



**Scientific Report of the European Food Safety Authority  
on the Assessment of the Geographical BSE-Risk (GBR) of  
United States of America (USA).**

Question N° EFSA-Q-2003-083

**Adopted July 2004**

**Summary**

The European Food Safety Authority and its Scientific Expert Working Group on the Assessment of the **Geographical Bovine Spongiform Encephalopathy (BSE) Risk (GBR)** were asked by the European Commission (EC) to provide an up-to-date scientific report on the GBR in the United States of America, i.e. the likelihood of the presence of one or more cattle being infected with BSE, pre-clinically as well as clinically, in USA. This scientific report addresses the GBR of USA as assessed in 2004 based on data covering the period 1980-2003.

The BSE agent was probably imported into USA and could have reached domestic cattle in the middle of the eighties. These cattle imported in the mid eighties could have been rendered in the late eighties and therefore led to an internal challenge in the early nineties. It is possible that imported meat and bone meal (MBM) into the USA reached domestic cattle and leads to an internal challenge in the early nineties.

A processing risk developed in the late 80s/early 90s when cattle imports from BSE risk countries were slaughtered or died and were processed (partly) into feed, together with some imports of MBM. This risk continued to exist, and grew significantly in the mid 90's when domestic cattle, infected by imported MBM, reached processing. Given the low stability of the system, the risk increased over the years with continued imports of cattle and MBM from BSE risk countries.

EFSA concludes that **the current GBR level of USA is III**, *i.e. it is likely but not confirmed* that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent. As long as there are no significant changes in rendering or feeding, the stability remains extremely/very unstable. Thus, the probability of cattle to be (pre-clinically or clinically) infected with the BSE-agent persistently increases.

**Key words: BSE, geographical risk assessment, GBR, USA, third countries**



## **Background**

### ***History***

In 1998, the EC asked the Scientific Steering Committee (SSC) to perform a risk assessment in order to establish the GBR of a country. In July 2000 the SSC adopted its final opinion on "The Geographical Risk of Bovine Spongiform Encephalopathy (GBR)" (as updated in January 2002). It describes a method and a process for the assessment of the GBR and summarises the outcome of its application. Detailed reports on the GBR-assessments were published on the Internet for each of these countries.

### ***Determination of BSE status***

In 2001, Regulation (EC) No 999/2001<sup>1</sup> established the rules for the determination of BSE status of a country. It determines certain measures concerning the control of BSE and concerning trade and importation of certain live animals and animal products.

Annex II of this Regulation lays down the method for the determination of BSE status. This includes two steps: an initial risk assessment, and the evaluation of additional criteria. The method is similar to that laid down in the International Animal Health Code of the International Animal Health Organisation (OIE).

The categorisation of countries has been deferred until July 2005 awaiting a review of the OIE categorisation system. In the meantime a number of transitional measures are in place, in particular concerning specified risk material and import conditions.

### ***State of play***

The Scientific Steering Committee issued an opinion on GBR (using the methodology established by the SSC in June 2000 and updated January 2002) for one third of the countries requesting the determination of their BSE status.

### ***Prioritisation***

The first priority is the re-assessment of GBR I countries, as currently no TSE related import restrictions (certification of absence of specific risk material (SRM)) apply to GBR I countries.

If the preliminary re-assessment indicates that the current GBR I will not be confirmed, any delay might have negative consequences on consumer health protection. Furthermore, the GBR assessment of neighbouring countries with intensive trade contacts should be dealt with at the same time, because the outcomes are interdependent.

The major trading partners with a GBR II classification should be dealt with as second priority, in view of the SSC opinion on tallow derivatives and the draft guidance note of EMEA.

## **Terms of reference**

In view of the above, the European Commission asks the EFSA to advice on the risk assessment for the appearance of BSE in USA.

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<sup>1</sup> Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies OJ L 147, 31.5.2001 and updates.



## Assessment

EFSA refers to the Working Group Report ([annex](#)) prepared by the EFSA Scientific Expert Working Group on GBR for full details on the assessment.

### *External Challenge*

USA was exposed to a **moderate external challenge** for the period 1980-1990, a **very high external challenge** for the period 1991-1995, and an **extremely high external challenge** for period 1996-2003.

### *Stability*

For the overall assessment of the stability, the impact of the three main stability factors, (i.e. feeding, rendering and SRM-removal) and of the additional stability factor surveillance has to be estimated. Again, the guidance provided by the SSC in its opinion on the GBR of July 2000 (as updated in 2002) is applied. On the basis of the available information, it has to be concluded that the country's BSE/cattle system was **extremely unstable** until today, i.e., it would have recycled and amplified BSE-infectivity very fast, should it have entered the system.

### **Feeding**

Until August 1997, ruminant meat and bone meal (RMBM) was legally fed to cattle. Feeding was therefore **"not OK"**. In August 1997, an RMBM-ban was introduced but feeding of non-ruminant MBM to cattle remained legal as well as feeding of RMBM to non-ruminant animals (farm animals and pets). An RMBM ban is difficult to maintain, as only labels can distinguish the various MMBMs. This makes control of the feed ban very difficult because analytical differentiation between ruminant and non-ruminant MBM is difficult. Due to the highly specialized production system in the USA, various mammalian MBM streams can be separated. Such a feed ban would therefore be assessed as "reasonably OK", for all regions where this highly specialized system exists. However, several areas in the USA do have mixed farming and mixed feed mills, and in such regions an RMBM ban would not suffice. Additionally, official controls for cattle feeds to control for compliance with the ban started in 2002. Thus, for the whole country, the assessment of the feeding after 1997 remains **"not OK"**, but improving.

### **Rendering**

The rendering industry is operating with processes that are not known to reduce infectivity. It is therefore concluded that rendering was and is **"not OK"**.

### **SRM-removal**

SRM were and are still rendered for feed, as are (parts of) the fallen stock. SRM-removal is therefore regarded as **"not OK"**.

### **BSE surveillance**

Before 1989, the ability of the system to identify (and eliminate) BSE-cases was limited. Since 1990 this ability is improved, thanks to a specific (passive) BSE surveillance. The initiated introduction of active surveillance in risk populations should improve the system significantly.

## Conclusions

The European Food Safety Authority concludes:

1. The BSE agent was probably imported into USA and could have reached domestic cattle in the middle of the eighties. This cattle imported in the mid eighties could have been rendered in the late eighties and therefore led to an internal challenge in the early nineties. It is possible that meat and bone meal (MBM) imported into the USA reached domestic cattle and lead to an internal challenge in the early nineties.
2. A processing risk developed in the late 80s/early 90s when cattle imports from BSE risk countries were slaughtered or died and were processed (partly) into feed, together with some imports of MBM. This risk continued to exist, and grew significantly in the mid 90's when domestic cattle, infected by imported MBM, reached processing. Given the low stability of the system, the risk increased over the years with continued imports of cattle and MBM from BSE risk countries.
3. The current geographical BSE risk (GBR) level is *III*, *i.e. it is likely but not confirmed* that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent.
4. This assessment deviates from the previous assessment (SSC opinion, 2000) because at that time several exporting countries were not considered a potential risk.
5. It is also worth noting that the current GBR conclusions are not dependent on the large exchange of imports between USA and Canada. External challenge due to exports to the USA from European countries varied from moderate to high. These challenges indicate that it was likely that BSE infectivity was introduced into the North American continent.
6. EFSA and its Scientific Expert Working group on GBR are concerned that the available information was not confirmed by inspection missions as performed by the Food and Veterinary office (FVO – DG SANCO) in Member States and other third countries. They recommend including, as far as feasible, BSE-related aspects in future inspection missions.

## Expected development of the GBR

As long as there are no significant changes in rendering or feeding, the stability remains extremely/very unstable. Thus, the probability of cattle to be (pre-clinically or clinically) infected with the BSE-agent persistently increases.

*A table summarising the reasons for the current assessment is given in the table below*

## Documentation provided to EFSA

- Letter with the ref D (2003) KVD/ip/420722 from the European Commission requesting a geographical risk assessment for the appearance of BSE in a country.



## **EFSA Scientific Report (2004) 3, 1-6 on the Assessment of the Geographical BSE Risk of United States of America (USA).**

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- Country Dossier as prepared by the country in response to the EC and EFSA data collection request.
- Other sources of data information i.e. exports from third countries and Eurostat data.
- SSC, July 2000. Final opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR).
- SSC, January 2002. Updated opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR).

### **Acknowledgment**

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### **Annex**

Details of the assessment are presented in the report as prepared by the EFSA Scientific Expert Working Group on GBR:

[http://www.efsa.eu.int/science/efsa\\_scientific\\_reports/gbr\\_assessments/scr\\_annexes/574\\_en.html](http://www.efsa.eu.int/science/efsa_scientific_reports/gbr_assessments/scr_annexes/574_en.html)



USA, Summary of the GBR Assessment, July 2004					GBR Level : III**	
EXTERNAL CHALLENGE		STABILITY				INTERACTION of EXTERNAL CHALLENGE and STABILITY
1980-1990: Moderate 1991-1995: Very High 1996-2003: Extremely high		1980-2003: Extremely unstable				Any external challenge would have met the extremely unstable system and infectivity would have been recycled.
<i>Live Cattle imports</i>	<i>MBM imports</i>	<i>Feeding</i>	<i>Rendering</i>	<i>SRM-removal</i>	<i>BSE surveillance</i>	INTERNAL CHALLENGE
From UK: 323 (CD*) or 327 (other sources of data)  <u>From other BSE risk countries:</u> 16.656.490 (CD) or 15.496.449 (other sources of data).	From UK: 5 tons (CD) or 101 tons (other sources of data)  <u>From other BSE risk countries:</u> 406.547 tons (CD) or 229.701 tons (other sources of data)	1980-2003: Not OK.  Feeding of ruminant MBM to cattle legally possible until August 1997.	1980-2003: Not OK.  No proof of an effective process in reducing BSE-infectivity is given.	1980-2003: Not OK.  SRM are still rendered for feed.	Passive but improving with some testing of risk groups.	An internal challenge was possibly present from 1980 to 1990 and was likely to be present and growing from 1991 to 2003
						EXPECTED DEVELOPMENT OF THE GBR
						As long as there are no significant changes in rendering or feeding, the stability remains extremely/very unstable. Thus, the probability of cattle to be (pre-clinically or clinically) infected with the BSE-agent persistently increases.
*CD: country dossier						

\*\* GBR level III: 'it is likely but not confirmed' that domestic cattle are (clinically or pre-clinically) infected with the BSE-agent.



## European Food Safety Authority

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Scientific Expert Working Group on GBR

**Working Group Report on  
the Assessment of the Geographical BSE-Risk (GBR) of  
UNITED STATES OF AMERICA  
2004**

**NOTE TO THE READER**

Independent experts of the EFSA Scientific Expert Working Group on GBR have produced this report, applying an innovative methodology by a complex process to data that were supplied by the responsible country authorities. Both, the methodology and the process are described in detail in the final opinion of the Scientific Steering Committee (SSC) on "the Geographical Risk of Bovine Spongiform Encephalopathy (GBR)" of 6 July 2000 and its update of 11 January 2002. These opinions are available at the following Internet 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)>**



## **1. DATA**

- The available information was sufficient to carry out the qualitative assessment of the GBR.
- Reasonable worst case assumptions have been used in cases where the available information was not fully adequate.

### Sources of data

- Country dossier (CD) consisting of information provided from the country's authorities in 1997-2004, including the study entitled "Harvard Risk Assessment" (hereafter abbreviated as HRS).

### Other sources:

- EUROSTAT data on export of "live bovine animals" and on "flour, meal and pellets of meat or offal, unfit for human consumption; greaves" (customs code 230110), covering the period 1980 to 2003.
- UK-export data (UK) on "live bovine animals", and on "Mammalian Flours, Meals and Pellets" MBM<sup>1</sup>, 1980-1996.
- Available export data from other BSE-risk countries.

## **2. EXTERNAL CHALLENGES**

### **2.1 Import of cattle from BSE-Risk<sup>2</sup> countries**

An overview of the data on live cattle imports is presented in **table 1** and is based on data as provided in the country dossier (CD) and corresponding data on relevant exports as available from BSE risk countries that exported to the USA. Only data from risk periods are indicated, i.e. those periods when exports from a BSE risk country already represented an external challenge, according to the SSC opinion on the GBR (SSC July 2000 and updated January 2002).

- According to the country dossier, 323 cattle were imported directly from the UK, all between 1980 and 1989, and 10 via Canada in 90, 91 and 92. According to Eurostat, 327 cattle were imported from UK. Of these cattle 96% were beef breeding cattle, 4% were dairy cattle. After 1989 an import stop for UK cattle was in effect.

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<sup>1</sup> For the purpose of the GBR assessment the abbreviation "MBM" refers to rendering products, in particular the commodities Meat and Bone Meal as such; Meat Meal; Bone Meal; and Greaves. With regard to imports it refers to the customs code 230110 "flours, meals and pellets, made from meat or offal, not fit for human consumption; greaves".

<sup>2</sup> BSE-Risk countries are all countries already assessed as GBR III or IV or with at least one confirmed domestic BSE case.



### **Annex to the EFSA Scientific Report (2004) 3, 1-17 on the Assessment of the Geographical BSE Risk of USA**

- Cattle imported from the UK were traced-back in 1995. This trace back exercise provided the details on which the assessment of the HRS of the import risk assessment is based. The animals still alive in 1995 (117 cattle) have been purchased, diagnostic samples were taken, and the carcasses were incinerated. These animals were not taken into account for the external challenge. All these animals tested negative for BSE (histopathology and IHC). Of these 117 cattle 52 came from UK-herds in which one or more cases of BSE later on developed.
- For 173 cattle imported from the UK in the 80s, information on their final use is, according to the HRS, lacking and it is indicated that it is possible that some of these animals could have been rendered. In the HRS it is also noted that these animals were imported before the peak of the epidemic and none came from a birth cohort in which a BSE case is known to be developed. However, based on realistic worst case assumptions it has to be assumed that they created a risk if rendered for feed.
- EU export data show that from the EU (excluding UK), 1,663 cattle were exported to the USA since 1980; according to the CD only 460 cattle have been imported from the EU.
- According to the CD, 162 cattle were imported from Ireland between 1980 and 1988 (according to Eurostat 233). The trace back of these animals showed that 22 were found as being excluded from rendering in the US system and 4 were born in US quarantine and were therefore not taken into account for the external challenge.
- According to the CD, 6 cattle from Belgium (Eurostat also 6), 46 from Germany (Eurostat 430), 3 from Austria (Eurostat 0) and 8 from Italy (Eurostat 21) have been imported. The 40 breeding-cattle imported from these countries in 1996 and 1997 were all traced back and none of them entered the US system.
- According to Eurostat, 12 cattle from Denmark and 558 cattle from the Netherlands were imported to the USA. These imports were not indicated in the CD.
- Additionally according to the CD, 235 cattle have been imported from France (403 according to Eurostat) and 103 cattle from Switzerland (48 according to other sources).
- The discrepancy in the EU export data and the import data in the CD (See table 1) can in some cases, be explained by the use of the fiscal year data (from October to September) in the CD.
- Between 235.000 and 1.7 Million (CD and Other sources) cattle per year are imported to the USA from Canada. According to the CD, feeder/slaughter cattle represent typically more around 80% of the imported cattle from Canada; therefore, only 20% of the imported cattle have been taken into account.
- From Japan, 242 animals from a special beef breed were imported. These animals were traced, and were mostly excluded from the US rendering system. At most 39 of these animals have been rendered.



Annex to the EFSA Scientific Report (2004) 3, 1-17 on the Assessment of the Geographical BSE Risk of USA

Live cattle imports, raw data

Country:	Data	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	0	1	2	3	Total (R1+R2)
Austria	CD																		3							3
	other																									0
Belgium	CD																	6								6
	other																	6								6
Canada	CD									584732	873791	904688	1273226	1201787	1010299	1132691	1510285	1378825	1316213	989885	968435	1308670	1688814	513344	13019248	
	other						234732	165853	363884	511118	603576	820997	1104555	1190675	998374	832705	1480514	1267385	1369353	737887	944798	1296135	1572146		11689972	
Denmark	CD																									0
	other						7								5											12
France	CD				5	166	64																			235
	other	2		50	176	90	1							82						2						403
Germany	CD					14	4											23	5							46
	other					31	6									360		24	9							430
Ireland	CD	70			21	62		0	0	9	0	0	0	0	0	0									162	
	other	67		2	76	59	14			6										1		8				233
Italy	CD						5													3						8
	other		2			5						11		3	2											21
Japan	CD							0	0	0	0	0	0	0	0	36	48	0	81	63	9	5	0	0	242	
	other																					0			0	
Netherlands	CD																								0	
	other			49				382					9	77	8	41	41								558	
Switzerland	CD				45	41	17																		103	
	other				35	13																			48	
UK	CD	1		23	21	87	48	28	58	25	22	6	3	1	0	0										
	other	8	35	20	23	37	59	30	62	19	25			8		1										
ALL TOTALS																										
non UK	CD	70	0	0	71	283	90	0	0	9	584732	873791	904688	1273226	1201787	1010335	1132739	1510314	1378917	1316276	989894	968440	1308670	1688814	513344	16656490
	other	69	2	101	287	198	21	235121	165853	363890	511118	603587	821006	1104635	1190767	998780	832746	1480544	1267395	1369355	737887	944806	1296135	1572146	0	15496449
UK	CD	1	0	23	21	87	48	28	58	25	22	6	3	1	0	0	0	0	0	0	0	0	0	0	0	323
	other	8	35	20	23	37	59	30	62	19	25	0	0	8	0	1	0	0	0	0	0	0	0	0	0	327

**Table 1: Live cattle imports into the USA (CD) and corresponding exports from BSE risk countries. Source for export data: Eurostat and UK export statistics and, where available, export statistics from other BSE risk countries. Note: Only imports in risk periods (shaded) are taken into account for assessing the external challenge. Risk periods are defined according to the SSC opinion of January 2002. The numbers shown in the table are the raw import figures and are not reflecting the adjusted imports for the assessment of the external challenge**



## **2.2 Import of MBM or MBM-containing feedstuffs from BSE-Risk countries**

An overview of the data on MBM imports is presented in **table 2** and is based on data provided in the country dossier (CD) and corresponding data on relevant exports as available from BSE risk countries that exported to the USA. Only data from risk periods are indicated, i.e. those periods when exports from a BSE risk country already represented an external challenge, according to the SSC opinion on the GBR (SSC, July 2000 and updated January 2002).

- The CD reports import of 5 tons of MBM from the UK. According to Eurostat, 63 tons have been exported from the UK to the USA between 1980 and 1996; however, according the updated MBM statistics from the UK (August 2001) 24 tons of MBM were exported from the UK to the USA between 1980 and 1996; 39 tons exported in 1989 were not confirmed by the updated UK export statistic and therefore not taken into account. A further 38 tons were exported in 1997-1998 and 39 tons in 1999. As it was illegal to export mammalian meat meal, bone meal and MBM from UK since 27/03/1996, exports indicated after that date should only have included non-mammalian MBM. Therefore, these imports were not taken into account.
- According to the CD, MBM was imported from Denmark, France, Italy and the Netherlands. It was claimed but not substantiated that these imports were not from ruminant origin, and therefore did not contribute to the BSE risk of the USA.
- The Eurostat export statistics indicated additional exports from Belgium, Greece, Ireland and Spain.
- Very large amounts of MBM (CD and other sources) between 18.000 and 44.000 tons annually were imported from Canada.



Annex to the EFSA Scientific Report (2004) 3, 1-17 on the Assessment of the Geographical BSE Risk of USA

		MBM imports, raw data																							Total		
Country:	Data	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	0	1	2	3	(R1+R2)	
Belgium	CD																									0	
	other																10									10	
Canada	CD										21350	0	20816	33755	23299	18472	23263	31340	30840	20595	33740	29524	36709	43670	38490	329942	
	other																			30948	20595	33740	29524	36709	43189	32867	227572
Denmark	CD										0	0	0	0	0	0	18	78	63	127	39	139	0	0	0	464	
	other															72	19	37	83	62	19	90				382	
France	CD										0	0	0	0	0	0	6	0	0	0	0	1	19	37	39	63	165
	other																										0
Greece	CD																										0
	other														55												55
Ireland	CD																										0
	other						20					2		3		14	141										180
Italy	CD										0	0	0	0	21	0	0	0	0	0	0	0	15	0	0	0	36
	other										100	65	123		7	15	315	126	514				111				1376
Netherlands	CD										0	0	0	0	0	0	0	0	0	0	0	0	19	0	0	0	19
	other										46	23			3	5	3						38				118
Spain	CD																										0
	other																				8						8
UK	CD										5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	
	other		12			10	2				39									37	1	39					101
ALL																											
TOTALS																											
non UK	CD	0	0	0	0	0	0	0	0	0	21350	0	20816	33755	23320	18472	23287	31418	30903	20722	33780	29716	36746	43709	38553	406547	
	other	0	0	0	0	0	20	0	0	0	146	90	123	3	65	106	488	163	31545	20665	33759	29763	36709	43189	32867	229701	
UK	CD	0	0	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	
	other	0	12	0	0	10	2	0	0	0	39	0	0	0	0	0	0	0	0	37	1	0	0	0	0	101	

**Table 2: MBM imports into the USA (CD) and corresponding exports from BSE risk countries. Source for export data: Eurostat and UK export statistics and, where available, export statistics from other BSE risk countries. Note: Only imports in risk periods (shaded) are taken into account for assessing the external risk. Risk periods are defined according to the SSC opinion of January 2002. The numbers shown in the table are the raw import figures and are not reflecting the adjusted imports for the assessment of the external challenge**



### **2.3 Overall assessment of the external challenge**

The level of the external challenge that has to be met by the BSE/cattle system is estimated according to the guidance given by the SSC in its final opinion on the GBR of July 2000 (as updated in January 2002).

#### **Live cattle imports:**

In total the country imported 2038 (other sources) or 1128 (CD) live cattle from BSE risk countries other than Canada, of which 327 (other sources) or 323 (CD) came from the UK. From Canada the imports were >500,000 animals per year. The numbers shown in **table 1** are the raw import figures and are not reflecting the adjusted imports for the assessment of the external challenge. Broken down to 5 year periods the resulting external challenge is as given in **table 3**. This assessment takes into account the different aspects discussed above that allow to assume that certain imported cattle did not enter the domestic BSE-cattle system, i.e. were not rendered into feed. In the case of the USA, all the animals for which tracing information showed that they were not rendered were excluded from the external challenge.

#### **MBM imports:**

In total the country imported 689 tons MBM (CD) or 2,230 tons MBM (other sources) from BSE risk countries other than Canada, of which 5 tons (CD) or 101 tons (other sources) were exported from the UK (UK export data). From Canada, the imports were about 30 000 tons per year. The numbers shown in **table 2** are the raw import figures and are not reflecting the adjusted imports for the assessment of the external challenge. Broken down to 5 year periods the resulting external challenge is as given in **table 3**. This assessment takes into account the different aspects discussed above that allow to assume that certain imported MBM did not enter the domestic BSE/cattle system or did not represent an external challenge for other reasons. As it was illegal to export mammalian MBM from UK since 27/03/1996, exports indicated after that date should only have included non-mammalian MBM. In the case of the USA imported MBM from UK in 1989 and between 1997 and 1999 was not taken into account.



External Challenge experienced by the USA				
External challenge		Reason for this external challenge		
Period	Overall Level	Cattle imports	MBM imports	Comment
1980 to 1985	Moderate	Moderate	Negligible	When Canadian import data are excluded from the assessment, the overall level varies from low to high.
1986 to 1990		Negligible	Low	
1991 to 1995	Very high	High	High	
1996 to 2000	Extremely high	Very high	Very high	
2001 to 2003			Extremely high	

**Table 3:** External challenge resulting from live cattle and/or MBM imports from the UK and other BSE risk countries. The challenge level is determined according to the SSC-opinion on the GBR of July 2000 (as updated in January 2002).

On the basis of the available information, the overall assessment of the external challenge is as given in table 3.

### 3. STABILITY

#### 3.1 Overall appreciation of the ability to avoid recycling of BSE infectivity, should it enter processing

##### Feeding

###### Use of MBM in cattle feed

- Until 1997 ruminant MBM (RMBM) could legally be included in cattle feed and was indeed commonly fed to cattle of different age and type. Prior to the feed ban the US authorities estimated that 10% of all MBM would deliberately have been fed to cattle.

###### Feed bans

- A ban to feed (several types of) MMBM to ruminants was put in place in August 1997. Derogation from the ban was granted for pure porcine and equine protein (MBM) coming from designated (single species) rendering plants. This MMBM might still be fed to cattle. Therefore this feed ban is a ruminant to ruminant ban.
- It is planned to prohibit the use of all mammalian and poultry protein in ruminant feed and prohibiting materials from non-ambulatory disabled cattle and dead stock from use in all animal feed.



Potential for cross-contamination and measures taken against

- The animal production chain in the USA is large-scale industry, which allows for a high level of specialisation and many farm and factories for slaughter, rendering and feed production are dedicated to one species only. This reduces the risk of cross-contamination to a large extent, but this does not apply to regions with a lot of mixed farming.
- Cross-contamination of non-ruminant MBM with RMBM is theoretically possible whenever transport of this material from rendering to feed plants is done in bulk and with the same means of transport. It is unknown if this can be excluded.
- Cross-contamination in feed mills is possible as many feed mills produce compound feeds for different species on the same production line. No data on the structure of the feed industry in the USA were provided by the US authorities that would allow estimating the amount of cattle feed annually produced in mixed feed mills throughout the period 1980-2001. Information on inspection of feed mills shows that this problem is still found, by 2003, in a very small fraction of the industry.
- Since 1997, FDA regulations provide for either the use of separate lines in the production of ruminant feed or specify detailed clean-out procedures to be used between production batches. However, experience in Europe shows that flushing batches etc are not capable to eliminate cross-contamination, even though they reduce it. The efficiency of the required measures cannot be assessed as detailed control data are lacking and samples are not taken for this purpose.
- Feed containing RMBM has labels not to be fed to ruminants, but “on-farm” cross-contamination is regarded to be possible.
- Hence, as reasonable worst case scenario, it is assumed that cattle, in particular dairy cattle, can still be exposed to RMBM and hence to BSE-infectivity, should it enter the feed chain.
- Rendering plants and feed mills are, according to the CD, regularly inspected for compliance with the regulations, throughout the country.
- It is planned to require dedicated equipment or facilities for handling and storing feed and ingredients during manufacturing and transportation, to prevent cross contamination.

**Control of Feed bans and cross-contamination**

- Since 1997, feed mills that are allowed to use RMBM, and also produce cattle feed (without RMBM), are inspected annually, other may also be inspected. Two types of violations were registered. One type not involving RMBM, the others involving this, this mainly concerns cross-contamination problems. These firms were re-inspected soon. In several cases, products were recalled, sales were closed and/or products were destroyed. Cattle feed is not sampled to test for presence of illegal MBM.
- According to information provided in 1999/2000 by the feed producers, the compliance is assumed by the US authorities to be in the order of magnitude of 70% to  $\leq 90\%$  since 1998, and 30% to  $\leq 70\%$  before. Official control data concerning rendering and feed mill industries were provided and show that action at shortcomings in the production processes (a few percent of the firms) have



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become severe by the beginning of 2003. However, samples from ruminant feed are not regularly tested for the inclusion of MMBM. Reports from the feed industry in 2000 and 2001 indicate significant shortcomings in the implementation of the ban in that period. This does confirm the known difficulty of implementing and enforcing such a feed ban.

- No examinations are performed to assess cross-contamination with RMBM of the protein (e.g. through non ruminant MBM) that enters cattle feed.

### **Rendering**

- The domestic MBM production averages 3 million metric tons per year.
- Almost 60% of the MBM produced originate from ruminants (cattle 59%, sheep 0.6%), 20% from pigs and 20% from poultry.

#### **Raw material used for rendering**

- Ruminant material is rendered together with material from other species (approx. 50% of all plants). This is particular significant as SRM will be included. "Free renderers" are known to also process fallen stock.
- Slaughter by-products from different species, including SRM, is the raw material for most rendering plants that are associated with slaughterhouses.
- Some plants process material from one species, e.g. pigs or horses or poultry only.
- The CD does not provide the numbers of plants falling under each category nor of their respective annual production.

#### **Rendering processes**

- Four major rendering systems are used in the approximately 280 rendering plants in the USA. All systems operate under atmospheric pressure with temperatures ranging between 100 and 150 °C and different heating times:
  - Batch cooker plants (46): 115-125 °C, 30-240 min.
  - Continuous tube and disc cooker systems (220): 131-150 °C, 45-90 min.
  - Continuous multi-stage evaporator systems (10): 115-125 °C, 20-40 min.
  - Continuous preheat/press/evaporator systems (4): 87-120 °C, 240-270 min.

Due to the fact that they operate under atmospheric pressure only, none of the described rendering processes are assumed to reduce BSE-infectivity significantly, should it enter the processing.

### **SRM and fallen stock**

- An SRM-ban for human food has been introduced in 2004. There was however never an SRM ban for the feed chain.
- SRM are rendered together with other slaughter by-products and, in case of independent renderers, together with fallen stock.
- It is planned to remove SRM from all animal feed, including pet-food.



### **Conclusion on the ability to avoid recycling**

- Before 1997, US system would not have been able to avoid recycling of the BSE-agent to any measurable extent. If the BSE-agent was introduced into the feed chain, it could have reached cattle.
- After the introduction of the 1997 ban in August 1997, the ability to avoid recycling of BSE-infectivity was somewhat improved. However, the rendering of ruminant material (including SRM and fallen stock) is inadequate (non pressurized), and cross-contamination potentials of cattle feed with other feeds remain.
- Therefore, the system is still unable to avoid recycling of BSE-infectivity if already present in the system or incoming.

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

#### **Cattle population structure**

- The total cattle population of the USA was approximately 111 Million cattle in 1980, 99 Million in 1990, 102.8 Million cattle in 1995 and 99.5 Million cattle in 1998. Of these, approximately 17.6 % (17.5 Million) were dairy cattle and 82.4% beef cattle (based on data 1995-1998). However, the HRS recognised that the official slaughter figures were only compatible with a stable total cattle population of about 140 million.
- Between 17% and 19% of all cattle slaughtered were >2 years of age. The average age at slaughter for dairy cattle is between 4 and 5 years.

#### **Husbandry systems**

- According to the country experts it was assumed that mixed farming did exist in the USA, but at a low (and decreasing) level. No figures were provided.
- The two main cattle husbandry systems are beef (82.4%) and dairy (17.6%).

Within both systems all levels of intensity are existing, however, both segments are now characterised by large, intensive operations. For dairy cattle a clear trend towards larger, more efficient holdings can be seen.

Maps were presented by the country experts in 1999 that indicate an overlap of intensive cattle, swine and poultry industry in certain geographic regions of the USA.

#### **Cattle identification and monitoring system**

- The existing animal identification system is jointly operated by State and Federal representatives and is maintained individually for each State. No centralised US-wide animal identification system is in place.
- It was estimated by the country experts that this system ensures that approx. 95% of all cattle are officially tagged and registered in State databases.
- A trace-back of individual animals is possible whenever the animal has not moved several times (through several herds) within a particular State. Intra-State



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movements are not recorded in any type of database, and any follow-up would rely on the documentation (records) or the memory of the respective owners.

### **BSE surveillance**

- All foreign animal diseases (exotic diseases) have been and are notifiable by Federal legislation. BSE, as an exotic disease, was notifiable since it first was described as a disease (1986).
- A surveillance targeting animals with clinical signs that could be consistent with BSE is in place since 1989/1990 and operating with larger sample sizes (900-1600 per year) since 1997. This program officially started in 1990 but some samples examined under this system go back to 1986. The samples come from:
  - Cattle exhibiting signs of neurological disease;
  - Cattle condemned at ante-mortem examination in slaughterhouses for neurological signs;
  - Rabies-negative cattle submitted to public-health laboratories (the country experts confirmed that samples were appropriately taken and should have allowed finding BSE if present);
  - Neurological cases submitted to veterinary diagnostic laboratories and veterinary schools/teaching hospitals;
  - Between 25% and 33% of the animals in the sample were supposed to be aged dairy cattle which are non-ambulatory (“downer cows”) at slaughter. Detailed information on the age distribution of those animals was not available.
- In addition to histopathology, immunohistochemistry is applied since 1994, initially on those animals for which a differential diagnosis could not be established. Since 1997 it is fully incorporated in the surveillance scheme and approx. 900-1.600 samples are examined annually by both tests. In 2000, a total of 2 870 submissions were examined.
- In 2001, the number of submissions doubled, and in 2002 and 2003, submissions totalled 19.777 and 20.277 respectively. The total number of samples examined through April 2004 is more than 72.500.
- A BSE case has been detected in December 2003. Intensive research showed that it was born and raised in Canada, and therefore, it is not a domestic case.
- In addition, since 1 June 2004, an extensive testing of the risk population is initiated. It is planned to test as many cattle from the risk population (the target is 268.000 cattle) in a 12-to-18-month period. The following categories will be tested: non-ambulatory cattle, cattle exhibiting signs of a central nervous system disorder, cattle exhibiting other signs that may be associated with BSE and dead cattle. The surveillance program will also include a limited number of random samples from apparently normal, aged animals.

### **3.3 Overall assessment of the stability**

For the overall assessment of the stability, the impact of the three main stability factors, (i.e. feeding, rendering and SRM-removal) and of the additional stability factor surveillance has to be estimated. Again, the guidance provided by the SSC in its opinion on the GBR of July 2000 (as updated in 2002) is applied.



**Feeding**

Until August 1997, RMBM was legally fed to cattle. Feeding was therefore **"not OK"**. In August 1997 an RMBM-ban was introduced but feeding of non-ruminant MBM to cattle remained legal as well as feeding of RMBM to non-ruminant animals (farm animals and pets). An RMBM ban is difficult to maintain, as only labels can distinguish the various MMBMs. This makes control of the feed ban very difficult because analytical differentiation between ruminant and non-ruminant MBM is difficult if not impossible.

Due to the highly specialised production system in the USA, various mammalian MBM streams can be separated. Such a feed ban would therefore be assessed as "reasonably OK", for all regions where this highly specialised system exists. However, several areas in the USA do have mixed farming and mixed feed mills, and in such regions an RMBM ban would not suffice. Additionally, official controls for cattle feeds to control for compliance with the ban started in 2002. Thus, for the whole country, the assessment of the feeding after 1997 remains **"not OK"**, but improving.

**Rendering**

The rendering industry is operating with processes that are not known to reduce infectivity. It is therefore concluded that rendering was and is **"not OK"**.

**SRM-removal**

SRM were and are still rendered for feed, as are (parts of) the fallen stock. SRM-removal is therefore regarded as **"not OK"**.

**BSE-surveillance**

Before 1989, the ability of the system to identify (and eliminate) BSE-cases was limited. Since 1990 this ability is improved, thanks to a specific (passive) BSE surveillance. The initiated introduction of active surveillance in risk populations should improve the system significantly.

Stability of the BSE/cattle system in the USA over time					
Stability		Reasons			
Period	Level	Feeding	Rendering	SRM removal	BSE surveillance
1980 to 2003	Extremely unstable	Not OK	Not OK	Not OK	Passive but improving with some testing of risk groups

**Table 4: Stability resulting from the interaction of the three main stability factors and the BSE surveillance. The stability level is determined according to the SSC-opinion on the GBR of July 2000 (as updated in 2002).**



On the basis of the available information, it has to be concluded that the country's BSE/cattle system was extremely unstable until today, i.e., it would have recycled and amplified BSE-infectivity very fast, should it have entered the system. The stability of the BSE/cattle system in the USA overtime is as given in **table 4**.

The present assessment modifies the stability assessment of the previous GBR report in 2000 mainly due to a different perception of the impact of BSE surveillance on stability and of the efficiency of the RMBM feed ban.

#### **4. CONCLUSION ON THE RESULTING RISKS**

##### **4.1 Interaction of stability and challenges**

In conclusion, the stability of the USA BSE/cattle system in the past and the external challenge the system has coped with, are summarised in **table 5** below.

From the interaction of the two parameters “stability” and “external challenge” a conclusion is drawn on the level of “internal challenge” that emerged and had to be met by the system, in addition to external challenges that occurred.

<b>Interaction of stability and external challenge in the USA</b>			
<b>Period</b>	<b>Stability</b>	<b>External Challenge</b>	<b>Internal challenge</b>
<b>1980 to 1985</b>	<b>Extremely unstable</b>	<b>Moderate</b>	<b>Possibly present</b>
<b>1986 to 1990</b>			
<b>1991 to 1995</b>		<b>Very high</b>	<b>Likely to be present and growing</b>
<b>1996 to 2000</b>		<b>Extremely high</b>	
<b>2001 to 2003</b>			

**Table 5: Internal challenge resulting from the interaction of the external challenge and stability. The internal challenge level is determined according to guidance given in the SSC-opinion on the GBR of July 2000 (as updated in 2002).**

An external challenge resulting from cattle import could only lead to an internal challenge once imported infected cattle were rendered for feed and this contaminated feed reached domestic cattle. Cattle imported for slaughter would normally be slaughtered at an age too young to harbour plenty of BSE infectivity or to show signs, even if infected prior to import. Breeding cattle, however, would normally live much longer and only animals having problems would be slaughtered younger. If being 4-6 years old when slaughtered, they could suffer from early signs of BSE, being approaching the end of the BSE-incubation period. In that case, they would harbour, while being pre-clinical, as much infectivity as a clinical BSE case. Hence cattle imports could have led to an internal challenge about 3 years after the import of



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breeding cattle (that are normally imported at 20-24 months of age) that could have been infected prior to import.

In the case of the USA a few potentially infected cattle were imported from the UK and more from other BSE-risk countries. Furthermore, large numbers of imported animals came from Canada. This implies that cattle imported in the mid eighties could have been rendered in the late eighties and therefore led to an internal challenge in the early 90s.

On the other hand imports of contaminated MBM would lead to an internal challenge in the year of import, if fed to cattle. The feeding system is of utmost importance in this context. If it could be excluded that imported, potentially contaminated feed stuffs reached cattle, such imports might not lead to an internal challenge at all.

In case of the USA this implies that it was possible that imported MBM reached domestic cattle and lead to an internal challenge in the early 90s.

If Canadian imports would be excluded from this assessment, we find that the USA receives a moderate challenge for all 5-year intervals since 1980, a high challenge between 1985 and 2000 and a low challenge thereafter. If combining these moderate to high challenges due to imports with the extremely unstable system, the conclusion would still be that the occurrence of an internal challenge is possible during the early 80s and likely in the late 80s.

### **4.2 Risk that BSE infectivity entered processing**

A processing risk developed in the late 80s/early 90s when cattle imports from BSE risk countries were slaughtered or died and were processed (partly) into feed, together with some imports of MBM. This risk continued to exist, and grew significantly in the mid 90s when domestic cattle, infected by imported MBM, reached processing. Given the low stability of the system, the risk increased over the years with continued imports of cattle and MBM from BSE risk countries.

### **4.3 Risk that BSE infectivity was recycled and propagated**

A risk that BSE-infectivity was recycled and propagated exists since a processing risk first appeared, i.e. in the early 90s. Until today this risk persists and increases fast because of the extremely/very unstable BSE/cattle system in the USA.

## **5. CONCLUSION ON THE GEOGRAPHICAL BSE-RISK**

### **5.1 The current GBR as function of the past stability and challenge**

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

Note1: It is also worth noting that the current GBR conclusions are not dependent on the large exchange of imports between USA and Canada. External challenge due to exports to the USA from European countries varied from moderate to high. These



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challenges indicate that it was likely that BSE infectivity was introduced into the North American continent.

Note2: This assessment deviates from the previous assessment (SSC opinion, 2000) because at that time several exporting countries were not considered a potential risk.

### **5.2 The expected development of the GBR as a function of the past and present stability and challenge**

- As long as there are no significant changes in rendering or feeding, the stability remains extremely/very unstable. Thus, the probability of cattle to be (pre-clinically or clinically) infected with the BSE-agent persistently increases.
- Since recent improvements in the safety of MBM production in many countries or significant recent reductions in the incidence of BSE are not taken into account for the assessment of the external challenge, the external challenge assessed after 2001 could be overestimated and is the worst case assumption. However all current GBR conclusions are not dependent on these assumptions in any of the countries assessed. For future assessments and when the impact of the production, surveillance and true incidence changes have been fully quantified, these developments should be taken into account.

### **5.3 Recommendations for influencing the future GBR**

- Measures that improve the stability of the system, will, over time, reduce the probability that cattle could get infected with the BSE-agent. Possible actions include
  - removal of SRM and/or fallen stock from rendering of animal by-products into feed,
  - high pressure standards in rendering processes,
  - significant improvement of ban on use of ruminant MBM in cattle feed, supported by regular sampling of feed for the occurrence of such MBM.
- Improved passive and active surveillance, i.e. sampling of animals not showing signs compatible with BSE from “at-risk” cattle populations, such as adult cattle in fallen stock and emergency slaughter, by means of rapid screening, would allow monitoring the efficiency of stability enhancing measures.

### **Documentation provided to EFSA**

- Letter with the ref D (2003) KVD/ip/420722 from the European Commission requesting a geographical risk assessment for the appearance of BSE in a country.
- Country Dossier as prepared by the country in response to the EC and EFSA data collection request.
- Other sources of data information i.e. exports from third countries and Eurostat data.
- SSC, July 2000. Final opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR).



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- SSC, January 2002. Updated opinion on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR).

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