3 **BSE IN A COUNTRY.**

4 **1. General Comments**

5 OIE has not developed a new method, rather given guidelines as what parameters should be  
6 taken into account when carrying out a RA. Not included in the OIE is the surveillance data.

7 The OIE – Terrestrial Animal Health Code, section on Risk Analysis (section 1.3) outlines  
8 methods for the risk assessment as they are related to issues for the importation of animals or  
9 animal products. The OIE identifies the components of the risk analysis process as: hazard  
10 identification, risk assessment, risk management and risk communication. The risk assessment  
11 is the component of a risk analysis that estimates the risk associated with a hazard. Risk  
12 assessment methods should be chosen in relation to the specific situation. They may be  
13 qualitative or quantitative.

14 The method for the assessment of the (*European Commission initiated and taken over by the*  
15 *European Food Safety Authority*) Geographical BSE-Risk (GBR) is one of the possible  
16 qualitative methods that can be used for the risk assessment component of this process. It is an  
17 innovative approach, however, using terminology somewhat different to those applied in the  
18 risk assessment literature and the OIE-chapter on risk analysis. The method for the assessment  
19 of the GBR is comparable to the OIE-guidance on risk analysis and in particular the chapter  
20 on risk assessment.

21

22 **2. Comparison of BSE-status according to OIE and GBR Categorisation**

23 The OIE International Animal Health Code, Chapter 2.3.13 related to BSE, adopted May  
24 2005, states that the status of a country or zone should be determined from the outcome of a  
25 risk assessment.

26 The release assessment required according to the OIE-guidance and described in Article  
27 2.3.13.2., could be compared with the assessment of the external challenge and the internal  
28 challenge and their interaction as described in this opinion. The GBR assessment is still  
29 completed even if the risk of an external challenge has been identified as negligible. This is  
30 contrary to the OIE-guidance that conducts the exposure assessment only, if the release  
31 assessment identifies a risk factor. The GBR approach is justified by the high degree of  
32 uncertainty with the epidemiology and biology of the BSE-agent as well as with its monitoring  
33 and surveillance. The GBR method attempts to address the stability of the assessed BSE/cattle  
34 systems as a means to establish its capacity to resist future challenges that are currently  
35 unknown.

36 The assessment of the inherent stability of a given BSE/cattle system with regard to BSE  
37 might be compared, to a certain degree with an analysis of the pathways needed to allow the  
38 exposure of animals to BSE. In an unstable system the pathways are open and would lead to  
39 exposure whereas in a stable system the risk of exposure occurring is much lower because the  
40 pathways are closed. Typically, a pathway assessment would depend on the specific situation  
41 and could, according to the OIE, vary from country to country. The GBR-method applies  
42 systematically one model of the BSE/cattle system that describes the pathways in a fully

43 transparent and standardized manner. This provides a basis for obtaining comparable results in  
44 different countries.

45 The GBR-method derives a similar end-point as an exposure assessment described in the OIE-  
46 guidelines for risk assessment: it provides a qualitative estimation of the likelihood of the  
47 exposure to an identified hazard (the BSE-agent), at a given point in time. However, the SSC-  
48 method requires assessing the consequences of past exposures, in the GBR-terminology the  
49 internal challenges, which together with the external challenges again interact with the  
50 stability and create a new exposure situation.

51 The GBR method tries to cover the last twenty years in view of the long incubation period of  
52 the disease and its initially apparent slow progress. However, this long retrospective period  
53 leads to poor quality data especially from the early stages (1980s). Therefore a shorter period  
54 covering only approximately two incubation periods (i.e. 10 years) could be envisaged in the  
55 GBR to increase the quality of the data. This would be somewhat in line with the time frame  
56 of the OIE that a country has to be controlled (8 years for a functioning MBM ban and no  
57 indigenous case of BSE for the last 7 years) to become “negligible” status.

58 Because of the importance of the time dimension in this delayed process the GBR-  
59 terminology seems to be more adequate to describe the positive feed-back loop that is  
60 responsible for the BSE risk than the more static terms used in conventional Risk Analysis  
61 and Risk Assessment.

62

### 63 **3. Methods and parameters**

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

68 According to the BSE-chapter of the Terrestrial animal health code of the OIE, it has to be  
69 evaluated whether potentially infected material was imported, and, in such a case, whether the  
70 conditions in the country were/are sufficient to cope with potentially infected material, i.e. to  
71 prevent the disease being propagated. This is, indeed, exactly the objective of the GBR-  
72 method.

73 The points to consider for the BSE-risk assessment are described in the BSE-chapter and in  
74 detail in the “OIE-Guidelines on the factors to consider in conducting the bovine spongiform  
75 encephalopathy risk assessment”. However, since the adoption of the new BSE-chapter, these  
76 guidelines are not up-to date.

77 The OIE’s list of factors that should be taken into account when analyzing the release-risk  
78 includes some more factors than the GBR approach (Table 1). The list of factors for the  
79 exposure risk shows no differences.

80 From Table 1 below it appears that there is a close similarity between the relevant factors  
81 identified by OIE and those being used by the SSC to assess the GBR. Some factors are not  
82 addressed by the (SSC/EFSA) GBR-method because they are either judged insignificant  
83 compared to the other factors or reliable data are not available.

84 Table 1. **Factors to consider in the release assessment; comparison of OIE and GBR**

OIE	GBR	Remark
<b>Release assessment</b>		
the presence or absence of animal TSE agents in the country or <a href="#">zone</a> or <a href="#">compartment</a> and, if present, their prevalence based on the outcomes of surveillance		the SSC does not take account of other animal TSEs because (a) the available data were very poor and (b) the link with BSE is not scientifically established, even for scrapie;
<a href="#">meat-and-bone meal</a> or <a href="#">greaves</a> from the indigenous ruminant population	Taken into account in the exposure assessment and not in the release assessment	
Imported <a href="#">meat-and-bone meal</a> or <a href="#">greaves</a>	imported <a href="#">meat-and-bone meal</a> or <a href="#">greaves</a> (only taken into account : custom code 2301) not other codes... <i>e.g.</i> giving bones to animal as a source of phosphorus eg South Africa, dried bones, clean...if pure not risk – is basically a control issue. <i>E.g.</i> if VC is included, or skull with brain is included.	MBM-imports are the most important part of the external challenge which is assumed by the GBR to be the only initial source
While cattle imports are an essential element of the external challenge assessment, the GBR does not take account of other animals like sheep and goats as the risk via these animals is regarded to be insignificant in comparison to the import of MBM and infected live cattle + the SSC does not take account of other animal TSEs because (a) the available data were very poor and (b) the link with BSE is not scientifically established, even for scrapie);		
Imported animal feed and feed ingredients – no clear custom codes so nearly impossible to found out the real commodity.		Due to lack of data the GBR currently did not take account of feedstuff-imports
Imported products of ruminant origin for human consumption, which may have contained (SRM) tissues listed in Article 2.3.13.13., and may have been fed to cattle;		The GBR did not take into account, because it is nearly impossible to find out
Imported products of ruminant origin for in vivo use in cattle – no idea what is meant here by OIE – probably vaccines, hormones...		The GBR did not take into account, because it is nearly impossible to find out
Surveillance and other epidemiological investigations (especially surveillance for BSE conducted on the cattle population) relevant to the above	Surveillance and other epidemiological investigations	

85 **4. Additional parameters for OIE status**

86 The OIE requests moreover to the risk assessment that several measures, and their date of  
87 effective implementation (“relevant period of time”), should be considered when determining  
88 the BSE status (Table 2).

89 **Table 2: Comparison of OIE status and GBR**

	<b>OIE</b>	<b>GBR</b>
Objective	Status	Risk assessment
To consider	<p><b>Risk assessment and</b></p> <ul style="list-style-type: none"> <li>- on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Appendix on BSE surveillance</li> <li>- the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;</li> <li>- the examination in an approved laboratory of brain or other tissues collected within the framework of the surveillance and monitoring system.</li> <li>- Surveillance* (Type A or B)</li> </ul>	Risk assessment

90

91 \*When the risk assessment (which takes into account the surveillance referred to in the release  
92 and exposure assessments above) demonstrates non-negligible risk, the country should  
93 conduct Type A surveillance in accordance with Appendix on BSE surveillance.

94 \*When the risk assessment (which takes into account the surveillance referred to in the release  
95 and exposure assessments above) demonstrates negligible risk, the country should conduct  
96 Type B surveillance in accordance with Appendix on BSE surveillance.

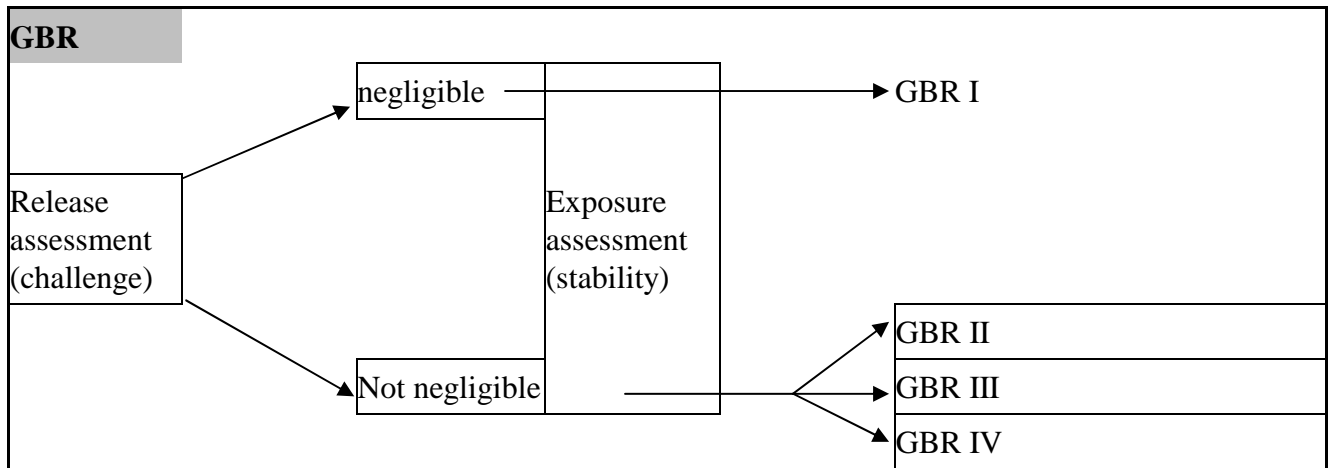
97 The (SSC/EFSA) SSC-method, however, considers them together with the other risk factors  
98 as part of the risk assessment.

99

100 **5. Foreseen use of GBR in the OIE context**

101 The GBR-risk assessment takes into account most of the parameters described by the OIE.  
102 Additionally to the risk assessment part, the OIE considers several other factors to determine  
103 the BSE-status. Therefore, countries assessed as “negligible risk” (according to GBR, GBR I  
104 countries) could be categorized based on the OIE-chapter, taken into account further  
105 parameters *i.e.* controlled or undetermined risk.

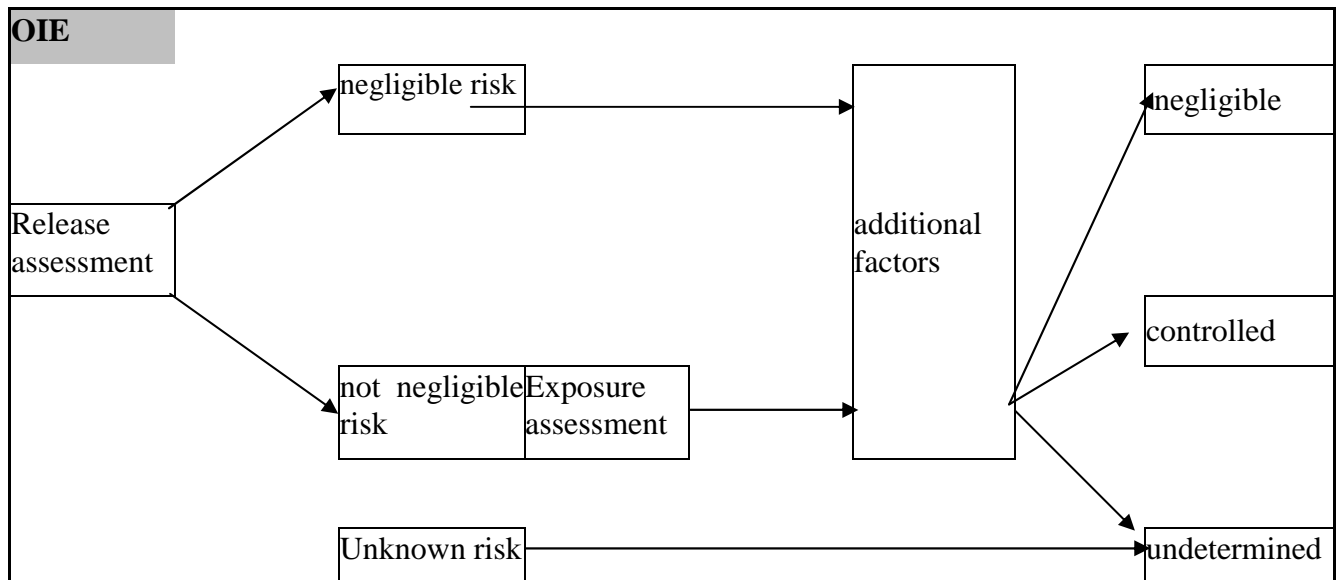
106 **Figure 1**



107

108

109 **Figure 2**



110



1 **ANNEX III**

2 **EFSA GBR – compared to SSC GBR**

3 In the EFSA GBR the gist of the change in comparison with the SSC GBR is to analyse the data  
4 whenever possible quantitatively, while the rules based assessment is a fallback procedure if a  
5 quantitative assessment is not possible *i.e.*, relevant data is not available..

6 **1. Changes of external challenge assessment**

7 In the SSC GBR methodology the magnitude (indicated as R values) of the external challenge was  
8 regarded independent from the size of the challenged BSE/cattle system and in particular the size  
9 and structure of the total cattle population.

10 In the EFSA GBR methodology, this aspect is taken into account by using different weighting  
11 factor ( $w$ ) values (instead of the R values used in the SSC GBR) depending on the size of the  
12 challenged bovine population, including two population sizes: (1) more than 20 million cattle and  
13 (2) less than 20 million cattle. For a not very high challenge with no change in the stability in the  
14 exporting country, the progression period to a higher  $w$  value is extended by one 5 year period for  
15 countries with a very large cattle population (more than 20 million of cattle): so the  $w$  weighting  
16 factor increases in that case only after two 5 year periods instead of one 5 year period (*i.e.*, from R1  
17 to R2) in the former SSC GBR methodology.

18 In the SSC GBR methodology, the external challenge was assessed in a global way. In the EFSA  
19 GBR methodology, the external challenge is assessed in three clearly defined steps:

20 • Step 1: Acquisition of import data concerning live cattle and MBM from BSE-risk countries.  
21 The same approach as in the SSC GBR methodology is followed, but imports from countries that  
22 have not been assessed before might be considered as posing a risk due to imports from BSE risk  
23 countries and this can be taken into account as external challenge.

24 • Step 2: Determination whether the imports entered the BSE/cattle system.  
25 Although in the former SSC GBR methodology, some possibility for deduction were mentioned  
26 (*i.e.* cattle slaughtered under the age of 24 months), now it is clearly stated that other types of  
27 information such as common practices adopted in the country being assessed or recording  
28 systems may also be used to support the proposal for deduction. In cases where the available  
29 information indicates but does not conclusively show that the animals or MBM did not enter the  
30 fed chain, only a proportion of the imports may be deducted depending on the quality of the data.  
31 This was not possible under the SSC methodology.

32 The acceptable and unacceptable reasons for the exclusion are in the EFSA GBR methodology  
33 clearly defined, both for live cattle and MBM.

34 • Step 3: Estimation of the level of infectivity in the imported material.

35 In the EFSA GBR methodology, not only the number of live cattle exported from BSE risk  
36 countries is taken into account, but also the type of intervention measures that are taken by the  
37 exporting country to prevent the spread of the agent to live animals and subsequent to the animal  
38 products. A new terminology, instead of the “R” values used in the SSC GBR methodology, for  
39 the scaling of the external challenge is introduced;  $w$  or weighting factor, whereby if  $w = 1$ , this  
40 represents 1 “Risk Unit”. This  $w$  value can be estimated using BSURVE or another appropriate  
41 method if yearly prevalence estimates are available for the exporting country. Otherwise an  
42 estimation based on a rules system is proposed. Weighting factors are calculated taken into

43 account the risk from imported live cattle and MBM, ranging from 0 (very low) up till = or >  
44 10.000 (very high)

45

## 46 **2. Changes of stability assessment**

47 As for the assessment of the impact of SRM removal, fallen stock and feeding in the EFSA GBR  
48 methodology a semi-quantitative approach is proposed, using the most recent data on BSE  
49 infectivity distribution in an infected bovine, as well as the updated results from the attack rate  
50 studies are taken into account, i.e. the fact that as little as 0.1 g and probably also 0.01 g of infected  
51 brain is enough to infect cattle orally. In the SSC GBR methodology, only a qualitative approach  
52 was used (OK, reasonable OK, not OK).

53 In contrast with the SSC GBR methodology, in the EFSA GBR methodology, also the basic  
54 reproduction ratio of infection of BSE is assessed, taking into account the three main stability  
55 factors SRM removal, rendering and feeding.

56 A tree approach is developed, in which a reduction factor for each of the main control measures is  
57 multiplied, resulting in the calculation of the total effect of all the control measures together. This  
58 result represents basically the basic reproduction ratio.

59 The reduction factors are defined for the different levels of application of the three control  
60 measures:

- 61 • SRM removal: reduction factor between 1 (no SRM removal) and maximum 0.01 (full  
62 compliance, including control measures, of OIE or EU SRM list and exclusion of fallen  
63 stock).
- 64 • Rendering: reduction factor between 0.1 (atmospheric pressure) and maximum 0.001  
65 (133/20/3 fully applied or no rendering).
- 66 • Feeding: reduction factor between 0.2 (= UK pre 86, 20% of MBM production fed to cattle)  
67 and 0.001 (optimal feed ban).

68

## 69 **3. Changes in categories of assessments**

70 The table below provides an overview on the evolution of the SSC GBR methodology over time  
71 (1998-2002) based on revisions carried out by the Scientific Steering Committee (SSC)

72 Table: **Overview on the evolution of the SSC GBR methodology over time based on revisions carried out by the SSC (1998-2002)**

	January 1998	April 1999	July 2000	January 2002
GBR-definition	No definition provided	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.	A qualitative indicator of the likelihood of the presence of one or more cattle being infected with BSE, pre-clinically as well as clinically, at a given point in time, in a country. Where presence is confirmed, the GBR gives an indication of the level of infection	As in July 2000
GBR-levels	No levels provided	No levels provided	GBR levels I-IV introduced	As in July 2000
Factors assessed	1. Structure and dynamics of the cattle, sheep and goat populations; 2. Animal trade; 3. Animal feed; 4. Meat and bone meal (MBM) bans; 5. Specified bovine offals (SBO) and specified risk materials (SRM) bans; 6. The surveillance of TSE, with particular reference to BSE and scrapie; 7. Rendering and feed processing; 8 BSE and scrapie related culling	1. Structure and dynamics of the cattle population; 2. Cattle trade; 3. Cattle feed; 4. Meat and bone meal (MBM) bans; 5. Specified bovine offals (SBO) and specified risk materials (SRM) bans; 6. The surveillance of BSE; 7. Rendering and feed processing; 8. BSE related culling	Clarification that -semen and embryos - other TSE are not (and never were) taken into account. Clarification of the importance of cross- contamination.	As in July 2000
Definition of "external challenge"			Imports via infected MBM or live cattle from BSE affected countries (where BSE-cases have been reported). Guidelines for external challenge assessment introduced.	Imports from all BSE-Risk countries. BSE-Risk countries are all countries already assessed as GBR III or IV or with at least one confirmed domestic BSE case. Guidelines for external challenge assessment updated to take account of different BSE-risk levels in exporting countries and at the moment of export.

	January 1998	April 1999	July 2000	January 2002
<p>Definition for “stability”</p>			<p>Ability to reduce BSE infectivity circulating in the BSE/cattle system under assessment. The degree of stability is depending on the ability to identify BSE-infected cattle and exclude them from processing and the ability to avoid recycling of the BSE agent via feed.</p> <p>Guidelines for stability assessment introduced.</p>	As in July 2000

1 ANNEX IV

2 **QUESTIONNAIRE FOR THE PROVISION OF INFORMATION NEEDED FOR THE ASSESSMENT OF**  
3 **THE EFSA GEOGRAPHICAL BSE RISK (GBR) OF A GIVEN COUNTRY OR REGION**

4  
5 **Explanatory note:**

6 To put this questionnaire into context, consideration of the following documents is  
7 recommended:

8  
9 1. Commission Recommendation of 22 July 1998 concerning the information necessary  
10 to support applications for the evaluation of the epidemiological status of countries  
11 with respect to transmissible spongiform encephalopathy (98/477/EC)

12 [http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l\\_212/l\\_21219980730en00580061.pdf](http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_212/l_21219980730en00580061.pdf)

13 2. Annex II to the TSE-Regulation (EC) No 999/2001.

14 [http://europa.eu.int/comm/food/fs/bse/bse36\\_en.pdf](http://europa.eu.int/comm/food/fs/bse/bse36_en.pdf)

15 3. Opinion of the Scientific Steering Committee (SSC) on the GBR of 6 July 2000:

16 [http://europa.eu.int/comm/food/fs/sc/ssc/out113\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/ssc/out113_en.pdf)

17 4. Update of the SSC Opinion on the GBR of 11 January 2002:

18 [http://europa.eu.int/comm/food/fs/sc/ssc/out243\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/ssc/out243_en.pdf)

19 5. EFSA Opinion on an updated GBR methodology:

20 [http://www.efsa.eu.int/science/biohaz/biohaz\\_opinions/No\\_en.html](http://www.efsa.eu.int/science/biohaz/biohaz_opinions/No_en.html)

21 • A chronological list and overview on the EU legislation on BSE can be found at:

22 [http://europa.eu.int/comm/food/fs/bse/legislation\\_en.html#general%20framework](http://europa.eu.int/comm/food/fs/bse/legislation_en.html#general%20framework)

23 • Previous outcome of the GBR assessment on countries assessed by the former SSC:

24 [http://europa.eu.int/comm/food/fs/sc/ssc/outcome\\_en.html](http://europa.eu.int/comm/food/fs/sc/ssc/outcome_en.html)

25 • The outcome of the GBR assessment on countries assessed by EFSA:

26 [http://www.efsa.eu.int/science/tse\\_assessments/gbr\\_assessments/catindex\\_en.html](http://www.efsa.eu.int/science/tse_assessments/gbr_assessments/catindex_en.html)

27

28

29



30 **Information useful when completing this questionnaire:**

- 31 • It would be appreciated if all information could be provided in English. This will  
32 allow timely consideration of the information and finalisation of the assessment.
- 33 • This questionnaire may be requested electronically from, and response to this  
34 questionnaire would be preferable also be submitted in electronic form to, the  
35 following e-mail address: [efsa-gbr@efsa.europa.eu](mailto:efsa-gbr@efsa.europa.eu)
- 36 • Please supply a contact address of the responsible authority for the applicant country  
37 using the following template:

<b>Country:</b>
<b>Responsible Authority for filing this questionnaire (Please specify the complete name of the authority or agency and postal address):</b>
<b>Contact Person(s) (name and postal address) for additional clarifications/information:</b>
<b>Telephone:</b>
<b>Fax:</b>
<b>E-Mail:</b>

38 **Please send an electronic copy of the completed questionnaire to**  
[efsa.gbr@efsa.europa.eu](mailto:efsa.gbr@efsa.europa.eu)

39 **Information other than in electronic format can be sent to the following address :**  
European Food Safety Authority (EFSA)  
BSE/TSE Unit, GBR assessments  
Largo N Palli, 5/a  
43100 Parma, Italia  
Fax number : +39 0521 036 153  
**In case information is needed this can be obtained from :**  
**Dr. Bart Goossens, +39 0521 036 218**  
[Bart.Goossens@efsa.europa.eu](mailto:Bart.Goossens@efsa.europa.eu)  
**Or via [efsa.gbr@efsa.europa.eu](mailto:efsa.gbr@efsa.europa.eu)**

40                   1.       **INFORMATION ON "EXTERNAL CHALLENGE"**

41

42   **1.1.   Imports of cattle**

43   The GBR is based on the assumption that the BSE agent has to be imported, i.e. a domestic  
44   system has to be exposed to an external challenge. Live bovines are one of the imports that  
45   could carry the agent. It is therefore important to have as much as possible complete data of  
46   the imports

47   The assessment of the external challenge is carried out in three stages. In the first stage,  
48   information is compiled on all cattle imports from BSE risk countries. In the second stage,  
49   only those cattle that could have contributed to the exposure of domestic cattle are included.  
50   In the third stage, an assessment is made of the level of infectivity in the imported material.

51   Please provide information on the importation of

52   -   all live bovine animals from all countries from 1980 if possible (at least from 1986) and in  
53    addition

54   -   fill in the excel sheet named: “**ANNEXES 1-3\_IMPORTS from BSE risk countries.xls**”

55   *In sheet 1 (“cattle raw data”) of this excel file, please provide information on the number of*  
56   *cattle imported from the countries listed (BSE risk countries) in this sheet. This information*  
57   *should be grouped by country of origin and year of import. The numbers in each cell should*  
58   *correspond with EUROSTAT cattle export data if the animals originated from an EU country*  
59   *and with the official cattle export figures for other countries of origin. If the numbers do not*  
60   *correspond, please provide a detailed explanation for the difference with documentary*  
61   *evidence if available.*

62   Please note that if you have already provided information on the number of imported cattle for  
63   a previous assessment, it is included in sheet 1 and it is only necessary to provide additional  
64   data that has become available since the previous assessment.

65   *In sheet 2 (“cattle final data”), please insert in each cell, the number of cattle for which*  
66   *rendering into feeding stuffs cannot be excluded and which could have led to the exposure of*  
67   *domestic cattle to the BSE agent. Reasons for exclusion should be provided, with*  
68   *documentary evidence where available, for each group of cattle that are excluded from this*  
69   *sheet. Acceptable reasons for the exclusion of cattle from sheet are provided in section 6.4.2.1*  
70   *of this EFSA GBR methodology.*

71   If you have had a previous assessment, the number of cattle that contributed to the exposure of  
72   domestic cattle has already been estimated. In that case, it is only necessary to provide  
73   additional data for recent years that has become available since the previous assessment.

74

75   **1.2.   Export of cattle**

76   Please use Sheet 1 of the provided excel file named “**EXPORTS to other countries-EFSA.xls**”

77   Please include, as far as possible, information on the type of the exported cattle.

78

79

80 **1.3. Import of Meat and Bone Meal**

81 Processed ruminant protein is considered to be the most important, if not the only  
82 transmission vehicle for BSE. It is therefore important to have as much as possible complete  
83 data of the imports.

84 In the international customs statistic there is only one category (230110) that clearly refers to  
85 material of the above-mentioned type: “Flours, meals and pellets made from meat and offal,  
86 greaves; not fit for human consumption”. For the purpose of the GBR all materials listed  
87 under this category are called “MBM”. This term therefore refers hereunder to Meat and Bone  
88 Meal as such, but also to Meat Meals, Bone Meals, and greaves.

89 Please provide information on the importation of

90 - MBM from all countries from 1980 if possible (at least from 1986) and in addition

91 - fill the excel sheet named:

92 **“ANNEXES 1-3\_IMPORTS from BSE risk countries-EFSA.xls”**

93 *In sheet 3 (“MBM raw data”), please attach information on the quantity of MBM imported*  
94 *from the countries listed (BSE risk countries) in this sheet. This information should be*  
95 *grouped by country of origin and year of import. The quantities should correspond with*  
96 *EUROSTAT export data under code 230110 if the MBM originated from an EU country and*  
97 *with the official export figures under code 230110 for other countries of origin. If the*  
98 *numbers do not correspond, please provide a detailed explanation for the difference with*  
99 *documentary evidence, if available.*

100 Please note that if you have already provided information on the quantity of imported MBM  
101 for a previous assessment, it is included in sheet 3 and it is only necessary to provide  
102 additional data that has become available since the previous assessment.

103 *In sheet 4 (“MBM final data”), please insert in each cell, the number of tons of MBM that*  
104 *could not be excluded, with certainty, from use as a cattle feed. Reasons for exclusion should*  
105 *be provided, with documentary evidence where available, for each quantity of MBM that is*  
106 *excluded from this sheet. Acceptable reasons for the exclusion of MBM from sheet 4 are*  
107 *provided in section 6.4.2.3 of this EFSA GBR methodology.*

108 Please note that if you have had a previous assessment, the number of tons of MBM that could  
109 not be excluded from use as a cattle feed has already been estimated and is inserted in the  
110 appropriate cells in sheet 4. In that case, it is only necessary to provide additional data that has  
111 become available since the previous assessment.

112

113 **1.4 Export of MBM**

114 Please use Sheet 2 of the provided excel file named “EXPORTS to other countries-EFSA.xls”

115 Please include, as far as possible, information on the type and composition of the exported  
116 MBM.

117 **2. INFORMATION ON "STABILITY"**

118

119 The second element that the EFSA GBR method takes into consideration is the stability of a  
120 domestic system. This is defined as its ability to avoid the BSE agent being recycled and  
121 amplified.



122 **2.1. Feeding**

123 Given the fact that feed is assumed to be the most important, if not the only transmission route  
124 of BSE, a complete view on the feeding of bovines in the assessed countries is essential.

125 It is assumed, for the purpose of the GBR assessment, that all bovines received some feed that  
126 contains MBM unless demonstrated otherwise.

127 In order to better estimate the probability that cattle were exposed to such feeds, please  
128 provide the information requested below.  
129

130 **2.1.1. Composition of bovine feed**

131 *Give a detailed description of the composition of the diet consumed by dairy calves and cows,*  
132 *by other non dairy bovines, including, if possible, the period 1980 to the present. If this*  
133 *composition was regulated by the government, please summarise the relevant regulations and*  
134 *attach a copy to this questionnaire.*

135

136 **2.1.2 Feed industry, structure and output**

137 **Table 2.1.2 Structure of the feed industry in the country**

	<b>Number of mills operational in the country per period by type of feed mill</b>					
<b>Type of feed mill:</b>	<b>1980-85</b>	<b>1986-90</b>	<b>1991-95</b>	<b>1996-2000</b>	<b>2001-2005</b>	<b>2006-</b>
Dedicated to pig feed						
Dedicated to poultry feed						
Dedicated to poultry and pig feed						
Dedicated to ruminant feed						
Mixed feed mills producing feed for ruminant and non-ruminant animals						

138 Dedicated plants do not produce feed for ruminant and non-ruminant animals on the same  
139 premises.

140

141

142

143

144 **2.1.3 Output of the feed industry in the country by type of feed mill, type of feed and**  
145 **period**

		Feed output of mills operational in the country per period by type of feed mill (tons)					
Type of feed mill	Type of feed	1980-85	1986-90	1991-95	1996-2000	2001-05	2006-
Mills dedicated to producing feed for ruminants or non-ruminants							
	Pig feed						
	Poultry feed						
	Ruminant feed						
Mixed feed mills (ruminant and non-ruminant feed produced on same premises)							
	Pig feed						
	Poultry feed						
	Ruminant feed						

146  
147 **2.1.4 Feed regulations. Feed Ban: Is there an official feed ban in your country ?**

148  YES  NO → go to 2.2.



<u>Type of feed-ban</u>	<u>Date of adoption</u>	<u>Start of controls</u>
<input type="checkbox"/> BMBM* to Bovines	.....	.....
<input type="checkbox"/> BMBM* to Ruminants	.....	.....
<input type="checkbox"/> RMBM* to Bovines	.....	.....
<input type="checkbox"/> RMBM* to Ruminants	.....	.....
<input type="checkbox"/> RMBM* to all farmed animals	.....	.....
<input type="checkbox"/> MMBM* to Bovines	.....	.....
<input type="checkbox"/> MMBM* to Ruminants	.....	.....
<input type="checkbox"/> MMBM* to all farmed animals	.....	.....
<input type="checkbox"/> other <i>explain</i> .....		

160 \* BMBM = Bovine MBM ; \* RMBM = Ruminant MBM;

161 \* MMBM = Mammalian MBM

162  
163  
164  
165  
166

167 **2.1.5 Overview of measures taken to prevent cross-contamination of bovine feed with**  
168 **MBM**

169 Provide information on any additional control measures that were used to reinforce the feed  
170 ban in the table below including the measures taken in the case of a mill that changes from  
171 producing non ruminant to ruminant feed.

172

<b>Check point</b>	<b>Measures* and results of audits</b>	<b>Date of implementation</b>	<b>Details of legal basis (if any)</b>
<b>Feed-mills</b>			
<b>Transport</b>			
<b>Farms</b>			

173

174 \*Measures may include flushing batches between non-ruminant containing MBM and  
175 ruminant feed, separated production lines for ruminant feed and other feed, separated transport  
176 systems for different feeds, labelling of non-ruminant feed as “not for ruminant consumption”,  
177 etc. Information already given under 2.1.1 does not have to be repeated.

178 **2.1.6 Results of the examination of bovine feed samples with regard to contamination with MBM or animal protein in general other than**  
 179 **milk**

180 *Provide information on feed sampling in the table below:*

<i>Year</i>	<i>Test method*</i>			<i>n° tested</i>	<i>n° of contaminated samples</i>	<i>n° positive</i>	<i>Criteria for a positive sample**</i>
	<i>M</i>	<i>E</i>	<i>O</i>				
<i>1990</i>							
<i>1991</i>							
<i>1992</i>							
<i>1993</i>							
<i>1994</i>							
<i>1995</i>							
<i>1996</i>							
<i>1997</i>							
<i>1998</i>							
<i>1999</i>							
<i>2000</i>							
<i>2001</i>							
<i>2002</i>							
<i>2003</i>							
<i>2004</i>							
<i>2005</i>							



**Annex IV**  
**Revision of the GBR methodology. Public Consultation**

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- 181 \* Test methods: **M**= microscope, **E**= ELISA, **O**= other (specify)
- 182 \*\* Give minimum contamination above which a sample is declared being “positive”,  
183 e.g. >0.5%, >0.1%, >0% and/or any other criteria used.
- 184 Describe in detail the sampling procedure (size of batch and number of samples per batch and  
185 fraction of batches sampled; place of sampling, i.e. end of line in feed mill, after  
186 packing/loading, at retailers, on the farm) and the method of examination. Indicate the  
187 sensitivity of the examination method.
- 188 Give information on the follow-up taken by the authorities in cases where breaches of the feed  
189 ban were found.

190 **2.2. Rendering (please include data from 1980 up to the present)**

191 Rendering of BSE-contaminated material can reduce BSE infectivity by a factor of  $10^3$ . To have this effect, material of a particle size of no more than  
192 50mm and a moisture content of about 60% must be exposed to a pressure of 3bar reaching a core temperature of 133°C for at least 20min.

193

194 **Structure of the rendering industry**

195 **2.2.1. Number of rendering plants by type of raw material that is processed and by product and period**

Number and accumulated MBM-output (tons) of rendering plants operational in the country per period and by type of plant													
Type of rendering plant by raw material that is processed	1980-85		1986-90		1991-95		1996-2000		2001-05		2006		
	N°	Tons	N°	Tons	N°	Tons	N°	Tons	N°	Tons	N°	Tons	
Dedicated to:													
<b>Poultry material</b>													
<b>swine material</b>													
<b>Swine and poultry material</b>													
<b>bovine material</b>													
<b>any other mammalian species*</b>													
Processing material from <b>different mammalian species</b> , including bovine waste material													

196 **Include all plants that were operational in a given period, even if they were only operational for a part of that period. Please note that bone**  
197 **meal production plants are to be included.**

198           \*specify which other mammalian species the rendering plants were/are dedicated to.

199

200   Provide additional explanations if rendering plants were newly started, changed or closed during a specified period. Describe if rendering plants existed  
201   that only processed material selected on the basis of other criteria, such as a higher risk of potential contamination with high-risk biological agents,  
202   toxins, etc. Give details on raw material intake and product output of these plants as well as on the use made of these products.

203   Explain how (and why) dedicated rendering plants ensured that no other raw material entered their process. Describe procedures for ensuring avoidance  
204   of contamination with raw materials entering the process in dedicated rendering plants.

205   Assuming that bovine material could only be rendered in plants dedicated to bovine material or processing material from a variety of species (including  
206   cattle), the following details are only required for these two types of rendering plants.

207

208 **2.2.2. Production (metric tons) of the rendering industry in the country by type of rendering plant, type of process, process conditions and**  
209 **use of product, over the periods indicated**

			<b>MBM output of rendering plants operational in the country per period and type of plant (metric tons)</b>						
<b>Type of rendering plant</b>	<b>Type of process</b>	<b>Process conditions*</b>	<b>1980-85</b>	<b>1986-90</b>	<b>1991-95</b>	<b>1996-2000</b>	<b>2001-05</b>	<b>2006-</b>	
Dedicated to ruminant	Continuous	System 1							
		System 2							
	Batch	System 1							
		System 2							
	Mixed plants	Continuous	System 1						
			System 2						
Batch		System 1							
		System 2							

210 *\*Please provide details (temperature, duration, pressure) for each processing system and amount produced per system. (If necessary please add lines*  
211 *for additional systems).*



212 **2.2.3. Average number of bovines annually slaughtered for human consumption**

	<b>Average number of bovines annually slaughtered</b>					
<b>Age at slaughter [months]</b>	<b>1980-85</b>	<b>1986-90</b>	<b>1991-95</b>	<b>1996-2000</b>	<b>2001-05</b>	<b>2006-</b>
<b>&lt; 30</b>						
<b>&gt; 30</b>						

213

214

215 **2.2.4. Specified Risk Materials (SRM) and fallen bovine stock**

216 Please describe the treatment in your country of SRM<sup>1</sup> and of material from fallen stock (animals dead/killed on farm, dead at arrival, condemned in  
217 ante mortem inspection), or of bovine material condemned in post mortem inspection.

218 Use made of bovine brains, spinal cords/vertebral and fallen stock

219 **Rendering of brain and spinal cord of cattle and of bovine fallen stock (dead/killed on farm or in transport), emergency slaughter animals or**  
220 **bovine animals condemned at ante mortem inspection) by period, and process**

Period	Brain and spinal cord/vertebral column of healthy bovines (1)		Fallen bovine stock, emergency slaughter animals or bovines condemned at ante mortem (2)	
	Rendered <i>(in %; specify its fate)</i>	Not rendered <i>(in %; specify its fate)</i>	Rendered <i>(in %; specify its fate)</i>	Not rendered <i>(in %; specify its fate)</i>
1980-1985				
1986-1990				
1991-1995				
1996-2000				
2001-2005				
2006-				

<sup>1</sup> SRM=Specified Risk Materials. For the purpose of the GBR assessment this is, in case of bovines, mainly the brain and spinal cord and vertebral column of cattle over 12 months of age.

- 221 *If only a fraction of the mentioned materials (1) or (2) is rendered, explain how this fraction is determined and how large it was in the different periods.*
- 222 *If brain and spinal cord are/were consumed by humans, estimate the fraction of brains and spinal cord that was not regarded edible and was therefore*
- 223 *rendered. If only a part of the animals dead on farm is/was collected for rendering, estimate the fraction and explain what happened to the non-*
- 224 *rendered carcasses. (Please extend the table if required).*

225

226 **2.3. Bovine population structure**

227 Knowledge of the bovine population structure is necessary background information for the rest of the questionnaire.

228 **2.3.1. Key data on the bovine population**

Year		All ages [n°]	Less or equal 24 months old [n°]	Over 24 months old				
				Male		Female		
				Beef	Breeding	Beef	Dairy	Breeding
1980	n°							
	age*							
1985	n°							
	age*							
1990	n°							
	age*							
1995	n°							
	age*							
2000	n°							
	age*							
2005	n°							
	age*							

229 (age\*: average age at slaughter)

230 Double purpose cows are to be included in the dairy column. In addition attach information on other types of bovine, such as working animals, as  
231 appropriate.

232

233 **2.3.2. Co-farming of bovines with pigs and/or poultry and/or horses. Includes also farms with only dairy cows as economic activity but**  
 234 **having some poultry and/or pigs and/or horses for their own use or as secondary business**

235

Co-farming	Number and percentage of all bovine holdings									
	1985		1990		1995		2000		2005	
	n°	%	n°	%	n°	%	n°	%	n°	%
<b>Bovines &amp; non ruminant farmed animals (pigs, poultry)</b>										

236

237 **2.3.3. Cattle identification and traceability**

238 Please describe in detail the system for identifying cattle. How long has this system in operation? Who is responsible for cattle identification on the  
 239 farms and who carries out the supervision? If available, please provide compliance figures (e.g. on spot checks of veterinary authorities, plausibility  
 240 checks etc.)

241 Please describe in detail the system for tracing the movement of imported and indigenous cattle. If appropriate, please, give some information on the  
 242 structure and the maintenance of the cattle movement database.

243 Please provide details of the system, if implemented, for registering cattle herds. Does this involve the recording of individual animals? Are BSE test  
 244 results recorded in the database?

245 **2.4. BSE-surveillance**

246 **Notification**

247 - Date since BSE was officially defined as a notifiable disease: .....

248

249 - Attach a description of the criteria for a notifiable BSE-suspect, and describe their  
250 development over time.

251

252 - Measures taken to ensure/enforce notification (incl. their development over time and attach  
253 a detailed description including their development over time):

254 - awareness training:  YES, since .....  NO

255 - compensation for cases:  YES, since .....  NO

256 amount paid: .....

257 for BSE-suspects:  yes; amount paid: .....  NO

258 for BSE related culled animals:  yes; amount: .....  NO

259 - incentives for reporting suitable surveillance candidates (fallen stock, clinical suspects),

260 specify:

261 - lab-personal trained:  YES, since.....  NO

262 where: .....

263 - other (specify): .....

264 .....

265

266 **Attach a detailed description of the methods used for the examination of BSE-suspects**  
267 **(past and present).**

268 **Attach a detailed description of the criteria used for the confirmation of BSE-cases (past**  
269 **and present).**

270

271 Table TSE testing in bovine animals above 30 months of age

	BSE Eradication (1)		Healthy Slaughter (2)		Fallen Animals (3)		Casualty slaughter (4)		Suspect (5)	
	Number	Positives	Number	Positives	Number	Positives	Number	Positives	Number	Positives
1990										
1991										
1992										
1993										
1994										
1995										
1996										
1997										
1998										
1999										
2000										
2001										
2002										
2003										
2004										
2005										

	<b>BSE Eradication (1)</b>		<b>Healthy Slaughter (2)</b>		<b>Fallen Animals (3)</b>		<b>Casualty slaughter (4)</b>		<b>Suspect (5)</b>	
	<b>Number</b>	<b>Positives</b>	<b>Number</b>	<b>Positives</b>	<b>Number</b>	<b>Positives</b>	<b>Number</b>	<b>Positives</b>	<b>Number</b>	<b>Positives</b>
<b>2006</b>										
<b>Total</b>										

272

(1) Birth and rearing cohorts, offspring of BSE cases, animals from herds with BSE

273

(2) Bovine animals subject to normal slaughter for human consumption and animals without clinical signs of disease slaughtered in the context of a disease eradication campaign other than BSE

274

275

(3) Bovine animals which have died or have been killed on the farm or in transport, but not slaughtered for human consumption nor killed in the framework of an epidemic

276

277

(4) Casualty slaughter

278

(5) Animal reported as BSE clinical suspects of TSE

279

A detailed definition of the different categories can be found at appendix 3.8.4 (OIE terrestrial animal health code)



1 ANNEX V

2 GUIDELINES TO THE USE OF THE INTERACTION CHART

3

4 Table 1. Country A with an improved stability over time

5 Onto the following graph are reported all the external challenges (EC) that took place in this country  
6 from 1980 onward.

<b>Levels of challenge</b>						
<i>extremely high</i>						
<i>very high</i>						
<i>high</i>			<b>IC=OC</b>	<b>IC=OC</b>		
<i>moderate</i>		<b>IC=OC /EC</b>		<i>EC</i>	<b>IC=OC</b>	
<i>low</i>	<i>EC</i>		<i>EC</i>		<i>EC</i>	<b>IC=OC</b>
<i>very low</i>						
<i>extremely low</i>						
<b>Stability</b>	1980-1985	1986-1990	1991-1995	1996-2000	2001-2005	2006-2010
	Extremely unstable	Very unstable	Very unstable	Neutrally stable	Extremely stable	

7

8 **Step 1:** In this example, the country is very unstable between 1986 and 1990, and an external  
9 challenge arises at a **low level** in 1980. On the 1986-1990 period, we can expect the BSE-infectivity  
10 to be recycled over time and amplified. The internal challenge for the period 1986-1990 will  
11 therefore result from the increase of one risk level since 1980-1985. The internal challenge (IC) will  
12 then be considered as: low + 1 level upgrade, that is **moderate**, as shown below.

13 **Step 2:** From 1986 to 1990, a moderate external challenge (EC) takes place in a very unstable  
14 system. Both internal and external challenges are at the same level, i.e. moderate. Therefore we can  
15 infer the overall challenge (OC) as being moderate. Because of the very unstable system in the  
16 1991-1995 period and this moderate OC, the internal challenge (IC) for the 1991 to 1995 period will  
17 then be considered to be one step higher than this moderate overall challenge: it is said to be **high**.

18 **Step 3:** From 1991 to 1995, a low external challenge (EC) takes place and the country is neutrally  
19 stable for the following period. The internal challenge for this period being higher than the external  
20 challenge (high level of challenge), we can infer the overall challenge (OC) as being equivalent to  
21 the level of the IC, i.e. high. Because of the neutrally stable system and the high OC, the internal  
22 challenge (IC) for the 1996 to 2000 period will then be considered to be at the same level as this  
23 high overall challenge: it is said to be **high**.

24 **Step 4:** From 1996 to 2000, a moderate external challenge (EC) takes place and the country is  
 25 extremely stable the next period. The internal challenge for this period being higher than the  
 26 external challenge (high level of challenge), we can infer the overall challenge (OC) as being  
 27 equivalent to the level of the IC, i.e. high. Because of the extremely stable system and the high OC,  
 28 the internal challenge (IC) for following time period will then be considered to decrease by one risk  
 29 level: **moderate**.

30 **Step 5:** From 2001 to 2005, a low external challenge (EC) takes place and the system is still  
 31 optimally stable between 2006 and 2010.. The internal challenge for this period being higher than  
 32 the external challenge (moderate level of challenge), we can infer the overall challenge (OC) as  
 33 being equivalent to the level of the IC, i.e. moderate. Because of an extremely stable system and the  
 34 moderate OC, the internal challenge (IC) for the 2006-2010 period will then be considered to  
 35 decrease by one level: **low**.

36

37 Table 2. **Country B with a large cattle population and extremely unstable system over time**

38 Onto the following graph are reported all the external challenges (EC) that took place in the USA  
 39 from 1980 onward.

Levels of challenge					
<i>extremely high</i>			<i>EC</i>		<b>IC=OC</b>
<i>very high</i>				<b>IC=OC</b>	
<i>High</i>		<i>EC</i>	<b>IC=OC</b>		
<i>Moderate</i>	<i>EC</i>				
<i>Low</i>					
<i>very low</i>				<i>EC</i>	<i>EC</i>
<i>extremely low</i>					
<b>Stability</b>	1980-1985	1986-1990	1991-1995	1996-2000	2001-2005
	Extremely unstable	Extremely unstable	Extremely unstable	Extremely unstable	Extremely unstable

40

41 **Step 1:** In this example of country B, an external challenge arises at a **moderate level**. On the next  
 42 10-year period, regarding the size of the country, we can expect the BSE-infectivity to be recycled  
 43 over time and amplified. Moreover, the country is considered as extremely unstable for the period  
 44 1991-1995. The internal challenge for the period 1991-1995 will therefore result from the increase  
 45 of one risk level since 1980-1985. The internal challenge (IC) will then be considered as: moderate  
 46 + 1 level upgrade, that is **high**, as shown below.

47

48 **Step 2:** From 1986 to 1990, a high external challenge (EC) takes place. On the next 10-year period,  
 49 regarding the size of the country, we can expect the BSE-infectivity to be recycled over time and

50 amplified. The internal challenge for the period 1996-2000 will therefore result from the increase of  
 51 one risk level. The internal challenge (IC) will then be considered as: high + 1 level upgrade, that is  
 52 **very high**, as shown below.

53 **Step 3:** From 1991 to 1995, an extremely high external challenge (EC) takes place. On the next 10-  
 54 year period, regarding the size of the country, we can expect the BSE-infectivity to be recycled over  
 55 time and amplified. The internal challenge for the period 2001-2005 will therefore result from the  
 56 increase of one risk level. The internal challenge (IC) will then be considered as: very high + 1 level  
 57 upgrade, that is **extremely high**, as shown below. Between 1991 and 1995, the EC level being  
 58 higher than the IC's at the same period, the OC can be considered as equivalent to the EC, i.e.  
 59 **extremely high**.

60 **Step 4:** Between 1996 and 2000, the EC level being lower than the IC's at the same period, the OC  
 61 can be considered as equivalent to the IC, i.e. **very high**.

62 **Step 5:** Between 2001 and 2005, the EC level being lower than the IC's at the same period, the OC  
 63 can be considered as equivalent to the IC, i.e. **extremely high**.

64

65 Table 3. **Country C with a small cattle population and an extremely unstable system over time**

66 The same methodology is applied for this country and leads to the following results.

67

Levels of challenge						
	1980-1985	1986-1990	1991-1995	1996-2000	2001-2005	2006-2010
<i>extremely high</i>					IC=OC	IC=OC
<i>very high</i>				IC=OC		
<i>high</i>			IC=OC	EC		
<i>moderate</i>		EC=OC			EC	
<i>low</i>		IC				
<i>very low</i>	EC		EC			
<i>extremely low</i>						
<b>Stability</b>	Extremely unstable	Extremely unstable	Extremely unstable	Extremely unstable	Extremely unstable	

68

69 **Step 1:** In this example, the country is extremely unstable between 1986 and 1990, and an external  
 70 challenge arises at a **very low level** in 1980. On the 1986-1990 period, we can expect the BSE-  
 71 infectivity to be recycled over time and amplified. The internal challenge for the period 1986-1990  
 72 will therefore result from the increase of one risk level since 1980-1985. The internal challenge (IC)  
 73 will then be considered as: low + 1 level upgrade, that is **low**, as shown below.

74 **Step 2:** From 1986 to 1990, a moderate external challenge (EC) takes place in a very unstable  
75 system. The external challenges for that particular period is higher than the internal challenge, i.e.  
76 moderate. Therefore we can infer the overall challenge (OC) as being equivalent to the higher of the  
77 two, i.e. moderate. Because of the extremely unstable system in the 1991-1995 period and this  
78 moderate OC, the internal challenge (IC) for the 1991 to 1995 period will then be considered to be  
79 one step higher than this moderate overall challenge: it is said to be **high**.

80 **Step 3:** From 1991 to 1995, a very low external challenge (EC) takes place and the country is still  
81 extremely unstable for the following period. The internal challenge for this period being higher than  
82 the external challenge (very low level of challenge), we can infer the overall challenge (OC) as  
83 being equivalent to the level of the IC, i.e. high. Because of the extremely unstable system and the  
84 high OC, the internal challenge (IC) for the 1996 to 2000 period will then be considered to be one  
85 step higher than this moderate overall challenge: it is said to be **very high**.

86 **Step 4:** From 1996 to 2000, a high external challenge (EC) takes place and the country is still  
87 extremely unstable the following period. The internal challenge for this period being higher than the  
88 external challenge (very high level of challenge), we can infer the overall challenge (OC) as being  
89 equivalent to the level of the IC, i.e. very high. Because of the extremely unstable system and the  
90 very high OC, the internal challenge (IC) for following time period will then be considered to be  
91 one step higher than this moderate overall challenge: it is said to be **extremely high**.

92 **Step 5:** From 2001 to 2005, a moderate external challenge (EC) takes place and the system is still  
93 extremely unstable between 2006 and 2010.. The internal challenge for this period being higher than  
94 the external challenge (extremely high level of challenge), we can infer the overall challenge (OC)  
95 as being equivalent to the level of the IC, i.e. extremely high. Because of an extremely unstable  
96 system and the extremely high OC, the internal challenge (IC) for the 2006-2010 period will then be  
97 considered to remain as for the former period: **extremely high**.

98















Live cattle summary		Country:
Year	risk units	challenge
1980	0	Negligible
1981	0	Negligible
1982	0	Negligible
1983	0	Negligible
1984	0	Negligible
1985	0	Negligible
1986	0	Negligible
1987	0	Negligible
1988	0	Negligible
1989	0	Negligible
1990	0	Negligible
1991	0	Negligible
1992	0	Negligible
1993	0	Negligible
1994	0	Negligible
1995	0	Negligible
1996	0	Negligible
1997	0	Negligible
1998	0	Negligible
1999	0	Negligible
2000	0	Negligible
2001	0	Negligible
2002	0	Negligible
2003	0	Negligible
2004	0	Negligible
2005	0	Negligible
2006	0	Negligible
2007	0	Negligible
2008	0	Negligible

MBM summary		
Year	risk units	challenge
1980	0	Negligible
1981	0	Negligible
1982	0	Negligible
1983	0	Negligible
1984	0	Negligible
1985	0	Negligible
1986	0	Negligible
1987	0	Negligible
1988	0	Negligible
1989	0	Negligible
1990	0	Negligible
1991	0	Negligible
1992	0	Negligible
1993	0	Negligible
1994	0	Negligible
1995	0	Negligible
1996	0	Negligible
1997	0	Negligible
1998	0	Negligible
1999	0	Negligible
2000	0	Negligible
2001	0	Negligible
2002	0	Negligible
2003	0	Negligible
2004	0	Negligible
2005	0	Negligible
2006	0	Negligible
2007	0	Negligible
2008	0	Negligible

TOTAL IMPORTS summary			
Year	risk units	challenge	cumulative challenge
1980	0	Negligible	0
1981	0	Negligible	0
1982	0	Negligible	0
1983	0	Negligible	0
1984	0	Negligible	0
1985	0	Negligible	0
1986	0	Negligible	0
1987	0	Negligible	0
1988	0	Negligible	0
1989	0	Negligible	0
1990	0	Negligible	0
1991	0	Negligible	0
1992	0	Negligible	0
1993	0	Negligible	0
1994	0	Negligible	0
1995	0	Negligible	0
1996	0	Negligible	0
1997	0	Negligible	0
1998	0	Negligible	0
1999	0	Negligible	0
2000	0	Negligible	0
2001	0	Negligible	0
2002	0	Negligible	0
2003	0	Negligible	0
2004	0	Negligible	0
2005	0	Negligible	0
2006	0	Negligible	0
2007	0	Negligible	0
2008	0	Negligible	0

Live Cattle by period

1980-1985	0	Negligible
1986-1990	0	Negligible
1991-1995	0	Negligible
1996-2000	0	Negligible
2001-2005	0	Negligible
2006-	0	Negligible

MBM by period

1980-1985	0	Negligible
1986-1990	0	Negligible
1991-1995	0	Negligible
1996-2000	0	Negligible
2001-2005	0	Negligible
2006-	0	Negligible

ALL Imports by period

1980-1985	0	Negligible
1986-1990	0	Negligible
1991-1995	0	Negligible
1996-2000	0	Negligible
2001-2005	0	Negligible
2006-	0	Negligible

Total challenges  
1980 - 2003

Cattle	0	Negligible
MBM	0	Negligible
All import	0	Negligible

Live cattle summary		Country:
Year	risk units	challenge
1980	0	Negligible
1981	0	Negligible
1982	0	Negligible
1983	0	Negligible
1984	0	Negligible
1985	0	Negligible
1986	0	Negligible
1987	0	Negligible
1988	0	Negligible
1989	0	Negligible
1990	0	Negligible
1991	0	Negligible
1992	0	Negligible
1993	0	Negligible
1994	0	Negligible
1995	0	Negligible
1996	0	Negligible
1997	0	Negligible
1998	0	Negligible
1999	0	Negligible
2000	0	Negligible
2001	0	Negligible
2002	0	Negligible
2003	0	Negligible
2004	0	Negligible
2005	0	Negligible
2006	0	Negligible
2007	0	Negligible
2008	0	Negligible

MBM summary		
Year	risk units	challenge
1980	0	Negligible
1981	0	Negligible
1982	0	Negligible
1983	0	Negligible
1984	0	Negligible
1985	0	Negligible
1986	0	Negligible
1987	0	Negligible
1988	0	Negligible
1989	0	Negligible
1990	0	Negligible
1991	0	Negligible
1992	0	Negligible
1993	0	Negligible
1994	0	Negligible
1995	0	Negligible
1996	0	Negligible
1997	0	Negligible
1998	0	Negligible
1999	0	Negligible
2000	0	Negligible
2001	0	Negligible
2002	0	Negligible
2003	0	Negligible
2004	0	Negligible
2005	0	Negligible
2006	0	Negligible
2007	0	Negligible
2008	0	Negligible

TOTAL IMPORTS summary			
Year	risk units	challenge	cumulative challenge
1980	0	Negligible	0
1981	0	Negligible	0
1982	0	Negligible	0
1983	0	Negligible	0
1984	0	Negligible	0
1985	0	Negligible	0
1986	0	Negligible	0
1987	0	Negligible	0
1988	0	Negligible	0
1989	0	Negligible	0
1990	0	Negligible	0
1991	0	Negligible	0
1992	0	Negligible	0
1993	0	Negligible	0
1994	0	Negligible	0
1995	0	Negligible	0
1996	0	Negligible	0
1997	0	Negligible	0
1998	0	Negligible	0
1999	0	Negligible	0
2000	0	Negligible	0
2001	0	Negligible	0
2002	0	Negligible	0
2003	0	Negligible	0
2004	0	Negligible	0
2005	0	Negligible	0
2006	0	Negligible	0
2007	0	Negligible	0
2008	0	Negligible	0

Live Cattle by period		Total challenges
1980-1985	0	1980 - 2003
1986-1990	0	Cattle
1991-1995	0	MBM
1996-2000	0	All import
2001-2005	0	
2006-	0	
MBM by period		
1980-1985	0	
1986-1990	0	
1991-1995	0	
1996-2000	0	
2001-2005	0	
2006-	0	
ALL Imports by period		
1980-1985	0	
1986-1990	0	
1991-1995	0	
1996-2000	0	
2001-2005	0	
2006-	0	

**Include notes on justification for any deductions of imports in the "cattle FINAL" and "MBM FINAL" worksheets**

**Instructions to be added.....**

**Basic instructions can be obtained from the address below. A very useful tip is to always use "copy" and "paste special - values only"<sup>2</sup> when copying data between worksheets (e.g. from cattle(1) to cattle FINAL)**

Title: efsa GBR 'Excel Sheet' Risk Calculator v.2.5  
Created as part of European Food Standards Agency BSE Risk Assessment (website: )  
Extended version of SSC BSE Risk Assessment risk calculator (Mike Gravenor 2000)  
New Version JULY 20th 2006

Author: Mike Gravenor  
Contact details: School of Medicine, University of Wales Swansea, Swansea SA2 8PP  
e-mail: [m.b.gravenor@swan.ac.uk](mailto:m.b.gravenor@swan.ac.uk)  
<http://www.medicine.swan.ac.uk/bio-m.b.gravenor.html>

Please report any bugs to the above address

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As it stands, this program is distributed in the hope that it will be useful, but WITHOUT ANY WARRANTY; without even the implied warranty of merchantability or fit

## EFSA 地理的 BSE リスク(GBR)評価の改正案の概要

### ● 基本的な考え方

GBR 改正案では、以下のことを考慮。

- ・ BSE 有病率の低い国で、牛集団の大きい国からの侵入リスクが過大とならないようにする必要性
- ・ 安定性の評価における柔軟な評価の必要性
- ・ 2001 年以降の BSE サーベイランスデータ
- ・ 各国が講じた管理措置による BSE リスクの時間的変動
- ・ BSE 流行減少期における調和のとれた管理措置のためのリスクの評価
- ・ OIE ガイドラインとの整合性

### ● 侵入リスクについて

カテゴリー 1 の国から輸入した牛・肉骨粉による侵入リスクを評価する際、従来の GBR では考慮されていなかった牛集団の規模を考慮。(BSE 有病率の低い国で、牛集団の大きい国からの輸入リスクは、従来の GBR では過大なリスクとなっていたことを是正。)

リスクが大きくなり、安定している国から生体牛・肉骨粉を輸入する場合、輸入してリスクが大きくなるまでの期間を、一律 5 年とせず、牛集団規模が 2 千万頭以上と非常に大きい輸入国については、10 年とする。

3 つのステップにより評価を行う。

**第一ステップ** (BSE リスク国からの生体牛等の輸入データの取得):

リスク未評価の国からの侵入リスクは、リスク国からの輸入と同じリスクと見なす。

**第二ステップ** (輸入された生体牛等がフィードチェーンに侵入したかどうかの推定):

従来の GBR でも、侵入リスクから除外した理由として、「24 月齢以下でのと畜牛は除外する」などの記述はあったが、除外するかどうかの理由を明確化した。

**第三ステップ** (輸入された生体牛・肉骨粉の感染性レベルの推定):

リスク国からの生体牛の頭数だけでなく、生体牛や牛由来製品への BSE 病原体の拡散を防止するために輸出国が講じた措置も考慮。侵入リスクの大きさ目盛りとして、加重係数“w”を導入( $w=1$  は 1 リスク単位)、w 値は、BSurvE、その他の適切な方法を用いて、 $w=0$  (非常に低い) ~  $w=10,000$  (非常に高い) の範囲で計算される。

● **安定性(暴露・循環リスク)について**

SRM 除去、レンダリング、飼料規制の 3 つの安定要因について、感染牛における感染性の分布に関する最新データや、0.1g、さらに 0.01g の感染した脳が牛の経口感染の成立に十分であるなどの知見を使った半定量的なアプローチを提案（従来の GBR では、“ OK ”、“ reasonable OK ”、“ not OK ” の定性的評価）。

3 つの主な安定要因（SRM 除去、レンダリング、飼料規制）を考慮して、BSE 感染の基礎的再生産率（basically reproduction ratio）についても評価。3 要因について、それぞれリスク低減方策を数値化した低減係数（reproduction factor）をかけあわせて、それらの低減方策の総合効果を計算し、これが基礎的再生産率となる。

**SRM 除去：** 低減係数は、1（SRM 除去がない場合）～最大 0.01（OIE 又は EU の SRM リストの管理措置と、死亡牛の排除が十分遵守されている場合）

**レンダリング：** 低減係数は、0.1（大気圧下）～最大 0.001（133℃、20 分、3 気圧下が完全適用又は、レンダリングが行われていない場合）

**飼料規制：** 低減係数は、0.2（1986 年以前の英国で 20%の MBM が牛に給餌されていた状況と同じ場合）～0.001（最適な飼料規制の場合）

● **評価カテゴリーの変更**

旧 GBR	新 GBR
<p>可能性はほとんどない                      可能性は低い                      可能性は大きい                      あるいは低いレベルで確認されている                      高いレベルで確認されている</p>	<p>Likely :                      評価された牛集団に 1 頭以上の BSE 牛が存在する                      Likely and decreasing                      Likely and increasing                      Unlikely:                      評価された牛集団に BSE 牛が存在する可能性は低い</p>